# Manual of Practice Management for Ambulatory Surgery Centers

## An Evidence-Based Guide

Niraja Rajan
*Editor*

SOCIETY FOR AMBULATORY ANESTHESIA
Outpatient • Office Based • Non-Operating Room

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# ASC Design and Construction

1

William R. Phillips

## Introduction

Building and operating an ambulatory surgery center (ASC) is a great undertaking of substantial financial and personal commitment from beginning to end. For all practical purposes this presentation is a simplistic overview to set up reference guidelines for the overall ASC development process to ensure a successful outcome.

This chapter begins with the assumption that the property location or site has been selected, the property is an "improved" property and all of the site preparation related due diligence and impact fees have already been dealt with and therefore all of those processes are not part of this discussion. Whether or not the facility is a renovation project or a new clean build-out project will also not be discussed. We are going to discuss some of the processes that need to occur in order to make this endeavor a successful undertaking for the staff, physicians and owners.

The complexity of a project of the scope and size of a surgery center rivals that of a hospital project in many ways. One of the most important things to remember is that when constructing an ambulatory surgery center, we are in fact building out the most complicated section of a hospital– the operating room complex, into a standalone facility – the outpatient surgery center.

Although from many vantage points there are considerable similarities between a hospital operating room complex and an ambulatory surgery center, on closer inspection, there are many more differences. In the early days of the business the physical appearance of the surgery center was similar to an OR complex from any hospital. Today, the ambulatory surgery center has taken on a look and direction of its own. In terms of design, function and performance, an ASC is a completely different operation than a hospital OR complex. Recently, the design standards have

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been segregated to create standalone standards and guidelines for ambulatory surgery centers completely separate from other ambulatory patient care guidelines and hospital standards. In the early years of the development of surgery centers, primarily all cases were elective cases of short duration such as ophthalmology and endoscopy. Cases performed in the surgery centers presently are still primarily elective cases, but case types and patients are becoming more complex, integrating higher levels of technology and covering just about every surgical specialty including the integration of robotics. Consequently, the construction, design and expectations for the surgery center project have also become more complex. Another factor to be considered when building the ambulatory surgery center is that the throughput and efficiency of ambulatory surgery centers rivals and often exceeds that of their hospital cousins.

Throughout this presentation we would like to explore an outline of the means, methods and sequences to be considered for the development of a surgical center designed from the ground up. These types of projects are extremely complex with several predictable and conditional problems that are encountered. In this discussion we plan to present some of these problems and discuss potential ways to include proactive ideas to work through these challenges and avoid pitfalls.

## The Project Team

Our discussion of the project team will be confined to the design and construction of the surgery center leaving out the financial considerations and elements of the project. These are subjects of separate discussions and continuous arguments over best processes and out of the scope of this chapter.

There are primarily two methods by which the design team and the contractor work in conjunction with one another on projects of this type.

- ***The traditional method.*** This method considers the architect as the project leader of the design team and includes the engineer services required to complete the design of the project. This team is retained directly by the project developers whom from now on we will refer to as the *owner*. When the design is complete or nearly complete, a contractor is selected sometimes with the aid of the design team of architects and engineers and sometimes by the owner, independent of any input from the design team.
- ***The design build method.*** Under the design build concept, the contractor is selected as a primary lead in the project and the contractor retains design services of the architect and design engineers and coordinates the entire work project with the owner directly. The architects and engineers work for the contractor in this arrangement.

**Retention of services** There are many ways to craft a contractual arrangement between the design team and the contractor. Some parties retain legal services and produce unique documents specific to their project. The most economical method is

to use template documents offered by professional architectural and engineering associations with some minimal legal assistance to meet the requirements for their projects. The templates have been rigorously tested within the professional and legal systems as valid proven contract instruments; why reinvent the wheel!

It is important to have a well-crafted document that discusses the mechanics of the design and construction process and lays out the details for procedures that are to be followed and utilized by the project team to manage the project effectively. Without a predetermined process considerable discussion can be wasted to debate the methods to resolve disputes [1]. The American Institute of architects (AIA) and other national construction and engineering organizations offer templates for use as a foundation for solid contracts between design professionals, contractors and owners (See Resources). These documents provide a template for sound management practices for an effective functional project, minimizing disputes over contract semantics. It is recommended that the legal team utilize one of these contract templates as the basis for their agreements. It is very important to emphasize the change order process as part of the contract so this will work effectively to make for a well-managed and organized project.

## Who Else Works on the Project Team?

Other team members may be selected to assist in the development of the project. Some common selections include *interior designers*, *equipment planners*, *project estimators* and *project schedulers*. The need for interior designers and equipment planners is pretty much left to the discretion of the owners on the project, relative to their experience and needs. Sometimes the architect will offer interior design services. Many of the comments that will follow, relative to directing services of the design professionals, are also applicable to all of these other design or consultant professionals that may be selected for the work project.

The one team member that is very important and normally gets left off the project team is a ***project scheduler***. This individual or profession is left out sometimes as a cost-saving measure up front because the architect and the contractor insist that they can manage the schedule effectively and can assure a certain outcome. More often than not, healthcare projects run into delays that result in extended timelines which adversely impact opening dates and budgets. The delays occur because of conflicts on the job, changes in plans, material deliveries issues, and work inefficiencies all which have the effect of slowing down the project. The project scheduler lays out the project timeline in detail, and reviews progress through regular meetings keeping the project on track in spite of these other conditions that affect the project order of events. Some delays occur because of changes that arise or are required to be made in order to deliver the design intended or to meet regulatory requirements that surface during plan reviews or project site walk-throughs. The project scheduler reviews the project schedule and considers the impact of every issue, always addressing concerns to pick up time for necessary changes and keep

the project on track after every consideration is given to reasons why the project time should be extended or changed. Delays in the project will cause project cost overruns very quickly. The project scheduler evaluates the critical path keeping all processes on track even when taking into consideration design changes and/or proposed construction delays due to conflicts that may occur with the design, delays with construction materials or construction processes or delays for any other reason. The project scheduler keeps the project moving forward and is not a party to the cause of delays so is not sympathetic to inefficiencies brought on by these issues that affect project progress. Often the project scheduler, when utilized is solely responsible for the project finishing on time. So, if the project timeline is important, hiring an independent project scheduler to manage the scheduling of the project is highly recommended.

The owners need to consider the experience level and the expertise each professional brings to the project and pick a design team and contractor that they feel they will be the most successful in working with. Once the best possible team has been assembled for the project, the owner and operator of the ASC make the effort to drive and control the direction, design and construction of the surgery center and ensure that the project stays on track.

Architects are well versed in implementing the requirements of the codes and standards into their final design. Contractors know how to take the design and efficiently build it to create a usable finished product. But, what are they building? Answer: an ambulatory surgery center.

## The Importance of a Functional Program

The functional program provides a lot of information to the design team. Some of the basic information would be the preferred number of operating rooms, procedure rooms, recovery spaces and types of cases being performed in the surgery center. The design team uses this information to create a coordinating functional design incorporating all the requirements of the codes and standards and fitting it into the footprint or shape of the shell into which they are putting the surgery center (Figure 1.1). It is almost as though they are master puzzle makers shifting the pieces of design requirements around to fit in the defined project space. If building and design for the surgery center is constricted by a fixed square footage this restriction will no doubt affect the final design. Sometimes the shape of the shell space in which the surgery center is to be built will have a confining effect on the design or at a very minimum how departments interface internally. If the surgery center is to be a standalone center, site conditions may determine how spatial relationships may align. Meeting the codes and standards and putting this puzzle together is the primary responsibility of the design team.

The owner's responsibility is to put as much information into the functional program as possible. It is important to describe in detail, how patients will receive care and what services are going to be delivered in the patient care areas. In previous eras relative to design and space utilization, we referred to *pre-op services* and *post*

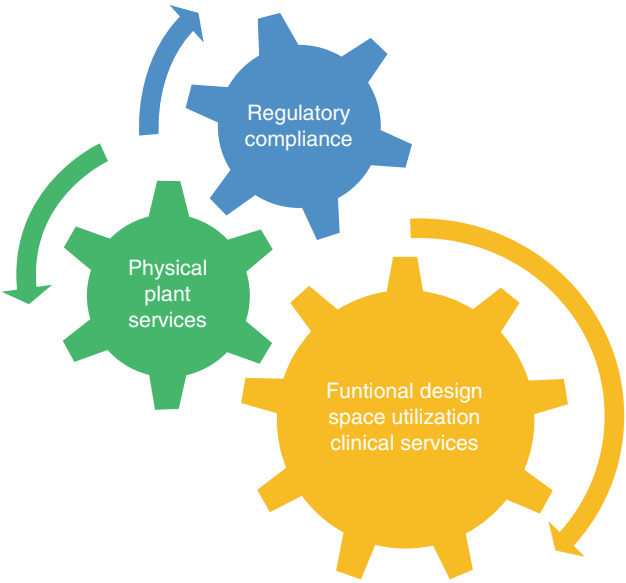


**Figure 1.1** Integration of design, space utilization, patient care and compliance

*anesthesia care unit* services (recovery). Today all of these areas are considered *patient care areas* and the owners can designate what these areas are going to be used for and communicate with the designers, what services are going to be delivered in each area and how they are to be delivered. Additionally, designers need to be provided with information on supplies, patient and equipment flow through the surgery center, staffing, and what is required from the physical plant to support these services. Detailed descriptions regarding the patient flow pathway from the point the patient enters the building, as the patient passes through the building while various services are performed to receive care and treatment, what criteria need to be met to discharge the patient, and the ideal environment in which services would be delivered should be provided. Descriptions should include specific parameters necessary including temperatures, humidity, special use for spaces, special access, what types of equipment might be used at various points within the facility inclusive of imaging equipment and sterilization equipment. All of these factors help the design team to work more efficiently to develop the project. We will cover some of these aspects only in outline format but we cannot overemphasize the importance of the functional program. This is perhaps the single most important element left out of any project (Figure 1.2).

**SERVICEABILITY and MAINTAINABILITY** Part of the functional program that is commonly "assumed" by designers is the after project service requirements and support capability of the surgery center staff. To communicate these requirements the functional program should include a section devoted to this aspect of the design elements of the project. Considerations to include are listed as follows:

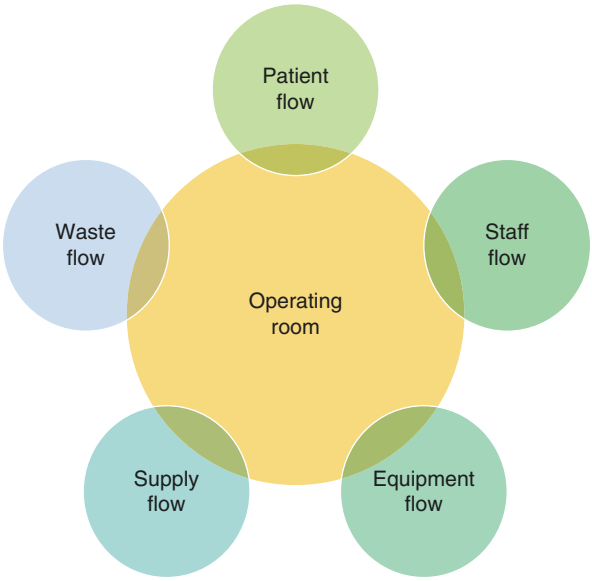


**Figure 1.2** Flow of elements needed for an effective operating room

- Simplicity of systems.
- Automatic reset for alarms and monitoring limits.
- Accessibility and labeling of serviceable items.
- Service life expectancy and service life costs.
- After reviewing the functional program the design team will produce a design for review. This design process goes through several stages or steps.

**Schematic diagrams** The first product of the design team after reviewing the functional program will be a schematic diagram. The schematic diagram illustrates the layout and relationship of spaces to each other and shows staff and owners the functional direction and patient flows and equipment flows throughout the facility. Staff and owners should review the schematic layout with the design team and discuss the pros and cons of things that work and do not work as related to elements of the functional program. An important aspect of this segment of the design process is to assess the flows of staff, patients, materials, equipment and supplies through the facility, ensuring that the design enables staff to be compliant with the regulatory requirements and also enhances the patient experience all the while optimizing staff efficiency. Making changes to review options in this phase is relatively simple and inexpensive. (See Table 1.1)

**Design development** The engineers are introduced to the design as part of the design development phase. This is where systems that support the surgery center become integrated into the design and the placement and structure of these systems are important to the overall design. Support spaces for systems often have to be included in the design and may change the schematic diagram of the facility that

**Table 1.1** Schematic Review

| Owner/operator participation; input |
|---|
| Review patient flows through admitting, procedure and discharge |
| Review flow of supplies in and through to the procedure room |
| Review equipment flows |
| Review staff areas for efficiency; avoid redundancy |
| Review waste stream flows |
| Review equipment reprocessing flows |
| Review infection control boundaries - define |

**Table 1.2** Design Development

| Owner/Operator participation; input |
|---|
| Integration of systems |
| Location of required monitoring stations |
| Layout of utilities in the OR and procedure rooms |
| Equipment service/access |
| Equipment functions/auto restart; emergency operation |

**Table 1.3** Construction Documents and Specifications

| Owner/Operator participation; input |
|---|
| Review equipment selections; less cost to maintain – service life; reliability |
| Service options – availability of support |

was previously decided upon. Some of these design development changes are needed to house and contain certain elements of the engineering components that need their own spaces. Once the design development is completed, the functions of all aspects of each system should have been detailed enough to be discussed with the owner and development team. Requirements should be compared once again to the functional program and to the schematic design. Required changes should be made to accommodate elements of the building systems integration. The design development phase is also a good time to have a project estimate performed by project estimator to compare costs relative to budget. Project costs always make a difference in an effective project and this is the ideal time to make design and equipment changes within the physical plant layout. At this point such changes are easily made to save costs. (See Table 1.2)

**Construction documents** In this phase the architect and engineer produce the final documents that will be delivered to the contractor and be utilized to build out the project. Every detail required by the code is referenced or depicted in the construction documents. Items that are not shown at the required level of detail are submitted to the design team by the contractor for approval. Sometimes information in this format is referred to as “shop drawings”. Shop drawings are provided by the contractor and subcontractors to the engineers and architects of the design team for certain elements of the project, referencing more detail, or a particular construction sequence, or design detail in addition to what was provided by the construction documents. (See Table 1.3)

## Anesthesia Services

Important aspects of the functional program are considerations related to anesthesia services.

- ***Temperature and humidity.*** The design standard calls for operating room temperatures to be maintained between 68 and 72 °F and relative humidity between 30% and 60%. Practically every operating room in the USA has temperature and humidity set at 65 degrees Fahrenheit or cooler and 50% respectively. If the functional program does not specifically state the desired temperature for design, design engineers will design the heating ventilating and air-conditioning (HVAC) system to maintain the minimum specified in the standards which will then, from the first day of opening, be unacceptable.
- ***Vacuum system/EVAC system.*** The EVAC system is utilized to scavenge gases from the anesthesia machine, out of the operating room and is now a requirement in any location where general anesthesia is delivered. This process was historically achieved by connecting the hoses from the anesthesia machine into any vacuum outlet on the wall but now has a dedicated port to do so. If the scavenger valves on the anesthesia machines are left fully open, even if the valve outside of the operating room to the vacuum system is closed, the vacuum system will run continuously leading to premature failure and expensive repairs to this system. For this reason, it is recommended in the functional program that a call out concern be added for the vacuum system to have timers installed to shut the vacuum system off outside of normal working hours.
- ***Sterile field.*** Sub sterile rooms provide an easy way for staff to enter an active operating room without disrupting the sterile field or impacting the air exchanges of the ventilation system during a case. Whether using a sub sterile room or the main door, the anesthesia group should be consulted to examine the medical gas layout (which dictates patient positioning) suggested by the architect and engineers so that when moving from room to room using the main door they are not walking directly into the sterile field. This is accomplished by determining the most common patient position. Many architects have designed operating rooms for 30 years and have done this incorrectly.
- ***Anesthesia workspace.*** There is a requirement for all operating suite designs to have an anesthesia workspace. This could be a dedicated room, and often is, but it also can also be a dedicated counter space or workstation which saves money and space.

One of the contracted providers of services that should participate in preparation of the functional program for an ambulatory surgery center is the anesthesiologist group. Many owners do utilize a consultant to develop the functional program, but some owners still prefer to do this on their own and leave a lot of information out.

## Standards of Design

There are many basic standards related to building codes and engineering design that affect the way systems are to be installed and integrated within the building and what the configuration of engineered systems must include specifically related to provisions for the surgery center [2]. The local codes and standards dictate specific callouts on elements of construction such as wall details of how components connect. An important document produced by the *Facilities Guidelines Institute* serves as a recipe book if you will for all space requirements and is referred to as *Guidelines for Design and Construction of Healthcare Facilities* [3, 4]. This document, depending on which year the facility is required to be built, describes the spaces that are required depending upon the type of patient care that will be performed. Many elements of this design document are interconnected and affected by the functional program. Having an effective functional program tells designers which elements of this document will pertain specifically to the desired facility design, what needs to be included and what can be compromised.

The remaining two documents of significance affect the operational budget and planning over the entire life of the facility. These have to do with operational requirements to meet licensure, Medicare (CMS) and accreditation mandates and are *Life Safety Code (NFPA 101)* and *Healthcare Facilities Code (NFPA 99)* [5, 6]. These documents are refreshed and updated approximately every three years. The governing agency that has jurisdiction (AHJ) periodically adopts different versions of these standards over time [7]. The baseline consideration for compliance usually depends on the CMS or Medicare standards at the time of construction.

Within the scope of the standards of design is a complete change of nomenclature for how spaces for care are considered. The guidelines offer greater levels of flexibility; keep up with the nomenclature and design elements. The design professional has the details and specifics for sizing and physical plant concerns for each patient care element but the owner's input may serve to further define some of these elements. Here are some examples:

### Operating Rooms

- Operating/procedure rooms will no longer be classified as Class A, B or C. The new classifications are PROCEDURE ROOM and OPERATING ROOM.
- The size restrictions have also been changed: an operating room must be a minimum of 250 SF net, but designed to accommodate the type of surgical procedures expected to be performed (so the functional program and plan are significant), allowing for maintenance of the sterile field.
- General anesthesia will be permitted in an ambulatory surgery operating room, even at 250 SF; this does away with the 400 SF requirement we have been living with for the past few years; although some state licensure requirements may still mandate the minimum 400 SF sizing.

- For each operating/procedure room, size and types of procedures performed will determine the requirements for equipment storage, general storage, sterile storage and waste staging area sizing.

## FGI Now Defines Invasive Procedures

- Invasive procedure types are defined. Based upon this new definition the only outpatient procedures that can be performed in a PROCEDURE ROOM are endoscopy and pain management procedures.

The requirements for temperature, humidity, air flow, air changes and filtration remain the same, but with smaller OR's, obviously, the equipment can be smaller, saving on both initial and long term operating costs.

## Pre-Operative Areas and Recovery Areas

- Pre-Operative areas and recovery bays will be referred to as Patient Care Stations.
- The size of a recovery bay remains the same but instead of requiring 3 beds per operating room as is the case now, the new guideline requires 1.5 beds per OR.
- Pre-operative bed slots remain at one [1] bed per OR, but the size is reduced from 80 SF per bed to 60 SF per bed. Some centers integrate the preoperative and recovery areas into a flex bed arrangement for staffing efficiencies.
- The actual number of patient care stations included in an ASC will be determined by the procedures being performed and the case volumes. The Guidelines only provide a "minimum" requirement.

## Support Areas

- A substantial change, making layouts and designs more accommodating, will be that staff dressing areas no longer are required to have direct access to the restricted or semi- restricted sterile areas. Staff dressing areas can be located anywhere in the ASC.
- Other support areas including medication, nourishment and prep areas do not have to be behind closed doors in separate rooms; these may be in alcoves or dedicated spaces. This saves space and provides for convenience.
- Sterilization. If sterilization is not on site, staging areas for sending and receiving off-site sterilized material and equipment may be required.
- Parking areas may need to be reviewed and considered such as four parking areas per OR/procedure room plus one space for each staff member and reserved parking spaces for patient pickup after recovery. Dedicated parking spaces may be required to be identified for the surgery center, if the center is a tenant facility.

## Contractors – Scope of Work

Prior to beginning construction, permits are obtained and the design review process is completed, with any changes arising during document review, both incorporated into the project design, and covered by a change order with the contractor.

Throughout the project conflicts over design elements may occur requiring changes in the scope of work. These changes could be related to design issues, physical plant material changes, or due to changes made as a result of inspection walk-throughs by code and regulatory authorities.

An important consideration at this point, is owner furnished equipment which is either provided by an equipment planner or by the owner directly. The contractor needs specific details in order to install utilities and services for this equipment. The manufacturer information that shows locations for utility connections is usually referred to as a "cut-sheet". This information should be provided to the contractor as early as possible to accommodate construction and buildout of the spaces where this equipment is to be located so as not to cause delays in the project.

The contractors, based on their experience and knowledge, may bring up issues related to integration of materials and how elements of the project coordinate on site, throughout the job. It important that the architects and engineers are responsive to these requests. These requests, referred to as "requests for information" (RFI), should be submitted in writing, serialized, recorded and referenced throughout the project.

RFI's may result in change orders that affect project cost or timelines.

Generally speaking, the contractor's scope of work is that which is outlined in the construction documents produced by the architect and engineer or design team. Anything required outside of the original scope of work may result in additional costs to the project.

Once a contractor completes the work required under the construction documents, the code authority will complete a review of the project to make a determination whether or not the end result meets the intent of the design in accordance with required building codes and standards and *sign off* on the project. Substantial completion is a significant project milestone and refers to the time when the contractor effectively turns the project over to the owner for beneficial use. At this time the contractor's responsibilities on the project site diminish and the contractor work warranty period begins, which is typically one year after substantial completion.

Also, as part of this process at this time there is an accompanying walk-through with design team representatives, the owner and staff – with the contractor to produce a list of final details for the contractor to complete. This list is often referred to as *"the punch list"*. It is important that the owner make a thorough review of the project, to have everything that they want the contractor to complete, on this list. Once the contractor is off the job and the warranty period is over, anything that doesn't work properly or is not installed properly will become an operations cost to fix or repair later.

## Costs and Budgets

The cost of the project determined at the outset, is a rough estimate of unknown details of the project and does not take into consideration, details of the complexity of any specific surgery center design. While establishing and maintaining a project budget, it is recommended that the owner request and review project estimates throughout the project design process.

The design team fees and costs are often predicated on the overall project costs and represent a percentage of the overall cost.

There are several points in the project design process where a revised budget estimate should be taken. First, after a design team is selected and a functional program has been developed. This will usually be a square footage estimate. Second, after the space program has been detailed and the functional program integrated into that schematic. Third, after design development.

These early estimates may be performed by the architect and engineers on the project, or by the contractor. To be accurate, it may be preferable that these estimates be performed by an outside independent estimator. If the project is not within budget, changes may be necessary and can be made to the design incurring minor cost changes to the project.

Wholesale changes made after the design is complete, and the contractor's estimate has been received are often referred to as "value engineering". Unmanaged value engineering may cause compromises to the design that produce greater costs later in the construction process. Any value engineering is to be carefully addressed by the architects and engineers as to the impact on the overall design and compliance with standards.

After completion of the construction documents, the contractor is selected based on the bid submitted. It is recommended, at that point, that the contractor, design team and owner, review the project to make sure the contractor has not left anything out of the project bid proposal.

## Other Things to Consider

The processes involved in licensure and accreditation of the surgery center need to be included in the budget planning. The period of time from substantial completion to the point when the surgery center becomes licensed may vary greatly from project to project. Lack of planning could result in loss of beneficial use of the space while waiting for licensure and accreditation. To this end, surgery center staff will need to be hired and retained at some point before substantial completion.

## When Can We Do Surgery?

After substantial completion, and before the surgery center can open for business, equipment and supply delivery begins so the staff can set up the surgery center in order to receive patients and perform cases. At the same time a series of inspections by licensure and accreditation agencies take place for obtaining licensure and CMS certification.

The successful completion of these inspections requires a series of documents, referred to as *"turnover documents",* provided by the contractor to the owner at the end of the project. Turnover documents include drawings, specifications, equipment records and startup testing and many more forms of submittals. Some of these records for startup testing and initial certification will be required to be reviewed on site by the inspection teams for accreditation, licensure and Medicare certification. These initial inspections and tests should be maintained in document notebooks separate from all other turnover documents for as long as the surgery center exists or until the next renovation project affecting the systems occurs. These are the master documents for the facility.

Another set of important documents for the facility are project waivers. These refer to all the plan review changes that have occurred during the course of the project. Every project has complex details where systems cannot be designed precisely by the design architectural/engineering elements to meet specific attributes of the codes and standards as written, resulting in comments made by the plan reviewers/code authorities, which have been responded to by the facility design team and accepted by the authority having jurisdiction. Records of this project correspondence should be maintained by the owner until the next renovation or long as surgery center is operational.

## Summary

An effective project for the ambulatory surgery center begins with a well-defined purpose for the surgery center and a thorough well-written functional program. The functional program not only impacts the design but also the budget and future licensure of the facility for the life of the facility. Important elements left out of the functional program limit the capacity of the design team and therefore limit the effectiveness of the contractor's work project (Figure 1.3).

A solid functional program, a well-organized design team and an effective budget, project coordinator and project schedule managed by a professional scheduler will result in a successful project that stays on track, finishes on budget and on time. (See Table 1.4)

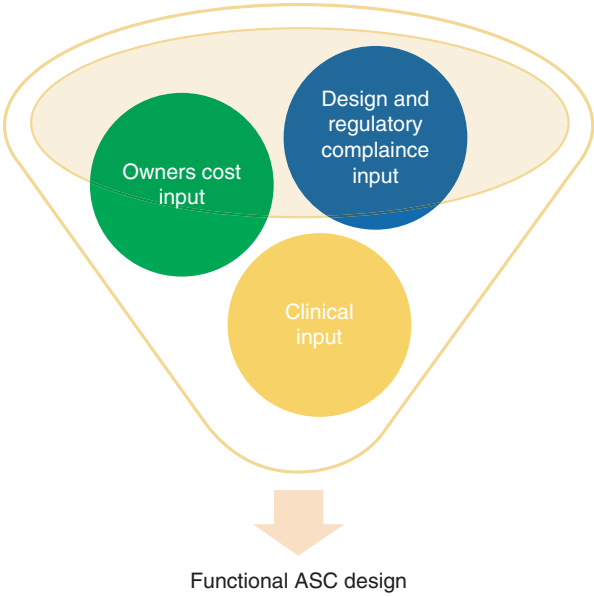


**Figure 1.3** The design process

**Table 1.4** Honorable Mentions Do's and Don'ts

| Should do | Beware and don't |
|---|---|
| **If the ASC is a tenant:**<br>Make sure access to building equipment is assured to the ASC<br>All testing of systems is provided or offered for compliance<br>Parking and handicapped spaces are provided; reserved for the ASC<br>ASC controls all environmental controls<br>Physical plant of building meets ASC minimums<br>Other important items<br>Always participate in the design and planning process<br>Assert and make designers aware of regulatory conformance<br>Design for serviceability and functionality not appearances / cosmetics only<br>Involve staff members as much as possible<br>Always have a functional program | Engage services of a design professional with NO active experience in ASC development – make sure your team members have the experience not just the firm<br>Do not use consultants that have not been in the ASC environment; An ASC is not a dental office, office base surgery and certainly not a hospital<br>When staff are involved make certain staff members are aware of regulation compliance requirements<br>Avoid proprietary equipment selections; controls operations costs<br>Always consider extended warranties from manufacturers on equipment offered only at time of purchase |

## References

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2. Ambulatory Surgical Care Services; Federal Standards Title 42 Part 416|Subpart C|§416.54; Title 42|Chapter IV|Subchapter B|Part 416|Subpart C → §416.54; Electronic Code of Federal Regulations e-CFR https://ecfr.io/Title-42/se42.3.416_154.
3. Facility Guidelines Institute: Guidelines for Design and Construction of Hospitals and Outpatient Facilities Circa. 2014.
4. Facility Guidelines Institute: Guidelines for Design and Construction of Hospitals and Outpatient Facilities Circa. 2010.
5. National Fire Protection Agency (NFPA) codes and standards; LIFE SAFETY CODE – NFPA 101 Circa. 2012 – Medicare Compliance Standards Circa (2015) most states standards.
6. National Fire Protection Agency (NFPA) codes and standards; HEALTHCARE FACILITIES CODE – NFPA 99 Circa. 2012 – Medicare Compliance Standards Circa (2015) most states standards.
7. CMS State Operations Manual: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c03.pdf.

## Resources

Design and Construction Documents – Templates.

The Engineers Joint Contract Documents Committee (EJCDC®) https://www.ejcdc.org/ejcdc/ EJCDC Marketing Executive Linda Yelton / Locust Grove / Phone: 703-403-4812 linda@ejcdc.org.

The American Institute of Architects; 1735 New York Ave NW; Washington, DC 20006-5292 Fax: (202) 626 7547 https://www.aiacontracts.org/.

# Obtaining ASC Contracts and Responding to RFPs

2

Judith Jurin Semo

## Introduction

Obtaining and maintaining practice opportunities are a uniquely important focus in ambulatory anesthesia practice in comparison with hospital-based anesthesia practice. Significantly, most ambulatory surgical centers ("ASCs") "have some degree of physician ownership".[1] In contrast, as of 2017, over three-quarters of registered community hospitals in the United States are either nongovernmental nonprofit hospitals (58.9%) or state or local government hospitals (19.8%), without ownership by individuals.[2] With referring physicians, having ownership interests in ASCs, the selection of which anesthesia practice will provide anesthesia in ASCs is more affected by the relationships with the physician owners than in a hospital.

In addition, there are changes in the anesthesia community affecting anesthesia practice at all sites – inpatient hospital sites, outpatient hospital departments, ASCs, and offices. Consolidation trends in the health care community in general and in the ASC industry in particular also greatly affect the ability of an anesthesia practice to obtain and retain its ambulatory business.

[1] MedPAC, *Report to the Congress: Medicare Payment Policy*, March 2018, at p. 137.

[2] American Hospital Association, *Fast Facts on U.S. Hospitals, 2018*, available at https://www.aha.org/statistics/fast-facts-us-hospitals (accessed 3/19/18).

Disclaimer

This chapter is for informational purposes only. The information in this chapter does not constitute legal advice. Readers should consult their own attorneys and not rely upon information in this chapter as legal advice.

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The focus of this chapter is on considerations relating to obtaining and maintaining contracts to provide anesthesiology services, responding to requests for proposals ("RFPs"), and regulatory issues that need to be considered in connection with obtaining ASC contracts.

## Consolidation in the ASC Industry

It is important to understand the ongoing changes in the health care industry in general, and in the ASC industry in particular, and how these changes affect opportunities for anesthesiologists.

Consolidation is occurring in all areas of health care, from commercial payors, to hospitals and health care systems, to physician practices, and to ASC companies. From 2014 through 2017 in the ASC industry, several developments should be noted.

- First, a small number of ASC companies control a large number of ASCs nationwide.[3]
- Several ASC companies have acquired, or have relationships through affiliated entities, with anesthesia practices.[4]

To the extent that a company operating or managing ASCs either has a relationship (through its own company or an affiliated company) with anesthesiologists and nonphysician anesthetists, the potential exists for an affiliated ASC to look "in-house" for anesthesiology services. Indeed, as discussed below in the section "Background: Why the Problem Exists", some referring physicians, who are not anesthesiologists, have formed their own anesthesia groups in arrangements known as "company models," and use their own anesthesia company to provide anesthesiology services at their ASCs. The legality of such arrangements needs to be scrutinized closely under federal and state law. For practical purposes, however, relationships between ASC companies and anesthesia groups, and the variety of

[3] Among them, Tenet/USPI, Envision/AmSurg, Surgical Care Affiliates/OptumHealth, HCA, and Surgery Partners own or operate over 900 ASCs in at least 35 states and DC. See Tenet Healthcare Corp., Form 10-K (filed Feb. 26, 2018), p. 7, available at http://investor.tenethealth.com/sec-filings (accessed 3/19/18); Envision Healthcare Investor Presentation, p. 3, available at http://investor.evhc.net/sites/emsc.investorhq.businesswire.com/files/doc_library/file/EVHC_March_2018_Investor_Presentation.pdf (accessed 3/19/18); UnitedHealth Group, Form 10-K (filed Feb. 13, 2018), p. 6, available at https://seekingalpha.com/filing/3880689 (accessed 3/19/18); HCA Healthcare, Inc. *2017 Annual Report to Shareholders*, p. 2, available at http://investor.hcahealthcare.com/sites/hcahealthcare.investorhq.businesswire.com/files/report/file/HCA_2017_Annual_Report.pdf (accessed 3/19/18); and https://www.surgerypartners.com/facilities (accessed 3/19/18).

[4] Seehttps://www.amsurg.com/news/amsurg-corp-to-acquire-sheridan-healthcare-in-transformational-transaction-valued-at-2-35-billion/ (May 29, 2014) (accessed 3/26/18); http://www.providenthp.com/wp-content/uploads/2015/12/AllCare-PR.pdf (accessed 4/2/18); http://ir.surgerypartners.com/static-files/6dad113b-f43c-4a7b-91ab-5479525beb22, at p. 4 (accessed 4/2/18); https://www.sec.gov/Archives/edgar/data/1638833/000163883317000007/ye2016exhibit211.htm (accessed 4/2/18); http://www.covenantsp.com/ (accessed 4/2/18).

company model and similar types of arrangements, may result in fewer opportunities for independent anesthesia groups to practice at ASCs.

Separately, health systems are moving to consolidate their agreements for outsourced physician services. The author has observed several health care systems, including for-profit and nonprofit systems, move to a single agreement for anesthesiology services, sometimes characterized as a "master services agreement," covering multiple facilities, including both hospitals and ASCs. In some instances, a master services agreement provides simplicity of having a single contract covering multiple facilities, so that the health system does not need to negotiate with multiple anesthesia practices for services. In other instances, the goal of the master services agreement is to minimize the level of financial support the health system may need to provide: By including several ASCs where anesthesiology services are expected to be self-supporting, the health system may be able to offset some of the cost of providing anesthesiology services at one or more hospital locations where compensation otherwise might be required to support anesthesiology services.

Together, these developments have resulted in a constriction of opportunities at ASCs. Certainly, opportunities may present themselves when a new ASC is opened or when an existing ASC decides to bring in a new anesthesia group. Anesthesiologists should, however, appreciate the market forces that are at play, and how they affect opportunities at ASCs.

## Obtaining ASC Agreements

### Introduction

Obtaining agreements to provide anesthesiology services at ASCs can be the result of luck, being in the right place at the right time, reputation in the community, personal relationships with key surgeons who own ASCs, an existing contractual relationship with the health system that owns an ASC, or a combination of all of these factors.

The location of an ASC may also tend to dictate which anesthesia group provides services at the ASC. An ASC that is housed in the same structure or on the same campus as a hospital may share the same anesthesia group with the hospital. Often, a hospital will own such an ASC, and the hospital may want the same anesthesia practice to staff both the hospital and the ASC for multiple reasons, including familiarity with the anesthesia practice, proximity and the efficiency of having anesthesia personnel readily available to staff all hospital and ASC locations, and, if applicable, the ability to cross-subsidize anesthesia services at the hospital with anesthesia services at the ASC.

Existing anesthesia practices may have some practical advantage in that they have a track record of providing services at one or more sites and longstanding relationships with surgeons and proceduralists. On the other hand, eager new anesthesia practices can be formidable competitors.

The discussion below outlines steps an anesthesia practice may take to improve its chances of being selected to provide anesthesiology services at an ASC.

## What Surgeons and Proceduralists Want

Obtaining contracts to provide anesthesia services at ASCs means understanding what the "customer" wants. Surgeons and other physicians who practice at ASCs want convenience and ease of practice. From an anesthesia perspective, that means that they want:

- Anesthesiologists and nonphysician anesthetists who are familiar with their practice, including the types of cases they perform and their preferences;
- Anesthesiologists who are proficient in performing regional blocks to address patients' postoperative pain needs;
- Anesthesiologists who move quickly and do not delay operating room ("OR") starts; and
- Anesthesiologists who do not cancel cases or raise objections to administering anesthesia to a patient in the ASC setting.

It should be noted that these "wants" are not necessarily consistent with good medical practice. Patient selection is particularly important in the ASC setting, as there are fewer equipment, personnel, and emergency resources in comparison with a hospital setting. Understanding what surgeons want can help a group to obtain a contract, but knowing when *not* to accommodate a surgeon's request can serve to promote patient safety.

ASCs seeking anesthesia groups also ask for other services, some of which can raise regulatory concerns. For example, an ASC may request that the anesthesia group perform a history and physical ("H&P") on patients. Anesthesiologists need to consider billing compliance issues, including, for example, whether such H&P is bundled into the global surgery package for the procedure, as well as the medical necessity for the anesthesiologist's services. If anesthesiologists cannot bill for the services they are required to provide, their agreement to perform services without regard to the ability to be paid for them could be viewed as an inducement to obtain the contract.

Requirements by ASCs or the surgeon-owners that they bill for the anesthesiologists' services also are fraught with regulatory risk. See discussion in section "Problematic Arrangements with ASCs", below.

## Relationships with Surgeons and Other Proceduralists

A group's responsiveness to surgeons and provision of high quality and efficient services in a hospital can lead to invitations to provide anesthesiology services in other settings. One of the most common ways for anesthesiologists to obtain ASC

agreements is to work with the surgeon-owners in other settings, most often, inpatient settings. As surgeons become familiar with the anesthesiologists in a practice, the surgeons then want to work with them in other settings. Invitations to provide anesthesiology services at ASCs frequently result from prior working relationships with the ASC physician owners.

Other relationships with surgeons outside the clinical setting, such as social relationships, may also provide a basis for an opportunity to respond to a request for proposal to provide services in an ASC, but those non-clinical relationships may not be as helpful, as surgeons want to understand an anesthesia group's ability to operate in the clinical setting.

Reputation in the community also can provide an entrée to an opportunity to bid on providing services at an ASC. It is common for ASC owners to assess multiple options for anesthesia services, even if the ASC owners are fairly certain that they want to go with a particular anesthesia practice. Having a good reputation in the community, or a strong national reputation, including doing a good job at an existing ASC in the community, can lead to additional invitations either to provide anesthesiology services at other ASCs or to respond to an RFP.

## Advance Planning: Marketing

Some anesthesia practices are doing marketing, either themselves or using professional marketers. Their goal is to familiarize facilities and surgeon practices with their services and their interest in providing anesthesia services for such facilities and practices. Marketing can take multiple forms, including sending brochures and e-mail solicitations to facilities, arranging in-person meetings, publishing whitepapers on their websites, conducting webinars, and exhibiting at conferences. The anesthesia community is familiar with some large national anesthesia practices that exhibit at national anesthesia conferences. Increasingly, small and medium-sized anesthesia practices are marketing their practices.

For example, some anesthesia groups exhibit at conferences that cater to the ASC community, including national conferences of the Ambulatory Surgical Center Association, as well as national meetings of medical specialty associations, such as gastroenterology associations, and at ASC conferences sponsored by Becker's *ASC Review*. Some anesthesia practices are retaining marketing specialists to prepare marketing material and to conduct reviews of opportunities in the community, including surveying facilities regarding their anesthesia needs.

Looking at the publications and whitepapers of other anesthesia groups may be informative, as an anesthesia practice can see how others market themselves and their services.

Marketing may not secure practice opportunities for an anesthesia practice, but it can assist in ensuring that the anesthesia group is invited to bid on practice opportunities at ASCs. Marketing should be done carefully, so that efforts to publicize a group's capabilities do not constitute tortious interference with the contracts or relationships that other anesthesia groups have with ASCs.

Anesthesia groups should never underestimate the extent to which others are soliciting their facilities. Although marketing may seem to be unnecessary, anesthesia practices should appreciate the importance of creating widespread awareness of their practice and its capabilities.

## Advance Planning: Accreditation

Accreditation is not just for facilities. An anesthesia practice may want to consider becoming accredited by one of the several accreditation organizations. Achieving accreditation can set an anesthesia group apart by providing external, independent validation of the anesthesia group's ongoing commitment to improve the care and services that it provides. Accreditation documents an anesthesia practice's commitment to engage in self-evaluation and education and to be surveyed by independent surveyors on a periodic basis.

For anesthesia practices that specialize in providing ambulatory anesthesia services, accreditation by one of the accreditation organizations that specialize in ambulatory care may be desirable, such as the Accreditation Association for Ambulatory Health Care, Inc., the American Association for Accreditation of Ambulatory Surgery Facilities, Inc., and The Joint Commission (through its Ambulatory Care Accreditation Program).

Accreditation organizations tout multiple advantages of accreditation, including possibly reducing professional liability costs and possibly providing a competitive edge to obtain new business. Any advantages to an anesthesia group need to be carefully weighed against the costs associated with preparing to attain and maintain accreditation. The websites of these accreditation organizations, and those of other entities that accredit ASCs, including the Healthcare Facilities Accreditation Program, will provide additional information that will be useful in assessing the pros and cons of seeking accreditation.

## Advance Planning: Having a "Right of First Refusal" in Agreements with Hospitals

A key way for an anesthesia practice to secure the right to practice at an ASC is to have a contractual right to be the exclusive provider of anesthesiology services at any ASC or other ambulatory care center in which the hospital has an ownership interest – either in whole or in part, or that bears the hospital's or health system's logo. This strategy only works for ASCs that are owned in whole or in part by hospital systems. According to data from the Ambulatory Surgery Center Association, only 28% of ASCs have some percentage of hospital ownership.[5]

[5] ASCA 2017 Salary & Benefits Survey summarized at http://www.advancingsurgicalcare.com/advancingsurgicalcare/asc/benefitsofphysicianownership (accessed 3/19/18).

While having a right of first refusal, or a right of first option, to be the exclusive provider of anesthesiology services at an ASC can be a useful tool, it can be difficult to negotiate a broad right. The following points are among the ones to consider when negotiating a right of first refusal with a hospital.

## Scope of Right: ASCs Covered

### Scope of Hospital Entities Covered

The right of first refusal needs to apply not only to ASCs owned by the hospital itself, but by the parent hospital system and any affiliate, parent, or subsidiary entities (together, the "Hospital Entities").

### Partially Owned ASCs

Second, the right of first refusal needs to extend not only to ASCs that the hospital owns in whole, but also to those ASCs in which the hospital owns a partial interest. Since 89% of the hospital-owned ASCs are owned only in part by the hospital, and also by physicians (with some also owned by corporate interests),[6] the right of first refusal must extend to ASCs owned in part by the hospital or any of the Hospital Entities.

Hospitals sometimes push back and limit the right of first refusal to those ASCs in which the Hospital Entities own a controlling interest, rather than those entities in which the Hospital Entities own a minority interest. At a minimum, the anesthesia group will want the right of first refusal to extend to all ASCs in which the Hospital Entities own a majority interest, a controlling interest, or a veto power over ASC decisions.

If the hospital will not agree to cover partially owned ASCs in which the Hospital Entities do not own a controlling interest, the anesthesia practice will want to require in the right of first refusal language that the Hospital Entities agree to advocate and vote the Hospital Entities' ownership interest to have the anesthesia practice selected as the exclusive provider of anesthesiology services.

### Extent of ASCs Covered

It is in an anesthesia practice's interest for a right of first refusal with the hospital to extend not only to ASCs that the Hospital Entities own or control, but also those ASCs that the Hospital Entities manage, operate, otherwise participate in the operation or management, or that carry or advertise the hospital or health system name or logo. This approach may cover ASCs that the Hospital Entities do not own or control, but other ASCs at which the Hospital Entities make operational decisions.

### ASCs the Hospital Entities Acquire

When the Hospital Entities acquire an ASC that already has an anesthesia provider, the Hospital Entities may be reluctant to force displacement of the existing

[6] *Id.*

anesthesia provider. The anesthesia group negotiating with the hospital for a right of first refusal may want to consider any of the following options:

1. The group may want to require that it have the right of first option at any ASC the Hospital Entities acquire, so as to avoid losing (or minimize the potential to lose) cases to such an ASC.
2. The group may want to require that it have the right to be the exclusive provider of anesthesiology services at such an ASC either from the earliest time when such existing contract can be terminated, or (less desirably) when the existing contract expires. The group will want to limit the ability of the Hospital Entities to extend or renew any existing contract with the anesthesia provider.
3. The anesthesia group also may want to require, as part of the right of first option, that the Hospital Entities arrange an opportunity at an early stage of the planning process for the anesthesia practice to make a presentation to the governing board of the ASC being acquired regarding the anesthesia group's services. Such a presentation will not assure that the owners will select the anesthesia group, but it can serve to promote the awareness of the group and the quality of the anesthesiology services the group provides.

### Scope of Right: Anesthesia Practice's Rights

It is important that any contractual right of first refusal extend beyond providing simply a right for the anesthesia group to compete to provide anesthesiology services at an ASC covered by the right of first refusal. The anesthesia practice negotiating with the hospital will want the right to be the exclusive provider of (i) anesthesiology services and (ii) all anesthesiologists and nonphysician anesthetists at the ASCs covered by the right of first refusal.

### Remedy

To be effective, it is useful to include a remedy for breach or threatened breach of a right of first refusal, which includes the right to obtain injunctive relief to enforce the group's rights and to obtain attorneys' fees and other reasonable expenses the group incurs in enforcing its right. The remedy should survive termination or expiration of the hospital services agreement, in case litigation extends beyond the term of the hospital agreement.

### Right to Match

Anesthesia practices are not always able to obtain a right of first refusal that includes the elements discussed in this chapter. If a hospital will not include a full right of first refusal, and only will allow the anesthesia group to bid on an ASC, the anesthesia group will want the ability to match the terms under which a third party offers to provide anesthesiology services at an ASC owned or controlled by the hospital or one of the Hospital Entities. This right to match may also be useful to include even in broader rights of first refusal, in the event the group and the ASC are unable to agree upon terms of coverage.

A right to match is not always the solution it may appear, as offers by third parties may contain unrealistically low offers that an anesthesia group cannot match.

On the other hand, a right to match may provide the anesthesia group with useful leverage to secure the right to provide services at an ASC.

## Advance Planning: Restrictions on Outside Practice in Hospital Contracts

An assumption underlying this chapter is that an anesthesia practice has the freedom to provide services at ASCs. Anesthesia groups need to be careful that their professional services agreements with hospitals do not limit the ability of the groups to provide services to ASCs in the community.

Although anesthesiologists do not "take" cases from hospitals, as it is the surgeon or proceduralist who decides where to take the patient, the author has observed that many hospitals and health systems insist upon precluding the anesthesia practice at their hospital from providing anesthesiology services in a designated service area. The "restricted" area may be expressed in terms of the hospital's service area, a radius of a designated distance surrounding the hospital, or one or more named counties in which the anesthesia group is restricted from practicing. Such restrictions may apply only to the anesthesiologists and nonphysician anesthetists who provide services at the hospital; they may also extend more broadly to the anesthesia group itself and any entity owned in whole or in part by the anesthesia group or its anesthesiologists and/or nonphysician anesthetists.

A restriction on "outside" practice can effectively stifle an anesthesia group's ability to react to market changes and to provide services at ASCs in its community. As more surgery migrates to non-hospital settings, and as the population ages, hospitals with sicker and older patients may have more governmental payors, in comparison with the payor mix at ASCs. As a consequence, because Medicare[7] and many state Medicaid programs pay less for anesthesiology services than do commercial payors,[8] the inability to practice at ASCs in the area may lead to an anesthesia group becoming less profitable and reliant on a hospital system for compensation at fair market value levels to support inpatient anesthesiology services.

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[7] See General Accountability Office, *Medicare and Private Payment Differences for Anesthesia Services,* GAO-07-463: Published July 27, 2007 (publicly released: Aug. 27, 2007), available at https://www.gao.gov/products/GAO-07-463 (accessed 3/30/18).

[8] The highest Medicaid conversion factor for anesthesia services (as of July 2016) among all states was Alaska at $42.90 per unit and the lowest conversion factor for anesthesia services at that same time was New York at $10 per unit (see *The Silent M in CMS Packs a Big Punch*, July 2016, available at https://www.asahq.org/quality-and-practice-management/practice-management/timely-topics-in-payment-and-practice-management (accessed 4/3/18)), whereas the average commercial payor conversion factor for anesthesia services in 2016, based upon the American Society of Anesthesiologists survey of fees paid by commercial payors for anesthesia services, was $71.02 (see *ASA Survey Results for Commercial Fees Paid for Anesthesia Services – 2016,* ASA Monitor: 80:58–65 (Oct. 2016) (available at http://monitor.pubs.asahq.org/article.aspx?articleid=2555794 (accessed 4/3/18)). Stated otherwise, the highest and lowest Medicaid conversion factors were 40% and 86% lower, respectively, than the average commercial rate, without taking into account other methodology differences in payment by state Medicaid programs, which further reduce the level of payment in comparison with payment rates by commercial payors.

## Advance Planning: Develop a Relationship with an ASC Company

The strategy of developing a relationship with an ASC company may be difficult to implement, but it is worth noting that some anesthesia practices have secured contracts to provide services at other ASCs through such a relationship. In the few instances in which the author has observed this fact pattern play out, the anesthesia group provided services at an ASC owned by a national ASC company that was impressed with the service that the anesthesia group provided, in terms of the quality of anesthesia services provided, management of the anesthesiology department and development of policies and procedures relating to anesthesiology services, and efforts to promote efficiency and case turnover. The ASC management company took particular note of the proficiency of the anesthesiologists in performing regional anesthesia and providing post-operative pain blocks, which facilitated prompt recovery and discharge of patients and served to increase patient satisfaction.

In one instance, the national ASC company offered the anesthesia group, which was a relatively small independent practice, contracts at ASCs in other geographic markets. The result was somewhat the antithesis of the typical scenario, with a small anesthesia practice deploying its personnel and recruiting additional personnel in other markets, which were a plane ride, rather than a car ride, away.

This strategy may be more difficult to implement for many reasons, including the cost of arranging to provide services in other markets. It does serve to illustrate the importance of developing good relationships with the ASC(s) at which an anesthesia group practices.

## Understand the Changing Market of Anesthesiology Practice and Ambulatory Anesthesia Practices

The discussion in section "Consolidation in the ASC Industry", above, addresses consolidation in the ASC industry and the effect on the ability of anesthesia groups to obtain ASC contracts. At the same time as the ASC industry is consolidating, the physician community in general and the anesthesia community in particular is also undergoing a trend toward consolidation, with national anesthesia practices acquiring independent anesthesia groups and forming national anesthesia groups with multi-state operations.

The changing nature of the anesthesia market combined with consolidation of health systems and ASC companies (see section "Consolidation in the ASC Industry", above) can be anticipated to affect the availability of opportunities to practice at ASCs. Certainly, anesthesia practice is becoming more competitive and the existence of larger anesthesia practices with resources to market their services, to respond to RFPs, to recruit and credential anesthesiologists and nonphysician anesthetists, and to deploy transition teams to implement new contracts can be expected to make it more challenging for smaller anesthesia practices to compete for ASC agreements.

## Consolidation: ASC Companies Owning Anesthesia Practices

As noted in Section "Consolidation in the ASC Industry", above, some ASC companies are integrating vertically and adding ancillary service lines, which in some instances includes anesthesiology services. AmSurg's 2014 acquisition of Sheridan Healthcare, and the 2015 acquisition by Surgery Partners of an anesthesia practice in North Carolina[9] stand as two examples.

## Consolidation: Equipment Manufacturer Owning Anesthesia Practices

On December 2, 2014, CRH, a medical equipment company providing products and services for the treatment of gastrointestinal diseases, announced the acquisition of Gastroenterology Anesthesia Associates, LLC for a total purchase price (assuming achievement of all performance measures) of $73.2 million.[10] CRH has announced acquisitions of multiple anesthesia practices since 2014,[11] and, as of March 2018, in

[9] See http://www.providenthp.com/wp-content/uploads/2015/12/AllCare-PR.pdf (accessed 3/26/18).

[10] See https://www.prnewswire.com/news-releases/crh-medical-announces-significant-acquisition-284467481.html (accessed 4/2/18); http://investors.crhsystem.com/press-releases/december-2-2014/ (accessed 12/2/14).

[11] See https://www.prnewswire.com/news-releases/crh-medical-corporation-announces-majority-purchase-of-an-anesthesia-practice-in-north-carolina-and-provides-an-outlook-for-q3-2017-646777323.html (anesthesia practice in Raleigh, NC provides anesthesia services to three ASCs in NC) (accessed 4/2/18); https://www.prnewswire.com/news-releases/crh-medical-corporation-announces-majority-purchase-of-anesthesia-practice-in-central-colorado-643712263.html (anesthesia practice in Central Colorado provides anesthesia services to three ASCs) (accessed 4/2/18); https://www.prnewswire.com/news-releases/crh-medical-corporation-announces-majority-purchase-of-an-anesthesia-practice-in-west-florida-637957183.html (anesthesia practice in West Florida provides anesthesia services to one ASC) (accessed 4/2/18); https://www.prnewswire.com/news-releases/crh-medical-corporation-announces-majority-purchase-of-an-anesthesia-practice-in-decatur-georgia-612398893.html (anesthesia practice in Decatur Georgia provides anesthesia services to one ASC) (accessed 4/2/18); http://www.marketwired.com/press-release/crh-medical-corporation-announces-majority-purchase-arapahoe-gastroenterology-anesthesia-tsx-crh-2138948.htm (Arapahoe Gastroenterology Anesthesia Associates, LLC provides anesthesia services to one ASC in Littleton, Colorado) (accessed 4/2/18); http://www.marketwired.com/press-release/crh-medical-corporation-announces-majority-purchase-of-community-anesthesia-pllc-2134904.htm (Community Anesthesia, PLLC provides anesthesia to four ASCs in the Greater Boston area) (accessed 4/2/18); http://www.marketwired.com/press-release/crh-medical-corporation-announces-majority-purchase-austin-gastroenterology-anesthesia-tsx-crh-2130707.htm (Austin Gastroenterology Anesthesia Associates, LLC provides anesthesia services to two ASCs in Austin, TX) (accessed 4/2/18); http://www.marketwired.com/press-release/crh-medical-corporation-announces-the-acquisition-of-johns-creek-anesthesia-tsx-crh-2085207.htm (Johns Creek Anesthesia, LLC provides services to an ASC in the Johns Creek, GA area) (accessed 4/2/18); http://www.marketwired.com/press-release/crh-medical-corporation-announces-majority-purchase-macon-gastroenterology-anesthesia-tsx-crh-2081352.htm (Macon Gastroenterology Anesthesia Associates, LLC provides anesthesia services to an ambulatory surgical center in the Macon, Georgia area) (accessed 4/2/18); http://www.marketwired.com/press-release/

addition to the initial acquisition, CRH had acquired four anesthesia businesses in 2015, two in 2016, and six in 2017.[12]

## Preparing to Respond to Requests for Proposal

### Introduction

In some respects, it is difficult to provide general guidance regarding how to respond to an RFP, as the response necessarily needs to respond to the specific requests for information in the RFP. On the other hand, there are steps anesthesia practices need to take in advance to position themselves to respond to RFPs, whether from the ASCs at which the anesthesia groups already provide services or from new ASCs or existing ASCs that are exploring their options for anesthesiology services.

Many of the points in this section are common sense suggestions. The difficulty in implementing them is that often anesthesia groups either do not have the resources, or their leadership is so busy managing existing relationships that it does not have (or make) the time to implement some of the processes that later can serve to distinguish their services and better position them to respond to an RFP.

The suggestions outlined below represent the opinion of the author based on observation of multiple RFP processes.

### Preparation

Anesthesia practices need to consider how they will distinguish themselves from other respondents if an RFP is issued. What advantages does an anesthesia group offer? Many groups tout the quality of the anesthesiology services they provide, the qualifications of their anesthesiologists, and their ASC experience, but what support does a group have to demonstrate these qualifications? An anesthesia group needs to be prepared to outline and document why it should be selected or, in the current lingo, demonstrate its value proposition. Importantly, this preparation needs to take place before an RFP is issued, as (1) often there is a narrow window within which to respond to an RFP, and (2) it takes time to design and implement the processes outlined below and to quantify the data that these processes will yield.

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crh-medical-corporation-announces-majority-purchase-knoxville-gastroenterology-anesthesia-tsx-crh-2054573.htm (Knoxville Gastroenterology Anesthesia Associates provides anesthesia services to three ASCs in the Knoxville, Tennessee metropolitan area) (accessed 4/2/18); http://www.marketwired.com/press-release/crh-medical-corporation-announces-anesthesia-services-transaction-tsx-crh-2048759.htm (acquired the GI anesthesia business of Associates of Digestive Health, LLC in Cape Coral, FL) (accessed 4/2/18).

[12] See CRH SEC Filing 40-F, Annual Report for the Fiscal Year Ending December 31, 2017, https://www.last10k.com/sec-filings/1461119#reportStats, pp. 8–10 (accessed 4/2/18).

### Documentation of the Quality of Anesthesiology Services Provided

A key selling point of any anesthesia group is that it provides high quality anesthesia services. But how will the group demonstrate its quality? Does the group measure its performance on quality metrics of interest to an ASC? Has the group tracked metrics such as its reintubation rate, failed blocks, and transfer to a hospital? How does the group's performance compare with that of other anesthesiologists? A group needs to be able to benchmark its performance to that of other groups to support its claims of excellence and to respond to questions that may be included as part of the RFP.

### Documentation of the Group's Efficiency in Providing Anesthesiology Services

While efficiency is important in all settings – inpatient, outpatient, ASC, and office, ASCs selecting among bidders will be particularly focused on how an anesthesia group will promote efficiency in the ASC's operations. Being able to demonstrate that an anesthesia group can assist in prompt turnovers or otherwise assist in promoting the efficient operation of the ASC will be important. A group needs to have data regarding its turnover times for different types of surgical procedures, its cancellation rate, the average length of a patient's time in the PACU, and other relevant statistics to demonstrate its efficiency in the ASC setting. Simply relying on unsupported statements or anecdotes is less convincing.

### Documentation of the Group's Ability to Save an ASC Money

An outgrowth of effective, high quality anesthesia services and efficiency is the ability to save an ASC money. An anesthesia group that can document how it has saved facilities money in other settings – such as through promoting faster discharge from an ASC (consistent with no decrement in quality), through providing pain control and managing post-operative nausea and vomiting, or by fostering prompt turnover of cases, particularly if the group has made it possible to do another case – will be in a better position to compete for an ASC agreement.

### Surgeon, Patient, and Facility Staff Satisfaction Surveys

A key selling point of any anesthesia group is that it has qualified and personable clinicians: that surgeons like to work with its anesthesiologists, patients give the group's anesthesiologists high ratings, and facility (hospital and/or ASC) staff like to work with its anesthesiologists. An anesthesia group needs to be able to document its satisfaction scores for all segments: (1) surgeons and proceduralists, (2) patients, and (3) ASC (or Hospital, if the group does not provide services at an ASC) staff. Some ASCs want to see scores broken out by individual anesthesiologist (a group may prefer to share only aggregate information).

In addition to being able to document those scores, a group also needs to be able to benchmark its scores to those of other anesthesia practices. Without data, an anesthesia group will be at a competitive disadvantage.

### Leadership of the Preoperative Assessment Process

Facilities and surgeons commonly look to anesthesiologists to take the lead in developing and implementing processes for preoperative assessment to enhance patient care, improve operating room efficiency, minimize case cancellations, and increase patient and surgeon satisfaction. An anesthesia group competing in an RFP process can expect that the ASC will ask about how the group manages the preoperative assessment process, and should be prepared to describe specific steps the group takes to manage the preoperative assessment process.

Does the group have specific protocols it has implemented? Does it provide surgeons and proceduralists with specific tests the anesthesia group will want to see for higher risk patients? How does the group work with preadmissions nursing and administrative staff to ensure that patients are adequately evaluated in advance of the day of surgery? What is the process for group anesthesiologists to screen patients in advance of the day of surgery and, where necessary, to see them?

It may be that an anesthesia group takes many of these steps on a routine basis, but has not documented them in an orderly fashion to be able to implement them at other sites. To prepare to respond to an RFP, the group needs to memorialize its processes (and protect its ownership of such documents by copyrighting them) in protocols, policies, and procedures.

### Dashboards with Key Performance Measures

It is not uncommon for facilities to ask anesthesia groups in an RFP for the group's dashboard of key performance metrics. An anesthesia group that is not already tracking key performance metrics or indicators ("KPIs") should consider the KPIs that are most important for the group in an ASC setting. The metrics might include examining causes of delay and promoting first case on-time starts, implementing care protocols and an effective preadmission review process to ensure patients are optimized before they present for surgery, and instituting a post-operative pain control process that focuses on pain modalities most appropriate for different surgical service lines (*e.g.*, orthopedics, urology, ophthalmology, and gynecology).

To be most effective, an anesthesia group will want to have data for KPIs over a multi-year time period and be able to demonstrate how the group has worked to promote excellence in patient care as well as patient and surgeon satisfaction.

### OR Management

The need for OR management is important in an ASC setting, just as it is in an inpatient setting. It can be difficult to implement fixes for poor block time utilization and to enforce OR management policies in an ASC setting in which the surgeons and proceduralists own interests in the ASC. Nonetheless, an anesthesia group should be able to demonstrate how it has provided OR management services in ambulatory settings and otherwise has assisted the ASC to schedule cases and procedures in a more efficient manner.

## Information Regarding the Anesthesia Group and Its Anesthesiologists

Anesthesia practices typically are focused on caring for patients and meeting their contractual obligations to the facilities at which they provide services. At the same time, however, they should consider having narratives prepared that they update from time to time regarding their practice, history, organization (including governance structure), practice locations, leadership roles in which group anesthesiologists and nonphysician anesthetists have served, and mission. They also should consider preparing the following information regarding their groups.

### Curricula Vitae

An anesthesia group should prepare curricula vitae (each, a "CV") for each anesthesiologist and nonphysician anesthetist in the group, using a standard format. In addition to outlining the education, training, board certifications, and experience for each group anesthesiologist and nonphysician anesthetist, the anesthesia group should include information on the leadership positions that any such individuals hold or have held at different facilities, with particular emphasis on ambulatory settings; any publications; and any awards or other honors.

Having these documents prepared in advance can assist a group in putting together a prompt response to an RFP.

### Specialty Training and Relevant Certifications

A group should consider which of its anesthesiologists have fellowship training in clinical areas that ASCs commonly seek. For example, ASCs often want pediatric anesthesiologists even in ASCs that cater primarily to an adult patient base in order to be able to attract surgeons and proceduralists with a pediatric practice. ASCs also may be interested in anesthesiologists who have completed fellowships in regional anesthesia, to assist in providing anesthesia in the ambulatory environment and in performing post-operative pain services. The group also should identify relevant certifications, such as PALS, of its anesthesiologists in any summary of the group's physicians.

### Licensure in Other States

For anesthesia groups that practice in multiple states, that would like to practice in multiple states, or are located in a market that is close to one or more other states, the group should consider the states in which its anesthesiologists and nonphysician anesthetists are licensed to practice and whether it makes sense to credential its clinical staff in one or more other states. Again, this step may seem to be an unnecessary administrative and financial burden, until an opportunity arises and a group realizes that it does not have sufficient clinical personnel to staff a location in a neighboring state. In some states, anesthesia groups have discovered that it can take

a long time – six to nine months or longer – for an experienced anesthesiologist to become licensed in the second state. That time lag can preclude a group from being able to compete for an opportunity.

### Group Stability

In a time of enormous change in the health care industry, with consolidation of facilities, payors, and physicians, it can be a competitive asset to demonstrate that the anesthesia group has a history of retaining personnel and having a low rate of turnover among anesthesiologists and nonphysician anesthetists. ASCs frequently make requests for consistent staffing in the ASC and minimizing turnover of anesthesia personnel. Being able to demonstrate the group's ability to retain personnel can be a strong selling point.

### Governance

ASCs want anesthesia groups that can make decisions quickly and not have to wait for a group to review all matters in a group meeting. Another selling point for an anesthesia group with a strong governance structure is its ability to be nimble in making decisions. An anesthesia group with a well-organized governance structure should feature that capability in its summary of the group's operations.

### Strong Administrative Staff

ASCs want anesthesia groups with well-managed practices. Having a well-qualified practice administrator (whatever the individual's title) is evidence of a group's investment in its operations and is a point that the group should note in its summary of its operations. Having a strong administrative team to execute group decisions and oversee the business of the practice can assist in demonstrating a group's commitment to its practice. ASC administrators and ASC management firms want to know that they have a business counterpart within the anesthesia group who can address operational issues.

### Prior Successful History

Having a successful track record of having started at a new ASC, or having successfully transitioned at an existing ASC, can be a distinguishing selling point. ASCs want to know that the anesthesia practice group has successful experience in the ASC setting.

## Implementing these Recommendations: Identifying Resources

An anesthesia group may consider this preparation to be a time-consuming and resource-intensive endeavor, if it does not envision participating in an RFP process. On the other hand, not taking these steps can impede the ability of the anesthesia group to be nimble and to be able to respond promptly to an RFP. A group that is actively trying to manage the perioperative process may find that assembling this information consists of documenting the steps the group already takes. For other

groups, preparing this type of information may assist them to identify weak areas in which they can improve.

To implement these suggestions, an anesthesia group may want to task its practice manager or a committee with preparing portions of the information and combining the pieces. Another option is for an anesthesia group to retain outside assistance in preparing this information and implementing other steps, such as surgeon and patient satisfaction surveys. Many different firms provide these types of services, including marketing firms that specialize in marketing physician practices, including anesthesiology groups; consulting firms with expertise in anesthesia and in responding to RFPS and even running RFP processes and evaluating proposals; and attorneys who specialize in health care.

To identify such firms with expertise, an anesthesia group may want to consider the vendors that exhibit at anesthesia conferences, including the Society for Ambulatory Anesthesia ("SAMBA"), the American Society of Anesthesiologists ("ASA"), and state component society meetings. The ASA practice management and quality staff may be able to offer suggestions, and state component society staff or state medical association staff members may be able to assist in identifying marketing firms, consultants, and attorneys with expertise in anesthesia and relevant experience. Of course, word of mouth and networking can also be effective tools to identify resources.

## Implementing These Recommendations: Appearances Count

In connection with implementing these recommendations, an anesthesia group should consider appearances and how the group will present its information in an effective manner, if it needs to respond to an RFP. It can be important to use images and visuals, and not text alone, in responding to an RFP and to prepare a document that looks professional – including considering appearance details such as fonts, colors, and themes. The point is for the anesthesia group to consider all of these elements in advance and to identify the resources to utilize when the need arises.

In some cases, RFPs have been issued with proposals due in as short a time period as one to two weeks. Response times often are no longer than three weeks or a month. An anesthesia group will want to be ready to respond, and not rush to assemble a response.

## Other Basic Information About the Anesthesia Practice

An anesthesia practice should also consider ensuring that it has updated its website (if it does not have one, it should create one). If the practice does not have a logo and a tag line, a brief descriptive summary of the group and/or its mission, it should develop both. Branding involves making a group distinctive; a logo and a tagline serve to distinguish an anesthesia group from others. In an increasingly competitive practice environment, such basic identifiers can be important.

The anesthesia practice should also make sure that its anesthesiologists and administrative staff have business cards. If the group responds to an RFP and makes an in-person presentation, it will want to be able to provide contact information for its anesthesiologists and key administrative staff members. Even as society generally moves to electronic interfaces and communication, business cards are a useful business tool.

## Responding to RFPs

### The Response Depends Upon the Context

How an anesthesia group responds to an RFP depends upon many factors, including whether the group is the incumbent anesthesia group or is seeking to provide services at the ASC, as well as the reasons why the ASC is issuing an RFP. The incumbent group has the advantage of knowledge of the ASC's requirements and assessing the accuracy of the information in the RFP. Outside groups have the possible advantage of not having any negative history that may be associated with the incumbent group.

The comments in this section are generalities that need to be tailored according to the anesthesia group's situation and market dynamics.

For incumbent groups, this discussion assumes that the incumbent group is included in the RFP recipients and is asked to respond. That is not always the case, particularly if the ASC is looking to replace the existing anesthesia practice.

### Review the RFP Carefully; Understand the Deadlines

Although this point sounds basic, it is very important to review the RFP carefully, understand the time line, including the day and hour by which proposals must be received, and the date by which questions and requests for clarification must be submitted. Both the big picture – the information being requested – and the details – how many copies must be submitted – are incredibly important.

The group will want to review the RFP to assess areas of ambiguity or additional information that is needed. Often, the facility issuing the RFP sets a deadline by which questions must be submitted. The group should make sure it submits its questions in a timely manner.

The group also should review whether or not the ASC has included its template professional services agreement as part of the RFP. In some instances, the facility seeks to use the RFP process not only to identify possible groups, but also to foreclose negotiation on a services agreement by stating that any response to the RFP is an agreement to sign the draft services agreement. An anesthesia group responding will need to identify any areas of the agreement that the group believes need to be clarified or modified.

Working backwards from the due date, the group needs to prepare a timeline for preparation of the proposal, allowing adequate time for (1) drafting the proposal, (2) allowing time for review and revision, (3) allocating time for any further review, and (4) printing, assembly, and delivery of the proposal. In cases in which the ASC is not in the immediate geographic area in which the group is located, the group must consider how it will deliver its proposal. Even in the current environment in which electronic communication is common, ASCs commonly ask for multiple hard copies of the proposal.

The group should identify who will draft the proposal, what additional information the group needs to respond, what issues require decisions by the anesthesia group's decision-making body, and by what date the draft needs to be in final to allow time for printing and delivery. Too often, groups see a time frame of four weeks and think they have adequate time to prepare a response, only to see that a proposal takes time to prepare.

## Confidentiality Agreement

Some RFPs require that the anesthesia practice sign a confidentiality agreement in which, as a condition of responding to the RFP, the group agrees not to disclose the RFP or any information received in connection with the RFP. Those confidentiality agreements tend not to be subject to negotiation, though the group will want to ensure that the ASC agrees to maintain the confidentiality of all information the group submits, including after termination of the confidentiality agreement.

The ASC also may require that the group sign a letter of intent, binding the group to sign a professional services agreement, if the ASC selects the group. The group needs to consider whether any such letter of intent contains provisions that are problematic for the group.

## Technical Suggestions

At the risk of addressing very basic points, it is important to confirm whether the RFP states how responses are to be organized. In the absence of specific instructions, it is advisable to implement the following suggestions:

### Organization

Respond to each question or point in the RFP in the same order in which they appear in the RFP. Consider reprinting each question or request for information in its proposal, both to provide context for the response and to ensure that the group responds to each point in the RFP.

The group may wish to include an introductory section before it responds to the RFP. Any such opening text should be included at the beginning of the proposal and should be clearly designated as an introductory statement before the responses to the RFP appear. It is advisable for any such text to be concise.

### Identification
List the group's name and the page number (expressed as "page xx of yy") on each page, in case pages become separated at some point.

### Contact Information
Ensure that the name and contact information of the group's primary representative appear on the proposal cover page to facilitate communication with the group, even if the RFP requests this information later in the proposal.

### Printing and Binding
Consider binding the proposal in some manner to facilitate review without having the pages become out of place. The group may want to include a cover page in color, with the group's logo and tag line, to distinguish the group from other bidders and to provide for a professional appearance.

### Formatting
The proposal needs to be readable. Consider using graphics or other visual images to assist in making the proposal easy to follow. If the proposal is primarily a text document without graphics, be sure that the paragraphs are not long and there are frequent headers to facilitate a quick read-through of the document. Also consider using boldface text, italics, or underscoring, or text boxes, to highlight key points. It also is advisable to include a table of contents.

## Substantive Suggestions

The RFP will dictate the substance of the anesthesia group's response. That said, the group will want to weave in the themes outlined below into its responses (not as separate sections) to establish and document its capability and desire to provide the requested services. Implementing the preparation steps outlined in section "Preparation", above, should facilitate preparation of the group's response to the RFP.

### Ambulatory Experience
An anesthesia group responding to an RFP from an ASC will want to highlight its ambulatory experience. ASCs are different from hospitals, in terms of the staffing and equipment available, at the same time as increasingly complicated and longer surgical procedures are being performed in ASCs. ASCs want to be sure that the anesthesia group it selects can function effectively in the ASC environment. ASCs and ASC management companies look for ambulatory experience, so the group will want to outline its ambulatory anesthesia credentials.

### Ability to Manage Multiple Locations
An anesthesia group will want to confirm its ability to manage the provision of anesthesia services at multiple locations and to deal with competing demands for personnel. This point is particularly important for groups serving one or more hospitals that are seeking to expand to the ambulatory arena.

### Capability and Staffing, Including Subspecialty Expertise of Group Anesthesiologists

In responding to an RFP, an anesthesia group will want to highlight the credentials of its anesthesiologists, particularly as they relate to skills needed at the ASC. As noted in section "Information Regarding the Anesthesia Group and Its Anesthesiologists", above, the group will want to identify any training and experience that is relevant to the ASC's operation, such as fellowship training in pediatric or regional anesthesiology. The group also will want to make sure to identify any relevant certifications, such as ACLS and PALS.

Depending upon the location of the ASC, it may be useful to address qualifications beyond clinical competency, such as proficiency in a foreign language. Such proficiency can be especially valuable in communities with non-English-speaking populations or populations in which English is not the primary language spoken.

### Ability to Interpret and Provide Operational and Efficiency Data to the ASC

An anesthesia practice is in a unique position to have very valuable information regarding how a facility's operating and procedure rooms function. Being able to present such data in a manageable and timely fashion can assist an ASC in managing its operations more efficiently. An anesthesia group will want to feature its ability to provide the ASC with data (the group will, of course, want to retain ownership of all such reports it prepares).

### Focus on Efficiency

ASCs are focused on efficiency and an anesthesia group bidding on an ASC agreement needs to describe with some specificity how it will assist the ASC in promoting efficient throughput of cases and patients in a safe manner. If the group has experience in managing OR and block scheduling, outline that experience. If the group can document how it has shorter recovery times for procedures that the ASC commonly performs, present those data as part of the proposal.

Many groups say they are efficient. Not as many groups can provide specific examples of steps they take in the ambulatory setting to promote efficiency. An anesthesia practice that can cite such examples – such as the group's record on achieving on-time starts (whether first case or more broadly for all cases) will be more persuasive than one that cannot.

If the group has data to document its history of working to promote efficiency in ambulatory settings, it should summarize such data and the specific steps the group has implemented. Better yet, if the group can demonstrate how it has achieved cost savings for an ASC, such examples can be compelling in distinguishing the anesthesia group as a strong candidate for an ASC.

### Leadership in Working with ASCs to Implement New Service Lines or Other Initiatives

To set itself apart, an anesthesia group responding should identify any leadership roles its anesthesiologists have taken to assist ASCs to plan for and implement new initiatives – of whatever type.

For example, if a group has worked with an ASC to implement a perioperative surgical home model in the ambulatory setting, it should identify what its role was and the results of implementing that model – in terms of patient care, patient satisfaction, cost savings, efficiency, or other positive outcomes for the ASC.

If the group has assisted an ASC to attract surgeons in one or more different service lines or otherwise to plan for new service lines, or to implement other initiatives, whether an electronic health record or bundled pricing initiative or other project, the group should highlight its role as a partner with an ASC to improve processes and grow the business of the ASC.

The discussion in sections "Documentation of the Quality of Anesthesiology Services Provided," "Documentation of the Group's Ability to Save an ASC Money," "Surgeon, Patient, and Facility Staff Satisfaction Surveys," "Leadership of the Preoperative Assessment Process," "Dashboards with Key Performance Measures," and "OR Management" may provide further ideas of areas an anesthesia group will want to highlight in preparing a proposal in response to an RFP.

## Problematic Arrangements with ASCs

### Background: Why the Problem Exists

For many reasons, anesthesia agreements at ASCs can involve a variety of arrangements that require close scrutiny for compliance with federal and state law. In the hospital settings, the focus is on the scope of coverage and the anesthesia practice's obligations. Due to the undervaluation of anesthesia services by federal health care programs,[13] and the tendency for hospitals to have a substantial proportion of federal health care program patients, anesthesia services at hospitals are often not self-supporting.[14]

[13] See General Accountability Office, *Medicare and Private Payment Differences for Anesthesia Services,* GAO-07-463: Published July 27, 2007 (publicly released: Aug. 27, 2007), available at https://www.gao.gov/products/GAO-07-463 (accessed 3/30/18); see also note 36, *supra*.

[14] Current data on the percentage of hospitals compensating their contracted anesthesia groups is difficult to locate. An article describes "anesthesia subsidies are common hospital operational costs, often costing millions of dollars." and references that "eight percent of hospitals [are] paying an anesthesia subsidy ⋯." See Greenfield, Howard, M.D., *Anesthesia 101: Anesthesia Subsidy Drivers*, available at https://enhancehc.com/anesthesia-101-anesthesia-subsidy-drivers/ (accessed 4/3/18). According to a 2012 nationwide survey, hospitals paid an average of $160,096 per anesthetizing location to anesthesia practices and 98.8% of the responding hospitals reported that they paid the anesthesia group compensation for services. See Healthcare Performance Strategies, *2012 Anesthesia Subsidy Survey Report*, available at http://drivinghp.com/consulting/2012-anesthesia-subsidy-survey-report-now-available/ (accessed 04/03/18). A Summer 2017 article, *Your Hospital Issues an RFP for Anesthesia Services: Now What?*, available at http://www.anesthesiallc.com/images/communique_files/summer2017_07_24_2017_12-00-26/Communique_Summer_2017.pdf (accessed 4/3/18), cites an MGMA statistic (MGMA, *Cost Survey for Anesthesia and Pain Management Practice: 2015 Report Based on 2014 Data*) that revenue from hospital sources to private anesthesiology practices was $118,014 per full-time equivalent physician.

In contrast, at ASCs, which tend to have a smaller proportion of federal health care program patients, anesthesia services often are self-supporting and can be profitable. As Medicare payment policy for ASCs and particular medical specialties has undergone changes, some ASC owners have looked to other sources of income. Some consultants have participated in these efforts by advocating that ASC owners can develop "ancillary" sources of income, such as taking a piece of the anesthesia revenue. The issue with any model (hereinafter, an "Arrangement") that deviates from the standard model under which the ASC bills for the facility fee and the anesthesia practice bills for (and retains) its professional fee is whether the Arrangement results in a financial benefit to the ASC owners and whether that Arrangement violates federal and/or state law that prohibits the exchange of anything of value in exchange for referrals of cases.

## Summary of the Nature of the Legal Risk

The most defensible arrangement from a legal perspective is one in which the anesthesia group bills and collects for the anesthesiology services its clinicians provide. Once the anesthesia group agrees to an arrangement in which it must give up a portion of its revenue from anesthesiology services to the source of the referrals – whether the ASC itself, which is owned in part by the referring physicians who practice at the ASC, or directly to the referring physicians, the arrangement becomes legally risky. If there are federal health care program patients at the ASC, and if the anesthesia group or anesthesiologists (or nonphysician anesthetists, for that matter) must agree to give up some of their anesthesia revenue as a condition of obtaining or maintaining the right to provide services (that is, to get the contract), the federal Anti-Kickback Statute ("AKS") is implicated.

A number of Arrangements involve situations in which the referring physicians, not the anesthesiologists, bill for the anesthesia services the anesthesiologists provide and then pay a fee to the anesthesiologist (or nonphysician anesthetist) for the "anesthesia services." Beyond potential regulatory risk under federal and state law, anesthesiologists remain responsible for the claims that are filed for their services.[15] Stated otherwise, anesthesiologists who assign their billing rights may incur liability under the False Claims Act for false claims submitted by other persons or entities for the anesthesiologists' services.[16] With False Claims Act penalties set at a minimum of $11,181 and a maximum of $22,363 per claim,[17] liability can mount quickly.

[15] The OIG issued an alert on this point in February 2012 titled *OIG Alerts Physicians to Exercise Caution When Reassigning Their Medicare Payments; Physicians May Be Liable for False Claims Submitted by Entities Receiving Reassigned Medicare Payments*," available at http://oig.hhs.gov/compliance/alerts/guidance/20120208.pdf (accessed 04/5/18).

[16] The OIG issued an alert on this point in February 2012 titled *OIG Alerts Physicians to Exercise Caution When Reassigning Their Medicare Payments; Physicians May Be Liable for False Claims Submitted by Entities Receiving Reassigned Medicare Payments*," available at http://oig.hhs.gov/compliance/alerts/guidance/20120208.pdf (accessed 04/5/18).

[17] The penalties are updated from time to time.

## The Federal Anti-Kickback Statute

The AKS[18] is a criminal statute written in broad terms. It makes it illegal:

- Knowingly and willfully (the intent element)
- To offer or pay, or
- To solicit or receive
- Any remuneration (anything of value, not just money)
- To induce referrals
- Of items or services
- That are reimbursable by federal health care programs.

For AKS purposes, federal health care programs include (among others):

- Medicare,
- Medicaid,
- Federal Employees Health Benefits Program,
- Military health care system (including Tricare and CHAMPUS),
- Veterans medical care,
- Medical services for federal prisoners, and
- Children's Health Insurance Program.

## Penalties for AKS Violations Increased in 2018

AKS violations are felonies and both parties – the party soliciting the kickback, and the party providing it – are culpable. A fine of up to $100,000 or imprisonment for up to five years, or both, may be imposed for violations.[19] Conviction will also lead to automatic exclusion from federal health care programs. In addition, civil monetary penalties of $100,000 per violation may be imposed for AKS violations, along with an assessment of three times the total amount of remuneration offered, paid, solicited, or received.[20]

## Other Changes to the AKS

The Patient Protection and Affordable Care Act ("ACA") amended the intent standard to establish violations of the AKS to provide that "a person need not have actual knowledge of [the Statute] or specific intent to commit a violation of this

[18] 42 U.S.C. § 1320a-7b(b).

[19] The criminal fines were increased from a maximum of $25,000 to a maximum of $100,000 as part of the Bipartisan Budget Act of 2018, Pub. L. No. 115–123, § 50,412 (2018).

[20] This civil monetary penalty also was increased by the Bipartisan Budget Act of 2018 from a previous maximum of $50,000 per violation.

section."[21] This revision makes it easier to prosecute individuals and companies for AKS violations.

The ACA made another important change in the AKS to provide that "a claim that includes items or services resulting from a violation of this section [the AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."[22] As noted above, effective January 29, 2018,[23] civil penalties for False Claims Act violations occurring after November 2, 2015 are a minimum of $11,181 and a maximum of $22,363 *per claim.*[24]

## The Need to Demonstrate Intent

Because the AKS is a criminal law, it is necessary to demonstrate intent. The question in any arrangement (either a contract or an unwritten arrangement in which the parties simply have an understanding) is what is the intent underlying the arrangement. If the intent is to solicit or require the transfer of something of value, such as revenue from anesthesiology services, or if the intent (on the other side of the deal) is to offer or to give something of value, in order to obtain, or in the hopes of obtaining, referrals of anesthesiology services (in the words of the statute, items or services payable by federal health care programs), the arrangement would appear to be a clear violation of the AKS.

## The "One Purpose" Rule

Importantly, the AKS has been interpreted to cover an arrangement if even a single purpose of the remuneration is to induce referrals.[25]

## Safe Harbors

Because the AKS is written in broad terms, the Office of Inspector General ("OIG") in the Department of Health and Human Services has promulgated a series "safe harbors" – arrangements that will not be prosecuted. One safe harbor applies to employment[26]; another safe harbor relates to investment in a "group practice,"[27]

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[21] 42 U.S.C. § 1320a-7b(h), as amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 6402(f)(2).

[22] 42 U.S.C. § 1320a-7b(g), as amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 6402(f)(1).

[23] 83 *Federal Register* 3944 (2018).

[24] 83 *Federal Register* 3944 (2018).

[25] *United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011); United *States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. Denied*, 474 U.S. 988 (1985).

[26] 42 C.F.R. § 1001.952(i).

[27] 42 C.F.R. § 1001.952(p).

which is a term of art with many requirements that must be satisfied. Many legally risky "anesthesia arrangements" involve ones with ASCs, which would not qualify as a group practice, or with entities that would not satisfy the multiple requirements of a group practice. In some instances, referring physicians have formed separate anesthesia companies that are separate from their own professional practice. This type of model is known as a "company model" arrangement and would not qualify for the investment in a group practice, as there are separate entities involved.

Yet another safe harbor protects "personal services and management contracts."[28] This safe harbor contains multiple requirements and might shield certain independent contractor arrangements. In a risky Arrangement relating to anesthesiology services, however, the compensation may not meet the requirements of the safe harbor, which requires, among other things, that (1) the compensation not vary with the "volume or value of referrals, (2) the aggregate annual compensation be set forth in the agreement, (3) compensation must be at fair market value levels, and (4) the arrangement must be commercially reasonable.

Whether or not other particular sets of facts would qualify for safe harbor protection or otherwise would be permissible under the AKS would depend upon the actual facts and circumstances surrounding them.

## OIG advisory Opinions Regarding Anesthesia "Arrangements"

As of early 2018, the OIG has issued two advisory opinions relating to anesthesiology services. In the first, Advisory Opinion 12–06,[29] the OIG found that a company model arrangement (see section "Safe Harbors" above) may violate the AKS.

The second OIG Advisory Opinion, 13–15,[30] relating to anesthesiology services involved a carve-out from an exclusive hospital anesthesiology services agreement, where the hospital had required the longtime anesthesia group to agree to allow a psychiatry group to have one of its psychiatrists (who ironically was also a Board-certified anesthesiologist) provide anesthesia for ECT patients and for the anesthesia group to provide coverage for the psychiatrist. Here, too, the OIG expressed concern that the arrangement implicated the AKS.

## Legal Interpretations of Advisory Opinions and Particular Arrangements

Legal experts differ as to the consequences of different types of Arrangements and their legality under the AKS and other applicable law. Counsel for referring physicians point to the fact that OIG advisory opinions apply only to the facts under

[28] 42 C.F.R. § 1001.952(d).

[29] Available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-06.pdf (accessed 04/4/18).

[30] Available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2013/AdvOpn13-15.pdf (accessed 04/4/18).

consideration, and take the position that some Arrangements are permissible under the Anti-Kickback Statute if changes are made in some of the underlying facts. Not surprisingly, in reviewing certain proposed Arrangements, counsel for anesthesiologists may reach a different conclusion about the legality of those Arrangements.

It bears repeating that the legality of an Arrangement depends upon the facts and circumstances. It also is necessary to consider whether or not an Arrangement involves federal health care program patients, as the federal Anti-Kickback law applies to referrals of such patients.

## Enforcement Action and Policy

A discussion of enforcement action is beyond the scope of this chapter. Readers may wish to review an August 2016 Department of Justice ("DOJ") settlement[31] with a series of anesthesia businesses collectively known as Sweet Dreams Nurse Anesthesia. Readers also should be aware that, in January 2018, DOJ issued a broad policy statement barring the use of agency guidance documents, such as OIG advisory opinions, as the basis for proving violations of applicable law in affirmative civil enforcement cases.[32]

## State Law

There also are other laws that need to be considered in connection with any Arrangement. These include state laws barring kickbacks in health care, state laws regulating physician self-referrals, and state laws regulating unprofessional conduct, such as the common provision in many states barring fee splitting and making it unlawful for physicians to receive anything of value in exchange for referrals of patients. Some states have disclosure requirements if physicians refer patients to a health care entity in which the physician has a significant financial interest.[33]

## Summary

A wide variety of anesthesia "Arrangements" have developed since the early 2000s. Despite the risks, referring physicians have continued to engage in models that allow them to capture some portion of the revenue from anesthesia services.

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[31] Available at https://www.justice.gov/usao-mdga/pr/sweet-dreams-nurse-anesthesia-group-pays-more-1-million-resolve-kickback-allegations, August 5, 2016 (accessed 04/5/18).

[32] Memorandum from the Associate Attorney General dated January 25, 2018, *Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases*, available at https://www.justice.gov/file/1028756/download (accessed 04/5/18).

[33] See, for example, Minn. Stat. § 147.091(p)(3) (2017) (listing grounds for disciplinary action, including fee splitting, which includes referring a patient to any health care provider in which the referring physician has a "financial or economic interest" unless the physician has disclosed the financial or economic interest in accordance with state law).

Anesthesiologists should review any such Arrangements with experienced health care counsel before agreeing to an Arrangement, especially if agreeing to the Arrangement is a condition of obtaining the contract to provide services.

## Conclusion

This overview of obtaining and maintaining practice opportunities at ASCs and responding to RFPs is written against the backdrop of a changing and consolidating health care environment and anesthesia community. Adequate preparation is essential to success, and a group needs to ensure that it has appropriate support to enable to respond to opportunities. Of particular note for smaller anesthesia groups, it is important to identify in advance the qualified administrative and professional staff or consultants they will need to retain to compete. The discussion is not intended to be an exhaustive review of all issues, but rather a discussion of key areas to consider.

# Nuts and Bolts of Ambulatory Anesthesia Billing

3

Jason Habeck and Kumar G. Belani

Understanding billing and compliance in the modern medical world can be a daunting task. It is important to know the basics of billing in order to avoid common errors that can decrease reimbursement. Knowing the basics of billing makes it much easier to understand the nuances that can help maximize reimbursement. In this section we will cover the basics or nuts and bolts of billing as a foundation that will also help in ensuring compliance with documentation.

The single most effective way to ensure good compliance and proper reimbursement for novices in the billing world is to align with a reputable billing company. These companies employ experts in the field that stay abreast of and help navigate the complex and ever-changing billing processes and regulations. In the absence of such companies, one needs to not only understand the process in more detail but remain dynamic and current with any changes in laws and requirements so as to not only be compliant but also avoid delays in reimbursements.

Firstly, are there any differences between billing at an ambulatory center and a hospital for those in the anesthesia world? Thankfully the answer is not very many. The majority of the billing differences are for the actual facility and procedure fees and how they are structured. One major difference for anesthesia is that in an ambulatory setting our supplies or technical fees as they are called are rolled into the cost of the procedure itself and typically cannot be billed separately. The second difference for the ambulatory setting is the types of procedures that can be performed in the ambulatory setting. Not all procedures are considered appropriate for an ambulatory setting.

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The definition of an Ambulatory Surgery Center (ASC) is, a distinct entity (not part of a hospital) whose purpose is to provide surgical services to patients who do not require hospitalization and the services are not expected to exceed 24 hours. The patient is also not expected to require active monitoring past midnight. There are other requirements in regards to an ASC's relationship with a hospital that are irrelevant in this discussion [1].

We will focus on Medicare requirements for ASC's as most insurance companies tend to follow rules similar to Medicare. Medicare uses the Outpatient Prospective Payment System (OPPS) to decide how to reimburse for outpatient services. This system arose in 2008 and greatly expanded the list of procedures eligible for ASC participation. Each year the Centers for Medicare and Medicaid Services (CMS) posts their lists of changes with comment period for procedures that will be added and subtracted from the list of qualifying procedures. An example is total knee arthroplasty that was added to the list. Based on this system certain services are covered together under the single payment. These include most supplies, nursing services, drugs and biologics as well as most anesthesia supplies. There is some ability to bill for certain drugs, implantable devices and radiology services. These are considered technical fees for the most part. Professional fees such as those for anesthesia services, are billed separately.

Billing for anesthesia services in an ASC setting follows in an almost identical manner to inpatient hospital services. The formula is Base Units + Time units (1-time unit = 15 minutes) times the anesthesia unit rate. Base units cover both preoperative and postoperative visits, administration of fluids and blood products and monitoring and interpretation of non-invasive monitoring. CMS publishes their conversion factor (CF) yearly and it is regionally based. The average CF in 2018 is somewhere around 21 U.S. dollars. So, for a case with 5 base units that took an hour, one would have 9 units times a conversion factor of 21 for a payment of 189 dollars. There are also some modifiers that can add units. ASA physical status 3 and over will add units. Extremes of age can add units as well as emergency cases, controlled hypotension, hypothermia and certain unusual positions. Some of these conditions may not apply to ASCs since ASCs typically do not perform emergency procedures or hypothermia. When a second anesthesiologist takes over the care of the patient only one bill is sent, by the anesthesiologist that spent most of the total time during the care of the patient. Note that anesthesia time includes time from the start to the end of anesthesia service. Time spent during interruptions in anesthesia care needs to be subtracted. When medically directing, an anesthesiologist may not relieve a CRNA. Similarly, for billing purposes, an anesthesiologist may only be relieved by an anesthesiologist.

All cases require a HCPCS (Healthcare Common Procedure Coding System) modifier [2]. AA designates a case performed by an anesthesiologist, QY medical direction of a single CRNA, QK medical direction of up to four rooms and AD which designates medical supervision of more than 4 rooms. The anesthetist HCPCS modifiers include QX when being medically directed and QZ when not being medically directed. Typically, after the HCPCS modifier is the physical status modifier that denotes the patient's physical status. (Table 3.1)

**Table 3.1** American Society of Anesthesiologists Physical Status Classification

| |
|---|
| PS1 – Healthy individual with minimal anesthesia risk. |
| PS2 – Mild systemic disease. |
| PS3 – Severe systemic disease with intermittent threat of morbidity or mortality. |
| PS4 – Severe systemic illness with ongoing threat of morbidity or mortality. |
| PS5 – Pre-morbid condition with high risk of demise unless procedural intervention is performed |

CFs for Medicare patients are set by the government yearly while CFs for private insurers are typically negotiated. CFs for private payers typically run about 3 times the Medicare CF or higher. CF's for private payers are typically contractually unable to be released so one group may not know what another has negotiated. A billing company with experience can help ensure that one is receiving a fair market value for reimbursement units. Anesthesia base units are based on the ASA relative value guide. Current Procedural Terminology (CPT) codes are still used for billing the cases but the American Society of Anesthesiologists Relative Value Guide (ASA RVG) will provide the basis for reimbursement. At times CMS values may slightly differ from the ASA RVG. Most private insurers will follow the ASA RVG. Most insurers require documentation of the ASA codes in lieu of the CPT code.

For anesthesia services there are different modes of delivery as indicated in the modifiers above (AA, QY, QK, AD & QD). The easiest is self-directed anesthesia as the anesthesiologist is involved in all aspects from start to finish. The two team models consist of medical supervision and medical direction.

## Medical Direction

Medical direction is the most common team model. In medical direction an anesthesiologist can be assigned to no more than 4 rooms at any one time. Also, anesthesiologists must comply with the 7 TEFRA (Tax, Equity and Fiscal Responsibility Act) criteria as follows:

1. Perform a pre-anesthetic evaluation and examination
2. Develop the anesthetic plan
3. Personally participate in the most demanding procedures in the anesthesia plan, including, if applicable, induction and emergence.
4. Make sure all procedures not personally performed are performed by a qualified anesthetist.
5. Frequent monitoring of the anesthetic
6. Be physically available for immediate treatment and diagnosis of emergencies
7. Provide post-operative anesthesia care

In this model both the anesthesiologist and the anesthetist will bill for services. The fee would typically be split 50:50 between the anesthesiologist and the anesthetist. The

**Table 3.2** Healthcare Common Procedure Coding System modifiers

| | |
|---|---|
| AA | Case performed by an anesthesiologist |
| QY | Medical direction of a single CRNA |
| QK | Medical direction of up to 4 rooms |
| AD | Medical direction of more than 4 rooms |
| *QX | CRNA medically directed |
| *QZ | CRNA not medically directed |

*For CRNA billing; CRNA = certified registered nurse anesthetist; add QC when supervising anesthesia resident.

anesthesiologist would bill with QY when directing one case and QK if directing more than one case (see Table 3.2 for qualifiers). The most important thing to remember is to ensure adequate documentation of the 7 TEFRA requirements failing which services may only qualify as medical supervision. Anesthesiologists need to be physically available but can perform other specific duties such as labor epidurals, periodic monitoring of an obstetric patient, tending to an emergency in the immediate area, conducting a preoperative examination of the next patient, caring for and discharging patients from the post-anesthesia care unit (PACU) and attending to scheduling matters. If more than one anesthesiologist participates in a case but not concurrently then the anesthesiologist who spent the most amount of time in the case should be used for billing purposes though the documentation of the case itself should reflect what each did. In unusual circumstances where the anesthesiologist and anesthetist were required to fully participate in the case from start to finish, the anesthesiologist can bill HCPCS AA and the anesthetist can bill QZ as not being directed and both can seek full reimbursement though there would need to be documentation as to why that was necessary. In academic institutions that employ residents the requirement is different. In this case the anesthesiologist may only supervise up to 2 cases at any time. Either 1 resident case, 1 resident and one anesthetist or 2 residents. For the resident cases the anesthesiologist would bill with the AA designation with a second modifier GC to account for the teaching aspect.

## Medical Supervision

Medical Supervision is being seen more frequently in places like GI centers where a single anesthesiologist supervises more than 4 rooms. Also, if a medically directed case doesn't meet any of the 7 TEFRA requirements it must be billed as medical supervision. In medical supervision the anesthetist can still bill for 50% of the allowed amount but typically the anesthesiologist will only receive 3 units for each case supervised. One can characteristically get an additional time unit if one can demonstrate personal presence during induction. In medical supervision the anesthesiologist would use HCPCS AD and the anesthetist would use QX.

## Monitored Anesthesia Care (MAC) Anesthesia

MAC anesthesia is another special circumstance that requires special coding. After the initial HCPCS designation the modifier QS is required to designate MAC anesthesia. Documentation is required to justify MAC anesthesia as a medical necessity.

A G8 modifier would designate the procedure as deep or markedly invasive and a G9 would be used to designate a severe cardiopulmonary history that necessitates MAC. Proper documentation as to the reason is necessary to prevent a claims denial.

When a patient has been evaluated but the surgery is cancelled, payment is allowed by using a physician fee schedule and documenting the reason for cancellation. Payment is also allowed as if a patient underwent surgery if anesthesia induction occurred and the surgery was cancelled.

## Regional Anesthesia

Regional anesthesia is performed either before, during or after a surgical procedure. If regional anesthesia is designated as only for use as part of the anesthetic it cannot be billed for separately from the surgical case itself. If designated for post-operative pain control and the surgeon's request is documented then a separate billing may be able to be generated (depending upon the primary anesthesia technique). An epidural or spinal placed preoperatively or intraoperatively, for the purpose of postoperative pain control, may be billed separately only when the primary anesthetic is general and the surgical procedure is not dependent upon the efficacy of the epidural. A peripheral nerve block placed preoperatively or intraoperatively, for the purpose of postoperative pain control, may be billed separately only when the primary anesthetic is general, spinal or epidural and the surgical procedure is not dependent upon the efficacy of the peripheral nerve block.

The modifier -59 for a distinct procedural service is required to differentiate the service from the intraoperative anesthetic. When using ultrasound guidance, the use of ultrasound can also generate a separate charge. In order to bill for the use of ultrasound an image including a description of the localization procedure must be saved in the patient's chart. The CPT code for ultrasound guided needle placement is 76942-26. It is important to document the start and stop times of all blocks performed. Postoperative pain blocks placed prior to induction or after emergence cannot have their placement time included in total billable anesthesia time. Blocks performed as part of the primary anesthetic technique may have their placement time included in billable anesthesia time.

Table 3.3 lists the acronyms commonly used when describing different components related to billing. MACRA is a bipartisan legislation that came into existence in 2015 to reimburse for demonstrable quality care and performance.[1] It repealed the SGR formula for billing and changed the way that Medicare rewards clinicians for value over volume. It streamlines multiple quality programs under MIPS and gives bonus payments for participation in eligible APMs. Anesthesiologists need to be aware of the quality payment program for compliance during billing to take advantage of the pay-for-performance methodologies and benefit from incentive payments while protecting one from penalties. Participation in PQRS in 2016 allowed anesthesiologists to take advantage of the 2% benefit in their fee schedule.

[1] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html (as accessed on November 10, 2018).

**Table 3.3** List of acronyms used during the billing process

| Acronym | Expanded abbreviation |
|---|---|
| QPP | Quality payment program |
| PQRS | Physician quality reporting system |
| MACRA | Medicare access and CHIP reauthorization act |
| MIPS | Merit based incentive payment system |
| QCDR | CMS-approved Qualified Clinical Data Registry |
| APMs | Advanced alternative payment modules |
| IA | Improvement activities |
| ACI | Advancing care information |
| ECs | Eligible clinicians |
| MSPB | Medicare spending per beneficiary |
| PSH | Perioperative surgical home |
| CEHRT | Certified electronic health records technology |
| SGR | Sustainable growth rate |
| AQI | Anesthesia Quality Institute |
| NACOR | National anesthesia clinical outcomes registry |
| QR | Quality registry |

Similarly, under MACRA, participating clinicians collected their outcome measures during 2017 and reported to CMS by March 31, 2018. The ASA has created a special website dedicated to MACRA for those interested in additional information. Anesthesiologists can take advantage of AQIs NACOR program to help with quality reporting.

## Summary

In summary, the most important component of proper billing is complete documentation. Complete and appropriate documentation of everything done during an anesthetic decreases the likelihood of a denied claim. Some of the basic items that need to be documented include:

1. Proof of all TEFRA requirements if billing for medical direction.
2. The correct HCPCS code designating what type of care model is being utilized and along with that the physical health modifiers.
3. All special modifiers should be noted such as extremes of age, certain positions, controlled hypotension, hypothermia, emergencies.
4. Anesthesia Start and Stop times. Times need to be consistent with case documentation as well as being the same if billed by an anesthesiologist and anesthetist. Most billing forms will want the time units listed in minutes.
5. Use of the QS modifier for MAC anesthesia and proper documentation of medical necessity for MAC.

6. Use of the -59 modifier for regional anesthesia if the procedure is distinct from the surgical anesthesia which typically means designating it as for post-operative pain control. CPT code 76942-26 should be used if billing for ultrasound (US) use for block placement. This will require a saved image and documentation of the procedure.
7. Participation in MACRA and using CEHRT and quality reporting to CMS to take advantage of performance related payments.

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1. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AmbSurgCtrFeepymtfctsht508-09.pdf (as on October 27, 2018).
2. https://engage.ahima.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=9af2a07d-26e1-4694-b1de-a4c59d0dbc30 (as on October 27, 2018).

# Accreditation for the Ambulatory Surgery Center

4

Steven F. Butz and Irving A. Hirsch

Accreditation can be seen by many as an Ambulatory Surgery Center's (ASCs) steps toward providing quality care. By having an outside organization evaluate and place a stamp of approval on an ASC, the ASC can advertise that consumers (patients) can expect certain levels of safety and quality. Other reasons a health care organization would seek accreditation are more business-centric. Not all states license ambulatory surgery centers (ASCs) and, therefore, an ASC may be required to have accreditation to be able to enter into provider contracts with insurance companies. If ASCs choose to accept Medicare or Medicaid patients, they will be required to be credentialed by the state. This is because each state administers this federal program at its own level.

Although there are many companies that perform accreditation, there is a similarity to what they offer and require from ASCs. Much of this can be explained by standards set by Centers for Medicare and Medicaid Services (CMS). CMS sets standards at the level of the federal government. Accrediting organizations can perform a deemed CMS survey provided they themselves have been approved by CMS to do so. As a result, many of the standards between agencies have a common root. We will cover some of these basic common standards in this chapter and briefly describe the various accrediting organizations available to an ASC.

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## Governance Structure

Primary to the accreditation process is identifying the governance structure of the ASC and mapping out responsibilities. The governing body has the onus to employ and credential appropriately qualified personnel. It must manage programs for quality, infection control, and risk management. The governing body, of course, must manage the business effectively and be able to provide a safe environment of care. There are no minimum criteria for the composition of the governing board as it can range from a single provider/owner to a complete corporation/board of directors. There are usually conditions to meet at least annually and requirements to cover certain topics that are evident in meeting minutes. Credentialing and privileging are top among these, but discussion topics should also include strategic goals, policy review and revision, contract reviews, financial topics, and review of quality, risk management, and infection control programs.

## Credentialing and Privileging

A committee or medical director may perform the act of credentialing and privileging, but the responsibility ultimately lies with the governing body. In much like a human resources function, the board must verify the training and experience of applicants to the medical staff. Licenses and DEA registrations must be kept current and reviews made for background checks and litigation. Lastly, peer review must be made part of the recredentialing process along with peer references for the initial and subsequent applications. Once a provider meets the initial qualifications to join the medical staff, the privileges granted need to be decided. These will follow by subspecialty generally, but the board may require extra training for certain circumstances. This may be for things that lie outside of typical training or be part of subspecialty training. Some examples may be pediatrics, new procedures or operating specific equipment like lasers or a new technique like robotic assistance for a current procedure already performed at the facility. Of course, credentialing of employed staff needs to be a similar process to make sure there are adequately trained nurses, technicians, and non-clinical staff to assure the business runs smoothly. Again, verification of education, work history, and references should be part of a routine human resources office function. Employed staff should be hired into positions that have job descriptions and are evaluated annually. All staff, hired or credentialed, should have an orientation before starting their duties.

## Peer Review

The peer review process should be more than a chart review. It should focus on outcomes. Things that trigger a peer review may be complications or a random audit. The definition of a “peer” generally means people doing the practice review are like-trained or credentialed. Excellent reviews are done by like specialties, but

often, in ASCs with single specialties or a small number of medical staff, peer reviews are done physician to physician. A person with a higher level of training can review a lesser-trained person as in the case of an anesthesiologist reviewing a CRNA, but the opposite is not permitted. A person that is a solo practitioner will have to go outside of their practice to find peer review. In this case, they can find another solo practitioner in need or pay someone to do this for them. Most accrediting organizations require annual peer reviews to be documented. The strongest version of peer review looks at results of care or outcomes. Activities like chart completion or other process measures are not the best measures to include in peer review. However, reviewing charts for procedure-specific history and physicals would be useful as it supports billing for the center and can be part of assessing the quality of patient work-ups. It can be very difficult to do peer review on allied health providers such as surgical assistants since they do not generate any of their own paperwork or outcomes separate from their surgeons. This can be remedied by simply doing an observation of their work that can be tracked over time.

## Quality Improvement

A quality program must exist to assure high quality care that is reviewed for results annually. To do this, the board must decide legitimate benchmarks to follow and perform studies to improve areas that fall below their selected parameters. Examples for a GI endoscopy center may include activities like tracking the time it takes for a colonoscopy to reach the terminal ileum, sign-off on pathology reports, follow up for positive biopsies, or documentation of endoscope cleaning. Measures can be process-based or outcomes-based, but all aspects of an organization should be monitored. This includes the business aspect of a facility. There are typically not a minimum number of quality improvement studies to be done, but survey teams are looking to see that data is being collected and analyzed and improvements are being made when a problem is found. The other type of quality activity is the reactive kind where investigations are made following an incident or event. This may be a postoperative wound infection or a serious event or sentinel event. The QI program should cast a broad enough net to capture data on any event that could have a negative impact on the organization.

## Risk Management

Risk management activities should start with an annual risk assessment of the facility. This should include everything from natural disasters, infection risks, breaks in policy, loss of property, life, or limb, or even terroristic acts. The four or five things that rate highest should have an action plan developed around them. This will help define the frequency of doing CPR, fire, and evacuation drills. It will also help focus specific risk management activities targeted to health hazards or communicable diseases such as MRSA, Tuberculosis or influenza. The permutations are endless, but

are also very specific to each practice. People in Florida are not expected to have a plan on dealing with a blizzard, and a GI practice is not likely concerned with performing malignant hyperthermia drills if they do not use triggering agents. Other risk management activities can include policies for product recalls, root cause analysis, and narcotic diversion.

## Infection Control

Infection control is a focus of many state agencies and credentialing organizations. An infection control plan can be very similar to the risk management plan and often the two can be combined. In the case of infection control plans, focus is made on activities that prevent the spread of contamination either to or from patients. Sterile processing and facility cleaning are very important and need to be done according to established guidelines. Hand washing protocols should be selected from a recognized source such as World Health Organization or Centers for Disease Control and Prevention. It is advisable to select a person with appropriate training to oversee the infection control activities. There should also be documentation that employees and credentialed staff received education for the policies selected by the board, to minimize infection risks. Other parts to this plan are vaccination policies for hepatitis and influenza. Plans should be proactive to look for wound infections and screen patients for communicable diseases. Other details will include activities for surveillance for outdates, safe injection practices, and sterile technique. More details are provided in the Sterile Processing and infection control chapter.

## Building Safety and Environment of Care

The facility itself has implications for accreditation. A facility like an ambulatory surgery center will carry the same standards as a mobile anesthesia practice that has no fixed environment. Ultimately, the physical plant must be able to maintain the safety and privacy of the patient. Maintaining safety requires the ability to sound an alarm and extinguish a fire, provide adequate equipment for resuscitation, maintain an acceptable level of sanitation, and provide ample space for operation of business. This does not mean that the entire building must be fitted with sprinklers and be adjacent to a fire department. It does require a defined means of egress and a functioning fire alarm. There must be measures to assure that flammability is limited and that there are fire extinguishers in adequate number and type for the business conducted. The facility does have a minimum requirement to be able to provide adequate emergency power for patient safety. This does not mean a generator is required, but it would if elevators are part of an emergency plan. The facility needs to be able to accommodate the equipment and drugs necessary to perform ACLS or PALS. The equipment chosen will very much depend on the patient population served and the procedures performed. The overall cleanliness of the building is

important, but so are the policies describing the cleaning of the operating rooms and patient equipment. Surgical equipment can follow the standards of Association for the Advancement of Medical Instrumentation (AAMI), but other equipment such as glucometers and patient monitoring equipment need to be addressed as well. There needs to be ample space to move equipment and patients throughout the facility. The facility cannot be so crowded that exits are blocked and the OR corridor is crowded. Storage of equipment needs to maintain integrity of the sterile packaging. This typically includes being stored off the ground on a solid shelf and not within 18 inches of the ceiling if a sprinkler system is present. Corrugated cardboard or shipping containers are not permitted within the "clean" environment. Finally, adequate amounts and proper use of personal protective equipment are required. Standards for OR laundry are to be considered and placed into a policy approved by the board. Logs for equipment repair and maintenance need to be kept current. The physical environment in the operating rooms such as temperature, humidity and airflow need to be maintained within acceptable range and documented.

## Standards of Care

Standards for anesthesia and surgery would apply to any facility performing a procedure. These will set forth requirements for consent, patient assessment, and the process of surgery. Patient rights become important in that there needs to be documentation that the patient understands the treatment proposed and has been offered alternatives. The patient also has the right to change providers if desired and to know if the providers have an ownership stake in the facility. Advanced directives have to be documented. If they are to be suspended for anesthesia and surgical care, there has to be a documented conversation about doing so. Policies to automatically suspend them for surgery are not permitted. The organization must have a health assessment of the patient and an immediate update prior to the surgery that substantiates that the indications for surgery are still present. The anesthesia provider must document that the patient is acceptable for anesthesia care. Consents for surgery and anesthesia may be combined but both need to be present. This is inclusive of supervising sedation performed by a nurse for a conscious sedation case or supervision of CRNAs and anesthesia assistants in an anesthesia care team model. If the facility is located in an opt-out state, surgeons need privileges to supervise CRNAs. The standards for patient monitoring should follow national guidelines and should include capnometry for cases of deep sedation and general anesthesia. If lasers are used, there are defined requirements to designate a laser safety officer (LSO). This person is responsible for safe operation of the laser and to ensure that adopted policies are followed. Training for the LSO and privileged medical staff needs to be documented. The policies should detail cleaning of the lasers and specific privileges for each laser type. If lithotripsy is performed, policies need to be made to detail elements of the procedure to be in the medical record and the urologist overseeing the program.

## Ancillary Services

Finally, issues to consider for a surgical facility would concern standards set for diagnostic imaging, pathology and pharmacy. CMS discontinued its insistence that a radiologist must be on staff to be in charge of imaging services. The Medical Director can fulfill this role, but must be appointed by the governing body. The specific issues to address include privileging those that use the equipment and assuring the results are included in the chart. Safety monitoring for equipment and shielding must also be in place. Most facilities do not operate their own laboratory. There are Clinical Laboratory Improvement Amendments (CLIA) waived testing for blood glucose and pregnancy. Further tests offered would not be waived and would require more stringent regulations. Either way, a director of laboratory services should be named. Pharmacy management should accommodate for medication practices like safe injection practices, medication reconciliation, and proper education. Narcotic storage and handling need to follow state and federal regulations. This includes providing prescriptions in a controlled manner with proper instruction to the patients. If a public pharmacy is part of the facility, again more regulations would apply. Recalls and expirations on medications must be addressed.

In order to accept payment from third party payers a Center must be licensed. Licensure also ties the Center to Medicare (CMS) certification. Since not all states license ambulatory centers, getting CMS certification or accreditation becomes even more important. With this accreditation, the health care organization is allowed to provide services and receive reimbursement for Medicare patients. The medical facility and the accrediting companies would like to believe that accreditation assures the safety of patients, which would lead to better outcomes. This may provide a marketing advantage in a competitive health care environment, and ensure community confidence in the care being offered. Unfortunately, there is little data to support these assertions.

There are many options available to Health Care Organizations to achieve accreditation. The center can seek State Authorization in those States that offer this option. Many centers choose to seek accreditation via a Medicare accredited inspection company. The accreditation companies essentially make the same claims. Patient care and quality will improve if you follow the Standards and pass the review process. For accreditation of surgical facilities, whether they be hospital-based or free-standing, choices for 2018 include the Joint Commission, Accreditation Association for Ambulatory Health Care, American Association for Accreditation of Ambulatory Surgery Facilities, Healthcare Facilities Accreditation Program, Det Norske Veritas Germanischer Lloyd, Institute for Medical Quality, and Center for Improvement for Healthcare Quality [1].

CMS itself was started in 1965 as part of Title XVIII and XIX of the Social Security Act. These acts created a national insurance policy to cover the elderly and disabled as well as indigent. In order to get these federal dollars for patient care, Title XVIII created conditions for participation that must be met. It was an early attempt at defining what quality care should look like. Elements included credentialing medical staff, providing appropriate nursing care, and utilization review.

These attempts unfortunately did not demonstrate improved care. As time passed, definitions of quality care changed. It initially was limited to resource utilization then progressed to diagnosis related groups and allowable payments. Later the federal government started the Institute of Medicine and Agency for Healthcare Research and Quality. There was development of the National Surgical Quality Improvement Program. All of these began to better define quality and focus more on outcomes rather than process data. This leads to the current state of affairs that involve many not-for-profit and for-profit companies that propose quality standards and can act as an agent of the federal government [2].

The largest of these Medicare accredited companies is the Joint Commission. Their stated mission is "to continuously improve health care for the public in collaboration with other stakeholders by evaluating healthcare organizations and inspiring them to excel in providing safer and effective care of the highest quality and value" [3]. Their vision statement includes, "all people always experience the safest, highest quality, best-value care across all settings [3].

Originally put forth as a quality effort by the American College of Surgeons (ACS), "the Minimum Standards for Hospitals" grew. "The American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association join with the ACS as corporate members to create the Joint Commission on Accreditation of Hospitals (JCAH), an independent, not-for-profit organization, in Chicago, Illinois, whose primary purpose is to provide voluntary accreditation [4]. They morphed into the Joint Commission and now certify 21,000 health care organizations. They claim to offer a customized, intensive review of the organization. Their Standards focus on state of the art performance improvement strategies that help organizations continuously improve the safety and quality of care. Although initially developed for hospital-based care, they are aggressively developing their share of the ambulatory surgery market. The Joint Commission provides deeming authority for Medicare and Medicaid certification and are recognized nationally and internationally [3].

Another large Medicare Accredited Inspection Company is the Accreditation Association for Ambulatory Health Care (AAAHC). Like the Joint Commission their mission statement encourages organizations "to improve healthcare quality through accreditation [5]. AAAHC was developed to fill a perceived hole in accreditation in ambulatory care. "The six founding members of AAAHC were the American College Health Association, the American Group Practice Association (now known as the American Medical Group Association), the Federated Ambulatory Surgery Association (now known as the Ambulatory Surgery Foundation), the Group Health Association of America (now known as the American Association of Health Plans), the Medical Group Management Association, and the National Association of Community Health Centers. The growth of the Board has helped AAAHC add new Standards in areas such as dentistry, behavioral health, and health education and wellness, while continuously updating existing standards to reflect cutting-edge ambulatory care knowledge and practice [6]. It, too, is a non-profit organization. AAAHC claims to develop standards to advance and promote patient safety, quality and value for ambulatory health care through a peer-reviewed

accreditation process with education and research. Their Standards are continuously being updated to reflect cutting edge ambulatory care, knowledge and practice [5], with the intention of having Standards that are more specific and relevant to the individual organization.

"In 1980 the American Society of Plastic and Reconstructive Surgeons recognized that surgeons operating in freestanding facilities were unable to access accreditation through JCAH or AAAHC and established the American Association for Ambulatory Plastic Surgery Facilities to design and operate a single-specialty accreditation program for outpatient plastic surgery centers." In 1992, it spread its accreditation activities to other specialties and changed its name to the current AAAASF, or American Association for Accreditation of Ambulatory Surgery Facilities [7]. AAAASF attempts to standardize quality measurement and hold the outpatient and office based facilities to hospital standards [8]. Board Certification and hospital privileges for the surgeons, and State licensure for therapists is demanded. Anesthesia professionals are required for administration of deeper levels of anesthesia. AAAASF are developing a new initiative they claim will be useful to health care organizations. The plan calls for collection of clinical and operational data which will allow facilities and as well as physicians to benchmark themselves to other centers and providers [8].

Det Norske Veritas Germanischer Lloyd, or DNV-GL, is a joint venture by Norwegian (DNV) and German (GL) companies in 2013. They initially started as setting standards in the maritime trade market over 150 years ago, but grew to become a large player in oil and wind energy fields. Eventually, they expanded their standardization process to include healthcare. They are relatively new to the American market, but have started with hospitals and hospital-based programs [9].

The Institute for Medical Quality (IMQ) is a non-profit organization that grew out of the California Medical Society. In 1996, they decided to create a process "to be different from other health-care-quality organizations in that they would make providing quality care easier and eliminate, rather than create, barriers to doing so" [10]. They have deemed status and have programs to evaluate practices, surgical facilities, and hospitals. Their roots are in California, but they survey throughout the United States. Part of their strength is to have "like" individuals surveying and advising "like" practices.

Center for Improvement for Healthcare Quality is a business that provides hospital accreditation, hospital support services, acknowledgement for centers of excellence, and professional certifications. It recently gained deemed status for its accreditation services. It was founded in 1999 "as a membership-based organization comprised primarily of acute care and critical access hospitals" [11]. Its vision statement is to provide safe and quality care to patients via regulation. It is based in Texas and provides accreditation throughout the United States.

Once a Health Care Organization has decided to seek accreditation or has decided to change their affiliation with their current accreditation company, what factors are most important in the decision making process? It may be easiest and cheaper to seek State licensure and accreditation if offered by that State. If the choice is to seek accreditation by a Medicare-deemed organization, what distinguishes each

Company? Is the largest and best known company offering clear advantages, or is that organization too large and potentially impersonal? Does a company like AAAHC, which claims to continually update peer produced Standards, offer the best choice? Or is AAAASF who promises to track and benchmark outcomes the way to go? As we have seen, all these Companies claim the same advantages.

Is cost a factor? Does the value of services offered justify the cost? Each company will also have different approaches to payments. Some have a one-time fee, others have more of an annual subscription that is a lower payment, but may be more or less than the single-payment option. Clearly, making this choice is difficult and should be done after careful thought and evaluation. Each health care organization should evaluate all options available. Whichever partner is chosen, the overall stated goal of providing value and improved quality of patient care should be a learning process and not a punitive test. The health care organization should be able to grow and improve patient outcomes as a result of the association.

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# EHR: Incorporating into Practice – Using Data Meaningfully, Obtaining Benchmarking and Metrics Information

5

Stanford R. Plavin

## EHR: Incorporating Into Practice – Using Data Meaningfully, Obtaining Benchmarking and Metrics Information

This chapter is designed and constructed to introduce the various aspects of what an electronic health record encompasses, identifying specific terms, and implementing an EHR into one's ASC or extension of office based practice. It will touch upon the technical components of this process as well as the pitfalls and challenges individuals have encountered while making financial, logistical and pragmatic decisions along the way.

**EHR** *Electronic Health Record*: There are numerous definitions, but the Health Information Technology division of the federal government provides a succinct definition- digital version of a patient's paper chart. EHRs are real time, patient centered records that make information available instantly and securely to authorized users [1].

**EMR** *Electronic Medical Record*: It primarily contains the standard medical and clinical data that is gathered in one provider's office. It has been traditionally utilized by providers for diagnosis and treatment. The fact that EMRs are digital records and not specifically paper records allows providers to: 1) track data over time; 2) identify patients who are due for preventive visits and screenings; 3) monitor how patients measure up to certain parameters (benchmark), such as vaccination rates, blood pressure readings, weight loss initiatives, smoking cessation, etc.; 4) improve the overall quality goals of a practice.

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The focus of this chapter will be on the EHR and the EMR. It is important to understand the differences between the two. EHRs have all of those specific items that EMRs possess; are designed to reach out beyond the provider's office or health organization's site of service that originally collects and compiles the information. **The National Alliance for Health Information Technology stated that EHR data "can be created, managed, and consulted by authorized clinicians and staff across more than one healthcare organization"** [2].

The basics key components of an EHR have been shown to include:

- Patient management component: This component is required for patient registration, admission, transfer, and discharge (ADT) functionality
- Clinical component
- Laboratory component
- Radiology information system
- Billing system

EHRs have also expanded the scope of their offerings to include data collection, care coordination, clinical decision support, and reporting of outcomes. These components and offerings will be paramount to the future use of EHRs and how patients and providers not only interact but engage in a meaningful way to improve the health and well-being of the patient.

## Meaningful Use (MU): 5 Pillars [3, 4]

There are 5 main pillars when discussing the term meaningful use (MU) and they are listed as follows:

- Improving quality, safety, efficiency, and reducing healthcare disparities
- Engaging patients and families in their health and well being
- Improving Care coordination
- Improving Population and Public Health
- Ensuring adequate privacy and security protection for personal health information

The American Reinvestment and Recovery Act was enacted on February 17, 2009. ARRA includes many of the measures to modernize our nation's infrastructure, one of which is the Health Information Technology for Economic and Clinical Health (HITECH) act. This act supported and continues to support the concept of electronic health records – meaningful use [4].

## What is Meaningful Use?

*The definition of meaningful use as it relates to being part of an EHR as defined throughout this HITECH act and process consisted of stages.*

Each of these implementation stages consisted of groupings of measurements which are further subdivided into core, menu, and quality measures. As shown below, meeting the criteria for each stage encompasses integrating and measuring these subsets in a way that meets the MU definition.

The specific core, menu, and clinical quality measures will differ depending upon the needs of the practice, surgery center, and clinician.

- Stage 1 = 15 core measures +5 Menu Measures +6 Clinical quality measures = MU
- Stage 2 = 17 core Measures +3 Menu Measures +9 clinical quality measures = MU
- Subsequent stages of MU have incorporated different components and attestations.

So, what are the key drivers for practices and ASCs when selecting an EHR? The meaningful use program instituted by the federal government was a key component of adoption of EHR technology by hospitals and physician practices. It didn't provide ASCs with any extra financial support or incentives in order to implement EHRs into their sites. This was in stark contrast to the aggressive posture taken towards individual physicians and practices with regards to their implementation incentives and goals.

The focus of this chapter is geared to the ambulatory surgery realm and EHRs. Ambulatory Surgery Centers are traditionally a site of clinical service where patients receive a more personalized, quality driven product at a more cost-effective price. ASCs have been able to identify and tailor their deliverables in a manner that encompasses the whole patient care experience. Over the last number of years, the use of EHRs has started to make its way into the patient care process of many ASCs.

There are a number of items that one should be aware of when initially evaluating EHRS; these include identifying the needs of the surgery center and marrying those to the goals and needs of the surgeon and the patient. It is also paramount that the EHR should be able to generate not only state-specific but also CMS-specific reporting requirements for ASCs. EHRs should be able to identify specific billing and coding data and ensure that any potential submission concerns are resolved prior to doing so. Systems should also be designed that are seamless and easy to navigate. Additionally, ASCs should identify EHRs that can integrate with the physician's offices in order to complete Histories and Physicals, informed consents, any

other pertinent data as well as any specific ASC requirements prior to surgery. This would reduce redundancies and inefficiencies and improve the patient care deliverable.

The following is a list of **10 Common EHR Pitfalls** that have occurred throughout the EHR selection and implementation process presented in no specific order of relevance:

1. The EHR software isn't or can't be customized to meet the practice's needs.
2. There is a lack of buy-in as well as unrealistic expectations by the physician owners.
3. Electronic workflows are not properly defined in advance of purchasing the product.
4. The physicians and staff members have not devoted enough practice/implementation time to learn the product/software.
5. EHRs need continuous investments in software updates, training, system development and/or equipment upgrades and no plans have been put in place to ensure this occurs.
6. There is a lack of understanding the initial cost of going "electronic"; financially and other.
7. The group/ASC has not provided a construct to elicit measurable goals for themselves
8. The physician's use of the EHR has not been made to be mandatory which erodes the commitment of the group and the center leading to extra work and inefficiencies and gaps in care.
9. A lack of thorough investigation and analysis of software applications; including evaluation of imaging capabilities and equipment interfaces.
10. The physicians/surgeons do not use the product and thus nothing else matters.

The next part of this chapter is devoted to a comprehensive 5 step guide that will enable the facility and its stakeholders to have a specific process to follow when making the commitment to go electronic.

## 5 Step Guide to EHR Implementation [5]

The following figure is presented to assist those stakeholders who will be planning this process, with the understanding and intentions that the practice site hopes to achieve with Health IT (Figure 5.1).

### Step 1: Advance Preparation

As part of the initial step, advance preparation must look at the specific workflows, billing, revenue/expenses, as well as the impact of the needed IT infrastructure. It is

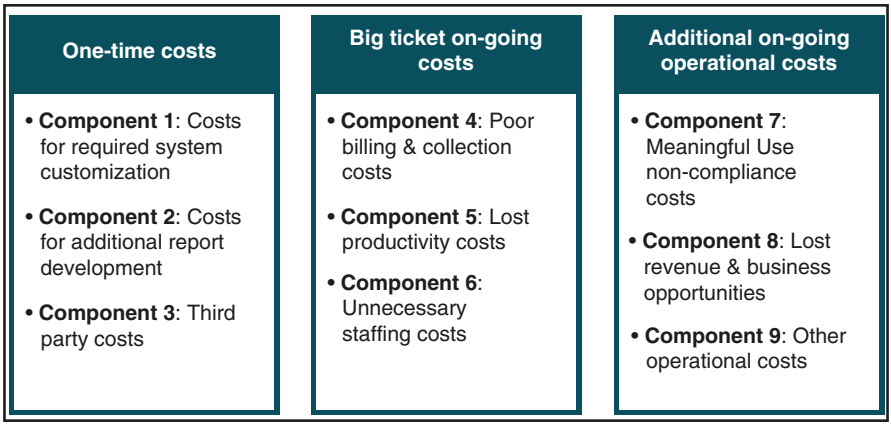


**Figure 5.1** Key Components of the Cost Analysis of Problem EHR Implementation From Open Minds, Executive Briefing, "EHR Implementation Not What You Had Hoped For? Join The Crowd", Joe Naughton-Travers, EdM. *https://www.openminds.com/market-intelligence/executive-briefings/protecting-ehr-advantage* (*Reprinted with permission of* OPEN MINDS / www.openminds.com)

imperative to specifically define the ASCs' needs for this product: these include a reduction of paper, better access to charts, legibility, tracking and reporting capabilities, achieving efficiencies, and meaningful use which as defined earlier is using certified EHR in ways that can be measured significantly in quality and quantity.

In addition to defining the needs, one must determine the constraints of this process. These constraints include the cost of the product, IT resources, clinical/practice staff support as well as project management.

How does one identify and determine the practice/site's readiness for the EHR? Are the physician stakeholders and staff supportive? Is there a physician leader and/or office/ASC administrator who are committed to making this work for the practice/site?

It is important to communicate with peers at other practices/sites in order to better understand the level of commitment needed to accomplish implementation. Mapping out workflow processes and goals are also needed in advance of any implementation.

Define specific personnel roles:

- *Physician/executive leader* defines and sells the vision of the implementation, identifies specific requirements, assists with selection of the health IT system, helps build and enhance the health IT and also is available to resolve conflicts.
- *Project manager* assists with health IT system selection; manages the coordination of software, hardware, special projects and training activities.
- *IT analyst* (subcontracted) builds and supports the health IT network; deploys the hardware (servers, printers, scanners electronic faxing, etc.). They are intimately involved in system configuration, hardware configuration, and special projects such as various interfaces as well.

Don't forget about the money! Establishing a budget is one of the most important parts of a successful EHR selection and implementation.

## Step 2: System Selection and Installation

*When considering an EHR vendor: EHR must be certified for all stages of meaningful use by certified technology vendors.* It is important to research and create a short list of vendors that meet one's technical requirements.

Part of the system selection is understanding the right questions to ask when identifying one's EHR choice. The following is an abbreviated list of questions to ask another center who recently implemented HER, that can provide valuable insight and information when establishing your selection and timeline:

1. When did you install your EHR?
2. How long was the installation/implementation process?
3. How would you describe the installation/implementation process?
4. Was the system you selected as user friendly or in line as the demonstrations by your salesperson/vendor?
5. How many patients per hour/ per day did you see before the installation/implementation of your EHR? This question can be phrased differently for ASC owners.
6. How many did you see after?
7. Approximately how much more time do you devote to entering exam/relevant data into your EHR now; compared to how you documented your exams/data before you began using an EHR?
8. Has your EHR completely eliminated paper charts in your practice/Surgery center?
9. Given your practice's/ASC's experience with your EHR; would you recommend it to a similar practice/ASC?

In addition to asking colleagues/peers the "right" questions, one needs to review the technical requirements from workflow analysis and other practice needs.

When having discussions and interviews with potential vendors, the ASC/practice must develop evaluation criteria to maintain consistency when ranking potential vendors. Some of these criteria should include; cost, usability and integration with current technology (if applicable), specific depth of training and technical support.

It is of paramount importance to include representatives from all areas of the practice/ASC when making this selection. Have each representative prepare specific detailed questions for each health IT vendor demonstration and submit these ahead of time to ensure they are addressed adequately.

Some additional questions and concerns to consider during this step of the EHR selection process include: 1) Evaluating your network (wired/wireless) 2) Will you need or consider ergonomic arms? 3) Will the practice use scribes? (Not typical for ASCs).

In order to help manage and become more familiar with all the new hardware (and software) that you will be adding to your office/ASC; it is important to set up a test environment and install all the hardware you're going to be deploying at least a month before going live.

Three additional items that need to be considered include **security, equipment interfaces, and backup systems.** As part of security, carefully consider who on staff should have access to data and who maintains it. This allows one to set up the appropriate login rights and maintain security.

How do you want to have data transferred from equipment? Are you currently utilizing interfaces? There are a number of equipment interfaces that are available to facilitate paperless entry. It is imperative in today's environment to have multiple methods of backup and recovery. Test your systems several times prior to going live!

## Step 3: Implementation

**Plan and schedule your implementation strategy and make sure it is the right fit.**

Implementation failure occurs when one tries to force one's practice/ASC to adopt a software designed for the "average practice". As you evaluate systems, seek out solutions which provide flexibility and allow your practitioners to easily customize all parts of the software offerings.

The implementation team must evaluate what customization will be required to your EHR software. This typically is done by taking several steps. It is essential that all stakeholders spend the time going through all parts of the EHR software.

When finalizing your implementation, it is imperative to evaluate patient and staff areas in order to have a good understanding of patient and staff flow and how the EHR system will function in your existing space. This is essential for planning where to place the new EHR equipment.

Hardwired and mobile computer stations should be placed in appropriately convenient locations in the office or ASC where staff and physicians can easily access them. This may require additional power and network infrastructure.

One cannot emphasize enough the importance of performing a detailed and thorough analysis of your facility workflow and processes. This will enable the potential for corrections that you may have not realized prior to implementation and also opportunities to improve on current workflows.

The following is a sample of specific items to evaluate during this detailed analysis:

- Pay attention and look for steps, actions, sub processes that we take for granted.
- Analyze the flow of data, paper documents, and patients; these are all interrelated and lead to either an efficient or a sloppy practice.
- Look for opportunities for improved efficiency and utilize tools in an EHR system. Consider designing new work flows and transitioning to them.

- It is important to be detail oriented and document every action and process and whether this needs to be incorporated into the EHR/workflow.
- Create new processes which take advantage of the things you do well and incorporate new or altered processes to help improve efficiency and allow the incorporation of electronic data flow.
- One should consider a goal of handling things only once and input data only once.
- Please be accepting that staff will have to do things differently, and it will take time for them to get comfortable with changes.
- The practice/ASC should also consider making computers available in more spaces to personnel who may have not needed a computer in the past.

Implementing an EHR is a constant work in progress and improved processes will continue to evolve as you and your team gain experience.

## Step 4: Training/Maintenance

As part of a successful implementation, it is important as mentioned earlier to avoid many of the pitfalls that practices and surgery centers encounter. These typically include a lack of planning and lead time, not enough training, not allocating enough time for training, and resistance to change.

In order to avoid these challenges, the stakeholders and team leaders need to create a comprehensive training plan for team members. This training plan needs to include those needing specific training and those providing the training. As part of this process, the vendor typically identifies some team leaders who have shown an aptitude and intuitiveness with the product.

Team leaders will schedule specific practice sessions at convenient times for all EHR users. These sessions should accomplish the following: 1) Identify problems or areas of confusion and then implement necessary changes; 2) Help staff become proficient with the use of the EHR module without having a patient in front of them; 3) Get real medical record information loaded into the EHR records; 4) Improve the speed and accuracy with each patient encounter. It is likely worth the investment to bring in your EHR vendor for detailed application-specific training.

## Step 5: Go Live

- It is important to remember that EHR is an ongoing process and not just a one-time event.
- Have your vendor trainer, the in-house trainer or power user, and project manager present at your go live day and during that critical first week.
- If possible, schedule lightly for the first week or so allowing for more time between patients and for patient encounters.

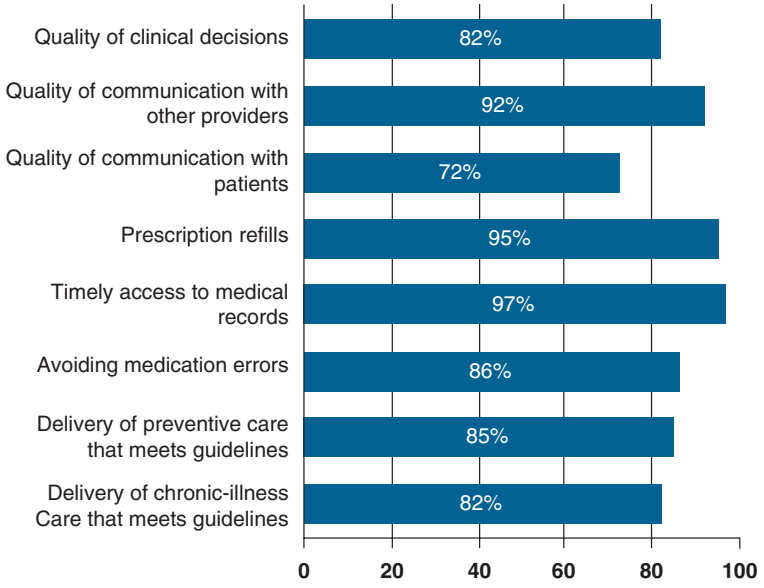


**Figure 5.2** Physicians with fully functional EHRs report a positive impact in clinical decision making and communication- *Benefits of EHRs-American Medical Software* (From *Annals of Internal Medicine*, Chaudry, Basil; Wang, Jerome. Systematic Review: Impact of Health Information Technology on Quality, Efficiency, and Costs of Medical Care. May 2006; 144(10). *Reprinted with permission of American College of Physicians, Inc.*)

- Always have a contingency plan when problems occur with the EHR or something else that you haven't planned for moving forward. This includes paper records and ability to scan or input data after the problems have been resolved.

## Conclusion

*The goal of a successful EHR implementation is to improve* revenue, profitability, productivity, efficiency, data management capabilities, quality of care and patient satisfaction. EHRs can be successfully implemented only when physicians are totally committed to the task (Figure 5.2) [4, 6].

## ASCs and Adoption of EHRs in the Marketplace: [7]

How have ASCs fared in adopting the technologies of EHRs into their sites? Some of the single specialty facilities have fared much better at adopting and incorporating EHRs due to the expansion of their office based practice EMRs. This includes

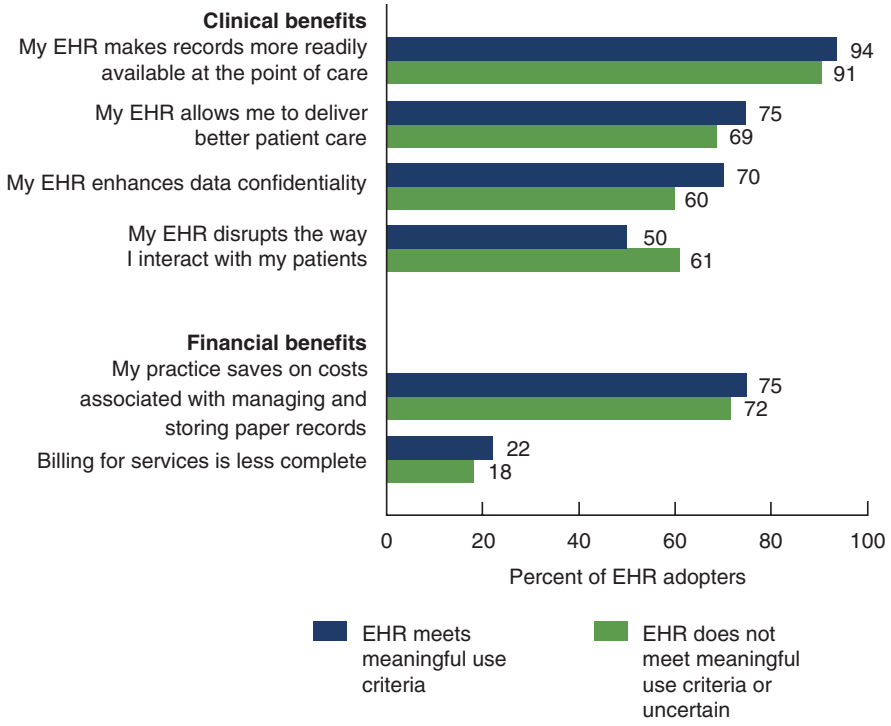


**Figure 5.3** Percentage of physicians using EHR systems and report agreement with selected clinical and financial benefits indicators, by whether the system meets meaningful use criteria: United States, 2011. From CDC/NCHS, National Ambulatory Medical Care Survey's Physician Workflow Survey, 2011/https://www.cdc.gov/nchs/products/databriefs/db129.htm

many Gastroenterology practices and other physician owned surgery center business models. A major hurdle is the financial burden that many ASCs have faced. Surgery centers have received no government incentives to implement and utilize EHRs for their facilities (Figure 5.3). As reimbursements continue to be challenged by many factors, the costs associated with purchasing and implementing EHRs for ASCs is daunting [7].

How does the incorporation of EHR technology impact the operations of the facility?

The use impacts many specific areas which can include: time, case volume, staffing levels, profitability, workflow, communication, customer support, and limited connectivity.

EHRs create many technical challenges when being incorporated into surgery centers and practice sites. There are currently no consistent data standards. There are concerns with the transfer of data which is part of HL7 incompatibility. One must decide on various computer vendors and operating systems. Governmental and regulatory changes can interfere and stress development timelines. HIPAA audit and reporting capabilities are missing and incomplete in many systems which can be quite problematic.

## EHRs Bring Additional Value to the ASC Market

How does the use of an EHR bring additional value to the ASC market? As competition for care continues to increase and the focus is on quality, cost, and access. EHRs can improve patient safety when clinical information is more readily available. Care coordination is easier in an increasingly interconnected care continuum. Quality tracking is more enabled as part of the clinical workflow.

Regulatory compliance will be easier to audit as will be ensuring chart completion and clinical documentation integrity. It will be easier to track who accessed protected health information with EHR and ensure HIPAA compliance and audits. As part of the return on investment (ROI), record retention, chart storage and retrieval, paperwork, staff time to audit and prepare charts all become easier with EHR.

## Functionality: Today's Needs

What is the role of functionality as it relates to EHR? The following are a number of items that provide various components of today's functional needs:

When evaluating and looking at EHRs, the role of interoperability is an important factor. This includes systems and platforms being able to exchange HL and message types and how web services can interact with Application program interfaces (API). Data management as in how an EHR manages discrete data in a consistent manner and also utilizes "big data" and its ability to have long term storage of information is an important component of functionality. Mobile computing should strive to be device agnostic and tablet friendly. Workflows should be able to accommodate concurrent charting, be configurable by physician and procedure, and have templates available for rapid charting. Regulatory compliance functionality should encompass chart completion monitoring, HIPAA audits logs and tracking, and also be mindful of Joint commission and AAAHC standards.

## Additional Must Haves for Today's Needs for the ASCs [8]

Evaluating the needs and must haves for surgery centers will be different for each stakeholder and practice site. The following list provides a framework and thought process when looking at additional items:

The needs of an ASC are likely very different than those of a practice. The EHR will need to support integration of other software vendors and medical devices. Interoperability with physician office EHRs and hospital partner's EHRs will be a must. Document management, clinical charting of workflow, management and regulatory reporting are practical must haves. The physician workflows must also be able to include anesthesia charting/orders/reporting as well. Like mentioned earlier, HIPAA audit tracking, security, implementation and training must all be incorporated into actionable items for an ASC. Additional thoughts include various cost modeling: software licensing model- consisting of concurrent user/unlimited ORs/locations.

When finalizing this adoption, please be sure to not neglect the hardware requirements of the site as well as the ongoing services and support. Many of these principles are part of the comprehensive 5 step process of selecting and implementing an EHR but are also specific points of emphasis as they relate to ASCs.

## Looking Ahead: Beyond Features and Functions [9, 10]

When evaluating and incorporating EHRs, one should consider patient ownership of their records. Additional functionality and features may consist of how to manage patients with higher deductibles, several out of pocket expenses and value based reimbursement models. ACO models, complexity of patient stays, extended stays and incorporating the complexity of patients will undoubtedly lead to further use of EHRs. Clinical decision support and predictive analytics will assist in coordination and risk stratification of the patient selection process.

## Using the EHR to Create Benchmarking, Performance and Outcomes Metrics and Improving Quality and Caliber of Care (Quality Measurements)

*Defining the process:*
The process of establishing a standard of excellence and comparing a business function or activity, a product, or an enterprise with that standard--will be used increasingly by healthcare institutions to reduce expenses and simultaneously improve product and service quality. A component of total quality management; benchmarking is a continuous process by which an organization can measure and compare its own processes with those organizations that are leaders in an area. Benchmarking should be viewed as a part of quality management programs, not a replacement.

**4 Kinds of Benchmarking [11]**
- *Internal* functions within an organization and compared to each other
- *Competitive* partners do business in the same market and provide a direct comparison of products and services
- *Functional and generic* are performed with organizations which may have a specific similar function such as payroll or purchasing but which otherwise are in different businesses

Benchmarking must be a team process because the outcome will involve changing current practices with effects felt throughout the practice, ASC or organization.

The benchmarking team should include members who have subject knowledge, communication skills, and computer proficiency. They should be skilled as facilitators and maintain outside organization contacts.

Benchmarking requires a quantitative measurement of the subject. The process or activity that is being benchmarked will determine the types of measurements used.

Benchmarks may be classified into one of four categories: productivity, quality, time and cost related.

*What is the most important benchmark a practice/ASC should monitor?* The facility should look at the overall big picture and decide on a benchmarking goal that is most aligned with its practice goals. There is no one benchmark that will apply to all practices or surgery centers, thus the uniqueness of each practice should determine the goals and focus.

If the ASC is part of a larger group of ASCs, it will be important to consider benchmarks across the group of centers. If the ASC is part of a larger industry led organization, there may be different opportunities to benchmark across the organization as well [12].

**Interoperability** The discussion points are part of the National quality forum [12–14]

Interoperability is the ability of a system to exchange electronic health information and use electronic health information from other systems without special effort on the part of the user. This definition is consistent with that used in the Nationwide Interoperability roadmap.

*21st Century Cures Act:* "Gold Standard" definition

- Interoperability- enabling the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on part of the user.
- Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law
- Does not constitute information blocking as defined in section 3022(a) of the legislation.

The interoperability measurement framework aspires to the goals described within this definition.

For two systems to be interoperable, they must be able to exchange data in an agreed upon format according to a standard and subsequently present that data in a way that a user can understand. Data exchanged through a fax or within a PDF doesn't fall under the definition and wouldn't be part of this interoperability framework as these devices do not collect or analyze data and are not functionally interoperable with other electronic data systems.

The topic of interoperability is not clear cut. There are a number of terms which must be learned and understood prior to grasping the full concept. In addition to terminology, HIT.gov has further defined IO into a number of domains, subdomains and other process driven modalities.

- "Electronically-exchanged information"(HIE) is defined as the electronic transmission of healthcare related data among medical facilities, health information organizations- companies that oversee and govern the exchange of this data- and government agencies according to national standards.

- Environmental SCAN- Interoperability: key findings- was created to provide an image of the current landscape in which interoperable, nationwide health information exchange occurs.

### Interoperability Key Components

IO supports the exchange of data across numerous systems to support public health, care coordination, patient engagement and innovation. How available is the flow of data with EHRs and other systems such as clinical data registries that support IO? Improving IO supports decision making by providers and patients by integrating data from various sources to present a unified view. This can facilitate data exchange as well as establish common formats for care coordination, quality reporting, and collaborative care. IO has been shown to have a significant impact on the accuracy of quality measurement in many areas- as well as quality reporting by using common data models and application programming interfaces (APIs) [2].

## Domains [4] and Subdomains: [2]

Domain: Interoperability can be broken down into domains and subdomains. The following outlines some of those components. 1) Exchange of electronic health information and its subsets include: availability of electronic health information, quality of data content, and method of exchange. 2) Usability of exchanged electronic health information and its subdomains include: relevance, accessibility, and comprehensibility. 3) Application of exchanged electronic health information and its subdomains include: human use and computable.

The impact of achieving higher functionality and improving interoperability between and among EHRs and information exchanges will have a dramatic effect in many areas. Patient safety can and will be improved. Cost savings will be achieved through a number of factors which include care coordination, productivity and improved healthcare processes and outcomes. This should improve patient/caregiver engagement [2].

The following figure shows a study that was reported after more uptick and adoption of EHRs throughout the physician community. This does not provide data about surgery center workflows but can provide some insight as to the benefits that have been achieved.

## Physician Workflow (Figure 5.4) [15]

- 79% of providers report with EHR their practice functions more efficiently
- 82% report that sending prescriptions with an EHR helps practice function more efficiently
- 68%- physicians view EHR as an asset with recruiting physicians
- 75% receive lab results faster
- 70% report EHR enhances data confidentiality

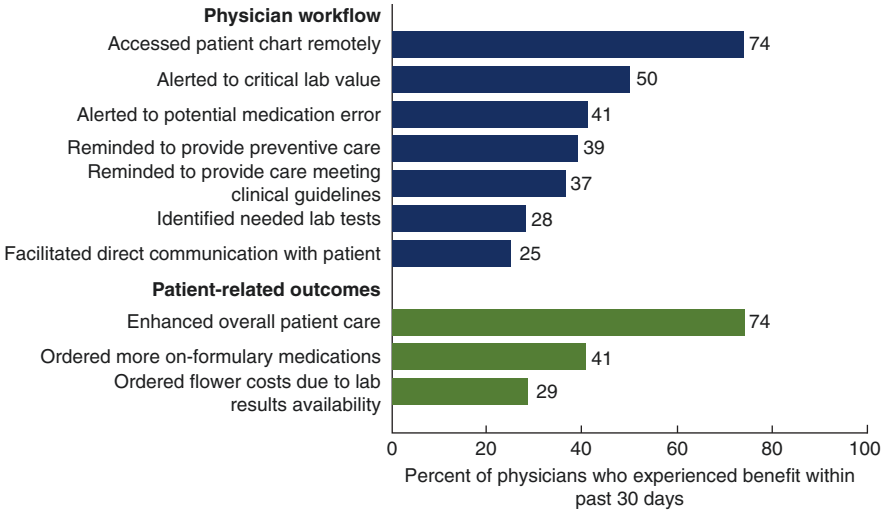


**Figure 5.4** Percentage of physicians whose electronic health records provided selected benefits: United States, 2011. Source: CDC/NCHS, Physician Workflow study, 2011/https://www.cdc.gov/nchs/data/databriefs/db98.htm


**Figure 5.5** The Future of EHRS- 5 steps to Improve EHRs by 2020. Source: Report of the AMIA EHR-2020 Task Force on the status and future direction of EHRs. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5009932/

SAVINGS related to adoption of EHRs are attributed primarily due to elimination of time consuming paper driven and labor-intensive tasks.

## Additional Benefits of EHRs

As adoption of EHRs has continued to increase and their use has extended into many practice locations and sites of service, a number of studies and data have shown that there are numerous benefits of adopting these technologies.

Medical practices have shown a number of efficiencies and cost savings due to the following: a reduction in transcription costs; reduced chart pull, storage, and re-filing costs; improved and more accurate reimbursement coding which includes documentation for highly compensated codes; a reduction in medical errors through better access to patient data and error prevention alerts; and finally improved patient/quality of care through better disease management and patient education.

EHRs can create more efficient practices and those EHR enabled medical practices report:

- Improved medical practice management through integrated scheduling systems that link appointments directly to progress notes, automate coding and manage claims
- Time savings with easier centralized chart management, condition-specific queries, and other shortcuts
- Enhanced communication with other clinicians, labs, and health plans
- Easy access to patient information from anywhere
- Tracking electronic messages to staff, other clinicians, hospitals, labs, etc.
- Automated formulary checks by health plans
- Order and receipt of lab tests and diagnostic images
- Links to public health systems such as registries and communicable disease databases.

EHRs can have a positive effect on revenue by automating clinical documentation and order sets which can translate into enhanced ability to meet important regulation requirements such as PQRI through alerts that notify the clinician to complete key regulatory data elements. There is a monetary benefit that can be achieved by a reduction of time and resources needed for manual charge entry resulting in more accurate billing as described earlier. This can translate into a reduction in charge lag days/vendor/insurance denials which are associated with late filings.

Charge review edits prompt physicians about performing tests at certain frequencies based on best practice guidelines. Alerts also prompt providers to obtain advance beneficiary notices which minimize claim denials and lost charges related to Medicare procedures. This has immediate impact in the ASC realm for specific items. EHRs reduce the paperwork, offer electronic prescribing and reduce duplication of testing all of which have shown to improve revenue and processes.

## Clinical Benefits of EHRs: Improved Diagnostics and Patient Outcomes

There a number of clinical benefits that have been realized since the introduction of Electronic Health Records.

- Improvement in diagnosing and treating diseases
- Reduction and prevention of medical errors
- Improvement in patient care related outcomes
- Risk Management and Liability prevention-
  - Providing clinicians and patients clinical alerts and reminders
  - Improvements in aggregating, analyzing, and communicating of patient information
  - Supporting diagnostic and therapeutic decision making processes
  - Storage and access of all relevant information in one place
  - Enabling evidence based decisions at point of care
  - Adverse event prevention- patient care, prescriptions
  - Enhancing research and monitoring for improvements in clinical quality

In addition to demonstrating the above risk mitigation opportunities and patient care related improvements, providers can potentially avert liability and malpractice actions by demonstrating adherence to best evidence based practices; producing complete, legible records that are readily available for defense and constructing what occurred at point of care; and disclosing evidence that suggests and confirms informed consent to treat.

- In addition to individual patient care outcomes, EHRs can improve public health outcomes. Population health is a growing field of study and evaluation and adoption of EHRs and information exchanges based on evidence and benchmarking will enable and empower us to guide treatments to improve patient outcomes.
- Studies have shown and supported better patient outcomes with EHRs. Prompts not only to physicians but also patients have improved compliance and quality of care. In fact, 92% of MDs were happy with e-prescribing and 90% of patients reported rarely or only occasionally going to the pharmacy and finding their prescription not ready. EHRs have assisted in higher provider satisfaction scores and reducing the overall rate of after-hours clinic calls.
- EHRs benefits are measurable in transforming clinical processes. There was a study in Vermont which showed a 60% decrease in near miss medication events, a 20% increase in completion of daily fall assessments and a 25% reduction in the number of patient charts needed to be pulled for signing orders.

EHRs continue to improve documentation and coding of patient care and studies have shown that over 50% of visits are “under coded” resulting in tremendous losses of revenue for institutions and physicians.

In closing, attached are a couple of figures which provide some overview and how we can incorporate these complex systems to effect change and improve our care.

**The Office of the National Coordinator for HIT: 10-Year Vision to Achieve an Interoperable Health IT Infrastructure** (Figure 5.5)

**Meaningful Use Data and Case Studies** (Figure 5.6)

- Care Coordination
- Public and Population Health
- Patient and Family Engagement
- Quality Measurement

## Summary of Current and Future Landscape

Healthcare is an ever-evolving behemoth. Although the information is relatively scant regarding the historical trends and use of EHRs; one can extrapolate that the motivations of extending the use of these potentially amazing resources will facilitate the triple AIM. Triple AIM is an accepted term that universally means- 1. Improving the patient experience of care (quality and satisfaction); 2. Improving the health of populations 3. reducing the per capita cost of healthcare. The delivery and utilization of health care resources is continuing on a rapidly developing trajectory. Incorporating digital and mobile health technologies as well as historical delivery models will enable our self-limited intelligence to potentially merge with artificial


**Figure 5.6** Population Health Management (*Used with permission from Netspective - Healthcare IT Consulting & Medical Technology Solutions © 1997–2018 Netspective Communications LLC. All Rights Reserved.*) https://www.netspective.com/medigy/#manage

intelligence and provide amazingly new patient care opportunities. The consumerism that is inherent in our society will become an important part of the patient engagement platforms that are being built and utilized today and moving forward. It is paramount that the healthcare community work together in a manner that will provide a balance between patient privacy, patient care, and integration of digital health platforms across populations. EHRs and their interoperability will be the foundation of this initiative.

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# Monitors and Equipment for the Ambulatory Surgical Care Setting

6

Tjorvi E. Perry and Kumar G. Belani

## Introduction

Ambulatory Surgery Centers (ASC), also known as Outpatient Surgery Centers, operate exclusively for the purpose of providing surgical and procedural services to patients not requiring hospitalization or additional postoperative observation for more than 24 hours. As of 2017, there were just under 5,500 Medicare-certified ASCs in the United States. Contrasted with the 5,564 registered hospitals in the United States, the ASC model now constitutes a significant portion of how patients in the United States receive their surgical healthcare [1]. The total number of surgeries and procedures performed in ASCs has risen from 50.5% in the 1990s to almost 66% in 2014 [1]. In the setting of disproportionally high healthcare costs, this growth has likely been driven by advancements in medicine and technology. According to a recently published study from VMG Health, gastroenterologic procedures constitute the majority of cases performed (25%) at ASCs followed by ophthalmologic (20%), orthopedic (16%), pain management (16%), otolaryngological (9%), general surgical (8%), oral (7%), plastic (5%), urologic (5%) and OB/GYN (4%) procedures [2].

The objective of any well-run ASC should be to deliver surgical and procedural care in a safe and cost effective manner. Anesthesiologists have long been known for their pioneering efforts in patient safety. After being plagued by a high rate of malpractice claims in the 1970's, E.C. Pierce, the then President of the ASA, and his

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colleagues at Harvard Medical School convened an ASA standing committee on Patient Safety and Risk Management, later to become the Anesthesia Patient Safety Foundation (APSF). Concurrently, electronic monitoring that allowed for continual and continuous monitoring of pulse oximetry, capnography, non-invasive blood pressure and electrocardiogram became available. With the aid of a Closed Claims Registry, the American Society of Anesthesiologists (ASA) and APSF were able to formally study physician and institutional behavior around patient safety, leading to the national standardization of evidence-based guidelines for patient monitoring during anesthesia. Today, patient safety is a central part of anesthesia trainee education and constitutes a large portion of anesthesia care-giver continuing medical education.

The following guidelines apply to all forms of anesthesia adminstered by an anesthesiologist or anesthesia care team including general anesthesia, regional anesthesia and deep sedation. They apply to both adult and pediatric patients cared for in an ASC setting. These guidelines are not intended for the care of obstetric patients or during the management of chronic pain. The ASA has declared that in certain circumstances, some of these monitoring guidelines may be impractical and that brief interruptions of continual monitoring during the care of a patient may be unavoidable. Furthermore, the ASA warns that even appropriate use of recommended monitoring methods may fail to prevent adverse clinical events. Appropriate monitoring is intended to facilitate the expertise of an anesthesiologist or anesthesia care team. Adhering to recommended monitoring guidelines is not intended to supplant or replace qualities of anesthesia providers. The ASA recommends that a qualified anesthesia provider be present at all times during the anesthetic care of a patient in the ASC setting [3]. In the event of an emergency, the ASA has recommended the anesthesia provider use his/her best judgement, weighing the safety of the patients for whom he/she is caring while evaluating the risk associated with leaving a non-qualified anesthesia provider to care for patient(s).

Standard ASA Monitoring [4], refers to basic physiologic monitors and equipment recommended by the ASA. These include pulse oximetry, electrocardiography, non-invasive blood pressure monitoring (NIBP) and temperature monitoring. Additionally, the ASA recommends measuring inspired oxygen concentration ($FiO_2$), end-tidal carbon dioxide concentration ($ETCO_2$) with a corresponding alarm for low inspired oxygen fraction and an alarm for if the ventilator is disconnected from the anesthesia circuit. Of note, the ASA makes a distinction between continuous monitoring and continual monitoring, where continuous is defined as prolonged monitoring without interruption, and continual is defined as frequently repeated monitoring. Of the standard ASA recommended monitoring, pulse oximetry, electrocardiography, $FiO_2$ and $ETCO_2$ measurements should be continuous, while NIBP monitoring and temperature monitoring can be continual. The ASA also strongly recommends continuous monitoring of the volume of expired gas ($F_E$gas) during each anesthetic. In addition to ASA recommendations, most all published standards of care stress the importance of having a trained anesthesia clinician present and available throughout all anesthetics, noting that subtle changes in any one of the

ASA recommended monitoring modalities can occur at any time. While adequate monitoring is essential, a patient's safety is hinged on the continuous presence and immediate availability of a trained clinician. While beyond the scope of this text, a basic checklist for setting up a safe operating room prior to surgery should include a properly functioning and serviced anesthesia machine, at least two separate in-wall oxygen outlets, two vacuum outlets and one evacuation or scavenging outlet, a properly functioning operating room bed, that can rapidly be tilted head down in case of significant hypotension, availability of properly sized and functioning face masks, oral airways, laryngoscopes and blades, endotracheal tubes and laryngeal mask airways. Having advanced equipment available in the event of a difficult airway or cardiac arrest, is strongly recommended and should be part of the ASC policies [5, 6].

Although the details are beyond the scope if this text, a basic understanding of the purchasing and maintenance of anesthesia-related equipment and monitoring is important. Depending on whether or not an ASC is privately owned or associated with a larger health system, pricing can vary considerably. It is not uncommon for large health systems to have considerable "buying power" based primarily on the size and extent of contracts they are able to put in place with the companies from whom they are purchasing. For instance, a typical health system will commit to purchasing over 200 anesthesia machines over the course of a 5-year span. Additionally, health systems commit to implementing an entire technology platform *de novo* or updating existing technology around anesthesia equipment and monitoring, an undertaking that is not insignificant in cost or time. Smaller, private ASCs are obligated to do the same, albeit on a smaller scale, but without the leverage on cost a large health system can have.

When considering purchasing new anesthesia equipment or monitors, it is imperative to have all key stakeholders participating from the beginning. These might include anesthesiologists, CRNA staff, surgical services, nursing staff, biomedical staff, supply chain staff and administrative leadership. It is important to identify everyone's needs at the beginning of the process in an effort to avoid misunderstanding once a commitment has been made. Many ASCs have a dedicated monitor and equipment manager that can play a vital role in coordinating these needs, saving all time and effort during the process. Following a request for proposal (RFP), key stakeholders will work closely with industry representatives and clinical specialists to find equipment that meets the needs of all. Depending on the size of the commitment, this process can take weeks to months. Following purchase, most service agreements with industry will include a training on how to maintain and service the equipment and monitors. Depending on the negotiated agreement, preventive maintenance (PM) will occur on a monthly basis, every 6 months and/or yearly. Moreover, longer-term warranties will be contingent on whether or not PM was followed correctly. Purchasing and maintaining anesthesia equipment and monitors can be a daunting prospect for most ASCs. We recommend close collaboration with other key stakeholders from the supply chain department and administrative leadership during the process.

The objective of any qualified anesthesia provider is to monitor their patient's oxygenation, ventilation, circulation and core-temperature. Meeting this objective in a safe, efficient and cost-effective manner will be the focus of this chapter. Adequate oxygen concentration in the blood is vital for the health and safety of all patients during all anesthetics. Meeting this objective starts with ensuring adequate oxygen concentration in the gas being delivered to the patient. Measuring inspired oxygen concentration can be achieved using an oxygen analyzer, while pulse oximetry is used to quantify the patient's blood oxygen concentration. Continuous capnographic monitoring of inspired and exhaled carbon dioxide, along with qualitative clinical assessment of chest excursion, breath sounds, condensation of air in the endotracheal tube or face mask are all ways to ensure adequate patient ventilation. Blood pressure should be monitored non-invasively, at the very least, every 5 minutes, while heart rate and heart rhythm should be displayed continuously and assessed frequently in all patients undergoing anesthesia. The ASA goes on to recommend that circulatory function be evaluated continually by at least one of the following in all patients undergoing general anesthesia: palpating of a pulse, auscultation of heart sounds, monitoring of tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring or pulse plethysmography or oximetry. Finally, according to the ASA, body temperature should be monitored in all patients receiving anesthesia in whom clinically significant changes are suspected, anticipated or intended. The ASA leaves this recommendation open for interpretation, and we recommend assessing core body temperature during the preoperative evaluation, at the beginning of each anesthetic, continuously when cases run beyond 30 minutes, at the end of each anesthetic and prior to discharge.

## Continuous Pulse Oximetry

Pulse oximetry is part of the ASA's standard monitoring bundle as well as being a part of the World Health Organization's patient safety checklist, and should be monitored continuously on all patients undergoing anesthesia. In adults, the pulse oximeter is commonly placed on the finger (we recommend avoiding the index finger as patients invariably reach for their face during emergence of anesthesia, putting themselves at risk for corneal injury). On occasion, when the upper extremities are cold and the pulse oximeter may not register, we recommend the ear lobe or nares. In children, it is not uncommon to place the pulse oximeter on the foot or across the palm in infants.

Most modern anesthesia monitors will display a numeric representation of the calculated oxygen saturation as well as a plethysmographic waveform. The clinician should be able to audibly assess the variable pitch pulse tone unique to pulse oximetry, as well as the low threshold alarm. This may require increasing the volume of each, or maintaining a quieter operating room setting in the event of excessive external noise. The utility of the plethysmographic waveform is not only to be able to quickly and accurately assess probe placement and function, but a properly placed high fidelity plethysmographic waveform will allow the anesthesia clinician to assess heart rate. A plethysmographic waveform can be used for crude assessment of stroke

volume i.e., whether or not premature atrial or systolic contractions are associated with cardiac output. Similarly, variability with respiration in the plethysmographic waveform can provide an indication of intravascular volume status.

## Continual NIBP

Currently, the standard device for monitoring NIBP is the automated oscillometric blood pressure cuff and monitor. In both adults and children, there are standardized blood pressure cuff sizes that generally range from small to extra-large. Accurate blood pressure readings are highly dependent on proper cuff size and placement. In theory, the length of the cuff bladder should be 80% and the width 46% of the circumference of the upper arm. In practice, the blood pressure cuff will cover two-thirds of the distance between the elbow and shoulder. When the upper arm is not an option for non-invasive blood pressure measurement, the forearm, calf and ankle are options in adults, and the leg or thigh in infants and children. When using the upper arm, it is important to position the non-invasive blood pressure cuff snugly against the bare skin with the bladder of the cuff positioned along the brachial artery. Failing to accurately place and position the correctly sized non-invasive blood pressure cuff may result in falsely elevated or falsely low blood pressures. When a cuff is too large, the technology tends to underestimate the blood pressure, and vice versa.

Oscillometric blood pressure cuffs have a tendency to overestimate the systolic blood pressure and underestimate the diastolic blood pressure. Because the mean arterial blood pressure corresponds closely with the maximum amplitude of pulsatile oscillation at the site of blood pressure measurement (usually the brachial artery), oscillatory blood pressure cuff technology most accurately measures the mean arterial blood pressure. While the exact technology behind oscillatory blood pressure measurement technology is beyond the scope of this text, suffice it to say that NIBP measurement using oscillatory technology, while accurate across a wide range of systolic blood pressures, underperforms at extreme blood pressures, both high and low, when compared with invasive blood pressure monitoring. Additional external factors that may impact blood pressure measurements using an oscillatory technology includes any patient motion, arrhythmia including atrial fibrillation or premature arterial contractions, faulty cuffs that result in air leak or tubing kinks. While the ASA recommends continual blood pressure monitoring without committing to a frequency, the common consensus in ambulatory patients seems to be at 3–5 minute intervals. At a frequency that exceeds 5 minutes, the clinician risks unidentified extremes of blood pressure, and more frequent intervals may result in venous congestion at the site of blood pressure measurement.

The results of recent investigations suggest a strong association between intraoperative hypotension and postoperative morbidity and mortality [7]. These findings have been corroborated by additional studies, the most recent a randomized trial that concluded that maintaining systolic blood pressure within 10% of baseline values reduced postoperative organ dysfunction [8]. For this reason, institutions are adopting continuous NIBP measurement technology in an effort to avoid intraoperative hypotension [9]. The benefit of these devices is that they are non-invasive and therefore

appealing during the ambulatory care of surgical patients. However, their long-term benefits still need to be established. With increasing use clinicians will become more familiar with the pros and cons of these attractive and appealing technologies.

## Continuous Electrocardiography

Heart rate and rhythm should be monitored continuously in all patients receiving anesthesia. The three-lead or five-lead electrocardiogram (ECG) can also be used to detect intra-procedural ischemic changes and electrolyte abnormalities. For a three-lead ECG, electrodes can be placed on the right and left shoulder, and anywhere along the left chest or abdomen. A three-lead system allows monitoring of a single bipolar lead i.e., between two leads with the third acting as a ground. For this reason, monitoring for cardiac ischemic changes is limited. The five-lead system consists of five electrodes, one placed on each extremity, and the fifth precordially in any positions from V1 to V6. This allows for monitoring of seven leads (I, II, III, aVR, aVL, aVF and the precordial lead. So in addition to being a more reliable monitor for heart rate and more complex heart rhythms compared with a three-lead ECG, the five-lead ECG is a more reliable monitor for cardiac ischemia. The sensitivity for ischemic changes has been quoted as high as 75% when the precordial lead is placed in the V4 or V5 position when compared to a standard 12-lead ECG. When an appropriately placed precordial lead is combined with lead II, the sensitivity for ischemic changes increased to 80%, and as high as 96% when 3 leads are monitored.

## Continual Temperature Management

The ASA recommends monitoring temperature in all patients when clinically significant changes in body temperature are intended, anticipated or suspected. In practice, this includes patients having a general anesthetic lasting longer than 30 minutes, or major surgery on patients in whom neuraxial anesthesia is used, including spinal and epidural anesthesia, or peripheral nerve blocks. We recommend measuring core temperature whenever possible. This might include the nasopharynx, the distal esophagus, the tympanic membrane or axilla, bladder or rectum. The optimal temperature monitoring site is often dictated by the type of surgery or type of anesthetic performed. In a recent study by Larach et al., inadequate temperature monitoring in patients that triggered malignant hyperthermia during surgery predicted mortality [10]. The authors strongly recommend core temperature monitoring.

## Continuous Capnography

End-tidal carbon dioxide ($ETCO_2$) is a non-invasive surrogate for the partial pressure of arterial blood $CO_2$ concentration, especially in intubated patients and also in properly sampled spontaneously breathing non-intubated individuals. Capnography can be used to measure $ETCO_2$ and should be used in all patients, adult and

children, undergoing either sedation or general anesthesia. Modern anesthesia machines equipped with carbon dioxide analyzers will provide an exhaled capnograph from which respiratory rate and $ETCO_2$ concentration can be derived. While the specific phases of a capnograph are beyond the scope of this text, appropriate ventilation should be confirmed in all intubated patients or patients with a tracheostomy, all patients in whom laryngeal masks airways (LMA) or other supraglottic devices are placed, and in patients under deep sedation, defined in the ASA continuum of sedation as a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation, and in whom the ability to independently maintain ventilatory function may be impaired.

## Bispectral Index

The bispectral index (BIS) monitor, developed in 1994, is one of several technologies used to assess a patient's depth of sedation. Because BIS monitoring technology can be affected by muscle movement and surgical equipment, BIS should be used as a monitor to approximately quantify sedation by central depressants and not as a sole monitor for prevention of awareness. Thus, it is a useful monitor to titrate sedation as demonstrated in a relatively recent publication. The authors conducted a meta-analysis of 1380 patients from 11 trials and demonstrated a 19% reduction in anesthetic usage, and a reduction in both the incidence of postoperative nausea and vomiting as well as a reduction in recovery room time. Despite these advantages, the investigators suggest that the cost of the BIS monitoring strip exceeds any potential cost saving [11]. Despite a wealth of publications describing the potential advantages and disadvantages of using the BIS in the ambulatory setting, its use is often based on institutional and preference and experience.

## Monitoring of Neuromuscular Blockade

The introduction of neuromuscular blockade to facilitate surgical procedures has been one of the most significant advances in clinical anesthesia in the past decades [12]. While safe and effective in reducing mortality in surgical patients, incomplete recovery of neuromuscular blockade after surgery continues to be a common occurrence and is associated with a number of adverse postoperative events including airway obstruction, hypoxemic episodes, postoperative respiratory complications, intraoperative awareness and symptoms of muscle weakness. In a recent review, Brull reports, and others have corroborated, a 20–40% incidence of postoperative residual neuromuscular blockade (PRNB) despite the routine use of anticholinesterase inhibitors [13]. Recent publications suggest that PRNB continues to be common in both adult and pediatric patients, routine use of pharmacologic reversal of neuromuscular blockade is highly variable with an incidence ranging from 18–32% worldwide, and the use of objective monitoring is as low as 17% worldwide [14].

The APSF Collaborative Panel on Neuromuscular Blockade and Patient Safety convened four Expert Discussion Groups who presented summary recommendations on the use of neuromuscular blockade and perioperative monitoring at the 2017 ASA Annual Meeting [15]. The first of four Expert Discussion Groups shed light on several provider knowledge deficits, including misconceptions related to the use of the head-lift and peripheral nerve stimulation tests, the use of facial muscles instead of the hand for monitoring, the idea that monitoring is not required if sugammadex is to be used for reversal, the perception that residual neuromuscular blockade is rare, and that in the event that it does occur, that it is not clinically significant. Clinicians are also unaware that PRNB correlated significantly to postoperative adverse respiratory events including prolonged intubation, pneumonia and increased PACU length of stay. The second group of experts pointed out that the barriers to the adequate and proper use of objective monitoring of neuromuscular blockade included lack of user-friendly devices, cost, unfamiliarity with the quantitative technology, lack of appropriate training, and that objective monitors are not considered standard of care. After finding that details about the use of intraoperative neuromuscular blockade, monitoring and reversal was not being reported to PACU staff in the majority of cases, the third group of experts recommended this be done in all cases at the time of transfer of care. The fourth and final group of experts made recommendations on educational and training requirements that included limiting the use of clinical tests, such as the head-lift and subjective or qualitative evaluation of residual neuromuscular blockade and the advantages of quantitative evaluation, proper use and application of stimulating electrodes, the importance of documenting baseline train-of-four (TOF), and the limitations of neostigmine reversal. They went on to recommend competency validation of monitoring at the institutional level.

In summary, the Panel made the following 4 recommendations; 1. Quantitative monitoring devices should be used in all cases where neuromuscular blocking medications are administered. These devices should be readily available and accessible in all anesthetizing locations, 2. In the event that quantitative monitoring is not available, the use of peripheral nerve stimulation is mandatory, 3. Clinical signs of reversal do not adequately guarantee resolution of PRNB and should not be used as the sole determinant of recovery, and 4. Professional organizations and institutions should develop best practice guidelines for the use of neuromuscular blockade, monitoring and reversal.

In their Practice Guidelines for Postoperative Care [16], the ASA states that "assessment of neuromuscular function primarily includes physical examination and, on occasion, may include neuromuscular blocking agent (NMBA) monitoring." However, due to overwhelming evidence that PRNB remains a common adverse event with significant implications for patient safety and well-being, SAMBA recommends using objective neuromuscular monitoring in all patients who receive NMBAs, and active pharmacologic reversal to avoid PRNB.

More specifically, and in agreement with recommendations for standards of monitoring during anesthesia and recovery published in 2016 by the Association of Anaesthetists of Great Britain and Ireland [17], we recommend the use of objective

and quantitative monitoring of neuromuscular blockade such as a peripheral nerve stimulator or a quantitative train-of-four (TOF) stimulator to assess residual neuromuscular weakness when NMBAs are used. We recommend stimulation of the adductor pollicis muscle at the wrist to assess function of the ulnar nerve. When unavailable, we suggest monitoring the facial or posterior tibial nerves. Peripheral nerve monitoring should be used from the time of induction to ensure adequate relaxation prior to placement of the endotracheal tube until the adequate recovery from neuromuscular blockade has been confirmed and the patient has returned to consciousness. While minimum qualitative assessment is mandatory, a more reliable assessment of residual neuromuscular weakness is a train of four >0.9. In the absence of quantitative assessment, conventional peripheral nerve stimulators to assess the post-tetanic count and subjective train-of-four should be used in all patients receiving neuromuscular blockade.

Despite conventional wisdom, pharmacologic reversal of residual neuromuscular blockade should be administered only after the 4th twitch has appeared on the train-of-four [18]. While even then, the risk of residual weakness exists, the likelihood of attaining a TOF ratio >0.9 is significantly higher than if pharmacologic reversal is administered with only 1 or 2 twitches present on TOF monitoring.

While published literature is limited, the use of sugammadex, a selective cyclodextrin and relaxant-binding agent, significantly reduces the risk of PRNB when compared with the use of neostigmine [19, 20]. Despite these promising results, the dose of sugammadex to ensure adequate reversal remains variable between patients. We therefor recommend objective peripheral nerve monitoring even when sugammadex is used for reversal of NMBAs.

## Near-Infrared Spectroscopy

Near infrared spectroscopy is gaining increasing awareness amongst clinicians for evaluation of regional cerebral oxygenation ($rScO_2$). Although currently it is most widely being used during open heart surgery in pediatric and adult patients, it may provide useful information during non-cardiac surgery [21]. During ambulatory surgery it may provide benefit during the care of patients requiring shoulder surgery in the beach-chair position. The readings can help the clinicians to fine tune the patient's blood pressure and ventilation to normalize $rScO_2$ readings [22]. An earlier study suggested the jugular bulb oxygen saturation was better predictive when compared to $rScO_2$ [23]. A review of recent malpractice claims suggests that the patients who are likely to suffer a central ischemic event are those in whom it is difficult to maintain blood pressure in the beach-chair position [24]. Abnormalities in the circle-of-Willis may also predispose some individuals to a central ischemic event. In conclusion, NIRS (near infrared spectroscopy) monitoring appears to be helpful but additional studies and more definitive information is required before any firm recommendations can be made with regard to its routine use.

## Summary

Well over half of all surgeries in the United States are performed in ASCs. As resources migrate from tertiary care centers to smaller, more isolated care settings, ensuring patient safety remains a priority. We recommend the use of continuous pulse oximetry and electrocardiography, and continual non-invasive monitoring of blood pressure and temperature in all adults and children under the care of an anesthesiologist or anesthesia care team in an ASC setting. We also strongly recommend considering the use of bispectral index and near infra-red spectroscopy monitoring, as well as monitoring of neuromuscular blockade following the administration of any paralytic agents. Patient safety remains a cornerstone of our profession, and must remain so even in the setting of innovative efforts to bring more efficient care to our out-patient surgical population.

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# Scheduling: Optimal Block Schedule, Improving Utilization

7

Mitchell H. Tsai, David W. Sobel, Jaspinder Sra, and Steven D. Boggs

*"Managing a company with monthly reports is like trying to drive a car by watching the rear view mirror and tracking the double yellow line."*

—Myron Tribus

## Introduction

The analogy of the ambulatory surgical center (ASC) and the perioperative process to that of a factory or production line has been ingrained in contemporary surgical schooling for many years [1]. ASCs are distinct from their mixed-use counterparts because of the nature of the surgical cases [2]. An outpatient surgery center, for example, performs a small variety and large volume of cases on reasonably healthy patients with a limited number of staff [3]. This workflow is in contrast to the

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inpatient hospital settings where sick patients with multiple comorbidities receive complex and diverse surgical and procedural interventions of many different types. The former environment is stable and predictable; the latter setting displays a significant degree of variability. This two-tiered model for a healthcare organization is not a new idea and implies that ASCs should have a competitive advantage when they are efficiently and effectively managed [4].

However, manufacturing processes and management frameworks fail to encompass the complexity and multitude of stakeholders and "touchpoints" that affect efficiency and safety [1]. Design thinking is an iterative process by which improvement is made to a dynamic system. Changes in the system are implemented and the resulting metrics are analyzed and used to inform further changes. But the process of design thinking reaches beyond individual improvement projects within each component of the ambulatory surgical center. Design thinking, much like gestalt theory, takes the whole entity as being distinct from its components [5]. Efficiency and optimization can be reached in each component using traditional metrics; however, if one does not consider the system as a whole, true optimization cannot be achieved.

When considering the design of an ASC, administrators need to understand the main cost drivers. For many ASC managers and owners, the costs of staffing and running an operating room is high, ranging from $22 to $133 per minute in different centers [6]. With an aging population, a burgeoning demand for surgery and procedures, and an increased worldwide need for surgery and anesthesia, all healthcare institutions are forced to choose between two options to meet the demand [7, 8]. One, the hospital can invest in the infrastructure and human personnel to increase capacity. Two, the hospital can improve throughput by optimizing its current capacity. Although the latter option seems more feasible from a logistics, legislative, or financial perspective, the optimization of any operating room requires a concerted, collaborative process [9].

Unfortunately, the ASC manager finds themselves in the following more typical scenario: they are asked to offer insights to other members of the ASC on how to retrofit an ASC facility with an established organizational psychology that increases the throughput for the safe, efficient provision of anesthetic care. The optimization of an ASC requires an approach that examines not just each component or constraint, but also considers the local environment, process, stakeholders, and barriers as a dynamic system each with stressors and opportunities for improvement. Arguably the most important area to achieve collaborative improvement is through the stakeholders themselves: the surgeons, the anesthesia team, nursing staff, and the administrators [10]. Ultimately, the efficient and safe ASC balances the goals of these individual stakeholders. This chapter will explore basic operating room management metrics, a methodology to establish a set of institutional-specific benchmarks, and a framework for self-governing processes.

## OR Management Metrics

OR management has traditionally been broken down into three modes of thinking and decision-making processes: strategic, tactical, and operational [11].

$$\text{Strategic} = \text{How we make it possible to do a}\left(\text{operation,procedure}\right)\left[\text{logistical}\right]$$
$$\text{Tactical} = \text{How do we allocate resources}\left(\text{operation,procedure}\right)$$
$$\text{Operational} = \text{Executing the plan / process}\left(\text{operation,procedure}\right)$$

Operational plans and clinical processes need to be streamlined and standardized in ambulatory surgery centers for optimal performance – both clinical and financial. A strategic decision to build and design an ambulatory center should also include the recognition that there are large investment opportunities and also that there is significant potential for loss [3].

On both a tactical and operational level, the financial impact of operational decisions may be divided into factors that affect under-utilized and over-utilized time [11]. Under-utilized time is defined as the time remaining at the end of the workday in a block allocation. This time represents a fixed cost although operating room managers at some institutions use this time as an opportunity to reduce expenses. Over-utilized time is defined as the time used after the end of the block allocation. This time represents a variable cost and the tactical decisions involved in managing an operating room predominantly center on allocation of block time efficiently to minimize over-utilized time [12]. The primary goal of OR management is to minimize both under-utilized and over-utilized time and the inefficiency of OR time can be defined with the following equation [11]:

$$\begin{gathered}\textbf{Inefficiency} \\ = \\ \left[\left(\text{cost per hour of under utilized OR time}\right)\times\left(\text{hours of under utilized OR time}\right)\right] \\ + \\ \left[\left(\text{cost per hour of over utilized OR time}\right)\times\left(\text{hours of over utilized OR time}\right)\right]\end{gathered}$$

Because the hours of under-utilized OR time has been previously allocated (e.g. OR staff are scheduled for 8 hours in OR #1 and 10 hours in OR#2, two to three months in advance of the day of surgery), the associated costs are fixed and will not change even if a room finishes early (unless you send the OR staff home without pay). Therefore, the equation can be shortened [11]:

$$\begin{gathered}\textbf{Inefficiency} \\ = \\ \left[\left(\text{cost per hour of over utilized OR time}\right)\times\left(\text{hours of over utilized OR time}\right)\right]\end{gathered}$$

Restated, if the OR finished before or on the allocated numbers of hours, then there is no increase in OR inefficiency because there is no increase in over-utilized OR time. If the OR finished beyond its allocated OR time, then the cost of OR inefficiency can be estimated by multiplying average OR costs per hour by the number of hours.

For many OR managers, surgical block time allocations and case duration estimates are a bone of contention at many institutions [13]. The literature has shown that despite the efforts to calculate, to standardize, and to predict OR utilization rates, the actual times on any given day are subject to the predictably irrational nature of human behavior. For example, many surgical centers use operating room utilization rates as a surrogate for productivity [14]. Utilization rates vary across subspecialties, however, do not correlate with financial success, can be artificially inflated, and are inaccurate for individual surgeons [15, 16]. Further, there is a difference between efficiency and productivity. Efficiency is defined as the optimal output with the minimal input. Productivity is defined as the output regardless of input. Furthermore, strategic decisions to expand and nurture specific services may necessitate a decrease in utilization rates [17]. For any perioperative system, there is an optimum utilization which the system can achieve [18].

The reductionism in the current OR management literature limits applicability since one size truly does not fit all. ASC managers should recognize the limitations of both tactical and operational decisions [19]. Block time allocations, or tactical decisions, represent a hedge against the staffing needs of the OR for elective and urgent cases for a time in the future. Improving utilization at an ASC is dependent on several factors. From a strategic perspective, hospital administrators and physician leaders need to recognize that the appropriate investment in equipment and operating room capabilities provides resilience and flexibility in downstream processes. Anesthesia providers need to be prepared to stratify patients in the preoperative period appropriately. Intraoperative and postoperative practice patterns that facilitate the movement of the patient through the perioperative period must be implemented. Perioperative nurses must be committed to the concept of flexible work schedules and cross-training across the different aspects of the perioperative process. Finally, ASC managers must recognize that an optimized ASC requires a broader perspective and must include the preoperative process and postoperative recovery [8, 9].

In theory, block allocations attempt to accommodate the daily variance in operational issues [20]. Once the allocations have been made, an OR manager then attempts to appropriately optimize the resources on the day of surgery appropriately. Here, Dexter et al. argued that operational decisions can be based on five ordered priorities:

1. maintain patient safety;
2. open access to the OR;
3. maximize OR efficiency;
4. reduce patient waiting times; and
5. personnel satisfaction [18].

In a checklist manner, the typical OR manager finds the available operational opportunities on the day of surgery. In addition, a set of rationally ordered priorities dictates that the lower priority cannot be fulfilled if the higher priority has not been satisfied. For instance, an OR manager would not delay an emergency case at 15:00 so that the case could be started in an OR at 16:00 because that specific OR had been allocated OR time until 20:00. While this operational decision would maximize OR efficiency, it does not maintain patient safety. In short, operational decisions attempt to minimize the daily, inherent variability that occurs on the on the day of surgery (e.g., case delays, malfunctioning equipment, emergent add-on case).

## Roll the Dice, Prepare to Play

One of the primary challenges for any ASC manager is developing a validated, transparent scorecard to monitor perioperative performances [21–23]. The ASC may be a contentious environment, especially when the expectations for surgeons, anesthesia health care providers, and nurses don't align. Conflict may or may not disappear when surgeons hold an equity stake in the financial state of the ASC. While it may be difficult to achieve consensus on benchmarks, an iterative process built upon continuous improvement and self-governing principles may allow the formation of a culture built upon long-term principles [23]. Simplistic predictive models of OR management are incomplete because they do not account for the context-specific attributes of every OR environment [17].

Improving ASC utilization requires design thinking, an iterative brainstorming process to imagine and develop solutions to dynamic systems. Similarly, Rathmell and Sandberg have actively encouraged the application of systems-based engineering to the perioperative process [24]. Sandberg described the frameworks as follows:

1. Process modeling to create a reference process against which actual process progress can be compared, seeking noteworthy exceptions;
2. Data integration of multiple electronic sources and different data types;
3. Continuous process monitoring by recursive queries of the anesthesia information management systems and other databases to identify process exceptions; and
4. Pushing useful data to key stakeholders, seeking to provide the right information to the most appropriate individual in a timely manner [25].

Anesthesiologists, ASC managers and investors need transparent metrics which information technology may provide. Further, this data management system should be coupled with a reliable financial accounting process and an information technology infrastructure for surgical and staff scheduling.

From the perspective of an ASC manager, we expand the preceding framework in order to optimize utilization:

1. *Minimize the distortion for a specific operating room management metric*. Dexter et al. have demonstrated through a surgeon survey that there is both an individual bias and lack of knowledge of the principles of OR efficiency [26]. Effective ASC managers need to develop transparent, self-regulating tactical and operational processes. In the words of George Bernard Shaw, "the single biggest problem in communication is the illusion that is has taken place." [27]
2. *Recognize that surgical times and case load are subject to positive and negative biases.* Dexter et al. showed that surgeons unwittingly behaved in an interesting manner:
   - If the surgeon knew that they had overbooked their day, their surgical times would shorten.
   - If the surgeon knew they had under-booked their day, their surgical times and/or turnover times (e.g. the surgeon becomes difficult to reach once the room was ready) would lengthen [28].

   In short, each member of the ASC uses their own lens and bias to make sense of the stressful surgical environment. Therefore, ASC managers need to use data-driven processes to uncover these biases.

3. *Maximize the limited operational opportunities.* At an ASC, the clinical director essentially manages operational decisions made before the day of surgery. For example, if a room is delayed and another room has available time, an OR manager can move cases around to start surgeons at their scheduled time, to accommodate urgent cases, or to flip-flop surgeons who are behind. In essence, OR managers are left with the mandate to complete the scheduled cases, accommodate urgent/emergent cases, and maximize OR efficiency. Again, an ASC should have a distinct advantage over their inpatient counterparts because the preoperative processes and postoperative considerations should select for patients that should move through an ASC efficiently [8].
4. *Develop transparent processes and institutional benchmarks.* Efforts to provide surgeons with the tools, resources, and time to do what they do are critical to a successful OR. These opportunities, however, depend on accurate information, especially surgical case durations. Restated, data-management tools that provide better estimates of surgical duration are substantial in value [22].

This recursive framework should identify the numerous opportunities to continuously refine a system. Systems-engineering and design thinking focus on continuous improvement throughout a system. In short, perioperative optimization mandates a dedicated, long-term investment of time and resources.

From a civil engineering perspective, the Golden Gate Bridge is repainted every year because its location at the entrance of San Francisco Bay exposes the structure to the elements [29]. City planners could have erected the massive structure and ignored the maintenance costs. Similarly, the development of OR benchmarks (the

bridge) is only the first step in a continual and iterative process to optimize performance. These parameters are the underlying structure of an efficient, optimized perioperative system. However, they need to be revisited and refined (maintenance) on a continuous basis.

## Moving Beyond Taylorism

### First-Case Start Delays and Start-Time Tardiness

Using this backdrop for OR efficiency, the impact of first-case-of-the-day delays becomes not a question of what time the OR started, *but what time did the OR finish* [30]. The topic of first-case-of-the-day delays has long been a source of conflict between surgeons and OR staff. In 1998, Vitez et al. demonstrated that the percentage of timely OR start times at an academic institution could be increased by implementing anesthesia performance standards and educating anesthesia personnel [31]. Similarly, reducing the time patients have to wait for their surgery after they arrive at the hospital is an essential consideration for the ASC manager [18]. If a case is supposed to start at 07:30 A.M. (patient enters OR), but the case starts at 08:00 A.M, then there is 30 min of tardiness.

From an operational perspective, well-functioning OR suites should strive for tardiness of start of scheduled cases totaling less than 45 min per 8-hour OR day [23]. The emphasis on on-time starts seems to stem from the fact that this is one variable that can be accurately measured. In general, facilities with long work days will have more significant tardiness as the day gets longer because there is more uncertainty about case start times.

*Minimize first-case start delays and minimize OR tardiness.* At the University of Florida, the perioperative service uses a staggered first-case start to get the day underway. Using a form of asymmetric paternalism, the surgeons state their preference for first case start times: 07:30, 07:45, and 08:00 [32]. The ASC manager can [1] properly determine when patients should be told to arrive, so as not to be too early or late; [2] schedule appropriate delays between successive cases; [3] move cases among ORs when a preceding surgeon's case in the same OR is running late; and [4] sequence each surgeon's list of cases in the same OR on the same day, with the most predictable case first and the least predictable (often the longest) case last.

1. *Recognize that both first case start delays and OR tardiness are subject to positive and negative biases.* Truong et al. showed that OR delays are common and only modest improvements can be achieved without cooperation from anesthesiologists and surgeons both arriving on time on the day of surgery [33]. Tardiness measures and aggregates the delays (or early starts) for the cases in the ASC [34]. It appropriately accounts for all the activities involved in the care of a patient. More importantly, it recognizes that cases are delayed for a myriad of reasons, notwithstanding, surgical.

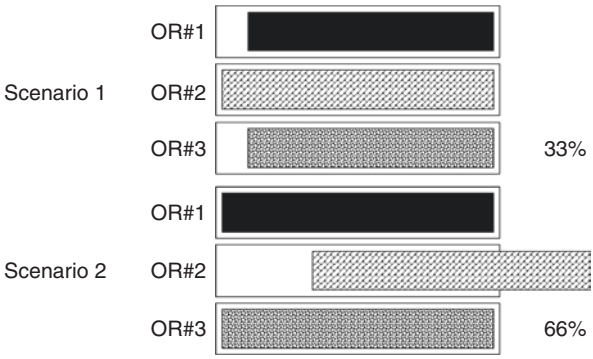


**Figure 7.1** First-case start delays and over-utilized time

2. *Maximize the limited operational opportunities.* On the day of surgery, if a room is delayed because of start-time tardiness, prepare to move the subsequent cases into another operating room, thereby minimizing over-utilized time and maximizing under-utilized time. Using the tardiness metric, Wachtel and Dexter have shown that total OR tardiness decreases throughout the day [34].
3. *Develop transparent processes and institutional benchmarks.* Here, ASC managers should recognize that the percentage of cases that begin late is misleading [30]. In the first scenario (Figure 7.1), two ORs started late, but all the OR finish on-time. In the second scenario, two of the ORs started on-time, but one of the ORs finished past the allocated block time. Although the calculated on-time start percentage is higher in the second scenario, the cost of over-utilized time is higher. The former scenario results in much less disruption to the OR schedule even though the percentage of cases starting late is greater. Moving behind the delay for the first cases of the day, OR tardiness is a more inclusive metric because it accounts for both the negative and positive biases.

Again, many ASCS focus on first-time starts because they can be measured may not contribute to optimal performance. Multifactorial, ineradicable factors contribute to first time start delays, including but not limited to malfunctioning equipment, patients either arriving late or not at all, consents not obtained by physicians, family not available to consent for incompetent patients, new changes in the patient's medical condition, and staff emergencies. Rather than focus on which cases are starting late, it would be a better use of resources to dissect the reasons why a specific room finished late or why a case started significantly later than initially scheduled. By doing so, OR staffing and resources will be freed up to focus on potential targets of significant improvement, possibly yielding greater returns than merely focusing on why in room time was 07:40 instead of 07:25. Finally, astute ASC managers should recognize that well-thought out strategic decisions create more tactical opportunities. The operating rooms should be built and the equipment purchased so that the operating rooms are interchangeable and

procedures with different staffing and equipment needs can be accommodated. When each operating room is equipped to handle a breadth of surgical cases, block allocations become interchangeable. On the day of surgery, this investment also leads opportunities at an operational level.

## Tactical and Operational Financial Costs

Mintzberg pointed out that management and leadership are similar to the right and left hemispheres of the brain [35]. Traditionally, the left-side is associated with analytic, data-driven skills, not dissimilar to the responsibilities of any manager. For ASC managers, the tasks of planning, budgeting, organizing, staffing, and problem-solving are all directed at creating predictable, stable processes. The right-side is usually associated with artistic and emotional processes; this is where the art of leadership comes into play. The key to any effective ASC manager is the ability to decide which skill set to use. There will be times when inspiring individuals and laying out a vision is critical. Other times, there will be a need to make sure that budgets are met and that staffing is available.

From the perspective of any hospital administrator or ASC manager, providing surgical care is extremely expensive. Dexter and Wachtel have shown that the elimination of unnecessary preoperative laboratory testing and the optimization of the OR schedule were the two primary drivers for cost savings for a perioperative surgical home in an ASC [36]. Broken down further, these costs may be measured in categories (some of these are listed) (Table 7.1). Quantifying OR capacity and the accurate estimation of surgical case duration are essential to optimizing OR throughput [37]. An ASC manager should plan staffing and allocated block time for the expected workload, underscoring why accurate estimates of these parameters are so critical.

**Table 7.1** Financial and operational costs for an ambulatory surgery center

| |
|---|
| Facility |
| Mortgage or Rent |
| Utilities |
| Insurance |
| Depreciation |
| Taxes |
| Equipment |
| Purchase or Lease of Durable Equipment |
| Maintenance costs |
| Material |
| Costs of Disposables |
| Staff |
| Employed Physicians |
| Advanced Practice Personnel |
| Nurses |
| Technicians |

1. *Minimize the gaps in allocated resources and planned case time*. For nurses and anesthesia health care providers, this may require flexible scheduling so that patients requiring regional anesthetics for surgery are accommodated in a manner that does not cause delay in the OR. Similarly, flexible PACU staffing may accommodate for uneven pockets of activity throughout a workday [38].
2. *Recognize that staffing costs are subject to positive and negative biases.* ASC managers need to employ a different skillset when it comes to managing the staff's perspective of operational expenses. Here, they need to establish direction, align employee's values, and motivate individuals. Staffing flexibility builds resilient systems. However, staffing flexibility does not occur without staff investment and reciprocity.
3. *Maximize the limited operational opportunities.* The ASC manager should recognize that the tactical block allocations and the OR schedule represent a hedge. On the day of surgery, the primary goal is to optimize the operational and financial costs of an ASC [18]. In many ways, it is a balance between providing safe, efficient clinical care and minimizing the staffing costs.
4. *Develop transparent processes and institutional benchmarks.* Here, an ASC manager needs to work with the hospital and physician leadership to develop monthly or quarterly financial reports. At a minimum, ASC managers should understand the financial and operational impact of each surgical service line (or surgeon) because the operational benchmarks affect the bottom line. This recursive reporting mechanism should elucidate more opportunities to optimize and fine-tune the system.

The manager has little short-term influence on fixed costs which include facility costs, most labor costs and the cost of equipment. Realistically, for optimal ASC performance in the short term, efficiency must be obtained by doing as many cases as possible within the framework of costs that have already been allocated (fixed), including salaries and disposables. The corollary of this is that variable costs, both labor (overtime) and material, need to be minimized. These costs do not include the financial instruments utilized to finance the construction or renovation of a surgical facility.

## PACU Admission Delays

Patients undergoing surgery at an ASC are following a multi-step pathway. They interact with the system through a series of touch points that shape their experience. These touch points also serve as potential bottlenecks. In the Theory of Constraints, Goldratt notes that the optimization of one bottleneck will create a bottleneck elsewhere in the system [39]. The post-anesthesia recovery unit (PACU) is one such touch point that is often identified as a bottleneck upon optimizing other areas of the ASC. To optimize the schedule and utilization of an ACS, an effective manager applies the benchmarks in the OR, but understands that there will be other constraints later in the pathway.

1. *Minimize the distortion behind the finger pointing for PACU delays.* When a clinical process dictates that the PACU call should be initiated 30 minutes before the end of surgical closure, OR staff may initiate a report on a PACU delay when the minute hand ticks past 31 minutes. ASC managers should keep a record of a PACU admission times, from phone call to admission. In all likelihood, the data is not normally-distributed [40].
2. *Recognize that PACU admission delays are usually multi-factorial.* The illusion of causality makes it easy to assign blame. The classic example here is a circulating nurse who calls the PACU for a postoperative bed and subsequently learns that there is not a bed available. It's simple to assume that delays are caused by the actions (or inactions) of one individual, but that delay may have resulted from a myriad of reasons (e.g. a nurse is occupied with the transfer of the patient to an inpatient setting for further workup, a patient waiting for a ride home). ASC managers should focus on communicating the reasons for PACU delay on a monthly or quarterly basis [41].
3. *Maximize the limited operational opportunities.* Here, the importance of flexibility staffing is pivotal. ASC nursing staff should be trained in both the preoperative and postoperative settings. In a typical OR environment, the preoperative setting is busiest in the morning and the postoperative recovery unit in the afternoon [42].
4. *Develop transparent processes and institutional benchmarks.* Macario notes that efficient hospitals should strive to have less than 10% of the workdays with at least one delay [23]. This benchmark is a long-term view. When one extends their perspective over a period of time, one PACU delay in the entire scheme of a busy ASC center may seem more tolerable. For the staff members, this serves as the foundation for a flexible and resilient system.

The primary driver of the cost in the OR is the staffing costs [43]. The staffing costs are higher in the OR mostly because of the number of staff per patient, which ultimately affect staffing ratios. Increasing throughput through the OR requires slack in other areas, flexible staffing, and clear expectations. From the perspective of an ASC manager, it necessities a systems-based engineering perspective that identifies slack in a system that accommodates the highest workload and not the minimal staffing expenses necessary.

## Prolonged Turnover Times

McIntosh et al. demonstrated that delays could be treated as an *increase in turnover times* and the duration can be added to the total turnover times for that specific OR [11]. Turnover times can be estimated for an individual hospital and they should be based on historical data [44]. A delay might have different impacts depending on the surgical case load in the room. For example, assume that an OR has one case scheduled for 8 hours and OR staff has been allocated for 8 hours. If the case is delayed by 10 minutes, there are no turnover times to consider and the room will finish,

early, on-time, or late. By contrast, if an OR has 20 cases scheduled for 8 hours and OR staff has been allocated for 8 hours, there will be 19 turnover times. In a fast-paced pediatric ENT room, the turnover times may average 10 minutes. In this context, a 10-minute delay will add approximately 30 seconds to each turnover time. Again, it is difficult to justify the additional administrative expense of tracking on-time starts when the averaged turnover time is almost insignificant. Quite simply, the OR will finish early, on-time, or late.

1. *Minimize the variance in turnover times.* On a tactical level, the cases lists should be organized by similar case types and laterality [45]. For instance, arthroscopic cases should be arranged so that the left-sided cases are performed first followed by the right-sided cases. Scheduling a case list in this manner minimizes the transfer of equipment from one side to the other. Similarly, hernia repairs and laparoscopic cholecystectomies should be bin packed for general surgical services.
2. *Recognize that turnover times are subject to positive and negative biases*. The classic example here is a surgeon who walks out of the operating room and the first-assist closes the surgical wound. As previously noted, the definition of turnover time should be clearly defined [46].
3. *Maximize the limited operational opportunities.* Delays in turnover times are due to a myriad of reasons (e.g. missing equipment, technical difficulties, facilities malfunction). In most instances, it is impossible to plan for these delays. ASC managers should adopt a high-reliability organization perspective when delays do occur: get the job done safely with the highest level of expertise available [47].
4. *Develop transparent processes and institutional benchmarks.* Macario notes that only 10% of the turnovers per month should be greater than 60 minutes [23]. The benchmark for turnover times represents an average. Astute ASC managers should track turnover times by surgical service line. Surgeries requiring more equipment will necessitate longer turnovers. For ambulatory surgery centers, ASC managers should strive for turnover times less than 30 minutes. The classic misperception of turnover times occurs for a surgeon who walks out of the operating room, allowing the first-assist to close the surgical wound. The surgeon returns after a "turnover time" of 25 minutes only to find the room empty and the anesthesia health care provider setting up for the case. ASC managers need to clarify the definitions for turnover times and they should not be conflated with OR tardiness [46].

Stepaniak et al. demonstrated that both turnover and procedural times can be reduced with an integrated, cooperative team approach and that the appropriate identification of sequential cases results in an efficient surgical list [48]. However, Dexter et al. have previously demonstrated that whole-scale efforts to reduce turnover times are mostly ineffective because the time savings usually do not permit the completion of another surgical case, start to finish [49]. Similarly, Brodsky questioned the concept of time savings [50]. ASC managers need to appreciate that

turnover times are a contentious issue. However, the astute managers should recognize that most turnover delays do not impact the operational and financial expenses. Ultimately, the impacts are mitigated by operational and staffing decisions.

## Case Cancellation Rates

Case cancellations rates vary across institutions, service lines, and surgeons. Again, Dexter and Wachtel noted that the elimination of unnecessary preoperative laboratory testing represented one of the two primary drivers of cost savings for a perioperative surgical home [36]. Case cancellations affect the operational and financial aspects of an ASC by creating an inefficiency in the tactical and operational processes. Nonetheless, for each particular patient population and surgical service, optimization can be sought by attempting to:

1. *Minimize cancellation rates.* ASC managers should work with anesthesia health care providers and surgeons to develop and refine preoperative testing workflows and risk stratification; and to make sure that the appropriate patient educational materials and guidelines are readily available. As noted, the ASC has a built-in advantage over an inpatient perioperative service because it can select patients for surgery. Cancellation rates vary from 5% in the general OR where there can be upwards of an 18% cancellation rate for inpatients. By contrast, the cancellation rate is estimated at 4% for ambulatory surgical centers [51]. Further, ASC managers should continually revisit their supply chains to minimize case cancellations secondary to technical needs and clinical supplies [52].
2. *Recognize that the reasons underlying case cancellations are multi-factorial.* For example, the rate of case cancellations may be higher in a pediatric population presenting to the ENT service for myringotomy tubes in the winter than that of elective knee arthroscopies in adults. Patient may cancel on the day of surgery due to anxiety, lack of transport, or poor communication [53–55]. Worse, they may arrive on the day surgery with an inadequate preoperative evaluation. Unavoidable reasons for case cancellation include a change in a patient's medical condition, unavailability of OR equipment, and a surgeon's absence due to a concomitant emergent case, clinic conflicts, or personal reasons. Track reasons for cancellations and develop process improvements to address causes that are avoidable, such as NPO violations or non-compliance with medications which could be easily resolved by ensuring that patients are receiving appropriate instructions.
3. *Maximize the limited operational opportunities.* On the day of surgery, an ASC manager should mitigate the financial and operational impact. Subsequent patients should be called in earlier and available OR time can be made available to surgeons behind schedule.
4. *Develop transparent processes and institutional benchmarks*. Multiple indices can be used to track cancellation rates. At an ASC, acute medical conditions were responsible in 23.3% of cases, patient refusal in 22.2%, non-attendance in

2.1%, failure to follow pre-operative guidance in 23.3% and unavailability of resources in 29% [56].

Case cancellations create logistic, financial, and psychological hardships for patients and their families [57]. From a financial perspective, case cancellations are a surrogate for opportunity costs. When cases are cancelled on the day of surgery, schedulers cannot schedule an additional procedure, leading to lost revenue [51]. For ASC managers who are trying to optimize staffing, the downtime represents a sunk cost.

## Case Duration and Prediction Error

There is no operating room benchmark shrouded in more mystery than prediction error. Mathematically, prediction error equals the actual duration of the case minus the estimated duration of the case [58]. In short, prediction error indicates whether the initial estimates are consistently too high or too low. The difficulty in applying these metrics is twofold [59, 60]. First, estimating the actual case duration time is difficult. Most surgeons are unaware that case duration data is not normally distributed and is usually right-skewed [28]. Second, surgeons may attempt to game the system by under-estimating the length of their procedures, enabling them to book additional cases [61]. Optimizing a schedule for an ASC requires the information technology to extract prediction error by service and case. ASC managers should use the data to optimize the schedule before the day of surgery (e.g. adjust case times) and to educate surgeons about their correct or incorrect estimates.

1. *Minimize the variance in prediction bias.* Macario notes that efficient OR suites should have case duration estimate variance per 8 hour of OR time that is less than 15 minutes [23].
2. *Recognize that case durations are subject to positive and negative biases.* Dexter et al. showed that surgeons who intentionally (or unintentionally) under-book the duration of a case or list of cases, tend to work slowly [28]. Conversely, when they overbook a day's work, there is a sense of urgency. ASC managers should develop transparent data-driven processes that identify and track by surgeon case duration bias.
3. *Maximize the limited operational opportunities.* On the day of surgery, if a room is delayed because a case takes longer than scheduled, the ASC manager should be prepared to move the subsequent cases into another operating room, thereby minimizing over-utilized time.
4. *Develop transparent processes and institutional benchmarks.* ASC managers should publish reports to all the surgical services on their case durations on a monthly or quarterly basis depending on the surgical volume. These should be used to continually fine-tune the tactical planning and operational processes.

Over time, these prediction biases should be less variable allowing ASC managers to better optimize the staffing needs of the perioperative services. Importantly,

management decisions based on historical data versus speculation will help surgeons plan their days accordingly. Moreover, minimizing the variability in predicted and actual durations improves throughput and reduces unforeseen operational costs [62]. For the ASC, surgeons and all staff, understanding the true nature of case duration can be helpful in optimizing throughput for the center.

## Conclusion

OR managers should recognize that ASCs are complex adaptive systems and that these organizations require feedback mechanisms to evolve and improve performance [63]. These complex systems benefit from applying design thinking principles and addressing the process as a whole instead of addressing each of its parts individually. The management techniques necessary to optimize ASC performance are distinct from those utilized in traditional manufacturing systems. In addition, it should be remembered that various stakeholders all have their own vision of what is optimal [64]. Surgeons generate a substantial source of revenue for hospitals and many efforts are made to satisfy their desires. Similarly, nurses, administrators, anesthesia providers and others will all have their parochial view of what is "optimal" from their perspective. The objective of ASC optimization is to harmonize the requirements of each group. Every member of the OR is responsible for some form of management during the course of a surgery (e.g. nurses check the surgical equipment, operating room assistants clean the rooms, surgeons mark the patients, and anesthesia providers plan a safe anesthetic). To optimize an ASC, all the stakeholders must understand that they are not individual actors, but rather part of a larger team.

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# Lean Management: Inventory, Waste Management

8

Ahmad Elsharydah, Maria A. Michaelis, and Niraja Rajan

## Introduction

Lean management is a set of strategies and methods to maximize value and decrease waste in the business process. Lean management aims to keep and enhance the value-added steps (Figure 8.1) while identifying and eliminating the none-value-added steps and activities defined as waste [1]. It was generated and applied initially in the car manufacturing industry, specifically the Toyota Production System (TPS). Many other industries, such as healthcare, began to adopt lean strategies after the successful implementation by Toyota [1]. Lean strategies use the same principles in different industries for continuous improvement, waste elimination, and value augmentation. The tools used in lean management are similar to many tools used in healthcare. One example is Six Sigma, which works to eliminate defects [2], and 5S (sort, simplify, sweep, standardize, sustain) which is used to organize the healthcare work environment [1]. Successful implementation of lean strategies requires a common vision for lean management, along with the healthcare organization's commitment to provide the necessary tools [3, 4]. The practice management at ambulatory

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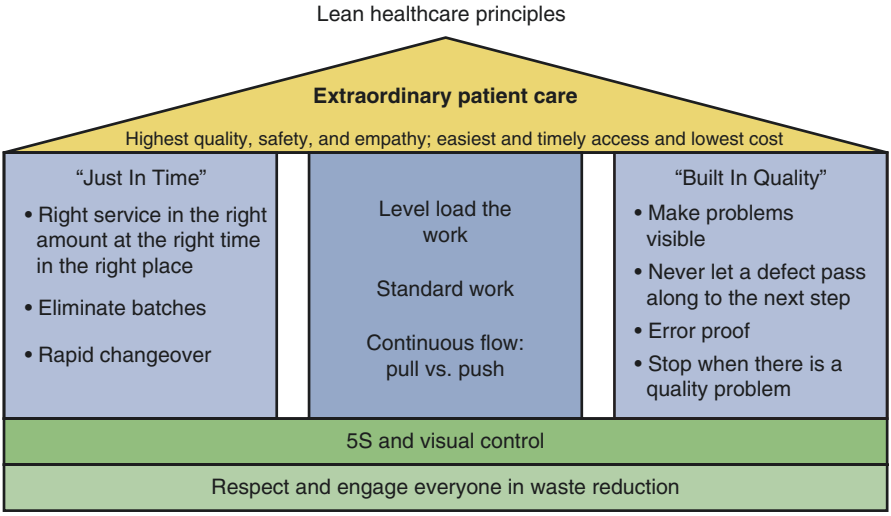


**Figure 8.1** Diagram of the lean management process in an organization. Each row may be considered a level to be continuously improved as well as the basis for developing the levels above. (From Wellman et al. [5] with permission of Taylor and Francis Group LLC Books)

surgical centers (ASCs) mainly centers on care that is more convenient for patients, provides higher satisfaction and lowers healthcare costs. To achieve these goals, lean management strategies are natural choices for this type of practice. Inventory management causes one of the main sources of waste at ASCs. ASC inventory includes the different items used in the daily operations, such as medications, equipment and instruments. Having the right amount and type of inventory at the right time may lead to reduced inventory and eventually decrease waste. This requires careful tracking of utilization and active management of the supply chain.

## Ambulatory Surgical Center Waste

Lean management is based mainly on waste elimination in the business process. Seven wastes have been generally identified while applying lean in different industries [1, 5]. They include transportation, waiting, overproduction, defects, over processing, motion and inventory. The extent and magnitude of these wastes are different from industry to industry. Here are some examples of the seven wastes in the daily ASC activities (Table 8.1) [1]:

1. Transportation: ASCs are generally smaller medical centers with limited space for supplies and materials. Unnecessary movement of supplies and equipment may lead to case delays and wasted time.. For example, moving bulky equipment such as an eye microscope for specialized cases from room to room wastes valuable operating room (OR) time.

**Table 8.1** The seven types of wasteful activities

| Waste | Definition | ASCs Activities Examples |
|---|---|---|
| Transportation | Unnecessary movement of materials or supplies | Moving samples/specimens, equipment, supplies-such as moving large equipment from room to room (for example, anesthesia machines, ophthalmology microscope) |
| Inventory | Supplies, equipment, or information not needed by the customer now | Medications, linens, equipment, parts, supplies, instruments, documents-many have expiration dates |
| Motion | Unnecessary movement of people | Moving patients, moving staff, searching for items and equipment if not organized in one area. |
| Waiting | Delays in the value stream (absence of flow) | Recovery room bed assignment delays, testing/ treatment delays (such as blood glucose or pregnancy test), discharge delays |
| Over processing | Work that creates no value | Duplication of work, rework, complexity, re-testing, repeat paperwork such history and physical exams |
| Overproduction | Producing more than customer needs right now | Treatment or testing done to optimize staff or equipment productivity, not patient needs |
| Defects/Poor quality | Product or service that does not conform to customer requirements | Medication error, wrong or incomplete surgical or anesthesia consent |

2. Motion: Unnecessary patient and staff movement may also lead to significant wasted time with less accomplished. One example: a patient travels to different stations upon admission in the ASC for pre-operative evaluation, x-rays or blood work-up. Having these stations close by and convenient may save time and improve patients' satisfaction. Most ASCs are constructed to permit unidirectional patient flow.
3. Waiting: Faster service and quick turnover times are expected in the ASC daily activities. Either patient or clinician waiting may lead to lost time and less satisfied patients. Accurate scheduling and decreasing the number of patient care steps reduce waiting time for patients [6]. It is ideal to have required preoperative evaluation, laboratory or imaging tests done in one-step and one place. Furthermore, clinicians waiting for equipment or laboratory tests or other services may lead to lost revenue and disruption in the ASC flow.
4. Overproduction: Lean management is consistent with having the required services, tools and equipment for the right process at the right time. Overproduction of materials and supplies may cause significant waste. Extra intravenous set-ups or drawing up more drugs than needed are examples of overproduction creating waste. A reliable system to predict and adapt to the ASC daily needs for materials and services would decrease the extra and unnecessary production of prepared supplies. This requires careful planning for the day and attention to detail.
5. Over processing: Over processing is a common source of waste in healthcare. Defensive medicine and the current medical malpractice environment increase over processing in medicine. Clinicians ordering unnecessary preoperative tests and anesthesia personnel preparing too many drugs and devices, such as

endotracheal tubes, are examples. Over processing leads to an increase in waste and healthcare costs. These pre-prepared drugs and equipment end up being thrown out at the end of the day. Using a reliable system to have things ready for safe patient care may decrease over processing and waste. For example, having a drug readily available in the operating room without drawing it up in the syringe or an endotracheal tube stylet unopened but ready if needed, because most intubations can be performed safely without a stylet, can minimize over processing waste.

6. Defects: Defects and errors in products, equipment, and tools can be costly for ASCs. Identifying these problems earlier in the process decreases harm and waste. For example, an unchecked anesthesia machine with a problem or non-functional standard monitor in the morning may lead to patient harm, delay in start time, cancellations, and/or frustration of the patient and the surgeon. Similarly, incorrect surgical trays with missing items can cause waste in time and possible cancellation of cases. Defect prevention is the best way to manage this waste [2]. For example, developing a standardized way for checking anesthesia machines and monitors with scheduled maintenance would reduce the chance of defects and errors. Similarly ensuring availability of equipment and standardization of surgical trays could reduce delays and cancellations.
7. Inventory: ASC inventory includes all supplies, equipment, instruments, documents and medications. Inventory usually is stored at the ASC facility and some of the inventory is in motion between the ASC and its chain of supply. Some inventory requires special conditions to store, such as medications that may require a cold environment for storage. Inventory is a major source of waste at ASCs. For example, unavailable ASC operating room supplies may lead to delays or cancellations with unsatisfied physicians and patients. Furthermore, many ASC supplies, especially medications, have an expiration date. Therefore, to have more supplies than needed may cause significant waste. Forecasting and prediction of the ASC needs for inventory is a critical step to minimize inventory waste [1]. Some ASCs use automated inventory management systems with advanced analytics to predict the ASC supply needs in order to get the needed supplies on time. Moreover, organizing the supplies in the appropriate storage area is important to avoid missing supplies that may expire before being utilized. Radiofrequency identification (RFID) systems are very helpful in this matter [7]. RFID systems can track supplies, and in some applications, can track staff and patients at the facility. These systems can lead to a decrease in waste related to motion.

## Inventory Management Strategies

Supply chain management is much broader as it involves the planning and management of all activities involved in sourcing and procurement. For lean management strategies to be truly effective, they must focus on the entire supply chain. Inventory costs can be as high as 100-120 K per OR. A large area for waste is duplication of

supplies. Potential sites for duplication include: the OR, specialty carts, case pick areas, case carts, and bulk storage areas. Other causes for waste are non-standardized surgeon preferences, lack of automated inventory management systems and multiple categories of supplies. Some strategies ASCs can employ to minimize waste include consolidation of supplies, product standardization (involving all the surgeons and standardizing preference cards for each type of case), improved acquisition and distribution (different suppliers offer discounts and perks), and controlling new products and vendors. Staff education and involvement are key to implementing any lean management strategies. Some barriers to effective inventory management include: lack of data, the tendency to open unnecessary supplies "just in case", lack of integration between supply chain personnel and surgical services, lack of defined par values for items, and lack of communication between the clinical staff and the materials manager who often does not have a clinical background. Effective inventory management requires a team approach involving the materials manager, OR leadership (surgeons and anesthesiologists in addition to nurse managers), and the administrator. Data on usage and duplication is an important starting point to decrease waste. Another key area to improve utilization and minimize waste is involving OR staff and anesthesia providers by making them more aware of the cost of supplies. For example, you could display prices of supplies in the workroom or on the case cart.

## Application of Lean Management at ASC

ASCs range in their size from a small business unit to a large surgical center with multiple operating rooms. Some ASCs are stand-alone and others are part of a large medical center. Applying the core principles of lean strategies is similar among the different ASCs with respect to the patient, healthcare provider and business process. However, leadership commitment and the details of application are usually different. Generally, the initial application of lean methods is expensive and takes a lot of effort. Therefore, small ASCs may not have the resources for implementation of lean methods. In any case, to achieve real improvement, an organized approach is required. Depending on the size of the ASC and nature of the problems to be remedied, different approaches and methods have been utilized including the 5S (Sort, Simplify, Sweep, Standardize and Sustain), PDSA (Plan, Do, Study, Act) and Root Cause Analysis (RCA) methods. Here is a summary description of the 5S method and its application at ASCs:

## 5S Method in Lean Management

This approach can be utilized for optimal work environments. Each of the 5 S's (Sort, Simplify, Sweep, Standardize and Sustain) in this approach go through different levels. A level I including documenting the baseline of the work and gradual upgrade and involvement in the improvement process through level II which

involves focusing on the basics to level III which is more visual and involves a higher level of activities and commitment for the improvement process and finally level IV to improve reliability and sustain progress [5]. This approach works well for the perioperative arena because efficiency of operating rooms, including ASCs, depends greatly on their inventory: supplies, equipment, and instruments. For example, sorting anesthesia medications in one area with having the needed medications ready and the as needed medications readily available improves efficiency and minimizes waste. Furthermore, simplification of the OR supplies in terms of their location and labeling allows anybody in the OR to find the required item. In addition, a clear organized work area (for example, over the anesthesia machine table) decreases errors and reduces waste. Making these changes and improvements, along with standardizing supplies based on the specific patient and procedure can help contain cost and improve quality. The last step in this approach is to sustain these changes with continuing assessment, education, and revisiting the process on a regular basis to minimize regression and staff loss of interest.

## Summary

The main objectives of medical organizations, including ambulatory surgical centers (ASCs), are compatible with the concepts of lean management. ASCs strive to be leaders in high quality healthcare and patient safety combined with great service and affordability. However, many wasteful activities may impede achievement of these goals. Lean is an innovative management approach that has proven successful in many health care organizations. Application and implementation of lean principles and philosophies in daily activities are essential to decrease waste, improve efficiency and quality, and ultimately lead to safer patient care in ASCs. Lean implementation is an arduous, never-ending improvement journey. It needs the commitment of the whole organization. It engages the entire staff in identifying and solving problems based on an attitude of continuous improvement.

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# Medication Safety: Unique Aspects in ASCs

9

Neil S. Bailard

## The Burden of Medication Errors and Adverse Drug Events

A medication error is "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer" [1]. This should be distinguished from an adverse drug event, which is "an injury resulting from medical intervention related to a drug" [2]. Medication errors may be responsible for more than 7,000 deaths and $3.5 billion in increased health care costs every year in the United States [3]. Treatment costs for medication errors in hospitalized patients have been estimated to range from $8,439 to $8,898 per incident [4]. The incidence of medication errors in ASCs has not been studied as such, but perioperative medication errors in general are more frequent than we would like to admit. The incidence of anesthetic medication errors in one recent review ranged from 0.08% to 0.75% of cases [5], but these rates were largely based on self-report and facilitated incident reporting. A much higher rate was found using direct observation and chart review of 277 operations in a tertiary care academic center; approximately 50% of operations resulted in a medication error and/or adverse drug event. Of 3,671 medication administrations, 153 preventable medication errors were committed, representing 4.2% of all medication administrations. Of these, 51 resulted in an adverse drug event and observed patient harm, and a further 70 were judged to have the potential for patient harm. Most of these errors involved labeling errors or an incorrect dose [6].

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## Medication Manager vs. Medication Management Committee

Centers for Medicare and Medicaid Services' (CMS) Conditions for Participation for ASCs require that "The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services" [7]. This responsible individual will usually, but not always, be a licensed pharmacist, depending on applicable state pharmacy laws. A pharmacist-in-charge may be an employee of the ASC or may be a consultant pharmacist contracted on a part-time or full-time basis. If the ASC engages a consultant pharmacist, they must have a written contract with that person detailing their responsibility over the ASC's pharmacy services.

Although the CMS statute allows for one person to hold responsibility over medication management in the ASC, it is best to implement a multidisciplinary approach. The Association of periOperative Registered Nurses suggests that a medication management committee include perioperative RNs, licensed independent practitioners, anesthesia professionals, pharmacists, risk management/quality personnel, purchasing personnel, infection prevention specialists, and administrators [8]. In an ASC some individuals may fill several of these roles.

A complete discussion of Joint Commission or other accreditation standards is beyond the scope of this review, but it will serve to orient medication managers toward unique issues which have proven problematic for other ASCs. To that end, this review is aligned with the Joint Commission's *Comprehensive Accreditation Manual for Ambulatory Care,* which serves as a useful rubric for ASC medication managers to evaluate their processes and policies relating to medication planning, selection and procurement, storage, ordering, preparing and dispensing, administration, monitoring, and evaluation [9].

## Planning

**"The ASC plans its medication management process and safely manages high-alert and hazardous medications."** [9]

The Institute for Safe Medication Practices (ISMP) describes high-alert medications as those which pose increased risk to patients when they are given in error. These medications have no single unifying class or mechanism of action; they include insulins, opioids, paralytics, concentrated electrolytes, local anesthetics, and anti-arrhythmics, among others. Although ASC-specific data is lacking, a study of 1,276 error reports submitted from a large hospital system in the southwestern United States found that the drugs most commonly associated with adverse drug events were furosemide (34.6% of medication errors resulted in harm), enoxaparin (29.7%), insulin (15.2%), and vancomycin (14.1%) [10]. Although each facility is required to develop its own list of high-alert medications, there is little guidance on how to do so systematically. The ISMP's list may be considered as a starting point [11], but any list adopted will require review and update at least yearly, perhaps even

quarterly. For example, substitute medications used during shortages should be incorporated into the high-alert list, as these are rarely exact pharmaceutical equivalents for the unavailable articles and may have decreased efficacy or increased risk for adverse effects. Merely maintaining a high-alert medication list will not be sufficient; each high-alert medication requires its own mitigation strategy [12]. For example, the oncologic medications vinCRIStine and vinBLAStine are distinguished through the use of "tall man" lettering, but this strategy is of little use for insulins, where independent double-checks before each administration are more appropriate [13]. High-alert medications lists developed for adult patients will differ from those for pediatric or neonatal patients due to their smaller size, their immature physiology, and the need for more exacting dosage calculations [14]. Some medications are considered high-alert primarily because their route of administration (i.e. steroids administered intrathecally or epidurally) confering higher risk of injury if they are incorrectly administered.

## Selection and Procurement

"**The ASC selects and procures medications."** [9]

Each ASC's formulary lists the medication forms and concentrations approved for use in that facility. The medication management committee approves any additions, changes, or deletions, and is responsible for communicating these to ASC personnel. Formulary management has been made more complicated by the frequent drug shortages of the last two decades (Figure 9.1). In 2011, the peak year of

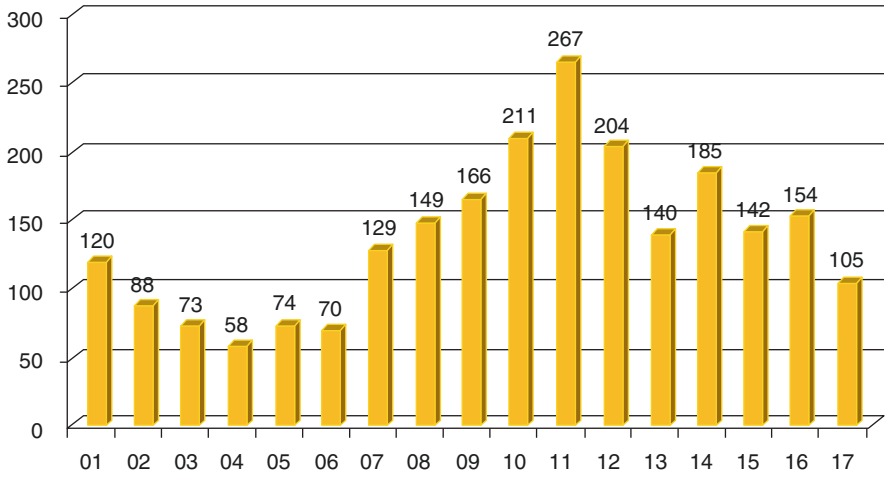


**Figure 9.1** National Drug Shortages: Annual New Shortages by Year, January 2001 to September 30, 2017. (Used with the kind permission of the University of Utah Drug Information Service).

the shortage crisis, some 267 new shortages were reported. Shortages have shown few signs of disappearing despite efforts by the Food and Drug Administration and Congress to ameliorate them; as of this writing there were 138 current ongoing medication shortages. Particularly affected have been generic medications given by injection, which constitute a substantial proportion of an ASC's medications. Because profit margins are low for generics, there are usually few competing manufacturers for any given medication, and the manufacturers generally lack redundancy in their production lines. As most manufacturers are already operating at near full capacity, any disruption in the manufacturing process is liable to interrupt supplies [15]. The ASC medication manager must be proactive in seeking alternate sources for critical medications while being mindful of the risks. The FDA maintains a website listing medication shortages, resolved shortages, and discontinuations [16], as does the American Society of Health-System Pharmacists [17]. These sites helpfully list alternative manufacturers and expected resupply dates. Shortages are not mere inconveniences; surveys have linked at least 17 deaths to medication unavailability or the use of inadequate alternatives [15]. On a larger scale, a systematic study of 26 US hospitals which experienced norepinephrine shortages from 2011–2012 concluded that hundreds of excess deaths from sepsis may have resulted from the substitution of phenylephrine for the unavailable norepinephrine [18]. Formulary substitutions on short notice not only increases risks to patients but also boosts facility costs, as drug prices may increase up to 300–500% [19].

Alternatively, a sterile compounding pharmacy may be used to supply syringes or individual vials of key drugs. Compounding pharmacies appear to be at greater risk of issuing medication recalls due to contamination than do noncompounding drug manufacturers [20], and several recent disease outbreaks have been linked to improper compounding processes. The worst of these incidents occurred in 2012 when more than 14,000 patients were exposed to mold-contaminated methylprednisolone; 750 patients were sickened and 64 died [21]. Due to the public outcry and resultant increased scrutiny, 30 recalls of compounded products were conducted between March 2013 and December 2013. Some 23 of these 30 recalls involved *all of the subject pharmacy's sterile products*. Due to the nebulous regulatory status of sterile compounding pharmacies, which traditionally have been regulated by state pharmacy boards, the FDA is not always able to mandate recalls, even when inspectors directly observe safety problems. In response to the crisis, the Drug Quality and Security Act (DQSA) of 2013 created a new class of voluntary registrant with the FDA. Outsourcing facilities, which operate under the direct supervision of a licensed pharmacist in a registered facility, are held to a lower standard than large drug manufacturers [22]. Although ASCs are not compelled to do so, it is the clear intent of the FDA that healthcare facilities choose registered outsourcing facilities wherever possible: "As a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling." [23]

As part of procurement, the ASC must also plan for disposal of hazardous pharmaceutical waste. ASCs are responsible for medications that enter the facility from "cradle to grave." Pharmaceutical waste is not a homogeneous category, but instead comprises different streams of waste which must be handled and disposed of in different ways. The Resource Conservation and Recovery Act (RCRA) defines as hazardous wastes certain medications which appear on prescribed lists. Some of these medications are evident toxins (e.g., mercury, chemotherapeutic agents) but others (e.g. nicotine patches, hexachlorophene disinfectant, anti-scabies lotion) may not be intuitive. ASCs must have a plan for identifying formulary items which appear on the federal P and U lists [24] and educating staff about the proper collecting and storage of these wastes. For these items, the ASC must contract with a licensed hazardous waste hauler for disposal. Other drug formulations, even though not P- or U-listed, must nonetheless be treated as hazardous waste because they are ignitable, corrosive, reactive, or toxic. Internal compliance can be a challenge, but the civil penalties for even inadvertent noncompliance can be substantial [25].

## Storage

**"The ASC safely stores medication and manages emergency medications. It also safely controls medications that patients, families, or licensed independent practitioners bring into the facility."** [9]

The literature is replete with examples of injury resulting from look-alike, sound-alike medications in which the name of one medication is mistaken for the name of another. Also of concern is look-alike packaging, i.e. medications whose appearance or packaging share visual similarities. For example, confusion is possible between propofol, the IV antihypertensive clevidipine, and the catheter lubricant Rotaglide, all three of which are milky white emulsions supplied in 20 mL vials [26]. Drugs with look-alike packaging should never be stored near each other in supply rooms or in anesthesia carts. Look-alike packaging can complicate the handling of all forms of packaging, including vials, ampules, droppers, bottles, and bags. A near-catastrophe occurred when tranexamic acid was injected for spinal anesthesia instead of the intended bupivacaine. The patient developed myoclonus of the lower extremities, seizures, and respiratory failure but nevertheless made a full neurologic recovery [27]. This problem can be particularly acute when manufacturers adopt a standardized "trade dress" for their medications. Figure 9.2 illustrates very similar ampules of atracurium, dopamine, flumazenil, and magnesium sulfate available from one manufacturer.

At each step in the chain from the pharmaceutical manufacturer to the patient, there are opportunities for drug diversion by ASC personnel. Procurement, preparation and dispensing, prescribing, administration, and control of waste medications are all points of vulnerability. Some approaches are relatively crude, such as diverting the overfill present in some vials of liquid medications. At the other extreme are more sophisticated schemes in which Drug Enforcement Agency (DEA) forms are stolen to generate individual orders for controlled substances [28]. Drug diversion by a single employee can have incredibly far-reaching effects. Epidemiologists


**Figure 9.2** Ampules of four different medications easily confused for each other. (Used with the kind permission of EZDrugID.org).

tracing a hepatitis C outbreak in Colorado found that a surgical technician had been removing pre-drawn fentanyl syringes from anesthesia carts and self-injecting. She would then replace these with fentanyl syringes she had already used and refilled with saline [29]. Subsequently, 5,970 patients were notified of possible exposure; 18 patients later developed hepatitis which was genotypically related to that found in the surgical technician.

Patients will occasionally self-administer medicine from their own supply while under the care of an ASC. This should be discouraged, but will occasionally be unavoidable. At a minimum, ASC policy should describe the steps that licensed personnel should take to visually inspect patient-supplied medication and verify the medication, dose, expiration date, and integrity. Any DEA controlled substances such as anxiolytics or narcotic analgesics must be strictly secured while the patient is under the ASC's care. Only medicines legal for use in the ASC's jurisdiction should be permitted.

Emergency carts must be kept secure from tampering, theft or diversion of medications, but at the same time must be kept ready to use. Numbered breakaway locks, balancing security with availability, should be used for this purpose rather than padlocks or other such devices. The integrity of the breakaway locks must be monitored.

Anesthesia medication carts must also be secured against access by unauthorized individuals. These carts may be left unlocked between cases, so long as they are in a part of a larger OR unit that is under constant surveillance with access controls. However, "After hours when the OR unit is not manned in a like manner, the carts must be properly secured. Whether the carts are locked or unlocked, they must be

stored in a secured area which prohibits access and tampering by unauthorized individuals (e.g., in a separate locked room or in the secured OR unit where unauthorized access is prohibited)" [30].

## Ordering

"**Medication orders are clear and accurate."** [9]

Each ASC must have a written policy defining the essential elements of a valid medication order, including the indications for use when applicable. The policy must also describe what is to be done when a medication order is incomplete, illegible, or appears to be in error. Prohibited abbreviations cannot be used in the ASC; the ISMP's list of these is a useful resource [31]. Verbal orders, whether face-to-face or via telephone, must be followed by read-back and verification by the ordering physician. Each verbal order must then be signed, dated, and timed in the patient's written medical record. This should be done as soon as possible afterwards.

Although computerized physician order entry (CPOE) systems might be expected to minimize problematic medication orders, their uptake by ASCs has been slow, largely because of their substantial acquisition and training costs. It has been estimated that CPOE could prevent as much as 60% of all preventable adverse drug effects [2]. CPOE can still be susceptible to error, as when the system fails to alert when the patient has a documented medication allergy, or when the ordering physician "mis-clicks" and makes an incorrect selection of medication or dose [32]. Regardless of whether CPOE has been implemented, standardized order sets should be adopted wherever possible.

Standing orders or preprinted order sets may be used to facilitate the care of patients who have similar requirements, but they must be tailored to specific clinical situations, patient conditions, or diagnoses. For example, the ASC may have one set of standing orders for preoperative cataract patients describing the dosage and timing of preoperative eye drops, another set specifying the postoperative care of patients who have undergone total knee replacement, and another set detailing the initial care of a patient who complains of chest pain. Before implementation, any such standing orders or protocols should be reviewed by the ASC's medical staff, nursing director, and individual in charge of pharmacy services. Wherever possible, they should be based on nationally recognized and evidence-based guidelines. Standing orders should be regularly reviewed to ensure that their continuing usefulness and safety. Once in use for a particular patient, these orders should be dated, timed, and authenticated promptly by an appropriate practitioner and placed in the patient's medical record.

## Preparing and Dispensing

"**The organization reviews the appropriateness of all orders for pharmaceuticals to be dispensed in the ASC and safely prepares medications. The facility**

**safely obtains and dispenses medications when it does not operate a pharmacy...”** [9]

All medications used in perioperative and procedure areas, whether on or off the sterile field, must be labeled with name, strength, amount (if not obvious), diluent name and volume (if not obvious), and expiration date and time [33]. This holds true even if only one medication is being used during the procedure, as unlabeled solutions cannot be identified. To facilitate compliance, preprinted labels may be incorporated into an ASC’s custom sterile procedure pack. One widely publicized incident, which also served as a case study in disclosure of medical errors, occurred in 2004 when unlabeled solution basins were used during an interventional radiology procedure. After a patient received an intra-arterial injection of chlorhexidine rather than the intended radiological contrast media, the resultant vasoconstriction resulted eventually in her death [34]. Current standards require the identification and labeling of all medications and solutions placed onto the sterile field in the operating room, reconfirmation during the procedure itself, and review of medications and solutions whenever there is any change in personnel, such as breaks or shift changes. Observational studies have found that compliance with these standards can be as low as 60% [35]. Practitioners occasionally combine local anesthetics with differing pharmacological profiles. A typical mixture might consist of a short-acting agent such as lidocaine with a longer-acting agent such as bupivacaine, with the intention that the resulting mixture have a more rapid onset and a longer duration of action that any available single agent. Mixing agents in this way introduces the possibility of arithmetic or labeling errors. Best practices would mandate that for these or any other mixtures, two licensed providers (i.e. two registered nurses or a registered nurse and a physician) verify the identity of each component as it is drawn up and correctly labeled with the final concentration and beyond-use date before it is accepted onto the surgical field. Mixing medications at the point of use makes it difficult to calculate the actual doses administered; as local anesthetics all share a common mechanism of action, the patient may be at risk of additive toxicity [36]. Furthermore, this practice in many cases may not accomplish the desired aims. Mixtures of local anesthetics have generally been shown to result in an unchanged or only slight shorter time of onset, with no increase (or even a decrease) in duration of action [37–39].

Single-dose vials should never be used for multiple patients, as these vials usually lack an antimicrobial preservative. Container size or volume cannot be used to distinguish between single- and multiple-dose vials, as both may come in many shapes and sizes. In any case, hand hygiene must be performed before any medication is prepared, and the diaphragm of any vial must be cleaned with alcohol before puncture [40]. Six percent of clinicians responding to a recent survey reported that they “sometimes or always” used single-dose vials for multiple patients [41]. To prevent inadvertent transmission of disease, the Centers for Disease Control recommend that single-use vials be used whenever possible [42]. Multi-dose vials must be discarded 28 days after they are first accessed, unless otherwise specified by the manufacturer [43]. Multi dose vials that are opened in a patient care area are to be treated as a single use vial and discarded. Due to the prevailing drug shortages,

some centers have obtained exceptions from their state DOH to use single dose vials for multiple patients. In this situation, the medication must be drawn up into aliquots in a non-patient care area under sterile conditions.

Seemingly benign lapses in medication handling can be devastating. A 2010 outbreak of 5 cases of septic arthritis occurred at an outpatient radiology center in Los Angeles when breaches in sterile technique caused the contamination of single-dose vials of magnetic contrast, which were then inappropriately used for multiple patients. The subsequent investigation revealed that "No written office procedures or policies for infection control were in place and there were no specific written procedures for injectable medication and contrast media preparation using aseptic technique," nor was there any documentation of staff training on infection control or aseptic technique [44]. Even seemingly low-risk multi-dose medication can lead to severe patient injury if mishandled; contaminated local anesthetic eye drops used during cataract surgery resulted in an outbreak of endophthalmitis in 13 patients, most of whom eventually suffered a severe decline in visual acuity [45]. Periodic in-servicing of ASC personnel in the proper use of single- and multi-dose vials will help mitigate this hazard [43].

In general, medications and intravenous fluid sets should not be prepared far in advance of use, as this increases the risk of microbial contamination. This has been a contentious issue for providers in high-turnover environments who are accustomed to preparing batches of medication syringes and pre-spiked IV fluid sets for efficiency reasons or to be ready for emergency cases. In 2011 the Joint Commission, after "push-back" from the American Society of Anesthesiologists and the American Association of Nurse Anesthetists and others, decided to "remove from the [interpretive guidance] FAQ the prohibition against pre-labeling" and stated that going forward they would require that all syringes be labeled, but would not direct how that process was to be achieved. Although pre-spiking IV fluid bags within four hours of use appears not to result in microbial contamination [46], this practice should nonetheless be discouraged, as the United States Pharmacopeia mandates that "Opened or needle-punctured single-dose containers such as bags, bottles, and syringes of sterile products … shall be used within 1 hour" unless they are opened in a laminar flow hood or clean-room environment, typically unavailable in an ASC [47]. The same guidelines apply to medications drawn into syringes for later use. Although the pre-spiking issue has not been definitively settled by survey organizations and professional societies, whatever time limit is adopted as written ASC policy must be strictly adhered to by its personnel. These precautions are especially important in the case of propofol, which supports microbial growth. Propofol is formulated with disodium edetate, sodium benzoate, or sodium metabisulfite to retard microbial growth, but these preparations are not considered antimicrobially preserved products. Syringes of propofol drawn up under aseptic conditions may be used for up to 12 hours, after which the syringe and vial must be discarded [48].

Some facilities may choose to employ prefilled medication syringes supplied by an outsourcing facility. This need not be an all-or-nothing decision; the ASC may choose to implement pre-filled syringes for commonly used medications, for anesthesia medications in particular, or for medications where waste is particularly

costly (e.g., neostigmine, ephedrine). Prefilled syringes have many advantages, such as proper labeling and decreased risk of syringe swap error, but they have higher acquisition cost. They also have a shorter "beyond use date" than do powdered medications in vials, with the possibility of costs due to stock expiration [49]. Not surprisingly, drug preparation appears to be significantly faster with prefilled syringes than with the traditional vial-and-syringe method. In that same simulation study, use of prefilled syringes was also associated with significantly fewer medication errors than vial-and-syringe preparation or use of Carpuject syringes. Errors were noted with just 1.4% of prefilled syringes vs. 73.6% of vial-and-syringe preparations (predominantly labeling errors) and 77.8% of Carpuject preparations (primarily withdrawal of Carpuject contents with an unlabeled needle and syringe) [50].

## Administration

"**The ASC safely administers medications."** [9]

From 2002–2012, there were almost 50 U.S. outbreaks of infectious disease resulting from unsafe injection practices, not counting medications that were contaminated at the point of manufacture [51]. In 2008, a Nevada outbreak of hepatitis C was traced to endoscopy procedures at an ASC which shared syringes and single-use propofol vials between patients. This stemmed in part from the erroneous belief that using a clean needle for every shared syringe or vial of propofol was sufficient because no visible blood contamination was observed. The largest public health notification of its kind then followed. 63,000 patients were found to have been potentially exposed to other patients' blood, and 9 were determined to have contracted hepatitis C in this manner. Another 106 cases of hepatitis were deemed "probably linked" [52, 53].

In a similar vein, reuse of single-patient-use items such as insulin pens has also resulted in the transmission of hepatitis; a patient label should be applied directly to these items to help prevent inadvertent sharing between patients. Likewise, fingerstick lancet-type devices should not be reused between patients, and glucometers should be disinfected between patients using the manufacturer's recommended protocol. Incredibly, reuse of syringes for more than one patient appears to be a continuing problem, with a 2017 survey finding that 12% of physicians and 3% of nurses reporting this practice occurring in their facility [54].

Although this has not been studied specifically in the ASC, bar coded medication administration (BCMA) appears to substantially reduce errors such as administration of an incorrect medication, the wrong dose, route of administration, or administration without an order. As well, bar codes appear to significantly reduce the potential for adverse drug events and patient injury [55]. Bar coding systems have substantial acquisition, maintenance, and training costs, but cost-benefit analyses have found that reduction in harmful errors can more than offset these costs within a few years of implementation [56, 57]. Care must be taken to involve stakeholders in planning implementation of such a system, and its performance should

periodically be reviewed. End users whose needs are not met develop work-arounds, such as removing the barcode label from a medication for later scanning or disarming the audio alarms on the scanning device. A review of BCMA use at five hospitals found that 10.3% of all medications administered involved the use of one of 15 different work-arounds [58].

## Monitoring

**"The ASC monitors patients to determine the effects of their medications and responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors."** [9]

Adverse drug events (broadly, "an injury resulting from medical intervention related to a drug" [2]) will be monitored as part of the ASC's ongoing, data driven patient safety program. Written policy should define medical errors and adverse drug events. Policy must also describe reportable events, including medication errors resulting in patient death or major injury. Adverse drug events must be documented in the patient's chart, and the physician responsible for that patient must be notified. Serious adverse drug events, such as those involving a contaminated drug or biologic provided by the healthcare facility, or medication errors resulting in patient death or serious injury, must be reported to the state's Department of Health. Vigilance should be highest when a patient is receiving the first doses of a new medication, as adverse reactions are most likely to occur at that time. Some medications are clearly associated with more frequent preventable adverse drug events than others, however. A study of preventable adverse drug events in hospitalized patients found that overall, 1 in every 400 drug injections was responsible for a preventable adverse drug event. Insulin was responsible for the most frequent preventable adverse drug events by a wide margin: 1 in every 86 injections, in contrast with cardiovascular medications (1 in 200) and narcotic analgesics (1 in 303) [59].

Aldrete scores or other readiness-for-discharge criteria which take into consideration activity level, respiratory effort, circulation, consciousness, and oxygen saturation will orient care-givers toward many adverse drug events occurring in the perioperative period. Postoperative follow-up phone calls may reveal adverse drug events manifesting after a patient is discharged from the ASC. Surgical and other procedures may generate pain requiring the use of opioid analgesics; thus many patients will be at risk of respiratory depression and hypoventilation. Procedural sedation may likewise result in respiratory depression. Patients naturally differ in their susceptibility to adverse drug events. Age > 65 years, male sex, prior opioid use, COPD, and cardiac arrhythmias were found to be risk factors for postsurgical opioid-related adverse drug events in one large retrospective study of hospitalized patients, suggesting that an increased level of monitoring should be used in patients with multiple risk factors [60]. Consideration should be given to the use of capnometry in all patients who have received sedatives and/or opioids, as capnometry is the most reliable practical means of detecting hypoventilation in the post-surgical patient. Supplemental oxygen, though it may increase a patient's pulse oximeter

reading, can mask significant hypoventilation and delay its detection until the patient decompensates. In one study of post-surgical patients randomly assigned to breathe either room air or supplemental oxygen on arrival to the PACU, the authors recommended that "Based on our findings, we advocate the application of supplemental oxygen only in patients who are unable to maintain an acceptable $SpO_2$ while breathing room air" [61].

## Evaluation

**"The organization evaluates the effectiveness of its medication management system. This evaluation includes reconciling medication information."** [9]

The medication manager (ideally, medication management committee) must periodically review internal data to detect any trends or patterns that may indicate systemic vulnerabilities. In addition, they should regularly review the current literature and professional guidelines to identify best practices that they can disseminate through the ASC. Excellent practical resources include:

- Institute for Healthcare Improvement (www.IHI.org)
- Institute for Safe Medication Practices (www.ismp.org)
- National Alert Network (www.nccmerp.org/nan-alert)
- Anesthesia Patient Safety Foundation (www.apsf.org)
- American Society of PeriAnesthesia Nurses (www.aspan.org)
- Association of periOperative Registered Nurses (AORN) (www.aorn.org)
- Food and Drug Administration (www.fda.gov)
- EZDrugID (www.ezdrugid.org)

Medication reconciliation is not a mere formality; transitions of care such as hospital or ASC discharge represent a point of high vulnerability for patients. In a large study of older adults after hospital discharge, 14.3% of patients who had even one medication discrepancy at discharge were rehospitalized within 30 days, compared to 6.1% of those who had no discrepancies. Five classes of medications comprised 50% of all discrepancies: anticoagulants, diuretics, angiotensin-converting enzyme inhibitors, lipid-lowering agents, and proton pump inhibitors; extra care should be taken in documenting these [62]. If the patient is unable to accurately report their current medications, ASC policy will instruct caregivers how more accurate information is to be obtained from family members or the patient's primary care physician. The ASC is responsible for making its best effort to determine the patient's current medications on admission so that an accurate accounting of the patient's updated medication regimen can be transmitted to the next provider of service. In most cases, this will be the provider whose name is on the discharge summary. The patient must also be given a copy of the revised medication list during the discharge process and the list must be reviewed with the patient and whoever accompanies them. Medication reconciliation at ASC discharge is necessarily more limited in scope than reconciliation occurring after hospital discharge; it will not be

possible to thoroughly review the appropriateness or efficacy of the patient's pre-existing medications.

## A Final Note

Focusing blame on a caregiver who commits a medication error without considering the failure of the ASC's mechanisms to intercept that error squanders opportunities to detect other points of weakness in the ASC's systems. A "blame and shame" culture inhibits well-meaning caregivers from speaking up about errors they commit or witness and prevents them from proactively bringing unsafe conditions or near-misses to a manager's attention. Human beings continually commit errors, and most medication errors are not caused by uncaring or incompetent practitioners. Nor do most medication errors inevitably lead to injury; the "Swiss Cheese Model" posits that most unsafe acts or conditions are stopped by the multiple layers of safeguards adopted in complex systems, as designed. Injuries ensue only when gaps in those layered defenses align in the manner of consecutive slices of Swiss cheese to allowing hazards to reach the patient [63]. In ASCs that experience high staff turnover rates it may be difficult to ensure that all personnel responsible for administering medications follow the latest guidelines, but every effort must be made to regularly refresh practitioners' knowledge about ASC policies and healthcare best practices. An open reporting culture, a robust, data-driven monitoring system, and proactive managers who seek out opportunities to learn from learn from the mistakes and unsafe conditions reported at other institutions are all essential if medication errors are to be minimized.

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# Sterile Processing and Infection Control in ASCs

10

Rita Mack and Niraja Rajan

## The Foundation

It is difficult to point out where and when the Infection Control Plan starts, so let's start at the bottom, the very bottom. The dirt, bricks and mortar of the building design. It is worth mentioning here, that the design of the building will indirectly influence the Infection Control Plan by impacting adequate storage, patient flow and separation of "clean" and "soiled" areas. Building design will, in effect, create the pathways for the flow of patients, and the instruments, supplies and equipment needed to care for patients. The difficulty of creating a space that will optimize the Infection Control Plan is two-fold: the standards, such as NFPA guidelines and Joint Commission standards, continue to change throughout the years the building is in service and secondly; the use of the building, another determinant of the success of the Infection Control Plan, will also change as patient volumes, technology, and services provided evolve. Along with the building design, the utilities, including water, steam, electricity, generator capabilities, sewer, fire suppression, HVAC system for air flows, temperatures and humidity controls will impact the Infection Control Plan. For these utilities, it is important that there be clearly defined policies and procedures in place to ensure their availability in time of disaster. The design of the building should not be dictated by meeting the immediate proposed needs of the center, but by considering the long-term goals of the needs of the community. The

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center must meet the needs of the population that it will be serving, but it must also be a space that is flexible enough to fit future needs as a viable and valuable space for both patients and staff.

## The Staff and Culture

Once the building is in place, the plan has been developed for the services to be provided, and the necessary equipment has been selected and an adequate amount of instrumentation has been obtained to prevent flash sterilization, the next step in assuring Infection Control standards is to hire staff that is like-minded in caring for patients. This includes the staff employed at the center, the staff who are providing surgical and anesthesia services at the center along with vendors and other support services needed at the center. Communicating the mission of the center to potential staff candidates is easier during the interview process by utilizing a specific interviewing tool that includes a skill assessment and a set of "Fit" questions. The fit questions determine team fit and enhancement of the talent pool at the center. The ideal situation is to hire staff in all areas of the center that act individually as guardians of patient safety. This behavior of patient safety must include members of the team who, in years past, were not thought of as patient care providers, including the Business Office staff, who most times have the first contact with the patient and act as the critical front-line defense. The culture at the center should allow and expect them to act as a patient advocate and report concerns that may range from a discrepancy that the case scheduling form references both a right and left-sided procedure, or that during the insurance verification call the patient casually comments that they were admitted to the hospital last week for pneumonia. The opportunity to have patient advocates in all areas of the center boosts patient safety. A culture of safety not only has to be a catch phrase but must arm the staff to be the eyes and ears as patient safety officers and infection preventionists for the patients the center. The Swiss cheese model of harm cannot be plugged by one person in a title role, it can only be defeated by everyone taking time to protect the patient. Along with the staff in the Business Office, the nurses and techs in the perioperative areas must be engaged and diligent in Infection Control practices. Hand hygiene, dress codes, reducing unnecessary traffic, shave preps and checking outdates are tools used in all areas of the center by the staff to support the Infection Control Plan.

Having excellent employee staff and equally excellent non-employee staff will only take you halfway to patient safety. The groups must maintain a mutual respect and a collaborative nature in how they work together. Unless every member of the group is given respect that their skills are necessary and important for the patient to have an outstanding experience and outcome, there will be potential for a patient safety event, including an infection control event to occur.

## Education

The education of both employees and non-employees plays a big part in the success of the plan. Education must include an understanding of the Infection Control Plan and the importance of the monthly auditing of infection control activities. It is a bit harder to engage and create a culture of safety for those at the center who are not directly employed by the organization. Creating an understanding of the culture of safety for the MDs, APNs, vendors, contracted and support services employees can be more difficult, especially at a center associated with a hospital system. The rules and regulatory guidelines at a surgery center are different than those guiding operations at a hospital. In order to communicate the safety culture, one may try including: a patient safety centered orientation for the physician and advanced practice providers including succinct credentialing requirements, physician safety champions that act as liaisons for staff to express safety concerns without fear of retribution, physician involvement in an active Medical Executive Committee, vendor qualifying programs that require them to sign their understanding and agreement with the policies and procedures in place at the center.

## Workflow

The Infection Control Plan and Patient Safety go hand in hand during the "daily huddle" meeting. The "daily huddle" is a brief 5 to10 minute meeting that is scheduled to happen at the same time each day. Participation at the meeting is flexible based on pressing topics or matters requiring attention. Normally, there is representation from all areas of the center (Business Office, Materials Management, Sterile Processing, PreOp, OR and Recovery Room). Typically, the huddle agenda includes: what went "well/wrong" yesterday, what is a concern today and what should we all know about tomorrow. Information relayed at the huddle are any observations of the staff regarding the center's environment or equipment. Although there are monthly environmental rounds at the center to determine any areas requiring repairs, the daily observations by all members of the team, keep the center in the best shape possible to ensure prevention of infection control issues. Again, we are talking about the basics of the center: cleanliness, intact wall surfaces free of exposed drywall, secure corner guards and floor cove base, air and heat vents that are clear of dirt and dust, well-lit hallways and bays, visible emergency/exit/eye wash station signage, sprinkler clearance, under sink areas and clean patient and visitor areas including carpeted areas and bathrooms. Incorporating these observations at the daily huddle ensures that the reporting of the concern is timely and that the responsible contact for the type of repair needed is notified.

## Pathways and Pitfalls

Before discussing the importance of the Infection Control Plan and Sterile Processing in the ASC in detail, let's walk the patient steps from being scheduled at the center through entry into the OR on the day of the procedure. Table 10.1 highlights the importance of staff engagement during just a few of the steps of the patient's journey from the time of scheduling to OR entry. Potential pitfalls at each step of the process are listed. The table shows how the basic lack of engagement, or knowledge or even adequate time to focus on the patient can create an opportunity for patient harm.

**Table 10.1** Good Catches and Pitfalls during the Patient's Journey through an ASC

| Step | Engaged Staff Good Catch | Disengaged Staff Pitfall |
|---|---|---|
| Scheduling | The Scheduler receives procedure information. This includes demographics, diagnosis, planned procedure including any laterality, contact isolation status, required equipment and anesthesia type. An engaged Scheduler picks up on any missing information: Incomplete equipment request, missing laterality, missing contact isolation status, and communicates with the appropriate individuals to complete the information. | Consequences of missing information include: Case cancellation, OR delay, missing equipment with the potential for "flash sterilization", and increased risk of infection, wrong site surgery |
| Insurance Verification | The Insurance Verifier receives the preauthorization and coding and reviews this information with the patient. A responsible Insurance Verifier takes time to confirm the details related to the procedure including laterality. | Overlooking details of the procedure could result in case cancellation or wrong site surgery. |
| Health History | During the health history call the accountable health history nurse will pay attention to the patient's responses to the questions rather than just marking a yes/no answer. When a patient mentions that during their last hospitalization everyone wore yellow gowns, the nurse will ask other pertinent questions to determine contact isolation concerns and mark the patient as contact isolation to ensure the appropriate change in case order. | Overlooking information about prior hospitalization, active infection or contact precautions information could result in last minute cancellation or OR delays. |
| Preoperative Admission | After admission to the center, the patient is assessed immediately prior to their procedure. The Preoperative Nurse carefully checks the schedule, the surgical consent and confirms the information with the patient/support team. | Missing communication about procedure variance, contact isolation status or day of surgery procedure change could result in cancellation, delays or infection risk from flash sterilization or not isolating a patient. |

## Components of an Infection Control Plan

Key components of an infection control plan include: the source of the basis of the plan's guidelines (CDC, APIC…), who is responsible for oversight of the plan, authority given the preventionist by the plan and the population the ASC serves and their specific environmental risks just to name a few. In an article in the June 2016 Becker's ASC, Heather Punke [1] names additional key components recommended for inclusion in the infection control plan. The Department of Health and Joint Commission provide resources that clearly outline the expectations of the infection control plan and processes at the ASC. Following one of these resources will ensure that the ASC remains compliant with regulatory requirements and that the accreditation survey will go more smoothly especially if used as a pre-survey tool so any areas for improvement can be spotted and a process improvement implemented.

## Sterile Processing

The ten concerns ASCs face regarding sterilization are: adequate separated space for the processing of instrumentation and equipment; maintaining proper positive and negative air flow, temperatures and humidity as dictated by standards; proper, dedicated sterile storage space; policy adherence by all members of the center staff; following the manufacturer's instructions for use in cleaning and processing of equipment and instrumentation; education of all staff of the Infection Control plan and its components; inclusion of the Sterile Processing Staff in scheduling and instrument purchase decisions; correct selection and maintenance of the processing equipment; monitoring and documentation of sterilization and testing processes and last, but frequently at the top of most accrediting organizations' list: flash sterilization. An article by Peggy Prinz Luebbert [2], "Top Ten Sterilization Issues in an Ambulatory Surgery Center", differs from the above list only by mentioning peel pouches and the incorrect use of chemical and biological indicators as additional topics. Another article by Sabrina Rodak [3], "5 Best Practices for Central Sterile Processing", mentions the above referenced concerns.

Finally, it is time to focus on the details of Sterile Processing and Infection Control. It is important to include the sterile processing staff in decisions related to instruments. This inclusion should consist of staff participation in the ordering of the instruments, selection of equipment used in the processing of instruments, attendance at staff meetings and membership on pertinent committees, purchasing of various instrument cleaning agents, inclusion in the scheduling of case order to permit adequate turnover time, trialing of electronic instrument tracking systems and the hiring of additional staff in the department. Treating the Sterile Processing Staff as integral to the Infection Control Plan, will provide the center with individuals who are well-versed, by the nature of their specialty, in infection control. The Sterile Processing Technician, who attains and maintains their certification, have

knowledge and a better understanding of the importance of decontamination and sterilization methodology than others in the center. Allowing the Sterile Processing Staff to lead discussions when facing new challenges in the processing of instrumentation, will yield creation of new pathways that will provide safe, effective delivery of instrument sterilization. For instance, when flash sterilization is the focus of a regulatory survey, unless the Sterile Processing Staff is included, chances are the submitted plan of correction, will fail at some point due to unrealistic expectations.

## Impact of Scheduling on Sterilization

The scheduling of patients at the center, is impacted by resource management including instrument availability. The number of instrument sets usually needed at the center can vary considerably based on the block schedule. A perfect block schedule which prevents overlapping or high volume needs of specific sets, does not exist except in the ideal ASC. Even a block schedule that is set up to optimally prevent overlap and high volumes for certain procedures, will be impacted by a surgeon who releases their block time which is then picked up by another surgeon requiring the same sets of instruments already in use. Bringing in the Scheduler, Operating Room Manager, Sterile Processing Staff and Clinical Director is usually how scheduling conflicts are best resolved. The tactics used to manage these conflicts include: rearranging cases to allow turnover of sets, requesting additional sets brought in as loaners (if the ASC has such an agreement with a nearby hospital or center) and a new option on the market: closed processing containers which are not considered flash sterilization related to their associated shelf life designation. Flash sterilization or Immediate Use Steam Sterilization (IUSS) is viewed as inappropriate processing of instruments and causes questioning of instrument purchasing practices and scheduling of cases. It would be problematic both financially and in terms of storage to own the numbers of a specific set to cover all the cases ever scheduled in a day. For instance, if an Otolaryngology surgeon usually schedules ten myringotomy and tube (M&T) insertions the center may own ten M&T sets, but since the physician is going to be out of office for a week, they decide to schedule 18 procedures. It would be a waste of resources for the center to increase the number of sets to 18 for that day. The schedule may be rearranged by placing other cases in between every 8 cases to permit reprocessing of the sets or purchase a limited number of the special processing containers mentioned earlier which would not cost as much as duplicating eight additional sets and they could also be used for other sets that are in high demand.

## Loaner Instrument Sets

When it comes to loaner sets, which are sets requested by the MD specifically for the patient plan of care, an entirely separate work flow must be created to manage the sets effectively. The Sterile Processing Staff must be involved in how that

process is set up to allow adequate processing of the sets, especially if they contain implants. The Loaner Policy that outlines the process for these requested sets, must be written with Sterile Processing Staff to clearly define two main points to maintain the Infection Control Plan. The policy must be defined to state the arrival times of the set(s). A reasonable time frame is by 2PM the day prior to the procedure. This time frame allows the Sterile Processing Staff to: report that the set has arrived, decontaminate the set, do a brief inventory of the set, wrap and sterilize and process the biological indicator for any implants. If the set is not received by the designated time, the Sterile Processing Staff will notify the O.R. Manager, and this will allow for time to track the set with the vendor rep. Secondly, the time for the loaner set to be picked up after the case is completed must be designated. Since the Sterile Processing Department is usually limited in space, storing sets after use will limit the amount of space for incoming sets and if left unchecked, the site becomes a convenient spot for vendors to store sets. Following these steps will reduce the need for flash sterilization which will be scrutinized by regulatory agencies. The Loaner policy must be included in the vendor credentialing system as information the vendors must read and agree with to have access to the center. The vendor credentialing system should also be in line with the Infection Control Plan. The ASC must select a partner for the vendor credentialing system that allows uploading of current, applicable policies and tracking of required immunizations. The vendor site should allow the center to track the compliance of representatives with the requirements and deny access if they have not completed the requirements. It would be prudent to involve the surgeon with whom the vendor representative is associated in case of noncompliance with regulatory requirements before denying them access to the center.

## Flash Sterilization

The term Flash sterilization was replaced by IUSS which stands for Immediate Use Steam Sterilization. This basically denotes that the sterilized item must be used immediately in the OR as it is not "packaged" for use at a later date, which is why the new "containerized" systems are not considered IUSS. IUSS sterilization rates, as previously mentioned, are on the top of the radar for regulatory bodies. When newspaper headlines scream of how hundreds of patients had to be notified after a potential exposure to an infectious disease at an ASC, it is certain that Sterile Processing practices will be thoroughly checked in all surveys being conducted at that ASC. A component of the Infection Control Plan is a review of Sterile Processing documentation to ensure that the monitoring and maintenance of the equipment is in accordance with manufacturer's guidelines. Collection of this information can be as simple or as complex as necessary for a complete analysis of the data. From purchased instrument tracking systems, mentioned below, to the center created Excel spreadsheet seen in Figure 10.1, the details in the spreadsheet, must help the center decrease the IUSS rate to zero as there is not a current benchmark for any specific number of acceptable IUSS cycles permitted per month. Figure 10.2 shows how the tracking of the items on the spreadsheet is then used to generate the IUSS rate and

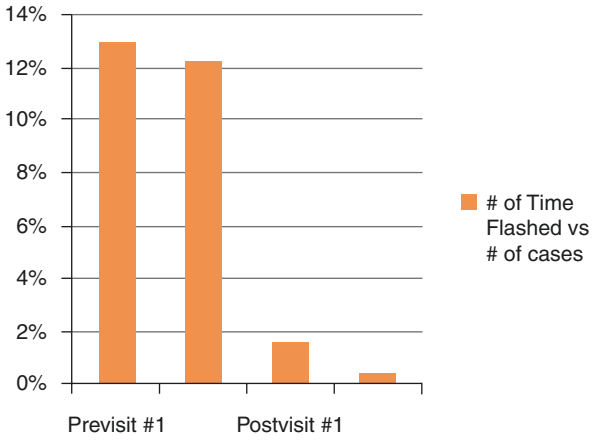
| Date | Account Number | Instrument | Dr on Sticker | Service |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**Figure 10.1** Recommended information to be collected to calculate IUSS rate

| # of Times Flashed vs Cases | | | |
|---|---|---|---|
| Month | Total # of Cycles | Total # of Cases | # of Cycles vs # of cases |
| Pre-visit #1 | 99 | 762 | 13% |
| Pre-visit #2 | 82 | 672 | 12% |
| Post-visit #1 | 10 | 628 | 2% |
| Post-visit #2 | 3 | 703 | 0% |

**Figure 10.2** Items on the spreadsheet used to generate the IUSS rate

**Figure 10.3** Visual graph generated by data collected




a visual graph (Figure 10.3) for poster or meeting display. The IUSS rate should be calculated by dividing the number of times in the month that an IUSS sterilization cycle was run by the number of patients scheduled for the month. In a review of literature, an article by Rose Seavey [4] stated that members from the Association of perioperative Registered Nurses (AORN), the Association of Professionals in

Infection Control and Epidemiology (APIC) and from the International Association of Central Service and Material Management (IAHCSMM) as well as other infection prevention bodies endorsed a position statement at an IUSS conference held in 2010. The entire statement is available for review at: http://www.aami.org/publications/standards/ST79_Immediate_Use_Statement.pdf. In synopsis, the statement supports: that the Sterile Processing Staff must be trained and knowledgeable in the handling of instrumentation; that the instructions for use, care and handling must be followed according to the original equipment manufacturer's direction and that there are certain items listed as exceptions to IUSS sterilization.

## Documentation and Logs

How does the ASC management go about arming the Sterile Processing Staff to be confident about how they work daily? Surveyors focus on how instruments are handled throughout the process and how easily staff are able to track them from preparation, to use, to processing them again. Not all Sterile Processing Departments have state of the art electronic-based information systems. Many departments still rely on binders which hold Instrument Recipes, which describe how to assemble the instrument sets and how to process the set. These binders become antiquated year to year as new sets are added to the center and original equipment manufacturers modify the processing of their instruments. An option is to provide the staff an online tool that maintains the most up to date information for thousands of sets and at the centers' request, the company will add any set(s) that are missing from their directory. The service is provided at a nominal monthly fee, but well worth the cost in lieu of the staff time involved in maintaining up to date paper forms. If you are in a center that runs one of many electronic instrument assembly and tracking systems, the updating of the information in the system is automated. The software in these systems, also allows the staff to clearly track the set to each patient that it was used on via bar-coding not only of the sets, but even to the instrument that has a bar-code acid-etched for more accurate assembly of the items in the set. For the smaller center, the cost of implementing Information Technology driven technologies may be cost-prohibitive so Sterile Processing Staff will need to be diligent in their documentation. IUSS sterilization documentation is required by regulatory bodies, but it is not enough to document the cycles. Staff must also continuously review and assess the items listed in the flash rate and create an effective plan to reduce the rate.

## Event Reporting

Event reporting is vital to a center's quality improvement, Infection Control Plan and patient safety. Significant events and events associated with patient injury are usually easy to document and adequately reported. It is a lot harder to track the events that are classified as near misses. Many of these events pertain to infection control practices and behaviors that are not in line with policies or best practices.

Reportable events may include a multitude of missteps including: incorrect scheduling of patient's contact isolation status, missed shave prep in the preoperative area, lack of engagement with the Time Out process to ensure necessary equipment/instrumentation, entering the OR Room without a mask during the set-up of the back table and omission of information in the flash log just to name a few examples. These are events that do not cause harm and may be overlooked by those involved as "lucky" or "that could have been worse" moments. Truth is, if these events are overlooked and not reported for resolution, they will lead to patient harm. These events must be reported per State requirements and more importantly, must be addressed by members of the appropriate improvement committee (Patient Safety, Quality Assurance or Performance Improvement) at the center, with an action plan to prevent harm.

## Summary

This chapter highlights the importance of all members of the team being engaged in patient safety and the role of management in setting the expectation of staff participation as patient advocates in a safety culture. The creation and consistent communication of the Infection Control Plan to all members of the patient care team is the foundation of delivering safe, effective patient care.

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# Perioperative Surgical Home Principles Applied to the Ambulatory Setting

# 11

Timothy J. Del Rosario, Jarrett Heard, Michael Guertin, David S. Beebe, and Kumar G. Belani

## Introduction

The challenge of maintaining patient safety and quality of healthcare in the face of rising costs has resulted in a global healthcare crisis. Perioperative care, especially, is perceived by patients as quite complex. Thus, for several years, there has been a focus on developing perioperative protocols and measures to achieve better outcomes and increase the value of healthcare delivery. The American Society of Anesthesiologists (ASA) defines the Perioperative Surgical Home (PSH) as "a patient centric, team-based model of care created by leaders within the American Society of Anesthesiologists (ASA) to help meet the demands of a rapidly approaching health care paradigm that will emphasize value, patient satisfaction and reduced costs." The PSH is a practice model and potential solution for managing a fragmented and costly perioperative system. The ASA recommends that the PSH model should consist of an interdisciplinary team of physicians, surgical and anesthesiology personnel, as well as supportive personnel, all coordinated by a perioperative services director. This should ultimately improve operational efficiency, decrease resource utilization, reduce length of stay and readmission rates, and lower overall

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perioperative morbidity and mortality while vastly improving the patient experience. The Perioperative Surgical Home (PSH) as illustrated by the ASA is shown in Figure 11.1.

As healthcare continues to evolve, there is more emphasis on performing surgeries on an outpatient basis, which currently include almost two-thirds of all surgeries. According to the CDC, emphasis on cost reductions and the rise in outpatient surgeries at a mean charge cost of $6,100, compared to a $39,900 total cost for inpatient surgery, gives an indication of how important it is to develop and refine initiatives such as the PSH. Therefore, the goals of the PSH and ambulatory surgery are not merely similar, but are synergistic, making it imperative to find novel and innovative ways to adopt PSH in the ambulatory setting. The overall goals of the PSH are 3-fold: improved clinical outcomes, better perioperative services and lower costs (Figure 11.2).

The following are the educational objectives of this chapter:

1. Identify the specific needs and challenges faced by patients and staff in an ambulatory surgery center
2. Review value-based healthcare and how PSH plays a part, particularly patient satisfaction and cost reduction
3. Review existing PSH protocols that are in effect and draw conclusions about their implementation in an ambulatory surgery center
4. Review outcomes associated with existing PSH protocols
5. Identify specific goals and measures to be achieved by adopting PSH protocols in an ambulatory surgery center
6. Identify challenges to implementing PSH in an ambulatory surgery center
7. Understand existing successes in PSH and how to implement them in an ambulatory surgical center

## The Preoperative Evaluation for Ambulatory Surgery in the Perioperative Surgical Home

In the PSH, the preoperative evaluation begins immediately after a patient's appointment with the surgeon. This leads to the patient entering a virtual and/or physical encounter with perioperative staff made up of advanced nurse practitioners or other professional staff who work in concert to get the patient ready for surgery.

During this phase an anesthesiologist or other qualified provider oversees the encounter to address perioperative risks that may affect outcomes and patient satisfaction with the end goal to ensure optimal outcome while reducing overall costs. This is the correct time to anticipate or direct the appropriate post-operative disposition of the patient. In the ambulatory setting, much of this process includes patient education, examining eligibility for ambulatory surgery, as well as facilitating the scheduling of patients in the appropriate venues for the day of surgery. This may be accomplished by in-person visits with nursing staff and/or an anesthesia provider, or "virtually" through video conferencing. Telephone interviews, while not preferred,

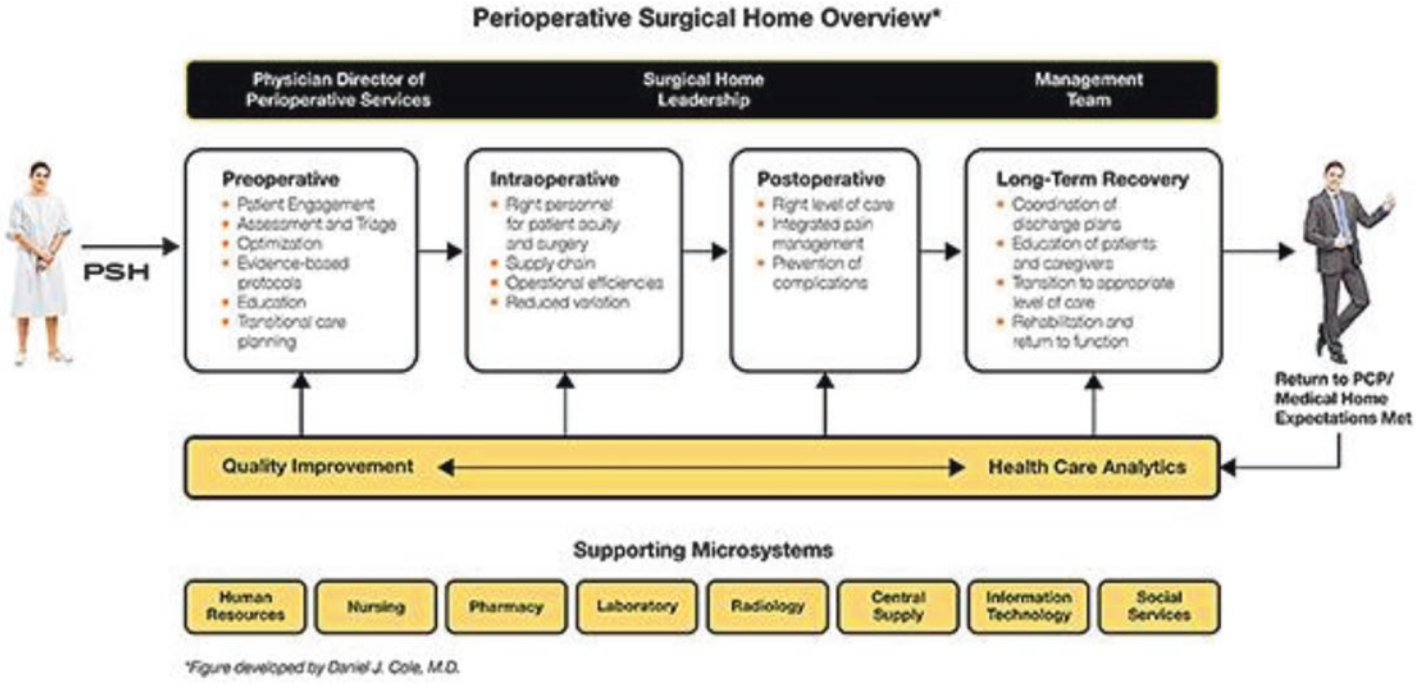


**Figure 11.1** An overview of the perioperative surgical home. *Reprinted with permission of the American Society of Anesthesiologists*, https://www.asahq.org/psh/about%20psh/an%20overview

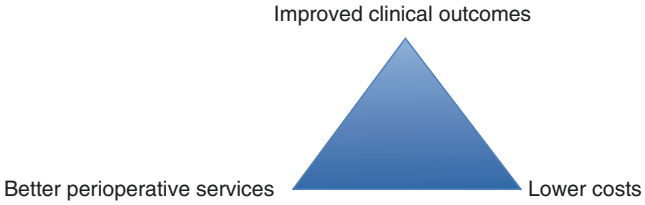


**Figure 11.2** Benefits of a PSH

are the only means of contact in some instances for patients who cannot be seen in-person and who have no access to a smart phone or computer. Ideally, this process occurs with all parties accessing the patient's electronic medical record, including the patient who should have immediate access to their medical records. After the initial encounter and patient visit, the process of patient optimization can proceed.

## Optimization and Pre-habilitation in the Perioperative Surgical Home

Optimization is a comprehensive process involving medical, surgical and anesthesia staff using evidence- based medicine, while utilizing a standard approach with reference to medical, surgical, anesthesia and nursing protocols as relevant to patient co-morbidities and risk factors. In the ambulatory setting this process should also be aimed at reducing costs and improving efficiency by reducing delays and cancellations within 48 hours of surgery as well as anticipating and preventing perioperative events that may either prolong recovery or require last minute overnight observation or admission. Cancellations or delays within 48 hours of surgery are particularly 'expensive' as the opportunity costs for a minute of OR time vary between $50–150 and the fixed cost is $18–30. A small number of unplanned postoperative admissions is inevitable but needs to be minimized as these lead to significantly higher costs that may or may not be recoverable for the facility. At the heart of this process is the implementation of standardized protocols to reduce variability. Variability has been shown to increases costs and error-rate [1]. Under the PSH model, care of a patient will be on a continuum to ensure continuity of care and to eliminate redundancies that may arise when tasks are not completed in a coordinated manner. In the traditional model of PSH, after the initial preoperative assessment and optimization, the process of pre-habilitation begins. This includes the completion of a preoperative exercise program, especially for geriatric patients and those with significant co-morbidities and/or functional limitations. The goal is to minimize any reduction in functional quality related to the surgery in the post-operative period. In the ambulatory setting, there is less emphasis on the need for pre-habilitation since the goal is to perform surgical procedures that cause less detriment to a patient's functional status and to pair these surgeries with the appropriate patient population. In lieu of a comprehensive pre-habilitation regimen, PSH in the ambulatory setting should

focus more on a very in-depth review of patient eligibility and management of a patient's co-morbidities and medication management leading up to surgery. This process is coordinated by anesthesiologists with the help of staff dedicated to perioperative medicine who should also involve the primary surgical team, the patient's PCP and other medical specialists or consultants to best optimize the medical management of the patient preoperatively. A preoperative anesthesia assessment needs to be a deliberate and dedicated process for outpatient assessment, to provide a continuous means for staff to implement a perioperative care plan for patients that is both standardized, yet customized to each individual patient. It needs to provide a means for continuous communication with the entire perioperative care team. This process can occur either in a dedicated physical or virtual space depending on the needs and physical capacity of the individual organization, and ideally should occur as soon as possible after a decision to proceed with surgery is made.

## Exercise, Nutrition, and Smoking Cessation

The number of total knee arthroplasty (TKA) and total hip arthroplasty (THA) procedures performed continues to increase in the United States. Greater than seven million Americans have undergone either a TKA or THA with the numbers expected to increase by 673% and 174% respectively [2]. Going forward, the majority of this increase will occur in an ambulatory surgery setting. In these individuals, pre-habilitation is focused on preoperative strengthening of the muscles and ligaments surrounding the joint of interest which has been reported to have a statistically significant benefit [3]. Pre-habilitated patients had more rapid improvement in function and decreased length of stay (LOS). The effective use of this modality will have the dual effect of increasing volume and improving outcomes of patients who would qualify and undergo total joint procedures as outpatients.

It is important to remember that exercise-based pre-habilitation is not limited to joint repairs. The use of inspiratory muscle training has been shown to effectively reduce length of stay and incidence of postoperative pulmonary complications. Given the increasing emphasis on outcome-based healthcare measured until the 30 day postoperative period, it is incumbent upon ASCs to develop a comprehensive physical pre-habilitation program as part of the PSH [4].

Patients suffering from malnutrition preoperatively have been shown to have increased morbidity and mortality following surgery as well as a longer hospital length of stay [5]. These patients are typically in catabolic states that decrease their ability to recover adequately from surgical procedures. Interestingly, nutritional intervention with protein supplementation has been found to enhance the effects of preoperative exercise regimens, increasing functional status prior to surgery. Patients may take supplemental protein with a goal of 1.2 g/kg total protein intake per day [3]. When planned in concert with an exercise program, it is recommended that supplementation occur 1 h following exercise to fall within the anabolic window. The inclusion of registered dieticians can help in establishing dietary goals that take into account the patient's specific macronutrient and energy requirements.

While not strictly considered pre-habilitation, the impact of tobacco use on wound infection/healing, cardiopulmonary complications, and mortality in the surgical setting has been well established [6]. Using the upcoming surgery as a teachable moment to encourage smoking cessation may be of help [7]. Moreover, intervention and counseling 4 weeks prior to surgery was found to be more effective in initial as well as long term cessation [3]. Additionally, early intervention was found to decrease wound and all-cause complications.

## The Intraoperative Period

The intraoperative considerations of the PSH in the ambulatory setting can be broadly addressed in two interrelated realms. One domain involves direct patient care, both in and out of the OR. The other encompasses the broader, structural and organizational approach to directing an ambulatory complex. Anesthetic approaches to PSH strategies, in general, can be broadly described as methods which improve patient comfort, cause a lesser degree of physiologic aberration, enhance recovery, and prevent anesthesia-related side effects. Such interventions occur in the immediate preoperative period, intraoperatively, and immediately postoperatively. Both regional and neuraxial anesthesia techniques, as well as general anesthesia, are utilized to achieve the goals of the PSH. The following are some of the clinical anesthetic considerations that have been described in the literature.

### Anesthetic Considerations

What is required by the PSH in the ambulatory surgery setting is not far from techniques currently employed by clinicians; a focus on patient comfort, rapid recovery, and fewer side effects (such as PONV). With advances in technology and drug development, such methods have increasingly become more common, and optimal results are achievable. These approaches allow for quicker discharge as well as quicker resumption of daily living activities. One particular meta-analysis found that among studies that have investigated various preoperative and intraoperative approaches within the context of the PSH, 82% reported positive results in terms of clinical outcomes, system/organizational efficiency, and overall costs [8].

### Preoperative Interventions

Interventions that can contribute to attaining these goals begin in the immediate preoperative period. Premedication has been shown to improve patient comfort and overall satisfaction, prevent untoward cardiovascular events, enhance glycemic control, and even contribute to decreased intraoperative blood loss. $\beta$-blockers continued in the perioperative period, by blunting the sympathetic response to surgery-induced catecholamine surges, have allowed for greater intraoperative

hemodynamic stability [9]. Similarly, $\alpha_2$-agonists such as clonidine and dexmedetomidine, have been reported to contribute to improved glycemic control, decreased opioid utilization, as well as a reduction in post-operative pain [10]. Both classes of agents have been shown to improve hemodynamic stability, as well as reduce myocardial ischemia, particularly in patients with pre-existing coronary artery disease. In the preoperative period, hydration status can also be optimized via interventions such as allowing the intake of clear liquids up to two hours preoperatively, as well as the administration of an intravenous fluid bolus prior to induction. Goal-directed approaches that avoid hypovolemia while also avoiding excessive fluid administration have been shown to be beneficial [10]. Other interventions that have also been found to improve patient satisfaction, intraoperative conditions, and post-operative outcomes include preoperative carbohydrate loading, antibiotic prophylaxis, antithrombotic prophylaxis, and the avoidance of bowel preparation (in the setting of intestinal surgery) [11, 12]. With regard to preoperative anxiety, positive outcomes have been reported with pharmacological (short-acting benzodiazepines) and well as non-pharmacological interventions (patient education). Effective interventions early in the perioperative period enhance outcomes not only intraoperatively and immediately post-operatively, but also in the period following discharge and beyond [13]. Emphasis has also been placed on the identification and treatment of patients with a propensity towards developing chronic post-surgical pain. In one study, a 5-day preoperative course of celecoxib (continued post-operatively) was shown to significantly reduce pain scores as well as opioid consumption well into the post-op period [14]. Furthermore, identifying patients who are on chronic opioid-therapy, and allowing for the administration of their usual opioid dose, has also been found to be beneficial [15].

## Regional Anesthesia

Regional anesthetic techniques hold several benefits which are desirable for ambulatory surgery, especially in the context of the PSH. Of significance is the degree of pain relief provided, most especially in the immediate post-operative period. There is evidence that pain relief may even persist up to several days after the procedure [16]. Along these lines, due to decreased use of general anesthetics (volatile agents) and opioids, the incidence of side effects such as PONV can be reduced, improving patient satisfaction. When used as the primary anesthetic in appropriate cases, the untoward hemodynamic effects of general anesthesia can also be avoided [17], and tracheal intubation, and subsequent emergence from anesthesia, can be circumvented.

In the setting of orthopedic and vascular surgery, ultrasound-guided peripheral nerve blocks of both the upper and lower extremities are commonplace and have become the standard of care in many institutions. This approach has led to improved patient safety, as well as lower block failure rates [18]. The most commonly utilized upper extremity blocks include interscalene, supraclavicular, infraclavicular, and axillary with each block targeting the brachial plexus at varying levels, depending

on surgical need. IV regional anesthesia (Bier block) continues to be useful in the setting of hand surgery. Lower extremity approaches include blockade of the femoral, saphenous, or sciatic nerve at various levels. Ankle blocks, performed by circumferential local anesthetic infiltration around the lateral and medial malleoli, continue to be successfully utilized in foot surgery. This approach blocks the cutaneous branch of the femoral nerve, and the four terminal branches of the sciatic nerve. As surgery in the ambulatory setting becomes more prevalent, a variety of other ultrasound-guided blocks continue to gain in popularity. Superficial and intermediate cervical plexus blocks, Transversus Abdominis Plane (TAP), rectus sheath, paravertebral, ilio-inguinal and ilio-hypogastric nerve blocks are a few commonly utilized procedures. Furthermore, regional anesthesia techniques can be tailored to provide pain management over an extended period. Continuous Peripheral Nerve Blocks (CPNBs), consisting of a percutaneously placed perineural catheter through which a constant local anesthetic infusion is administered, showed benefit in one study [19]. Patients randomized to a group receiving a CPNB and discharged the day after surgery, had similar outcomes to those without the catheter who remained admitted for a longer period. This not only had an impact on surgical outcome, but also on cost effectiveness.

Despite the fast-paced nature of the ambulatory surgery setting, it is imperative that the anesthesia provider remains vigilant for possible complications. Inadvertent vascular puncture, intraneural injection, phrenic nerve paralysis (with subsequent respiratory compromise), and local anesthetic systemic toxicity (LAST), are conditions that must be quickly recognized and treated.

Neuraxial anesthesia has also been successfully utilized in the ambulatory surgery setting. Intrathecal techniques are frequently used for ambulatory orthopedic, urologic, gynecologic and general surgery cases. Iwuchukwu and associates [20] described positive outcomes with standardized protocols using spinal anesthesia as the primary anesthetic in orthopedic surgery. The effective use of epidural anesthesia is also not uncommon in the ambulatory setting [21]. When employing neuraxial (particularly spinal) analgesia, the accompanying sympathectomy may not be tolerated by patients with cardiac conditions and thus it is important to determine this during the preoperative evaluation. Some potential impediments to rapid recovery and discharge include urinary retention, delayed return of sensory and motor function, and medication side effects such as pruritus, particularly when opioids are used as an adjuvant in intrathecal anesthesia. However, it has been suggested that complete return of urinary function is not necessary prior to discharge from ambulatory surgery [22].

## General Anesthesia and Monitored Anesthesia Care

Several approaches have been described for intraoperative anesthesia care to allow fast-tracking to occur in ASCs [23–28]. All of these approaches may be utilized when appropriate. Advances in drug pharmacology have provided clinicians with short-acting anesthetic agents that have more favorable side effect profiles. Propofol

continues to be widely utilized as both a primary induction and maintenance drug. It can be used as a sole agent, or in combination with a volatile anesthetic. It has a short context sensitive half-time, generally predictable pharmacology, and a favorable side effect profile. Another commonly used infusion drug is remifentanil, a potent but short-acting opioid. Its favorable pharmacokinetic profile is due to its metabolism by non-specific plasma esterases. Other IV agents with favorable pharmacologic and side effect profiles being increasingly used for enhanced recovery include dexmedetomidine and ketamine. More recently, intravenous infusions of lidocaine, at 2 mg/kg/hr., after a bolus dose of 1.5 mg/kg at induction have been described as a component of various fast-track and enhanced recovery protocols [29]. Despite the risk of local anesthetic toxicity which necessitates continuous cardiac monitoring, this approach has been found to improve post-operative analgesia and to blunt the sympathetic response to surgical stimulation. In the same manner, $\beta$-blockade can also be effectively utilized in the intraoperative period to dampen the response to catecholamines. Of note, the short acting beta blocker esmolol, metabolized by non-specific plasma esterases, has also been found to exert analgesic effects [30, 31]. In addition to this, other agents which have been part of various multi-modal approaches include glucocorticoids, NSAIDs, gabapentin and acetaminophen.

Apart from the intravenously administered agents described, volatile agents continue to be widely utilized in the maintenance phase of anesthesia. The most common agents include sevoflurane (1.6–2%), desflurane (6%) and nitrous oxide (often used as a 50% mixture in oxygen). These agents, due to their high saturated vapor pressure and low plasma solubility, have a quicker offset. However, these agents, aside from their unfavorable environmental footprint, also increase the incidence of post-operative nausea and vomiting. Total intravenous anesthesia utilizing propofol can overcome this effect.

Strategies to prevent PONV are an integral part of enhanced recovery regimens. Despite the identification of well described risk factors (Table 11.1) and the development of medications with improved side effect profiles, the incidence of PONV continues to be relatively high, occurring at a rate of 20–30%.

PONV has been described by patients as one of the most unpleasant aspects of undergoing surgery, and is a distinct reason why opioid-sparing techniques are favorable. The strongest recommendations call for a multi-agent approach based on the various mechanisms of action of anti-emetic medications [32]. The antagonism of histamine, dopamine, serotonin, and cholinergic receptors has been proven to

**Table 11.1** Clinically recognized risk factors for PONV

| |
|---|
| Female gender |
| Non-smokers |
| Susceptibility to motion sickness |
| Previously documented PONV |
| Administration of opioids |
| Inhalational anesthetics as main anesthetic |
| Nitrous oxide use during anesthesia care |
| Longer surgical procedures |
| Use of neostigmine for skeletal muscle relaxant reversal |

hold an advantage over placebo in preventing PONV. Most clinicians utilize a specific number of agents based on the number of PONV risk factors [33].

Another issue which may arise in the setting of recovery from general anesthesia is residual neuromuscular blockade. This condition can result in respiratory insufficiency leading to hypoxemia, aspiration events, and patient distress, all of which may significantly prolong recovery and discharge and increase the chance of inpatient admission and overall morbidity. Measures to prevent this include avoiding the use of neuromuscular blockers when possible, quantitative neuromuscular blockade monitoring, and administration of reversal agents (neostigmine + glycopyrrolate) and more recently, Sugammadex in the appropriate dose and at the appropriate time. The consistent and rapid reversal of even profound neuromuscular blockade by Sugammadex (given at dose of 2, 4, or 16 mg/kg), is especially useful for ambulatory surgery and fulfills the requirements of the PSH [34, 35].

Monitored Anesthesia Care (MAC) involves anesthesia-provider administration of varying degrees of anxiolysis, sedation, and analgesia with the ability to convert to general anesthesia when required. It is the technique of choice in up to 10–30% of procedures, and it is commonly utilized in combination with local anesthetic infiltration and/or a regional anesthetic approach. Similar to what has previously been discussed, the ideal anesthetic agents to be used for MAC should be easily titratable, short acting, and with favorable side effect profiles. Midazolam, propofol, dexmedetomidine, ketamine and remifentanil are commonly utilized in this regard, allowing for a quicker recovery. An important consideration is that the preoperative standards, intraoperative monitoring, and post-operative care for MAC are the same as those for general anesthesia. Furthermore, as respiratory depression can occur, careful intraoperative vigilance is imperative to safe patient care. Nevertheless, because the depth of anesthesia is typically less compared to general anesthesia when various levels of sedation are administered under MAC, and the severity of post-operative pain and opioid related side effects is decreased, the benefits afforded by these approaches are ideal for fast-track surgery in the ambulatory setting.

## Improving OR Efficiency and Throughput

An integral part of an effective PSH system involves not only direct patient care, but the efficient, cost-effective, and value-driven management of an OR complex. This is even more pertinent in the ambulatory surgery center setting. In general, two broadly encompassing goals of the PSH in the context of ambulatory surgery are measures directed towards improving patient outcomes as well as efforts to increase case throughput. Simply put, the PSH initiative should enable an institution to increase caseload, and increase the quality of care provided for each case, all while improving patient satisfaction and decreasing relative costs.

The use of barcode and local area network technology to devise a patient routing system was described in an earlier study [36]. Inefficiencies, as well as bottlenecks in care, were identified throughout the perioperative process and it was found that OR utilization was less than 50%. Furthermore, the inefficiencies were widely

caused by variations in process at multiple points [36]. Interventions were targeted towards standardizing the process at these identified points. Another important finding came from a study that examined the possibility of increasing throughput by decreasing case duration. By using a computer simulation, it was found that additional cases could not be added by decreasing the duration of scheduled cases [37]. Thus, optimizing case scheduling and avoiding inefficiencies throughout the day, are likely the most reasonable ways to increase throughput. Vetter and colleagues [38] described the PSH model utilized at one particular institution. An emphasis was placed on measures to avoid case delays and cancellations, not only via preoperative optimization, but also by achieving a consensus among providers and implementing specific criteria for case selection and scheduling. Furthermore, an innovative real time electronic dashboard reflecting OR schedule updates, as well as individual provider performance, allows staff to be constantly aware of overall system efficiency. Innovations have also been proposed in terms of the actual physical perioperative environment set up. One such approach involves a redesigned OR workspace, and anesthesia workflows, utilizing a parallel as opposed to linear model [39]. The simultaneous performance of perioperative tasks (i.e., anesthesia induction, OR setup, PACU hand-off of the previous case) within close proximity to each other allowed for increased case throughput.

An important consideration with regards to an optimal PSH design is the interaction between various members of the perioperative team. The PSH, as well as an ambulatory surgery facility in and of itself, require a multi-disciplinary approach to patient care. From the standpoint of surgeons, various technical and procedural aspects have been shown to improve outcomes, increase patient satisfaction, and decrease length of stay [10, 24, 40]. Technological advances in surgical techniques have allowed minimally invasive surgery to become increasingly popular. From a nursing standpoint, standardized clinical pathways throughout all phases of the PSH process have been shown to improve outcomes and efficiency [41]. Thus, it is critical that all stakeholders be involved in regular multi-disciplinary meetings, with an underlying goal of continuous quality improvement. Aside from clinical personnel, input from information technology services is valuable. Data gathering and analytics can often identify inefficiencies in the system that are not immediately apparent.

## The Post-operative Period

Traditionally, post-operative considerations in the setting of ambulatory surgery focus on interventions to hasten discharge. Hence, emphasis is placed on the immediate post-operative period, with attention given to multi-modal analgesia and PONV treatment [33, 42]. This continues to be an integral part of patient care. However, in the patient-centered and value-driven context of the PSH, modalities to improve outcomes beyond this period are becoming increasingly important [43].

Alem et al. [44] investigated various measures which led to decreased readmission rates after total joint arthroplasty. Here, intensive preoperative planning with

regards to aspects such as preferred pharmacies, rehabilitation facilities, and primary care physicians allowed for a more seamless transition of care in the post-operative period. Furthermore, possible actions to avert readmission when a patient presents to an emergency room post-operatively, were also identified. These included the use of POC ultrasound, multi-modal pain management and PONV treatment, and assistance with referrals to PCPs and specialists. Another study utilized standardized discharge protocols—consisting of physical therapy, ambulation, anticoagulation, and wound care—along with telemedicine-based follow-up and quality measure auditing [20]. This regimen led to a decrease in length of stay in patients who underwent *revision* total knee arthroplasty, making it comparable to *primary* TKA rates.

A recurrent theme in PSH literature is the emphasis placed on the need for standardization. In a retrospective study, Phan et al. [11] analyzed demographics and comorbidities in a group of patients, using the ASA Physical Classification score and the Charlson Comorbidity Index Score. These patients underwent joint arthroplasty within a PSH program with highly standardized pre-operative, intra-operative, and post-operative protocols. Data regarding various outcome measures (OR and PACU duration, LOS, transfusion rate, ED visits, and readmissions), were then collected. Results showed that in patients with different preoperative demographics and comorbidities, the PSH model decreased the post-operative outcome variability with regard to these measures.

## Summary and Conclusions

There is a role for the PSH in ASCs. Table 11.2 summarizes the steps an ASC may take to set up the PSH and apply it for different procedures. The challenges include adherence to protocols, teamwork and coordination of postoperative care. The rewards are patient-centered care plus patient engagement and active participation in the care processes.

The PSH paradigm complements the primary-care driven patient-centered medical home (PCMH) initiative and identifies methods for improving the patient

**Table 11.2** Summary of Steps to Set Up a PSH in an ASC

| |
|---|
| Requires a dedicated team |
| The team should develop clinical care pathways and expected outcomes |
| Select and implement clinical care pathways for each procedure |
| done by consensus agreement by *stakeholders* |
| adopt level 1 recommendations (when available) |
| Team consensus for other |
| Dedicated team to explain all stages and steps *to all stakeholders* |
| This is done to empasize: |
| *Standardization* |
| *protocol driven care* |
| *consistency* |

experience and clinical outcomes, while adding value and controlling costs in the care of surgical patients. The use of preoperative, intraoperative and postoperative initiatives has been shown to improve clinical outcomes [8].

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# Enhanced Recovery Program in the Ambulatory Surgery Setting

12

Girish P. Joshi

## Introduction

Ambulatory surgery accounts for about 65–70% of all elective surgical procedures performed in the United States [1]. Improvements in surgical and anesthetic techniques as well as modifications in postoperative care will allow further expansion of ambulatory surgery [2, 3]. Enhanced recovery pathways (ERP) or enhanced recovery after surgery (ERAS) pathways involve integration of evidence-based, multimodal, multidisciplinary interventions that are geared towards mitigating the undesirable effects of surgical stress response, and thus abate postoperative organ dysfunction and enhance rehabilitation [4, 5]. In recent years ERPs have been increasingly embraced for a variety of surgical procedures because they allow standardization of perioperative care and minimize variability. Evidence suggests that successful implementation of ERP reduce postoperative complications, accelerate recovery, and allow early return to baseline activities of daily living (ADL) [6–9].

While traditional ERPs designed for hospitalized patients have focused on length of stay (LOS) as a metric for defining the benefits of ERP [10], ambulatory surgery is unique in that patients are discharged from the surgical facility on the day of or within 24 hours of surgery. Thus, in the outpatient population, the better metric to assess the impact of ERP interventions would be the duration of postoperative stay in the surgical facility (i.e., duration of stay in the post-anesthesia care unit [PACU] and the Phase II unit), unplanned hospital admission rate and 30-day readmission rate as well as time to return of ADL [3]. Thus, perioperative interventions that influence postoperative complications (e.g., pain, nausea, vomiting, cardiorespiratory instability, and surgical complications) are critical in achieving rapid recovery.

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**Table 12.1** Overview of enhanced recovery pathway

| |
|---|
| **Preoperative Considerations** |
| Optimization of comorbid conditions |
| Patient and procedure selection |
| Patient and family education and counseling and discharge planning |
| Avoidance of prolonged preoperative fasting |
| Adequate hydration during the fasting period |
| Prehabilitation |
| Muscle strengthening and cardiovascular conditioning |
| Nutritional support |
| Smoking cessation |
| **Intraoperative Considerations** |
| Avoid preoperative midazolam |
| Use of fast track anesthesia technique (i.e., short-acting anesthetic agents at the lowest possible doses) |
| Avoid deep anesthesia (50% $O_2$ + $N_2O$ + inhaled anesthetic, ~1 MAC) |
| Minimize intraoperative opioid dose |
| Minimize muscle relaxant dose and reverse residual paralysis at the end of surgery with neostigmine/ sugammadex (dose based on the degree of blockade at the time of reversal) |
| Avoid fluid overload (balanced crystalloid solution 1–3 mL/kg/h, GDFT not beneficial) |
| Lung protective ventilation (TV 6–8 ml/kg IBW, PEEP 5–10 $cmH_2O$, maintain $ETCO_2$ ~40 mmHg) |
| Procedure-specific multimodal opioid-sparing pain management |
| Local/regional analgesia + acetaminophen + NSAIDs/COX-2 specific inhibitor |
| Multimodal antiemetic prophylaxis |
| Dexamethasone 8 mg, IV after induction of anesthesia and ondansetron 4 mg IV at the end of surgery |
| Maintain normothermia (core body temperature of 36–38 ° C) |
| Antibiotic and venous thromboembolism prophylaxis |
| Glycemic control |
| Minimally invasive surgical approach |
| **Postoperative Considerations** |
| Opioid-sparing multimodal analgesia |
| Early postoperative mobilization and physical therapy |
| Early oral feeding |
| Promotion of independence and participation |
| Measure outcomes and compliance with ERP |

Most ERPs consist of approximately 15–20 elements (components) that are considered necessary for enhanced recovery (Table 12.1). Although the relative contribution of each component remains unknown, it is well recognized that multiple interventions when combined together provide improved outcome. Of note, elements such as preoperative carbohydrate loading, avoidance of mechanical bowel preparation, and goal-directed fluid therapy lack definitive evidence with regards to improved outcomes [10]. This chapter discusses the optimal ERP that would enhance recovery after ambulatory surgery in adults.

## Preoperative Considerations

### Patient Selection

With older and sicker patients (e.g., morbidly obese patients with obstructive sleep apnea) undergoing complex surgical procedures (e.g., prostatectomy, thyroidectomy, mastectomy, total joint arthroplasty, and spine surgery) in an ambulatory surgery setting [11–16], it is well established that patient selection influences perioperative outcome [17]. An optimal ERP would include procedure-specific patient selection criteria that consider the interaction of patients' comorbid conditions, anesthetic technique (e.g., local/regional vs. general anesthesia), surgical procedure, and social factors (Table 12.2). It is generally accepted that patients with a high burden of comorbid conditions, particularly those with poorly stabilized medical conditions (i.e., American Society of Anesthesiologists [ASA] physical status >3) are not suitable for ambulatory surgery, particularly if the surgical procedure requires administration of general anesthesia [17].

**Table 12.2** Factors that influence patient and procedure selection for ambulatory surgery

| |
|---|
| **Surgical procedure** |
| Minimal blood loss not requiring blood transfusion |
| No specialized postoperative care required |
| No need for postoperative parenteral therapy |
| Postoperative pain manageable at home |
| **Patient characteristics** |
| Stable and well controlled coexisting medical conditions |
| Modifiable risk factors associated with perioperative complications |
| Glycemic control |
| Smoking |
| Nutritional status |
| Preoperative anemia |
| Functional status (physical disabilities such as use of walking aids) |
| **Social factors** |
| Responsible adult escort and availability of a responsible caregiver |
| Patient understands instructions |
| Reasonable access to a telephone |
| Reasonable access to healthcare |
| Able to return to hospital within reasonable time frame |
| Not expected to care for children or perform hazardous tasks |
| **Ambulatory setting** |
| Office-based |
| Free-standing ambulatory surgery center |
| Hospital-based ambulatory surgery center |
| Short-stay |

The risk factors for postoperative outcome can be classified into 'modifiable' and 'non-modifiable' categories. Non-modifiable factors include age, weight, and presence of sleep-disordered breathing. Although age alone should not be used to determine suitability for ambulatory surgery, most studies have suggested that patients older than 80 years may not be suitable for ambulatory surgery. Obesity is considered a risk factor for perioperative complications after ambulatory surgery; however, weight or body mass index (BMI) should not be the sole determinant of patient selection. Nevertheless, the Society for Ambulatory Anesthesia (SAMBA) recommends that patients with BMI <40 kg/m$^2$ may be suitable for ambulatory surgery assuming that their comorbid conditions, if any, are optimized [18]. The super obese (i.e., BMI >50 kg/m$^2$) should be chosen carefully as they have a higher incidence of perioperative complications. For patients with BMI between 40 and 50 kg/m$^2$, thorough preoperative assessment is necessary to identify obesity-related comorbid conditions (e.g., obstructive sleep apnea [OSA], obesity-related hypoventilation syndrome, and pulmonary hypertension, as well as resistant hypertension, coronary artery disease, and cardiac failure).

The SAMBA consensus statement recommends that patients with a known diagnosis of OSA, who are typically prescribed positive airway pressure [PAP] therapy, may be considered for ambulatory surgery if their comorbid medical conditions are optimized and they are able to use a PAP device in the postoperative period [19, 20]. On the other hand, patients who are unable or unwilling to use a PAP device after discharge can be considered for ambulatory surgery if their comorbid conditions are optimized and if postoperative pain relief can be provided predominantly with non-opioid analgesic techniques, similar to those with a presumed diagnosis of OSA, based on screening tools such as the STOP-Bang questionnaire [19, 20].

In the future, as more patients and surgical procedures are moved from inpatient facilities to outpatient facilities, it will be appropriate to develop exclusion criteria, rather than inclusion criteria, for patients that are not candidates for ambulatory surgery [17].

## Evaluation and Optimization

Preoperative evaluation and optimization of comorbid conditions is critical to improving perioperative outcomes [5]. Preoperative optimization 'convert' a patient from a higher risk to a lower risk category, thereby rendering them a candidate for same-day procedures. However, this could be challenging because patients typically arrive to the surgical facility on the day of surgery. Therefore, ERP protocols should include "triggers" such as weight, functional status, significant cardiopulmonary disease, and sleep disordered breathing, for referring a patient to the anesthesiologist for further evaluation [21].

## Smoking Cessation

Another factor that can influence postoperative outcome is tobacco use [22]. Nicotine has been associated with vasoconstriction, reduced peripheral blood flow, tissue devitalization, poor wound healing, and high surgical site infection rate [23].

Also, smoking increases carboxyhemoglobin, which reduces oxygen carrying capacity. Smoking cessation for 24 hours prior to surgery reduces carboxyhemoglobin levels, while airway irritability is reduced after 2 weeks smoking cessation, and 6–8 weeks should reduce secretions and pulmonary complications [22]. Therefore, smoking cessation should be encouraged 4–8 weeks prior to surgery.

## Nutrition

Poor preoperative nutritional status can have a negative influence on postoperative recovery including increased infection, delayed wound healing, and delayed ambulation [5, 24]. Markers of malnutrition include low serum albumin (<3.5 g/dL) and serum transferrin (<200 mg/dL). Malnourished patients should be referred for nutritional counseling [5].

## Prehabilitation

Preoperative rehabilitation, also known as "prehabilitation", includes cardiopulmonary conditioning and muscle strengthening, has been shown to influence postoperative rehabilitation by improving functional status and reducing frailty [24]. However, the specifics of preoperative rehabilitation after ambulatory surgery are lacking [10]. Future studies are necessary to define the role of prehabilitation as well as the indications and the specific types of postoperative physical therapy [10].

## Carbohydrate Loading

Administration of carbohydrate drinks prior to surgery has been shown to boost immune function, reduce hunger, thirst and anxiety as well as reduce postoperative insulin resistance and postoperative nausea and vomiting (PONV) [25]. Also, preoperative carbohydrate loading improves muscle function and accelerates convalescence. However, a recent network meta-analysis of 43 trials found that preoperative carbohydrate loading offered no benefit in comparison with water, although a small reduction in LOS was noted [26]. Thus, as it relates to ambulatory surgery where the patients are hydrated well during the fasting period as well as can resume oral intake immediately after surgery, it is unclear if carbohydrate loading would offer additional benefits [25]. Nevertheless, patients should be advised to hydrate well (i.e., drink water) during the fasting period.

## Patient and Family Education

Education of patients and their caregivers regarding the perioperative course is an important component of ERP [10, 27, 28]. The goal of patient education is to make the entire surgical process as transparent as possible and make the patient an active

participant in their care. Understanding the perioperative process should alleviate much of the psychological stress and anxiety associated with the surgical procedure [27, 28]. Preoperative education allows realistic expectations, as patients may think that they could return to normality once they are discharged home. Also, the patient's responsibility should be clarified. Patients and their caregivers should be informed about the symptoms and signs of potential procedure-specific complications including bleeding, infection or localized tissue ischemia. The need for increased vigilance after discharge home should be emphasized.

Outpatients should be capable of understanding instructions for preoperative and postoperative care. Patients should receive written and verbal instructions regarding what should be done preoperatively and postoperatively (e.g., if complications are noted). When providing patient education, it is important that the information is delivered in a culturally sensitive manner. The social situation should be evaluated to determine whether the patient has help at home for postoperative care.

## Intraoperative Considerations

It is well-recognized that intraoperative care influences not only immediate postoperative outcomes, but also long-term outcomes [29]. The anesthetic technique chosen should provide optimal operative conditions, while ensuring a rapid return of consciousness and protective reflexes upon completion of the operation, minimal residual sedative effects (so-called "hangover" effect), little impairment of postoperative cognitive function, and the absence of adverse effects [2, 21]. Also, it should facilitate early oral intake and ambulation after surgery.

### Premedication

Preoperative benzodiazepines (e.g., midazolam 1–2 mg, IV) are commonly used to provide anxiolysis. However, the benefits of preoperative midazolam are questionable, and its use can delay emergence from anesthesia and increase postoperative cognitive dysfunction [30–32]. Therefore, routine use of midazolam should be avoided, particularly in the elderly, morbidly obese, and sleep apnea patients, and those with significant comorbidities [21].

### Anesthetic Technique

Local/regional anesthesia should be preferred, when possible, as it avoids the side effects associated with drugs used for general anesthesia, such as cardiopulmonary depression, residual muscle paralysis, and postoperative confusion and delirium [33]. In addition, these techniques allow rapid recovery, provide postoperative analgesia, and reduce opioid requirements and associated adverse effects. However, it is critical that patients do not receive deep sedation in addition to local/regional

anesthesia during the procedure, as it can increase postoperative cognitive dysfunction, particularly in patients at risk [34].

There is lack of evidence regarding superiority of total intravenous anesthesia (TIVA) over inhalation anesthesia with regards to time to discharge home or unplanned admission to hospital [35]. The benefits of TIVA include the ability to provide general anesthesia without the need for an anesthesia machine. In addition, TIVA reduces the incidence of postoperative nausea and vomiting (PONV) particularly in patients at high risk, although this benefit has been questioned recently [36]. On the other hand, inhalation anesthesia technique allows easy titration and reduces the need for muscle relaxants.

The primary aim of any general anesthetic technique is to use short-acting drugs (sedative-hypnotics, muscle relaxants, and opioids), at the lowest possible doses. Nitrous oxide ($N_2O$) is the shortest acting inhaled anesthetic with amnestic and analgesic properties, which reduces the requirements of sedative-hypnotics (e.g., inhaled anesthetics) and analgesics (e.g., opioids) [37]. However, it is commonly avoided due to unfounded concerns of increase in PONV and expansion of closed spaces (e.g., bowel distention) [38–40]. In fact, $N_2O$ facilitates recovery and has no residual effects. Thus, there is no convincing reason to avoid $N_2O$ [40].

Opioids are commonly used as a component of balanced general anesthesia technique; however, they should be used judiciously because opioid related adverse events (e.g., sedation, nausea, vomiting, urinary retention, ileus, and constipation) could delay recovery and hinder rehabilitation [41]. Therefore, non-opioid analgesics and analgesic techniques should be used when possible. Intraoperative tachycardia and/or hypertension are usually used as surrogate for the need for opioids. However, tachycardia and hypertension may be due to causes other than pain (e.g., during laparoscopy from increased intra-abdominal pressure or tourniquet inflation). Also, attempts to achieve "tight" hemodynamic control may result in use of larger opioid doses. Large intraoperative opioid doses can increase the occurrence of acute tolerance and hyperalgesia, which may increase postoperative pain and opioid requirements [42]. Of note, intraoperative opioid overdose can only be recognized at emergence of anesthesia when the patient's spontaneous ventilation is delayed.

It is critical to avoid deep anesthesia [43]. Physiological parameters such as heart rate, blood pressure, respiratory rate, and response to noxious stimuli are not reliable predictors of awareness. It is recommended that when using inhalation anesthesia, alarms are set to detect low end-tidal anesthetic concentrations (age-adjusted minimum alveolar concentration [MAC] <0.7) and/or use of neuromonitoring (e.g., BIS monitoring) [44, 45]. In most patients, age-adjusted MAC values of 0.7–1 are adequate to prevent intraoperative awareness with recall [46]. For patients receiving TIVA, it is recommended that propofol doses be titrated to neuromonitoring [44].

Because even minimal postoperative residual paralysis (train-of-ratio ratio <0.9) can increase the incidence of critical respiratory events in the PACU, increase the need for reintubation, and prolong recovery time, as well as increase postoperative morbidity, muscle relaxants should be used judiciously [47–50]. Deep muscle paralysis is usually not necessary for most ambulatory surgical procedures including

laparoscopic procedures [51–54]. At the end of surgery, residual paralysis should be reversed with appropriate doses of neostigmine or sugammadex (when steroidal muscle relaxants are used).

## Airway Management

Supralaryngeal devices (e.g., laryngeal mask airway) are preferred over tracheal tubes, as they are tolerated at lower anesthetic concentrations and do not need muscle relaxants for their placement [55, 56]. Also, they allow easier titration of opioids based on the respiratory rate. These factors allow for earlier emergence from anesthesia and improve perioperative efficiency. However, supralaryngeal devices may not be suitable in patients at high risk of gastric regurgitation such as those with gastroesophageal reflux disease, morbid obesity, or requiring prone positioning.

## Mechanical Ventilation

Lung protective ventilation strategies including low tidal volumes (6–8 mL/kg, ideal body weight) with positive end expiratory pressure (PEEP) 5–10 cm $H_2O$ have been shown to reduce postoperative pulmonary complications, and thus should be employed for all patients [57–59]. In addition, it is necessary to maintain end-tidal carbon dioxide ($ETCO_2$) values around 40 mmHg rather than the traditional 30–35 mmHg. Higher $CO_2$ levels (i.e., mild to moderate hypercarbia) improve tissue and organ perfusion including cerebral perfusion and oxygen saturation [60–63]. Intraoperative hyperventilation ($ETCO_2$ values of 30–35 mmHg) may result in metabolic alkalosis and cause postoperative hypoventilation, particularly in the obese and sleep apnea patients who normally have a higher $CO_2$ levels.

## Fluid Management

Intraoperative fluid requirements for most ambulatory surgery cases are minimal given the minimally invasive surgical approach and the low propensity for blood loss. The overall goal is to achieve a ‘zero’ fluid balance [64–66]. Most adults undergoing minimally or moderately invasive surgical procedures with planned ambulation postoperatively could receive 1–3 mL/kg/h of a balanced electrolyte crystalloid solution with boluses of 200–250 mL, if necessary. Although goal directed fluid therapy (GDFT) is recommended for major surgical procedures, it appears to be less effective in the context of ERP as patients are encouraged to drink clear liquids (water) up to 2 hours before surgery and resume oral intake shortly after the surgery [66]. Therefore, GDFT and stroke volume monitoring has no role for routine use in the outpatient setting. In fact, several studies have found that a liberal intraoperative fluid regimen (20–40 mL/kg) reduces postoperative thirst, nausea, dizziness, pain, respiratory compromise, and hemodynamic instability [66].

Also, patients receiving higher intraoperative fluid load have less fatigue and a superior general sense of wellbeing [67, 68].

## Pain Management

Postoperative pain is one of the most common reasons for delayed recovery and unplanned admission and readmission. Procedure-specific, evidence-based multimodal analgesic techniques incorporated in an ERP facilitate postoperative ambulation and rehabilitation. An optimal pain therapy would be initiated in the preoperative period with identification of patients at risk of greater pain intensity [69, 70]. Predictors of postoperative pain are included in Table 12.3 [70].

The analgesic options for multimodal pain management are included in Table 12.4. Local/regional analgesia should be an important component of an

**Table 12.3** Preoperative predictors of postoperative pain

| |
|---|
| Presence of preoperative pain |
| Inappropriate patient expectations |
| Inappropriate anxiety of surgical outcome |
| Age and gender |
| Psychological factors |
| Low self-esteem |
| Severe anxiety |
| Major depressive disorder |
| Pain catastrophizing or hypervigilance (i.e., strong attention bias towards pain) |
| Functional pain states (e.g., fibromyalgia) |
| Genetic variance in opioid receptors |
| Acute opioid tolerance and opioid-induced hyperalgesia |

**Table 12.4** Analgesic options for perioperative pain management

| |
|---|
| Local/Regional analgesic techniques |
| Peripheral nerve blocks |
| Field blocks |
| Surgical Site infiltration |
| Acetaminophen |
| Non-steroidal anti-inflammatory drugs or cyclooxygenase-2 specific inhibitors |
| Analgesic adjuncts |
| Steroids (dexamethasone) |
| NMDA receptor antagonists |
| Ketamine |
| Gabapentinoids |
| Gabapentin |
| Pregabalin |
| Alpha-2 receptor agonists |
| Clonidine |
| Dexmedetomidine |
| Opioids |
| Non-pharmacologic interventions |
| Music |
| Cognitive behavioral modalities |

optimal multimodal analgesia technique [69, 70]. Surgical site infiltration should be utilized, when possible, as it provides excellent analgesia with no potential adverse effects. However, it is necessary that all layers of the surgical incision are infiltrated meticulously under direct vision immediately prior to tissue/skin closure [71]. For example, in patients undergoing abdominal surgery the peritoneal, musculofascial, and subdermal planes should be infiltrated. The injection solution includes the maximum dose of local anesthetic based on body weight (e.g., for average adults, bupivacaine ~150 mg or ropivacaine ~300 mg) diluted with normal saline to a total volume depending upon the size of the incision, typically 60–100 mL [71]. Of note, it appears that surgical site infiltration has a more gradual offset with typically less rebound pain.

Peripheral nerve blocks provide excellent pain relief for limb surgery [72]. Brachial plexus blocks are recommended for patients undergoing major upper limb surgery (e.g., shoulder arthroplasty, rotator cuff repair, and elbow arthroplasty) [72]. Similarly, popliteal-sciatic nerve blocks have been recommended for patients undergoing a major foot and ankle surgery [73]. Adductor canal blocks may be appropriate for patients undergoing knee surgery, particularly if the surgeon does not perform local infiltration technique or performs it inadequately [74]. However, a single-injection technique has a short duration (~6–8 h) [75]. The subsequent rebound pain after resolution of nerve blocks can be severe and difficult to control typically late in the evening or during the first night. Several adjuncts such as clonidine and dexamethasone are used to prolong the duration of peripheral nerve blocks; however, their role remains controversial [76]. Continuous peripheral nerve blocks extend the duration of analgesia, but their placement can be technically challenging and are associated with management problems (e.g., catheter dislodgement, kinking, or leaking) requiring 24/7 availability for patient consultation [77]. Therefore, their use in clinical practice is limited.

In recent years, numerous studies have reported analgesic efficacy of field blocks such as transversus abdominis plane (TAP) blocks in patients undergoing abdominal surgery. However, they are not necessary for laparoscopic procedures despite several systematic reviews suggesting improved pain relief [65]. Of note, surgical site infiltration and TAP blocks provide similar pain relief after lower abdominal surgery [78].

Local/regional analgesia techniques should be combined with acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs) or cyclooxygenase (COX)-2 specific inhibitors. In the absence of any contraindication, the combination of acetaminophen and NSAIDs or COX-2 specific inhibitors should be used for almost all surgical procedures on a regular "round-the-clock" or "scheduled" basis [69]. Of note, the combination of these analgesics has been shown to provide superior analgesia compared with either drug alone [79–82]. The cardiovascular and renal adverse effect profile of COX-2 specific inhibitors seems to be equivalent to that of traditional NSAIDs. However, COX-2 specific inhibitors lack antiplatelet effects, and may be administered preoperatively [83]. The analgesic efficacy of COX-2 specific inhibitors is similar to that of the traditional NSAIDs. In addition, a single dose of dexamethasone 8–10 mg, IV has been shown to provide analgesia without any

adverse effects (e.g., surgical site infections) [84]. Although dexamethasone may cause increased blood glucose levels lasting for up to 24 h, the hyperglycemia appears to be clinically insignificant [85, 86].

Low-dose ketamine has been reported to reduce postoperative pain scores and opioid consumption as well as delay time to first opioid administration [87, 88]. A systematic review revealed that ketamine provided significant analgesic benefits in painful procedures including thoracic, upper abdominal, and major orthopedic surgeries [87]. However, its benefits for surgical procedures associated with mild-to-moderate pain remain controversial. Also, the optimal dose and duration of administration is unknown [69]. Overall, there appears to be no role for a single bolus dose of ketamine in minimally invasive surgical procedures. Importantly, even low-dose ketamine can increased the incidence of neuropsychiatric disturbances including nightmares and cognitive dysfunction [89].

Gabapentinoids (e.g., gabapentin and pregabalin) have been shown to reduce postoperative opioid requirements and may be beneficial in patients with opioid tolerance and surgical procedures with a high incidence of persistent postoperative pain [90, 91]. However, concerns of adverse effects such as sedation, visual disturbances, dizziness, and respiratory depression may limit their use [92, 93]. Intraoperative intravenous lidocaine infusion has been reported to provide pain relief in patients undergoing major abdominal surgery, but the duration of analgesia is brief (~4 h) [94]. However, its role in ambulatory surgical procedures remains controversial. Overall, analgesic adjuncts such as intravenous lidocaine infusion, ketamine, and gabapentinoids are generally reserved for select patient populations and/or surgical procedures. Alpha-2 agonists (e.g., clonidine and dexmedetomidine) have no role as a component of multimodal analgesic technique in ambulatory surgical population due to lack of benefit and concerns of adverse effects such as bradycardia and hypotension as well as excessive postoperative sedation and drowsiness, which may delay ambulation [95, 96].

Opioids are used as "rescue" analgesics on an "as needed" basis rather than on a scheduled basis. Weak opioids (e.g., tramadol) may be used if the pain intensity is moderate, while strong opioids (e.g., hydrocodone and oxycodone) may be reserved for moderate-to-high intensity postoperative pain [97].

## PONV Prophylaxis

Aggressive PONV prophylaxis is necessary to facilitate early recovery. Although risk-based approaches for antiemetic therapy have been proposed [98, 99], the compliance with these strategies has been poor, and thus may not provide meaningful PONV prevention [100]. Therefore, routine multimodal antiemetic prophylaxis should be utilized in all patients. The number of antiemetic combinations could be based on the patient's level of risk including the type of surgical procedure. A combination of dexamethasone 8 mg, IV (after induction of anesthesia) and 5-hydroxytryptamine-3 (5HT3) antagonist (e.g., ondansetron 4 mg, IV, at the end of surgical procedure) could be used for most patients. Patients at very high risk of

PONV (e.g., history of motion sickness, history of previous PONV, high opioid requirements for pain relief) may receive additional antiemetic therapy such as preoperative transdermal scopolamine or intraoperative haloperidol 1 mg, IV. However, there is no clinical benefit of using more than 3 antiemetics for prophylaxis. In addition, TIVA may be considered in these high-risk patients.

### Emergence from Anesthesia

Towards the end of surgery, it is common practice to reduce the respiratory rate in an effort to build up $ETCO_2$ levels and facilitate respiration [21]. However, this practice reduces minute ventilation resulting in delayed removal of inhaled anesthetic, which may delay emergence from anesthesia. Therefore, the primary aim at the end of the surgery should be to maintain the minute ventilation in an effort to washout the inhaled anesthetic and facilitate emergence. Tracheal extubation should be performed in a semi-upright (25–30° head-up) position, when possible.

## Immediate Postoperative Considerations

Postoperative complications that can impede recovery and delay discharge home include pain, nausea and vomiting, respiratory complications, cardiovascular complications, temperature abnormalities, delirium, and surgical complications [101–103].

### Pain and PONV

Patients complaining of moderate-to-severe pain in the postoperative care unit (PACU) should receive rescue analgesia as soon as possible [69]. This could include small doses of intravenous opioid and/or oral analgesics (non-opioids and/or opioids). If appropriate, postoperative peripheral nerve blocks may be performed, if not done preoperatively. Pain during the stay in the PACU will provide valuable input on what to expect after discharge.

Patients requiring rescue antiemetic therapy in the PACU could receive low-dose promethazine (6.25 mg, slow IV) or dimenhydrinate (1 mg/kg). There is no benefit of repeating the same 5HT3 antagonist if it was administered intraoperatively. Patients at high risk of post-discharge nausea and vomiting (PDNV) may receive scopolamine patch if not administered preoperatively [98].

### Respiratory Complications

Respiratory complications (e.g., airway obstruction, hypoventilation, laryngospasm, brochospasm, and pulmonary aspiration of gastric contents) may be prevented by intraoperative interventions, such as minimization of opioids, appropriate

reversal of residual muscle paralysis at the end of surgery, and tracheal extubation after the patient is awake (i.e., avoidance of "deep" extubation).

## Cardiovascular Complications

Cardiovascular complications include hypotension, hypertension, myocardial ischemia, and rhythm disturbances. Postoperative hypotension may be due to effects of residual anesthetics, hypovolemia, and cardiac etiology. Limiting the doses of sedative-hypnotics and opioids, ensuring proper anesthetic washout, maintaining euvolemia with adequate fluid administration, and ensuring cardiac comorbidities are optimized may minimize these risks. Causes of hypertension include hypoxemia, pain, anxiety, hypothermia (with shivering), urinary retention, hypervolemia, and withdrawal from discontinuation antihypertensive medication. Treatment of the underlying cause (e.g., supplemental $O_2$, warm blankets, bladder catheterization) should be adequate in most cases. Patients on chronic antihypertensive medications should be encouraged to resume their normal dose to ensure blood pressure control in the postoperative period.

## Orthostatic Hypotension

Postoperative orthostatic intolerance is characterized by symptoms of dizziness, nausea, vomiting, blurred vision or syncope during sitting and standing during early mobilization. It is usually a transient condition, which resolves within 24–48 hours. Its incidence ranges between 12 and 60%, and is higher in patients undergoing more invasive surgical procedures [104]. Risk factors include female gender and use of opioids and anti-hypertensive medications. Although the exact pathophysiology is unclear, it is most likely due to attenuated endogenous vasopressor response during ambulation and increased vagal output, potentially associated with inflammatory activation from surgical stress response [104].

## Delirium

Postoperative delirium (POD) is a state of abrupt change in cognitive function, manifested either with agitation or silent (i.e., only evident after screening) [105]. Other symptoms associated with POD include change in level of arousal (drowsiness or decreased arousal or increased arousal with hypervigilance), problems with attention, difficulty concentrating, new memory problems, disorientation, and difficulty tracking conversations and following instructions [105]. It is the most common surgical complication in older adults, occurring in 5–50% of older (>65 years) patients, but is under-recognized. The consequences of POD can be severe including loss of functional independence, reduced cognitive function, major postoperative complications, unplanned admission, and prolonged hospitalization.

Delirium is potentially preventable in up to 40% of patients. Prevention strategies are typically based on identifying high risk patients, and addressing modifiable risk factors in these patients. Elderly patients should be routinely screened for POD (e.g., confusion assessment method [CAM]). The factors that precipitate delirium (e.g., dehydration, benzodiazepine, opioids, and deep anesthesia) should be avoided [106]. In addition, an ERP with multimodal opioid-sparing analgesia has been reported to reduce POD in elderly patients [107, 108]. Delirious patients who are severely agitated or distressed or who are threatening substantial harm to self and/or others may receive antipsychotics (e.g., haloperidol, risperidone) at the lowest effective dose for the shortest possible duration. Also, it is necessary to encourage oral intake and mobilization soon after surgery as well as promote good sleep patterns and sleep hygiene.

### Discharge Criteria

The recovery process should be modified to improve patient throughput, which includes change from traditional time-based to clinical-based discharge [3]. A clearly defined process should be established to ensure safe and timely discharge home. The post-anesthesia discharge scoring system (PADSS) is the most commonly used tool to determine home readiness. Fulfilling the usual discharge criteria is by itself a step in ensuring a smooth course further on. It is important to recognize that home-readiness is not synonymous with street-fitness. Prior to discharge home, patient-centered discharge instructions, discharge planning, medication reconciliation, and prescription for multimodal analgesics is critical. Early mobilization and the initiation of accelerated physical therapy should preserve muscle mass and function.

## Post-discharge Considerations

Not all patient complications may be evident prior to discharge home. Studies show that treatment-related complications can develop over the hours or days following discharge and may require subsequent visits to the emergency department or hospitalization [101–103].

### Pain Control After Discharge Home

With more extensive and painful surgical procedures being performed on an outpatient basis, pain management after discharge is increasingly challenging. Ambulatory surgical patients require an analgesic technique that can be adequately managed with oral analgesics (e.g., acetaminophen, NSAIDs or COX-2 specific inhibitors). Scheduled dosing with these non-opioid analgesic medications provides superior analgesia as this prevents the pain from becoming severe and decreases the

incidence of breakthrough pain. It is necessary to instruct patients to take scheduled acetaminophen and NSAIDs/COX-2 specific inhibitors even if their pain is minimal.

Moderate-to-severe pain not responding to non-opioid analgesics may require opioids. However, use of opioids such as codeine should be avoided, as 15–20% of patients have abnormal P450 metabolism [69]. Tramadol, a synthetic, centrally-acting analgesic is a weak opioid agonist with selectivity for μ-receptors and a weak inhibitor of the reuptake of norepinephrine and serotonin. Unlike other opioids, tramadol does not have clinically significant respiratory effects. The adult dose of tramadol is 50 to 100 mg every 4–6 h with a maximum of 400 mg per day. Although it is generally well tolerated, side effects include nausea, vomiting, dizziness, and drowsiness. Tramadol has a potential to cause seizures, and therefore it should be used with caution in patients with increased intracranial pressure and in patients receiving neuroleptic drugs. It is contraindicated in patients receiving monoamine oxidase inhibitors.

Patients should also be educated about non-pharmacologic ways of alleviating postoperative pain, such as the application of ice, elevation of the operated extremity, music, and cognitive behavioral modalities [109].

## Nausea and Vomiting

Post-discharge nausea and vomiting is a common and sometimes severe adverse outcome for ambulatory patients. The independent predictors of PDNV include female gender, age less than 50 years, history of PONV, opioids administered in the PACU, and nausea in the PACU [110]. It may be initiated by ambulation, motion sickness during transport home, and opioids. Use of long-acting 5HT3 antagonist (e.g., palonosetron) and scopolamine patch may be effective in preventing PDNV. Treatment includes use of oral ondansetron and other over the counter antiemetics.

## Cognitive Dysfunction

Postoperative cognitive dysfunction (POCD) is a decline in abilities to perform more complex cognitive tasks, such as doing a crossword puzzle, and reasoning about an issue. POCD has been shown to delay recovery. Possible risk factors of POCD include age, reduced preoperative cognitive reserve, lower educational level, major surgery, and hospitalization [111]. The influence of the type of anesthesia technique remains controversial. It is a reversible state, within days or months after surgery, as patients return to their baseline function. Patients and their family members should be aware of the transient nature of POCD, help the patient with tasks of demanding intellectual challenges, and provide a stable, predictable and secure environment for the patient. The incidence of POCD appears lower in patients within the ERP [112].

## Fatigue

Postoperative fatigue, presented as physical and/or mental tiredness or weakness, is a frequent condition that could last for weeks after surgery. Fatigue can delay ambulation and return to ADL. The incidence, severity, and duration of fatigue after ambulatory surgery are unknown. Similarly, the etiology of postoperative fatigue has not been adequately studied. It seems to be associated with the invasiveness of surgical procedure (i.e., extent of tissue damage and inflammation), preoperative psychological issues, and social factors. In addition, residual effects of intraoperative drugs such as sedative-hypnotics, muscle relaxants, and opioids as well as use of postoperative opioids may also influence fatigue.

## Surgical Complications

Surgical complications, particularly bleeding/hematoma, infection, and surgical wound issues, are the most common cause for a visit to the emergency department and readmission after discharge home [101–103]. Wound care issues include oozing and bleeding. Minor signs of redness and white secretion superficially from a wound may be treated with cleaning, local bacteriostatic liquid or ointment, or systemic antibiotics. Advising patients regarding the plan for wound care and expected issues avoids unnecessary visits to the emergency department. Patients should be instructed to look for specific signs of infection (e.g., localized pain, redness, tenderness, or generalized symptoms of fever) and bleeding according to type of procedure and patient risk factors. For patients undergoing abdominal surgery, there are concerns of peritonitis, which may lead to sepsis and multi-organ failure. Therefore, patients should be instructed to recognize the signs of peritonitis and evolving sepsis. Another complication includes tissue ischemia and compartment syndrome that may present as increasing pain and/or numbness. Patients should be instructed to look out for these symptoms and obtain immediate care.

Patients should be contacted after discharge home, typically the day after surgery to assess the postoperative course and ensure that instructions on medications and other measures are well understood and implemented. Someone should also be available to care for the patient during the first night after surgery and be able to assist them in obtaining emergency medical care if needed.

## Postoperative Urinary Retention (POUR)

Urinary retention can occur after ambulatory surgery with variable incidence [113, 114]. It is one of the reasons for readmission and need for urinary catheterization and urinary tract infection. Risk factors for POUR include advanced age, preoperative urinary symptoms (e.g., symptoms of prostate enlargement), use of spinal anesthesia, high-dose opioid use, and type of surgical procedure (e.g., urological procedures). Preoperative use of α-adrenoceptor antagonists is associated with reduced incidence of POUR. Unfortunately, there is a wide variation in management of POUR probably due to lack of an evidence-based definition [115].

**Table 12.5** Postoperative outcomes measures to assess recovery after ambulatory surgery

| |
|---|
| Morbidity |
| Significant pain, nausea, vomiting |
| Respiratory: bronchospasm, laryngospasm, inability to extubate, airway obstruction, respiratory depression, reintubation |
| Cardiac: arrhythmia, hypotension, hypertension, myocardial ischemia/infarction, heart failure, pulmonary edema |
| Neurological: cerebrovascular event (stroke/transient ischemic attack) |
| Delirium and cognitive dysfunction |
| Significant blood loss requiring blood transfusion |
| Surgical complications (e.g., wound-related, bleeding and hematoma, infection, and tissue ischemia) |
| Delayed recovery and discharge home |
| Unplanned hospital admission |
| Readmission after discharge home |

## Summary

Enhanced Recovery Pathways have revolutionized perioperative surgical care. It is necessary to develop comprehensive, multidisciplinary, procedure-specific clinical pathways that involve the entire perioperative team (e.g., anesthesiologists, surgeons, pharmacists, and nursing). Importantly, it is generally incorrectly believed that intraoperative care has little effect on significant or long-term outcomes (e.g., postoperative morbidity). Given how the residual effects of the hypnotic-sedatives, muscle relaxants, and opioids can increase postoperative morbidity and delay recovery, it is prudent to use minimal number of drugs, and the drugs that have to be used should be shorter-acting and administered at the lowest possible dose. Post-discharge planning should include prevention and treatment of postoperative complications particularly pain and antiemetic therapy. The primary postoperative goals include early ambulation and early oral intake. Measuring compliance with ERP through an audit program is essential to evaluate success and need for protocol modification. Continuous quality improvement approach allows ERP to be sustainable with continuous education and evaluation. The outcome measures that could be used to assess recovery after ambulatory surgery are included in Table 12.5. Further research is needed in the area of postoperative management in regards to optimal type, timing, and duration of physical therapy, as well as factors that influence readmission.

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# Pediatric Anesthesia

# 13

Chhaya Patel and Claude Abdallah

The demand for ambulatory anesthesia for pediatric surgery and procedures continues to grow. About 2.3 million ambulatory anesthetics were provided for patients younger than 15 years in 2006 in the USA [1, 2]. Pediatric ambulatory anesthesia care is required for several therapeutic and diagnostic procedures as well as imaging tests such as endoscopy and magnetic resonance imaging, to ensure comfort and immobility. Freestanding and hospital-based ambulatory surgery centers are performing procedures for different specialties, including general surgery, dentistry, ophthalmology, otolaryngology, orthopedics, plastic surgery, urology and gastroenterology. The most common procedures performed in patients younger than 15 years of age are myringotomy and tubes, tonsillectomy with or without adenoidectomy, orthopedic procedures, urogenital procedures, and hernia repair [2, 3]. Pediatric ambulatory anesthesia offers several advantages including minimized separation from parents, increased hospital bed capacities for sicker children, reduction of nosocomial infection and possibly, reduced costs. The current availability of different anesthetic techniques and short-acting medications, as well as advances in surgical techniques, allow for fast recovery and reduction of undesirable side-effects. Patient safety, patient and family satisfaction, staff training, convenience of surgery and economic success are the goals of an ambulatory pediatric practice. Prevention of morbidity and unanticipated postoperative admission requires constant vigilance regarding preoperative screening, anesthetic techniques and discharge criteria.

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## Preoperative Considerations

Prior to providing anesthetic services, the anesthetizing site must be surveyed. Different elements such as ventilation and scavenging capability, potential hazards, design, equipment, electrical service, personnel credentials, communications systems, lighting and traffic control should be evaluated.

Outpatient surgery can be performed safely in a variety of settings such as hospital-associated ambulatory care facilities, operating room suites within hospitals, free standing satellite surgery centers, and individual physicians' offices. The key driving factors for outpatient surgery are lower healthcare costs and greater patient satisfaction [4].

The design and setting of the outpatient surgery facilities should be specifically tailored for the pediatric patient population. Pediatric patients benefit from child-life experts, playrooms, changing stations, and specific pediatric feeding considerations. Administrative and medical personnel should be trained to be familiar with the particular needs of this patient population. Keenan and colleagues associated fewer adverse outcomes in the hands of anesthesiologists with more experience in anesthetizing children [5]. The American Academy of Pediatrics (AAP) section on Anesthesiology makes recommendations for facilities, equipment, and provider considerations in caring for various classes of pediatric patients. It is recommended that pediatric patients be cared for by fellowship-trained anesthesiologists or by anesthesiologists with ongoing experience in the field [6, 7]. These guidelines are intended to supplement the standards and guidelines from the American Society of Anesthesiology. The AAP guidelines outline policies relating to medical staff privileges, categorization of pediatric patients and procedures, and the minimum volume of cases required for anesthesia providers to maintain clinical competency in order to provide safe care of children. AAP guidelines recommend the following age categories for credentialing and outcome measurement: 0 to 1 month, 1 to 6 months, 6 months to 2 years, and older than 2 years. Due to the anatomic, physiologic, and psychological differences between children and adults, additional differentiation in pediatric age groups for patients older than 2 years is also recommended. Furthermore, anesthesiologists providing or directly supervising anesthesia care in the categories designated by the facility's anesthesiology department as having heightened baseline anesthesia risk should be graduates of an Accreditation Council for Graduate Medical Education pediatric anesthesiology fellowship training program or its equivalent, or have documented historical and continuous competence in the care of such patients. The American Board of Anesthesiology also established subspecialty certification in Pediatric Anesthesiology in 2013. In order to qualify for the board examination, a minimum of 30% of an anesthesiologist's clinical practice must be devoted to pediatric cases, including neonates and children younger than 2 years and procedures considered high risk. Lastly, pediatric-themed mock codes and disaster drills should be performed quarterly in accordance with guidelines from accreditation organizations to train medical personnel.

Patients' characteristics are another essential consideration. prior to scheduling an ambulatory surgical procedure. Pre-operative evaluation is crucial to plan anesthetic care and assess the risk of the procedure. Effective communication

between the surgeon and anesthesiologist is important for the smooth functioning of an ambulatory surgery center. Contact before the scheduled surgery provides the family and patient with necessary instructions and the healthcare providers with updated information regarding the health status of the patient. This pre-surgical screening also identifies patients potentially unsuitable for ambulatory surgery. Some centers may organize an orientation/demonstrative visit for the patients and families with the presence of child life specialists. This additional effort, when possible, would serve to reduce anxiety and provide a more patient-focused experience.

## Day of Surgery

### Preoperative Evaluation

A careful history, physical examination, and the ability to communicate with the patient and family are the most important components of an organized preoperative process. As ambulatory surgery is growing, so will the variety of patients presenting as candidates for elective surgery. Interpreters (in person, phone or video) should be available, if needed, during the preoperative assessment. The family should accept the responsibilities of postoperative care after discharge and the patient should be accompanied by a responsible adult (parent or legal guardian) who must remain in the center for the duration of the procedure.

A thorough preoperative evaluation would determine the appropriateness of ambulatory surgery care. Screening panels are not commonly used; however, laboratory and ancillary tests and consults should be ordered if indicated by the results of the preoperative preliminary assessment. In general, a history or predisposition for difficult airway or difficult intravenous access, an unstable or serious illness, poorly compensated systemic disease, anticipation of postoperative complications, significant anticipated blood loss or need for invasive monitoring, and inability or unwillingness on the part of families to understand perioperative instructions are criteria for exclusion of a pediatric patient from an ambulatory surgery. Regardless of the method of preoperative evaluation, the anesthesiologist will need to perform a final assessment of the patient on the day of the procedure. The most common preoperative challenges in the ambulatory surgery center practice are prematurity, NPO violation, pregnancy testing, pediatric patients with hypotonia, the presence of an upper airway infection (URI) and the pediatric patient with obstructive sleep apnea.

#### The Premature Patient

Although the pediatric ambulatory patient population is composed in majority of healthy children of different ages; there are significant physiologic and anatomic differences to take into consideration during the selection of patients, especially when it relates to the premature infant. The progress in neonatal medicine has improved the survival rate of many premature neonates, who eventually would present as candidates for ambulatory surgery (such as inguinal hernia repair, examination under anesthesia, etc.) early in their lives.

In pediatric anesthesia and especially in young premature patients, the risk of cardiovascular collapse during anesthesia and surgery can be explained by the fact that cardiac output depends more on heart rate and the high resting heart rate does not permit an increase in cardiac output. There is less ability to increase cardiac contractility because of decreased ventricular compliance. Bradycardia in general, especially if resulting from hypoxia is particularly dangerous. There is an increased risk of hypoxia, hypercarbia and acidosis because of low lung volumes and poor compliance and an increase in intrapulmonary shunt and ventilation/perfusion mismatch. Small changes in ventilation can lead to shunting and desaturations. Oxygen desaturations can be very rapid because oxygen consumption (per kg) is higher than that of the adult and because closing volume is within the range of normal tidal volumes. Premature infants fatigue more quickly. Their chest walls, which are highly compliant with decreased recoil, require them to do more work in order to move a similar tidal volume, and make them prone to lung collapse [8–10].

Several studies have reported that former premature infants are at increased risk of significant respiratory complications, especially apnea. Apneic episodes especially in premature neonates/infants, usually involve both a failure to breathe (central apnea) and a failure to maintain a patent airway (obstructive apnea). Apneic episodes are inversely proportional to post conceptual age (PCA).

Limitations to conclude the safety of ambulatory anesthesia and surgery at a specific age in these patients are secondary to several discrepancies in different studies, including small number of patients, differences in anesthesia techniques and documentation of apnea. Risk factors for apnea and bradycardia include lower gestational age, history of apnea and bradycardia, hemoglobin below 10 gm/dl, and chronic respiratory disease [11–14]. Cote et al. calculated the predicted probability of apnea after leaving the recovery room by weeks postconceptual age for infants who did not have anemia or apnea in recovery room. The risk does not fall below 1% with 95% statistical confidence until 56 weeks postconceptual age [11]. Very young infants should be scheduled early in the day to allow prolonged observation if needed.

A randomized, controlled trial comparing apnea after awake regional and general anesthesia in infants aged 60 weeks postconceptual age or younger, scheduled for inguinal herniorrhaphy, showed that the incidence of early apnea (0–30 min) was lower in the regional group, however the incidence of late apnea (30 min to 12 h) was similar in both the regional and general anesthesia group. Therefore, cardiorespiratory monitoring should be used for all ex-premature infants [15].

Isolated case reports of apnea in full-term healthy infants undergoing minor procedures have appeared in the literature [16–19]. Data supporting appropriate age for term children to undergo outpatient surgery is scarce and a more prolonged observation in the recovery room may be required prior to discharge.

Prolonged PACU monitoring may not be feasible at busy ASCs and routine preoperative labs are not cost-effective. Most ASCs therefore have an age restriction (usually 60 weeks postconceptual age) under which patients will be excluded from their center. In addition some state departments of health also have age restrictions on patients that can be cared for at a free standing ASC.

### Preoperative Fasting

Another area of interest in pediatric ambulatory anesthesia is preoperative fasting and the risk of pulmonary aspiration of gastric contents. Accepted practice guidelines for preoperative fasting to reduce the risk of pulmonary aspiration are: 2 h for clear liquids, 4 h for breast milk, 6 h for formula, nonhuman milk, and light meal, and 8 h for a fatty meal [20]. It should be noted that interpersonal variation in residual gastric volume exists [21], and that a more conservative approach for patients presenting with diagnosis of gastroesophageal reflux may be required. Vigilance even in patients who followed the NPO guidelines is recommended [22].

Children who have been permitted fluids up to 2 h preoperatively have a more comfortable experience in terms of hunger and thirst [23]. Fasting policy can be reinforced by a preoperative reminder in appropriate candidates via a telephone call the night prior to surgery. These calls also help reduce cancellations on the day of surgery by eliciting any change in the child's health status such as an acute illness.

### Preoperative Pregnancy Testing

Pregnancy testing policies require ethical, logistical and legal considerations [24].

Depending on the studies, the incidence of undiagnosed pregnancy varies [25–27]. Concerns include the risks of congenital malformation, spontaneous abortion and medicolegal risks. There may be difficulty obtaining an accurate history from the adolescent female on the day of surgery, even in the absence of parents. Many ambulatory centers have established a policy for preoperative pregnancy testing for female patients of child-bearing age. A signed waiver of testing would be obtained in case of refusal of testing or inability to obtain a urine specimen for pregnancy testing on the day of surgery. A delicate and careful approach of the subject with explanation of risks is always preferable. A support structure, including (social workers) and referral ability should be available if testing is performed.

### Hypotonia

Patients with hypotonia or undiagnosed weakness present an anesthetic challenge. A genetic consult may be in the process of being obtained or inconclusive. Clinical concerns include associated abnormalities especially airway abnormalities, presence of cardiac and respiratory compromise and choosing the appropriate and safe anesthetic drug. The anesthesiologist would keep in mind the risk of malignant hyperthermia (MH), hyperkalemia, and the propofol infusion syndrome.

A trigger-free technique is necessary when anesthetizing children at risk of MH. These patients may be scheduled for a diagnostic muscle biopsy. A family history and the presence of anomalies or syndromes associated with MH are strong indicators to the presence of MH susceptibility.

Succinylcholine has the potential of producing hyperkalemia in patients with undiagnosed hypotonia [28] with an underlying diagnosis of muscular dystrophy.

Some reports suggest avoiding volatile agents in muscular dystrophy [29]. This concept is not universally accepted, and studies in patients with muscular dystrophy receiving volatile agents [30] showed that they may be used safely.

Propofol Infusion Syndrome (PRIS) is a potentially fatal syndrome, generally associated with lengthy, high-dose propofol infusions (>4 mg/kg/h for >48 hours). Some literature suggests that patients with mitochondrial diseases may be especially susceptible to PRIS [31] because propofol reduces the ability of mitochondria to perform various functions [32, 33]. Patients with mitochondrial myopathy usually have a pattern of acute worsening symptoms during crisis periods brought on by catabolic stress [34–36]. Minimizing fasting periods, avoiding lactate-containing fluids, maintaining hydration, and supplementing with dextrose, as well as monitoring anesthetic depth, temperature, blood sugar and acid-base status should be considered.

The decision to take care of these patients in an ambulatory practice should be made with the goals of achieving a safe anesthetic and the ability to successfully monitor for and manage any complications.

### Upper Respiratory Infection

Children presenting on the day of surgery with upper respiratory infections (URI) are at risk for developing perioperative respiratory adverse events (PRAEs). Risk assessment should include diagnosing the presence of acute or chronic respiratory disease as well as the duration and severity of symptoms. A URI if current, or occurring within the last 2 weeks, especially if associated with severe symptoms such as fever, wet cough, purulent secretions and systemic findings such as lethargy and poor appetite is associated with a high risk of PRAE [37, 38]. The presence of underlying respiratory problems such as chronic lung disease or asthma also increases the risk of PRAES. Other factors associated with a higher incidence of PRAE risk are a lengthy surgery with airway involvement as well as endotracheal intubation. Tait et al. published an algorithm for the assessment and anesthesia management of the child with an upper respiratory infection. It is suggested that in the case of elective surgery requiring general anesthesia, the anesthesiologist would be assessing the severity of symptoms of upper respiratory infection, including risk factors such as a history of asthma, the use of an endotracheal tube, the presence of copious secretions, nasal congestion, parental smoking, a history of airway surgery, and a history of prematurity [38].

### Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) is a disorder of breathing during sleep characterized by prolonged partial and/or intermittent complete upper airway obstruction that disturbs normal ventilation and sleep patterns [39]. The diagnosis of OSA cannot be made on history or physical examination alone. Criteria for diagnosing pediatric OSA have been established by The American Academy of Sleep Medicine [40]. Risk factors for OSA in children include obesity, adenotonsillar hypertrophy, craniofacial abnormalities that cause upper airway narrowing, decreased muscle tone from congenital or acquired disorders, and Down syndrome [41]. In patients with OSA, the severity of hypoxemia, hypercarbia, and apnea/hypopnea events on polysomnographic testing relates to increased risk of postoperative respiratory complications. In severe situations, OSA may be associated with pulmonary hypertension.

OSA is mostly, but not exclusively seen in children presenting for tonsillectomy and adenoidectomy. Since not all pediatric patients with OSA have undergone polysomnography, screening tools should focus on BMI, neck circumference, anatomical nasal obstruction, craniofacial abnormalities, tonsillar hypertrophy, and a history of loud snoring and breath-holding during sleep, interrupted sleep, and daytime sleepiness. Tait et al. have demonstrated the ability of the Snoring, Trouble Breathing, Un-Refreshed (STBUR) questionnaire to identify children at risk for perioperative respiratory and postoperative opioid-related adverse events [42].

Careful patient selection is critical to safe outcome. Children younger than 4 years of age have a higher incidence of unplanned admission and return to the surgery center compared with older children having ear, nose, or throat surgery [43, 44]. Also, the risk of postoperative respiratory complications, including fatal events, is higher in children with severe OSA. The American Academy of Otolaryngology–Head and Neck Surgery recommends overnight admission for monitoring after tonsillectomy in patients younger than 3 years of age with OSA or if OSA is severe (apnea-hypopnea index of 10 or more events per hour or oxygen saturation < 80%) [45]. Children with OSA have been shown to have increased sensitivity to opioids [46]. A cytochrome P450 variant causing rapid metabolism of codeine led to the Food and Drug Administration issuing a warning against using codeine for post tonsillectomy analgesia in children in early 2013 [47]. There have been numerous reports of adverse events, including death, after tonsillectomy [48]. Children with the comorbidities listed below are not candidates for ambulatory surgery. According to the American Academy of Pediatrics clinical practice guidelines, children with OSA are at a high risk for postoperative complications following adenotonsillectomy if they have any of the following conditions [49]:

1. Cardiac complications of OSA (e.g., right ventricular hypertrophy);
2. Craniofacial disorders;
3. Neuromuscular disorders;
4. Cerebral palsy;
5. Down syndrome;
6. Failure to thrive;
7. Morbid obesity;
8. Prematurity;
9. Sickle cell disease;
10. Central hypoventilation syndromes;
11. Genetic/metabolic/storage disease; and
12. Chronic lung disease.

Prolonged continuous cardiorespiratory monitoring may be required even in older patients with a problematic recovery course [50].

### Congenital Heart Disease

Pediatric patients with congenital cardiac disease may present for a wide variety of surgical procedures. A detailed preoperative assessment is required in pediatric

patients with a history of congenital heart disease. This would include the current physiopathology, hemodynamic status, baseline vital signs, exercise tolerance, medications, cardiac studies and cardiology follow up note or consult. These patients are at increased anesthetic risk, and should be handled by experienced anesthesiologists and skilled personnel. The surgical center should be well equipped in emergently required monitoring and treatment. Patients with partially corrected cardiac anomalies or single ventricle physiology are at increased risk with potential hemodynamic perturbations and may not be candidates for ambulatory surgery.

### Obesity

Obesity is a worldwide epidemic. It is associated with obstructive sleep apnea, difficult airway, restrictive lung disease, gastroesophageal reflux, insulin resistance and diabetes, difficult IV access, high risk of thromboembolic events, arterial hypertension, undiagnosed coronary artery disease and left ventricular diastolic dysfunction. If lipid soluble anesthetics are used, emergence times may be longer, and postoperative ventilatory support may be required. In patients with OSA, narcotics should be minimized or avoided, if possible, or calculated based on ideal body weight and titrated to response. Severely obese patients or obese patients with OSA, daytime somnolence, resting hypoxemia, or evidence of Pickwickian syndrome are not suitable candidates for ambulatory surgical centers.

## Premedication

There is no consensus among experts about the value of routine pharmacological premedication in the ambulatory setting due to the possibility of an extended sedative effect delaying patient discharge. The most commonly used compound for premedication is midazolam; it reduces anxiety and improves the quality of behavior at induction. Oral midazolam is the most commonly used agent and benefits from a relatively rapid onset and reliable effect. An oral dose of 0.25–0.5 mg/kg should be administered 20–30 min prior to taking the child to the operating room. Intranasal dose of 0.15–0.2 mg/kg can also be used. Intranasal dexmedetomidine dose of 1–3 mcg/kg has also been used successfully. It causes preoperative sedation and an improved recovery profile. Alternative pharmacolgic agents are oral ketamine (5 mg/kg) or fentanyl (15–20 μg /kg), even though these agents are sometimes associated with prolonged recovery (ketamine) and nausea, vomiting, and pruritus (fentanyl). Child life specialists and distraction techniques such as preoperative coloring books, stories, video games and websites may be used to help children of all ages learn about surgery and anesthesia and may permit children to cooperate. Outpatient surgery presents a unique opportunity for parental presence at induction largely due to the healthy patient population. Parental presence at induction may increase cooperation and parental satisfaction with the perioperative experience. Parental presence is often used as marketing tool in the competitive outpatient surgical arena. However, parental presence at induction remains controversial due to lack of evidence supporting the reduction in patient anxiety. The most current evidence does

not support parental presence at induction of anesthesia because it does not reliably alleviate the anxiety of either the children or parents [51]. Video games on phones or other mobile devices have been shown to reduce preoperative anxiety and improve patient co-operation with induction of anesthesia [52].

## Intraoperative Considerations

Smooth anesthetic induction and quick emergence remain the cornerstone of outpatient surgery. A prompt recovery in the post anesthesia care unit and quick discharge home with minimal pain and postoperative nausea and vomiting (PONV) is ideal. Specific agents or techniques should be chosen to fit the needs of each individual patient. It is imperative that the anesthetic plan covers the postoperative period with particular focus on the prevention of pain, agitation and postoperative vomiting. The American society of Anesthesiology monitoring guidelines should be applied to all outpatient pediatric patients regardless of the setting in which the surgery is performed.

### Anesthesia: Induction and Maintenance

Inhalation induction of anesthesia with sevoflurane is the preferred technique used by pediatric anesthesiologists [53]. The majority of children do not arrive in the operating room with an intravenous (IV) line due to needle anxiety. Sevoflurane is utilized because of its pleasant odor and low blood gas solubility coefficient which allows for rapid induction and recovery from anesthesia with little to no cardiorespiratory depressant effects. However, the disadvantages of sevoflurane include pollution of the operating room and excitatory movement during induction [54]. A mask can be easily applied for an inhalational induction to a child that is awake, sedated, sitting up, lying down, or on the lap of a parent. The strong odor of sevoflurane can be reduced by scented oils or flavors in the face mask to increase acceptance. Many pediatric anesthesiologists like to begin with 60% to 70% nitrous oxide ($N_2O$) first and then add sevoflurane once the effect of the $N_2O$ is noted. This permits the child to become sleepy before noticing the smell of sevoflurane. An inhalational induction with a nitrous oxide and oxygen mixture with a gradual introduction of sevoflurane may reduce the anxiety and excitement associated with induction. Alternatively, a single breath induction technique with sevoflurane (7–8% sevoflurane and 60% nitrous oxide) can be used to speed the induction. This single breath technique is most successful when the patient is shown how to take a vital capacity breath from a circuit that has been primed with 8% sevoflurane and then allowed to practice taking a breath [55]. After an adequate depth of anesthesia has been achieved, an intravenous line can be started. Propofol, opioids, and/or muscle relaxant can be administered to facilitate intubation. Patients typically pass through an excitement stage during which any stimulation can induce laryngospasm. During this time, breath-holding must be distinguished from laryngospasm. If required,

steady application of approximately 10 cm of positive end-expiratory pressure will usually overcome laryngospasm.

Isoflurane and desflurane have pungent odors which cause airway irritation making them a poor choice for inhalational induction of general anesthesia. In addition, desflurane is associated with an increased risk for adverse respiratory events. Therefore, despite its excellent pharmacokinetic profile, desflurane is not considered to be the primary induction choice for pediatric outpatient anesthesia by many practitioners, but can be used for maintenance of anesthesia [54].

### Intravenous Medications

Intravenous induction of anesthesia may be the preferred method in older children. Propofol is an ideal intravenous anesthetic induction agent in this patient population due to smooth induction of anesthesia without a discernible excitation stage. In addition, its rapid redistribution and metabolism results in a short duration of action. This allows it to be administered via repeated injections or by a continuous infusion with minimal accumulation, making it a suitable choice for total intravenous anesthesia (TIVA). It is also a good antiemetic agent, which is a very desirable characteristic in ambulatory anesthesia.

Pediatric patients have a large volume of distribution and rapid clearance, therefore requiring a higher per kilogram dose of propofol than adults. Because of this, the rate of infusion as well as the induction dose of propofol is normally higher in pediatric patients than in adults. The typical pediatric induction dose of propofol is 2.5–3.5 mg/kg. Propofol may be associated with pain on injection, which may be attenuated by co-administering lidocaine and utilizing a modified Bier (intravenous regional) block in the IV catheter with the lidocaine prior to injecting the propofol.

Dexmedetomidine is a lipophylic α-methylol derivative with a higher affinity for $\alpha_2$-receptors than clonidine. It has sedative, analgesic, and sympatholytic effects that blunt many of the cardiovascular responses seen during the perioperative period. Most importantly, dexmedetomidine has minimal effects on respiration and allows for agitation-free emergence. When used intraoperatively, dexmedetomidine reduces intravenous and volatile anesthetic requirements. When used postoperatively, it reduces concurrent analgesic and sedative requirements. The recommended dosing of dexmedetomidine is a loading dose at 1 mcg/kg over 10 min followed by an infusion at 0.2–0.7 mcg/kg/hr. Its elimination half-life is 2 hours with a rapid distribution half-life of 6 minutes. Dexmedetomidine is known to cause significant hemodynamic changes in pediatric patients, which include a decrease in mean arterial pressure and a decrease in heart rate from baseline values especially when administered too rapidly. Dexmedetomidine should be used cautiously in patients with a critically rate dependent cardiac output because increased side effects may be observed [56]. Dexmedetomidine appears to be effective in the reduction of postoperative agitation in children at intravenous doses ranging from 0.3 to 0.5 μg/kg [57]. At higher doses of dexmedetomidine, longer recovery times in PACU can be observed compared to propofol [58]. In tonsillectomy and adenoidectomy patients, the use of a single dose of intraoperatively administered dexmedetomidine had the advantages of an increased time to first analgesic and a reduced need for additional

rescue analgesic doses in the PACU [59]. Dexmedetomidine may be most beneficial to select groups of patients, such as those with sleep apnea, in which the sedative and respiratory depressant effects of conventional analgesic supplements would be highly undesirable [60].

## Multimodal Analgesia

Pain management is vital in children undergoing outpatient surgery and must include parental education regarding the assessment of their child's pain and analgesic needs following discharge. The analgesic plan should be considered before incision and once again prior to emergence. Preoperative analgesic administration is an effective way of preventing postoperative pain. An analgesic plan should take into consideration a multimodal approach that includes non-opioids, opioid analgesics, and regional and local anesthetic techniques when suitable for the patient. Acetaminophen 10 to 15 mg/kg orally is the most commonly used analgesic for pediatric outpatient surgeries. Alternatively, the absorption of a 45 mg/kg rectal dose of acetaminophen can be erratic and prolonged. At an additional cost, the IV formulation of acetaminophen, approved by the Food and Drug Administration, may be used in children not tolerating oral intake. The maximum dose of acetaminophen should not exceed 75 mg/kg for infants and children with a maximum dose of 4 g/day for adolescents [61].

Non-steroidal anti-inflammatory (NSAID) drugs are a class of compounds that inhibit cyclooxygenase (COX) enzymes and provide mild to moderate pain relief. They have opioid sparing effects and are often used in combination with opioids. Commonly used opioid sparing NSAIDs in the pediatric ambulatory setting are summarized in Table 13.1. Ibuprofen, dosed at 10–15 mg/kg every 6 hours, is the most commonly used oral NSAID. Ketorolac and Ibuprofen are intravenous NSAIDS available in the United States. The current recommended dosing for ketorolac is 0.25 to 0.5 mg/kg every 6 hours. Ketorolac provides postoperative analgesia that is comparable to opioids, in children of all ages. It lacks opioid side effects such as respiratory depression, sedation, nausea, and pruritus, making it a very attractive choice for the treatment of postoperative pain, especially in the ambulatory setting. However,

**Table 13.1** Commonly Used Opioid Sparing NSAIDs in Pediatrics

| Generic Name | Band Name | Dose mg/kg Frequency | Maximum Daily Dose |
|---|---|---|---|
| Acetaminophen | Tylenol ®, Tempra® Ofirmev® | 10–15 PO q 4 h25–40 PR q 8 h12.5 IV q 4 h | 4000 mg/day60 mg/kg/d preterm80 mg/kg/d term90 mg/kg/d older |
| Ibuprofen | Motrin ®, Advil ® IV form: Caldolor®, NeoProfen® | 5–10 PO, IV q 6–8 h | 3200 |
| Ketorlac | Toradol® | IV or IM Load 0.5 Maint0.2–0.5 q 6 hPO 0.25 | 120 |

like other NSAIDs, it does carry the risks of platelet dysfunction, gastrointestinal bleeding, and renal dysfunction. The use of ketorolac in children undergoing tonsillectomy remains unclear due to the increased risk of bleeding complications. The most current evidence does not support the routine use of ketorolac in tonsillectomy patients [61, 62]. Oral ibuprofen is effective for management of post-operative pain after tonsillectomy [63].

Dexamethasone provides analgesia via its anti-inflammatory effects and reduction of prostaglandins at sites of tissue injury. It also has the added benefit of PONV prophylaxis.

Opioids play an important role in the management of postoperative pain. IV opioids for moderate to severe pain require careful titration of dosing and frequent assessment of the patient to ensure adequate analgesia. The use of opioids is associated with side effects including nausea, vomiting, pruritus, sedation and respiratory depression which can delay discharge in the outpatient setting. Codeine and oxycodone elixir are the most commonly used oral opioids in the outpatient pediatric population. Oral opioids when dosed appropriately and at regular intervals maintain constant blood levels. Children with obstructive sleep apnea have increased sensitivity to opioids and therefore, avoidance or careful dosing of opioids is recommended in this population [64].

### Regional Anesthesia

Regional analgesia is an effective and safe means of providing pain control in the outpatient pediatric setting. The advantage of regional analgesia includes reduction in the use of narcotics and their undesirable side effects. An appropriate plan to follow must be discussed with parents for when the block wears off. A peripheral nerve block as well as central neuraxial blocks (caudal) can be used in the outpatient setting. Most of the regional blocks are placed after induction of general anesthesia. Neuraxial blocks in the form of single-shot caudal blocks are commonly used for providing analgesia for urogenital and lower extremity orthopedic procedures. Caudal block allows the clinician to provide a regional anesthetic with a high success rate combined with a low morbidity. Newer modalities including imaging with ultrasonography are available to aid guidance, but most clinicians utilize a landmark-based approach with a loss of resistance technique, allowing expeditious completion of the block. Caudal block is the most commonly performed regional anesthetic technique in children because it is easily learned, reliable, and effective. Caudal block can be used for a wide variety of surgical procedures such as circumcision, hypospadias repair, orchiopexy and inguinal herniorrhaphy. The other common regional techniques in the outpatient setting include ilioinguinal-iliohypogastric nerve blocks for inguinal hernia repairs and orchiopexy, and penile block for circumcision and hypospadias repairs. To avoid motor block and urinary retention in the outpatient setting after central neuraxial block, a dilute concentration of local anesthetic (0.1–0.15%) and monitoring of side effects is recommended [65–68]. Local anesthetic infiltration should be applied whenever possible because of its simplicity and its role as an important component of multimodal analgesia [69].

## PONV Prophylaxis

Prevention of postoperative nausea and vomiting (PONV) is an important aspect of any anesthetic. PONV is a particularly troublesome problem in the ambulatory setting where associated delays in discharge and possible hospital admission can drive up costs. Appropriate efforts to reduce the incidence of PONV in the pediatric population are crucial to the success of an ambulatory program. Because nausea is difficult to diagnose in the pediatric population, only active vomiting is typically studied and treated.

The average incidence of PONV in childhood is between 33.2% and 82% and can be twice as high as in adults. Due to this high incidence, prophylaxis is typically required [70]. PONV is ranked by parents as the most unwanted side effect from anesthesia. Patient factors, surgical factors and anesthetic factors have been identified as causes of PONV. Surgical factors include duration of surgery and specific types of procedures such as strabismus, laparoscopic surgery and tonsillectomy while anesthetic factors include the use of a halogenated anesthetic, nitrous oxide, and opioids. Previous studies have identified four risk factors that predict PONV in children: age 3 years and older, strabismus surgery, duration of surgery greater than 30 minutes, and previous history of postoperative vomiting in the patient, parent, or sibling. As depicted in Figure 13.1, the risk of postoperative vomiting (POV) was predicted as 9, 10, 30, 55, and 70%, respectively, depending on the presence of 0, 1, 2, 3, and 4 of these risk factors [71]. Despite these findings, the routine use of antiemetic therapies is not necessary for all pediatric patients in outpatient setting. The 2014 consensus guidelines for the Society for Ambulatory Anesthesia suggest that the use of prophylactic antiemetics should be based on a valid assessment of

| Risk factors | Points |
|---|---|
| Surgery ≥ 30 min. | 1 |
| Age ≥ 3 years | 1 |
| Strabismus surgery | 1 |
| History of POV or PONV in relatives | 1 |
| Sum = | 0 . . . 4 |

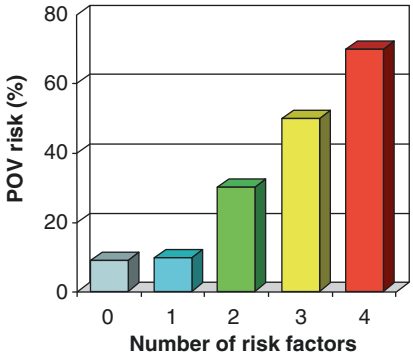


**Figure 13.1** Simplified Risk Score from Eberhart and Colleagues to Predict the Risk for POV in Children. When 0, 1, 2, 3, or 4 of the depicted independent predictors are present, the corresponding risk for PONV is approximately 10%, 10%, 30%, 55%, or 70%, respectively. (With permission from Gan et al. [79])

risk factors for POV as shown in Figure 13.1. These guidelines recommend that children deemed to be at moderate to high risk for PONV should receive combination therapy with prophylactic drugs from different classes.

*Dexamethasone* has been shown to be effective in reducing the incidence of PONV in children following tonsillectomy [72–75] and after strabismus surgery [76]. Dosing recommendations vary widely, but two dose-ranging studies found no additional benefits to using more than 0.25 mg/kg for decreasing PONV [74]. There was also improved pain control in tonsillectomy patients who received dexamethasone [74]. The potential for increased bleeding following tonsillectomy in patients receiving dexamethasone has been raised [76]. However, subsequent studies have not shown this effect and the improvements in PONV and throat pain appear to outweigh this risk. Appropriate dosing of dexamethasone is still unclear, although doses as low as 0.15 mg/kg have been effective to prevent PONV.

5-HT3 receptor antagonists (ondansetron and granisetron), steroids (dexamethasone), antihistamines (promethazine, diphenhydramine), and metoclopramide are the commonly used classes of drugs for PONV. Typical dosing for these medications is shown in Table 13.2. Ondansetron was the first 5-HT3 receptor antagonist to be FDA approved. It is available in generic form and has been studied extensively in adult and pediatric patients as a prophylaxis and for the treatment of PONV [77]. The recommended doses of ondansetron from the 2014 consensus guidelines for the Society of Ambulatory Anesthesia range from 0.05 to 0.1 mg/kg up to a total of 4 mg. Dose-response studies of ondansetron suggest that for maximal efficacy, prophylactic doses of 0.1 to 0.15 mg/kg up to 4 mg should be administered [78]. The safety and efficacy profile of ondansetron makes it the ideal choice for prophylaxis and treatment of PONV. Some rare side effects of ondansetron include QT prolongation and serotonin syndrome. Another 5-HT3 antagonist, granisetron, was effective when 0.2 mg/kg was administered orally prior to induction of anesthesia [79]. For prophylaxis against PONV, intravenous granisetron (0.04 mg/kg) has been shown to be highly effective with rare side effects. Granisetron is more potent with longer activity against vomiting associated with chemotherapy than ondansetron.

Reducing baseline risk factors is beneficial in preventing PONV in children. This can be accomplished by utilizing regional anesthesia, avoiding $N_2O$ and halogenated anesthetics, using propofol, providing adequate hydration, limiting opioids

**Table 13.2** Pediatric Antiemetic Dosing

| DRUG | INTRAVENOUS DOSE (mg/kg) | MAXIMUM DOSE (mg) | **Class of drug** |
|---|---|---|---|
| Ondansetron | 0.15 | 4 | 5HT3 antagonist |
| Dexamethasone | 0.15 to 0.25 | 8 | Steroids |
| Granisetron | 0.04 | 3 | 5HT3 antagonist |
| Dimenhydrinate | 0.5 | 50 | Antihistamine |
| Promethazine | 0.25–0.5 | 25 | Antihistamine |

in high risk patients, and administering prophylactic pharmacotherapy. Two-drug pharmacologic prophylaxis with ondansetron and dexamethasone has an expected relative risk reduction for PONV of approximately 80% [80, 81]. The current recommendations are to give prophylactic doses of ondansetron and dexamethasone to all children who are at moderate to increased risk of POV unless contraindicated. A meta-analysis of the combined administration of ondansetron and dexamethasone demonstrated that the combination of the two drugs was superior to either agent alone in preventing PONV in pediatric strabismus patients. Adequate hydration is another simple strategy to reduce postoperative emesis. High dose IV fluids at 30 mL/kg was associated with less emesis than the standard 10 mL/kg therapy during strabismus repair [82, 83].

## Post Operative Considerations

The recovery room should be equipped with the tools and personnel capable of managing crisis. The personnel involved must be adequately trained in pediatric care and be familiar with the specific problems encountered in that population. All nursing and medical personnel should be PALS (Pediatric Advanced Life Support) certified. A patient with postoperative concerns after anesthesia or surgery must be approached in a systematic fashion, using medical history, clinical findings and laboratory evaluation to rapidly identify and appropriately manage the most likely cause. The safety and adequacy of postoperative anesthesia care is highly dependent on the immediate availability of skilled help. In case of a major adverse event (respiratory or cardiac arrest) a code procedure must be in place in order to quickly recruit sufficient and pertinent support.

Cardiac arrest in healthy children is rare. Ambulatory recovery issues usually include mainly postoperative pain, airway and pulmonary complications, nausea and emesis, temperature abnormalities and delayed emergence [84, 85].

### Delayed Emergence

Delayed emergence is a major concern for the anesthesiologist. In most cases, causes of delayed emergence can be quickly clarified by clinical context. Different etiologies may be responsible for delayed awakening in a patient. The most common etiologies are classified as pharmacological, metabolic or neurological causes. Pharmacokinetics of various drugs differs significantly in children compared to adults. This may be due to immaturity of enzyme systems and clearance mechanisms and altered protein binding during the first years of life, leading to increased bioavailability and prolonged half-life of certain drugs. Immature hepatic function leads to decrease in drug metabolism. Reduced albumin synthesis leads to low albumin levels, thus enhancing the “free” concentration of anesthetic drugs that are highly bound to albumin. For a given dose of fentanyl, higher plasma fentanyl concentrations and a slower clearance of the drug will occur in infants(when

compared to older patients), which serves to prolong analgesia as well as prolong respiratory depression, increase the risk of postoperative apnea, and slow recovery of consciousness.

**Naloxone:** Reversal of the side effects of opioids (respiratory depression, CNS depression) by using naloxone (pure opioid antagonist with a greater affinity for the mu-opioid receptor) may be associated with severe pain and agitation. Therefore, if the patient is otherwise stable, and assisted ventilation is adequate, Naloxone is better titrated in a controlled setting while ensuring adequate ventilatory support. The onset time of naloxone is 1–2 min, and duration is dose dependent. Risk of "renarcotization" or "remorphinization" is always possible, since most opioids have a longer duration of action than naloxone. Prolonged follow up is recommended.

Naloxone may be administered via many routes, including intravenous, intraosseous, intramuscular, intratracheal and subcutaneous. For children who are ventilating but in whom opioid-induced respiratory depression necessitates antagonism in the perioperative period, it is reasonable to titrate naloxone intravenously in small doses of 0.25 to 0.5 mcg/kg IV, until improvement of ventilation. Some literature suggest that in order to ensure that recrudescence of the respiratory depression does not occur, the same cumulative total IV dose of naloxone is administered subsequently as an intramuscular injection. In some cases, a continuous infusion of naloxone may be required and adjusted to clinical response.

Allergy to naloxone has been described. Increased sympathetic activity, profound systemic hypertension, cardiac arrhythmias (including ventricular fibrillation), and pulmonary edema (noncardiogenic) have been reported with overzealous dosing of naloxone. Pulmonary edema may occur and may not be a dose-dependent side effect to naloxone [86]**,** since it has been reported after conservative doses.

**Flumazenil:** Reversal of hypnotic and sedative effects of benzodiazepines may be achieved with flumazenil. Since the duration of action of flumazenil is shorter than that of most benzodiazepines, reoccurrence of sedation is possible and patients should be monitored for maintenance of reversal, with repeat doses or IV infusion of flumazenil, if needed. For pediatric dosage; the initial dose is: 0.01 mg/kg (up to 0.2 mg) IV of flumazenil over 15 sec. It is suggested to administer an additional injection of 0.01 mg/kg/min where necessary, up to a max of 4 additional doses, until the desired level of consciousness is obtained; with a maximum total dose of 0.05 mg/kg or 1 mg, whichever is lower. Dizziness, nausea/vomiting, increased sweating, headache, abnormal or blurred vision, cardiac dysrhythmias, agitation, and injection-site pain may occur with flumazenil administration. Flumazenil has been associated with seizures [87].

### Residual Muscle Paralysis

Several factors may contribute to postoperative residual paralysis and prolonged neuromuscular blockade, including delay in metabolism and clearance, inadequacy of reversal, acidosis, electrolyte imbalance, hypothermia, and

interaction with other drugs [88]. Weakness of the pharyngeal muscles may result in upper airway collapse with airway obstruction after tracheal extubation. Hypoventilation resulting from residual neuromuscular blockade should be treated rapidly with ventilatory support, patient reassurance and sedation if needed until resolution of residual neuromuscular blockade. Reversal agents are supplemented in divided doses up to dose limits. Paradoxical weakness may result from excessive reversal agent administration [89]. Suggamadex is a relatively new reversal agent, effective in antagonizing rocuronium rapidly after the onset of neuromuscular blockade. It encapsulates rocuronium and prevents further action of rocuronium.

To date, there remain limited data regarding the use of sugammadex in pediatrics, from prospective trials in pediatric patients. Administration of suggamadex has been reported for the reversal of neuromuscular blockade in difficult clinical scenarios such as children with neuromuscular diseases including myasthenia gravis, Duchenne muscular dystrophy, and myotonic dystrophy [90]. Sugammadex was well tolerated in children with a faster recovery and extubation times and lower incidence of adverse events compared with neostigmine [91].

The workup for delayed emergence starts usually with the most common reasons. After considering residual anesthetic effects in a patient who experiences delayed emergence, a rapid check of the other common causes is undertaken such as increased sensitivity to anesthesia medications (Age, drug interactions, renal or hepatic disease, obesity...); delay in arousal may also result from hypercarbia, hypothermia and metabolic pathologies. Other causes are hypoxic brain injury, or neurological insult such as ischemia/ hemorrhagic stroke, acute increase in intracranial pressure, or undetected head injury. After ruling out residual drug effects, if decreased awareness persists beyond a reasonable period of observation, with normal serum glucose, arterial blood gases and electrolytes values, central nervous system (CNS) etiologies must be considered. Postictal status may be considered in a patient with seizure history. All of these situations will require transfer to a hospital for further work up and observation.

### Hypothermia

Children and especially infants are easily susceptible to hypothermia due to limited fat reserves and a larger surface area to volume ratio. Evaporative heat loss and insensible fluid loss as well as conductive and convective heat loss are increased in this age group compared to adults. Prevention of hypothermia is crucial to avoid pharmacological and physiological consequences such as hemodynamic, respiratory and metabolic effects, apnea and metabolic acidosis.

Effects of hypothermia include vasoconstriction with an increase in systemic vascular resistance and central venous pressure, a decrease in renal blood flow and glomerular filtration with cold diuresis, impaired coagulation and a leftward shift of oxyhemoglobin dissociation curve, as well as an increase in wound infections and an increase in duration of hospitalization. Hypothermia may be associated with electrocardiographic abnormalities. It decreases the response to hypercapnia, increases solubility of volatile agents, increases protein binding, reduces rate of

biotransformation and clearance of medications resulting in prolonged neuromuscular blockade. Hypothermia delays emergence and discharge from the recovery room and may prolong the need for ventilatory support.

### Airway and Pulmonary

The Pediatric Perioperative Cardiac Arrest Registry indicates that respiratory-related cardiac arrests occur among otherwise healthy patients, and that laryngospasm with hypoxia is a frequent trigger [92].

Young pediatric patients are obligate nose breathers, therefore, any unfavorable upper airway conditions like excessive secretions or inflammation can lead to increased work of breathing. The selection of an appropriately sized endotracheal tube and ensuring an adequate air leak around the tube cuff is important since a minimal amount of swelling of the tracheal mucosa may produce a significant obstruction in airflow. Whenever appropriate, and in the absence of risk of gastric regurgitation and absence of abundant pharyngeal secretions, the use of an LMA would help avoid tracheal irritation. The LMA may offer many potential benefits in ambulatory care in reducing sore throat, and in preventing complications of laryngoscopy and muscle relaxants.

Children younger than 3 years with OSA, especially if associated with an upper respiratory tract infection within 4 weeks of surgery are at increased risk of postoperative respiratory complications [93, 94]**.** A history of prematurity, significant neurological or neuromuscular disease and echocardiographic evidence of pulmonary hypertension increased the risk [95]. Of patients younger than 6 years undergoing an adenotonsillectomy for treatment of OSA, 6.4% developed a postoperative respiratory complication including oxygen desaturation below 90%, apnea or increased work of breathing (requiring insertion of a nasopharyngeal airway, continuous positive pressure ventilation, or endotracheal intubation), or atelectasis, pneumothorax, and pulmonary edema.

Enlarged lingual tonsils were reported to contribute to persistent obstructive sleep apnea after adenotonsillectomy and were found to be more prevalent in patients with Down syndrome [96]. All patients should be carefully assessed at the end of anesthesia and in the postoperative period.

### Pain

Pain remains one of the most frequent complications after ambulatory surgery. Available resources should be implemented in order to optimize pain management**.** Multimodal, opioid- sparing analgesic techniques decrease perioperative respiratory complications. The recovery room instructions should include clear doses and intervals for administration of pain medications. The instructions should also include information on whom to contact in the event of unrelenting pain and when to seek emergency medical treatment.

### Emergence Agitation

Emergence agitation or emergence delirium occurs mostly in patients younger than 6 years of age (more commonly in children 2–5 years of age) and is usually

manifest by the child who is thrashing, disoriented, inconsolable and unable to recognize parents or surroundings. Discharge from the PACU may be delayed in part because of the delirium or because of the recovery time from the effects of the medications and treatment administered to treat the delirium. Injury to the child who is extremely agitated is a concern and parental satisfaction may decrease when severe emergence delirium occurs. The etiology of emergence delirium is not totally clear and it may be difficult to differentiate from postoperative pain or pure agitation. Two scoring systems have been published and used to differentiate emergence delirium from pain. The Postanesthesia Behavior Assessment Scale (PABA) [97], based on perceptual disturbances, hallucination type, and psychomotor behavior and the Pediatric Anesthesia Emergence Delirium Scale (PAED) [98], based on eye contact with caregiver, presence of purposeful actions, awareness of surroundings, restlessness and inconsolability. Emergence delirium appears to occur more frequently after less-soluble inhaled anesthetics due to their rapid wash out. There may be a greater incidence of emergence delirium after painful procedures, but emergence delirium may develop after procedures free of pain. It generally lasts 5–15 min, and resolves spontaneously if the child is undisturbed or held by the parents. Interventions used to decrease the duration and intensity of emergence delirium may include the administration of opioids or propofol. A low dose of intravenous or intranasal fentanyl has been shown to decrease the duration and intensity of emergence delirium, even in the absence of significant painful stimuli. Dexmedetomidine and propofol have been shown to decrease the incidence of emergence delirium. Other adjunctive agents include ketorolac and acetaminophen [99].

## Discharge Criteria

The use of a postanesthesia discharge scoring system should be implemented in every ambulatory surgery center to ensure safe recovery and discharge after anesthesia. The postanesthesia recovery score (Modified Aldrete score) is used to evaluate the initial recovery of the patient. It is based on scoring for activity, respiration, circulation, consciousness, and skin color. The discharge of patients should be criteria based, not time based. Discharge criteria from an ambulatory surgical center are different from discharge criteria from the recovery room to a hospital bed. Outpatients should achieve their baseline consciousness, be able to ambulate (as per baseline), be well hydrated, hemodynamically stable, maintain adequate ventilation and oxygentation on room air, have well controlled pain, minimal to no nausea/vomiting, and able to tolerate oral intake (as per baseline). It is not necessary to void before discharge. Oral intake is not forced if the child does not want to eat or drink. After these criteria are reached, home readiness can be evaluated. The application of any discharge criteria scoring system must be combined with clinical judgment. Once the patient has satisfied the clinical criteria, written instructions and provisions for follow-up are discussed in the presence of an adult escort who is qualified to take care of the child.

## Safety and Quality

The success of safe and expeditious conduct of ambulatory surgical care resides in careful selection of patients and surgical procedures, appropriate intraoperative and postoperative anesthetic care, and prudent and timely discharge of patients. Despite a relatively low complication rate, ambulatory surgery facilities need to be prepared to manage life-threatening emergencies. Outpatient surgery requires the same equipment standards as inpatient hospital cases. Basic laboratory testing capabilities, processing facilities for equipment sterility and maintenance, and an informatics system for medical record utilization should be available on site. Resuscitation equipment specific to pediatric patients of all ages must be available. An airway cart that includes video laryngoscopy, a fiber-optic bronchoscope, and an emergency cricothyrotomy kit should be available. A plan and an agreement for transfer arrangements must be implemented to accommodate any patient who develops complications requiring more extensive care and hospital admission [6, 7]. Having a backup service to receive calls or address concerns after discharge and to promptly and expeditiously direct patients in case of complications or related concerns is an important requirement. The backup systems outside the hospital such as ambulance systems, phone access, road communication and available transport personnel need to be ready and dependable.

In order to ensure patient safety during the late recovery phase, most ambulatory surgical centers have a follow up system where the family receives a phone call on the first postoperative day. During this call, information about fever, bleeding, pain experienced and pain control, length of regional/ local anesthetic, ambulation and return to daily activities, nausea or vomiting episodes if any, and oral intake are collected. Any early postoperative complications are identified and either treated or the patient is directed to seek medical attention. Compliance with postoperative instructions is verified and clarifications are provided.

Ongoing quality assessment programs are an integral part of the ambulatory surgery center. Checklists, drills and simulated emergency scenarios as well as practice guidelines and emergency guidelines are important in educating and training the staff and establishing an efficient team. Adherence to guidelines set by the American Society of Anesthesiologists (ASA) as well as the Society of Ambulatory Anesthesia (SAMBA) is essential.

Registries of adverse events associated with anesthetic care for the pediatric population have influenced pediatric anesthesia practice through the years. In 2006, members of the Society for Pediatric Anesthesia (SPA) Quality and Safety Committee proposed that using process and outcome measures that reflect quality in anesthesia and identifying institutions that performed well on those measures would help other institutions improve the quality of their pediatric anesthesia care delivery. Subsequently, in 2008, the SPA developed the quality improvement (QI) initiative, Wake Up Safe (WUS). Wake Up Safe is a patient safety organization composed of pediatric institutions, that strives to use QI to make anesthesia care safer. The goals of the organization are to embed QI and safety analytics into pediatric anesthesia departments and institutions to decrease serious adverse events in

children undergoing anesthesia. Data obtained from Wake Up Safe have offered insight into adverse events occurring in pediatric anesthesia. Since data collection began, an average of 1.4 serious adverse events per 1000 anesthetics have been reported. Although it is possible that these numbers are affected by under-reporting or over-reporting, this rate corresponds closely to other rates in the literature [100]. Respiratory events were the most common serious adverse event and often arose from complete airway obstruction treated successfully before progressing to cardiac arrest. The next most common events in decreasing order were cardiac arrest, care escalation, and cardiovascular events. In total these categories comprised 76% of all reported events. Care escalation was defined as events that did not lead to serious temporary or long-term harm but required additional treatment and resources, such as unplanned admission to a hospital or ICU. Care escalation events arose from medication errors (65%), equipment dysfunction (24%), blood reactions (9%), malignant hyperthermia (1%), and operating room fire (1%) [96] These described QI initiatives are the ones most commonly used in ambulatory settings [101]. QI projects require a consistent framework for improvement. The framework provides the structure for outlining a process; identifying problems; and testing, evaluating, and implementing changes. The Quality and Safety Committee of the SPA is composed of more than 40 members representing the anesthesiology and pediatric anesthesiology departments of their member institutions and promotes QI and patient safety in pediatric anesthesia through initiatives, such as a critical events checklist and an intraoperative handoff tool, both of which are available on the SPA Web site (http://www.pedsanesthesia.org/).

Incident reporting system (IRS) is an important patient safety tool for identifying both risks and opportunities for improvement. Multiple studies have shown that voluntary incident reporting via an IRS is primarily limited by underreporting. Mandatory IRS data entry and interventions designed to support motivators of, and reduce barriers to incident reporting were associated with sustained increases in the reporting of adverse events [98]. IRS that is mandatory, secure, legally protected, and well-integrated into anesthesiology workflow appears to increase reporting.

The clinical success of a pediatric ambulatory anesthesia practice resides in appropriate qualifications and knowledge, efficient communication, team expertise and readiness in providing individualized care and making the experience safe and comfortable for both parents and children.

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# Sedation Guidelines

# 14

Rosalind Ritchie-Dabney and Uma R. Parekh

## Introduction

Sedation for painful procedures predates general anesthesia. Before the discovery of nitrous oxide, surgeons used agents as varied as alcohol and opium to reduce the pain and anxiety related to injury and surgery. In modern terms, these patients were not anesthetized but were semiconscious or awake but somnolent. It was not until the mid-nineteenth century, when a dentist by the name of Horace Wells noted that nitrous oxide could have a profound effect on consciousness and perceived pain, that clinicians began to offer patients a level of sedation that approached general anesthesia [1]. With the discovery of local anesthetics and their widespread use as a means to relieve pain during surgical procedures, the use of nitrous oxide as a sedating agent became less popular. Subsequently, nitrous oxide was combined with compounds such as chloroform and halothane, producing an unconscious state well beyond sedation. Nitrous oxide, by reducing anxiety and providing analgesia, then became an adjuvant to pain control when used with more potent agents.

Today healthcare providers administer sedation to patients via a variety of routes. The management of patients receiving sedation for surgical and non-surgical procedures requires a deep understanding of the continuum of consciousness associated with the administration of sedating drugs. Consciousness can be lost during attempts to sedate patients because the activity of agents that depress the central nervous system is not always predictable. This continuum of sedation, inadequate monitoring, poor patient selection, and insufficient training can lead to adverse events when

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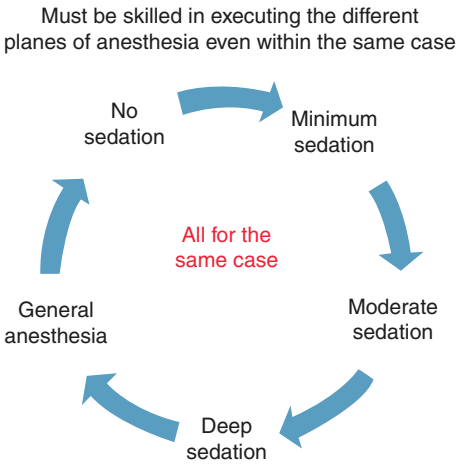


**Figure 14.1** Shows the different levels of sedation and general anesthesia. The optimal level of sedation varies with each surgical procedure. Anesthesia providers must be capable of effectively performing a continuum of anesthesia planes, sometimes for the same case to achieve the ideal level of patient comfort and safety

both anesthesia and non-anesthesia providers are involved. With the migration of inpatient surgeries to outpatient and office-based practices, the development of newer anesthetic drugs, the use of regional anesthesia, and new surgical techniques, sedation anesthesia and analgesia will continue to evolve, but will always require a complete understanding of applicable guidelines, regulations, and facility categories (Figure 14.1).

The purpose of this chapter is to define levels of sedation, to identify the risks of sedation, to address the requirements for patient safety in all clinical circumstances, and to evaluate current sedation guidelines. The most recent updates on sedation and its applicability in the ambulatory setting will be discussed.

## Definition of Sedation Levels

Consciousness reflects a biologic continuum. Sedation with agents that depress the CNS interrupts that continuum in ways that are not always predictable based on the agents themselves or the unique and highly individualized response in each subject. Though sedation is divided into three categories, light, moderate, or deep, in fact, this categorization does not reflect the reality of a lack of readily identifiable stop points in the movement of a patient from one level to the next. This lack of a dividing line is significant because the safety of the patient hangs in the balance. Deepening of sedation is associated with declining physiological self-protections, primarily within the airway. The point at which the circumstance is unsafe for the patient is variable. The conscious patient is capable of protecting the airway from foreign matter regurgitated from the esophagus and stomach. The sedated patient at some point in the continuum of consciousness cannot, and clinicians are rarely able to identify associated levels of risk despite experience in sedation management. The American Society of Anesthesiology (ASA) describes and defines three levels of sedation anesthesia [2]. Four parameters for each level of sedation, including general anesthesia, are used to define each level. It is paramount that the provider of sedation anesthesia completely understands these definitions for the following

reasons; (1) each clinician and non-clinician that administers sedation anesthesia have different requirements, degrees, training, and limitations; (2) facility categories also differ in regulations at both the state, local and federal level as to what type of anesthesia can be provided to patients.

Minimal sedation (anxiolysis) is a drug-induced state defined as a patient that has a standard verbal or non-verbal response to vocal stimulation, and the cardiovascular function, spontaneous ventilation, and airway remain intact and unaffected. Moderate sedation (conscious sedation) is a drug-induced state defined as a patient who has a "purposeful" response to vocal stimulation alone or in addition to tactile stimulation. Vital signs, spontaneous ventilation, and airway systems may remain unaffected in moderate sedation. Deep sedation is a drug-induced state defined as a patient who responds purposefully only to repeated painful stimuli because normal vocal or tactile stimulation do not easily arouse them. These patients may require intervention for airway and ventilation management; however, cardiovascular parameters usually remain intact. Patients under general anesthesia are unarousable to painful stimuli and need cardiovascular, ventilatory, and airway support (Table 14.1).

**Table 14.1** Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia

| | Minimal Sedation (anxiolysis) | Moderate Sedation/ Analgesia (Conscious Sedation) | Deep Sedation/ Analgesia | General Anesthesia |
|---|---|---|---|---|
| Responsiveness | Normal response to verbal stimulation | Purposeful* response to verbal or tactile stimulation | Purposeful∗ response after repeated or painful stimulation | Unarousable, even with painful stimulus |
| Airway | Unaffected | No intervention required | Intervention may be required | Intervention often required |
| Spontaneous ventilation | Unaffected | Adequate | May be inadequate | Frequently inadequate |
| Cardiovascular function | Unaffected | Usually maintained | Usually maintained | May be impaired |

Adapted from the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists [29] (*With permission of Wolters-Kluwer Health, Inc.*)

Minimal Sedation (Anxiologist) = a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventillatory and cardiovascular functions are unaffected

Moderate sedation/Analgesia (Conscious Sedation) = a drug-induced depression of consciousness during which patients respond purposefully∗ to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patient airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained

General Anesthesia = a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patient airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients who enter a state of general anesthesia

∗Reflex withdrawal from a painful stimulus is not considered a purposeful response

As simple as these definitions may seem, providing sedation can be challenging and uncertain. Sedation anesthesia and analgesia often occur in remote locations such as offices, MRI suites, dental clinics, hospital bedsides, endoscopy suites, emergency rooms, in addition to operating rooms. This dilemma of variable locations and providers poses a real hazard to patient safety,

## Patient Safety

Variability in levels of sedation and the perception that the actual procedures are short and inconsequential has led some to suggest that requirements for providing safe sedation can be curtailed without danger to the patient. These observations have often been exacerbated by the lack of complete knowledge of outcomes in patients sedated outside of medical centers. The lack of published reports of deaths and neurological injuries has been interpreted to mean that sedation without proper monitoring, training, and vigilance is safe. Recent closed claims analyses suggest otherwise.

Bhananker, Posner, and others reviewed all medical claims associated with Monitored Anesthesia Care (MAC) in the ASA Closed Claims Database. They found that over forty percent of claims related to sedation involved death and permanent neurological brain injury and was similar to the statistics for general anesthesia. They concluded that over-sedation, respiratory depression, and inadequate monitoring were the primary causes for mortality and morbidity during MAC cases [3]. Hug and others have suggested that patient injuries during MAC cases are due to the attitudes of anesthesia and surgical personnel. The notion that MAC is "safe" can lead to less vigilance and diligence on the part of the surgical and anesthesia team [4]. Hug proposed that MAC should stand for "Maximum Anesthesia Caution" [4].

The number of MAC sedation adverse events is unknown. Findings by Bhananker, Hug, and others were limited to the ASA Closed Claims Database. Sedation anesthesia was provided to patients in a vast number of locations and by a variety of non-anesthesia providers. The safety of these practices is currently not possible to estimate given that there are limited reported adverse events and clinical outcomes in the literature in these locations and by non-anesthesia providers. It is not until celebrities, such as Joan Rivers, suffered damage or death that the topics of patient safety, sedation guidelines, and provider credentials have come to national attention.

The Center for Medicare and Medicaid Services (CMS) issued a change in 2009 to its guidelines requiring that an anesthesiologist must oversee deep sedation anesthesia and analgesia [5]. Massachusetts General Hospital's department of Anesthesiology reviewed a historical cohort of endoscopic procedures. They studied the incidence of adverse events comparing patients who received sedation by gastroenterologist-supervised RNs to those who received sedation by anesthesiologists or anesthesiologist-supervised CRNAs. They found a statistically significant reduction in reported sedation-related adverse events when anesthesia personnel were involved (.38% RN vs. 08%CRNA) [6].

With the increase in complex surgical procedures, increasing numbers of elderly and pediatric patients scheduled in non-OR locations for surgical and diagnostic procedures requiring sedation, the American Society of Anesthesiologists and other

societies have developed clinical guidelines to ensure safe practices for administration of sedation.

The ASA guidelines clearly define which practitioners should be granted privileges for the administration of moderate sedation [7].

(i). Anesthesia Professional: anesthesiologist, nurse anesthetist or anesthesiologist assistant
(ii). Non-anesthesiologist Sedation Practitioner: Licensed physician, dentist, or podiatrist who has not completed postgraduate training in anesthesiology but trained to administer and supervise the administration of moderate sedation.
(iii). Supervised Sedation Professional: a licensed registered nurse or advanced practice nurse or physician assistant who is trained to administer medications and monitors patients during moderate sedation under the direct supervision of an anesthesiologist or a non-anesthesiologist sedation practitioner

This statement applies to any facility type: dentistry offices, physician offices, hospitals, surgery centers, MRI suites, endoscopy suites. Therefore, all non-anesthesia professionsals that administer medications via any route across the continuum of sedation anesthesia and analgesia should have the training and skills to rescue and resuscitate any patients whose level of sedation reaches an unintended state. They should be able to perform a complete patient history and physical examination, pre-operative anesthesia evaluation, anesthetic assessment plan and acknowledge any risks factors that may pose a risk to the patient. Anesthesiologists remain the experts in the physiology, pharmacology and clinical care of patients that are administered sedation anesthesia, analgesia, regional anesthesia, and general anesthesia. A non-anesthesia professional should initiate a consultation with an anesthesiologist for questions and patient concerns, and a request for patient care when the anesthetic care is outside the capability of the professional's skill set. The ASA clearly states that an anesthesia professional should be consulted to provide sedation anesthesia if a practitioner is not trained in the rescue of patients from general anesthesia, or for prolonged or therapeutic procedures requiring deep sedation, anticipated intolerance to standard sedatives or ASA class IV or V patients (Table 14.2).

**Table 14.2** ASA Classification

| ASA PS Classification | Definition |
|---|---|
| ASA I | A normal healthy patient |
| ASA II | A patient with mild systemic disease |
| ASA III | A patient with severe systemic disease |
| ASA IV | A patient with severe systemic disease that is a constant threat to life |
| ASA V | A moribund patient who is not expected to survive without the operation |
| ASA VI | A declared brain-dead patient whose organs are being removed for donor purposes |
| E | Denotes Emergency Surgery |

Adapted from the American Society of Anesthesiologists website, https://www.asahq.org

## Patient Selection and Pre-operative Evaluation

The first phase of sedation anesthesia and analgesia is patient selection and evaluation. A preoperative assessment is defined as the process of clinical evaluation that precedes the delivery of anesthesia for surgical and diagnostic procedures [8]. Anesthesia professionals are familiar with pre-operative anesthesia evaluation, however, this is not a usual practice or learned knowledge for non-anesthesia professionals. The preoperative anesthesia evaluation is an inherent part of the standard of care for anesthesiologists, regardless of the type of anesthetic delivered. The Joint Commission requires that all non-anesthesia professionals perform a pre-operative assessment when there is a potential for a compromised airway, respiratory depression, and cardiovascular dysfunction, as in the case of moderate or deep sedation [9]. The pre-operative anesthesia assessment should include a comprehensive review of the patient's past and current medical records, diagnostic tests, laboratory results, previous surgeries and anesthetics, and any related complications and a complete physical examination.. A thorough and comprehensive review of systems for each patient should be performed to assess the patient's ASA Classification and the imminent risk for anesthesia and surgical complications.

Preoperative evaluation deficiencies may lead to unanticipated adverse events, morbidity, and mortality. The Australian Incident Monitoring Study (AIMS) found that 11% of reported adverse anesthesia events in the Australian claim database were attributed to a pre-operative evaluation not being performed, and 23% of adverse events were because the anesthesiologist in the surgical case had not conducted a pre-operative anesthesia assessment (Table 14.3). Fifty-seven percent of these events were reported to be preventable with better preoperative anesthesia assessment and evaluation [10]. Metzner and colleagues looked at the ASA Closed Claims Database from 1990 and later to assess the patterns of injury and liability in office settings versus operating rooms (Table 14.4).

Nearly fifty percent of sedation anesthesia and MAC cases occur outside of the operating room. Metzner and others concluded that patients over the age of seventy (27%), patients with an ASA Classification of three and four (57%) and obese patients (56%) had complications related to sedation, anesthesia, and analgesia [11]. Adverse events, such as cardiopulmonary decompensation evident by desaturation, hypoxemia, hypercarbia, hypotension, and unintended moderate and deep sedation can occur in patients with increased co-morbidities. The ASA Task Force recommends that all major organ systems, previous anesthesia experience with sedation, general and regional anesthesia, allergies, medications, smoking history, and a focused physical and airway examination be performed and thoroughly reviewed. The current and updated ASA 2018 sedation guidelines for moderate sedation now recommend that the pre-operative anesthesia evaluation be done days to weeks before the day of surgery and again immediately before the procedure. This differs from the original ASA Task Force 2002 sedation guidelines that required that a pre-anesthetic evaluation be done immediately before surgery regardless of the level of anesthesia. The pre-anesthesia evaluation recommendations for deep sedation have not been published to date.

**Table 14.3** AIMS Contributing Factor

| Contributing factor | % Number of reports |
|---|---|
| Poor airway assessment | 29 |
| Communication problem | 23 |
| Inadequate evaluation | 21 |
| Drug management error | 10 |
| No anesthetic review | 7 |
| Inadequate pre-operative resuscitation | 6 |
| Inadequate blood x-matched | 3 |
| Patient factors | 1 |

Adapted from Kluger et al. [11] (*With permission of John Wiley and Sons*)

**Table 14.4** Characteristics of remote location claims associated with oversedation ($n = 26$)

| Characteristic | *n* | (%) |
|---|---|---|
| Aged 70 years or older ($n = 26$) | 7 | (27%) |
| ASA physical status 3–5 ($n = 26$) | 14 | (54%) |
| Obese ($n = 18$) | 10 | (56%) |
| Location ($n = 26$) | | |
| Cardiology | 4 | (15%) |
| Gastrointestinal suite | 15 | (58%) |
| Lithotripsy | 3 | (12%) |
| Radiology | 4 | (15%) |
| Sedative agents ($n = 22$) | | |
| Propofol and benzodiazepines/opioids/ketamine | 12 | (55%) |
| Propofol alone | 5 | (23%) |
| Benzodiazepine, opioid or both | 3 | (14%) |
| Methohexital | 2 | (9%) |
| Monitoring in use ($n = 26$) | | |
| Pulse oximetry only | 18 | (69%) |
| Both pulse oximetry and capnography | 4 | (15%) |
| Neither | 4 | (15%) |
| Preventable by better monitoring ($n = 24$) | 15 | (62%) |
| Death or permanent brain damage ($n = 26$) | 24 | (92%) |
| Substandard care ($n = 22$) | 19 | (86%) |
| Payment to plaintiff | | |
| Payment made ($n = 26$) | 19 | (73%) |
| Median (range) of payments ($n = 19$) | $460,000 | |
| | ($47,600 - 7,062,500) | |

Table recreated from: Metzner et al. [30] (*With permission of Wolters-Kluwer Health, Inc.*)
ASA, American Society of Anesthesiologists. Percentages are based on claims without missing data. Denominators are listed in parentheses
Payments were adjusted to 2007 dollars using the Consumer Price Index

The preoperative fasting rules should also apply to sedation anesthesia and analgesia as recommended by the ASA. Individual hospitals, diagnostic centers, office suites and non-operating room departments may have their own fasting guidelines. It is essential to become familiar with and review these guidelines to be in compliance with hospital policy and to be sure that these guidelines comply with the ASA guidelines. Currently, the literature is inconclusive as to the safety and efficacy of preoperative fasting. Some studies have concluded that longer fasting times are less

**Table 14.5** Fasting Recommendations

| Ingested Material | Minimum Fasting Period |
|---|---|
| Clear liquids | 2 hours |
| Breast milk | 4 hours |
| Infant formula | 6 hours |
| Nonhuman milk | 6 hours |
| Light meal | 6 hours |
| Fried foods, fatty foods, or meat | Additional fasting time (e.g., 8 or more hours) may be needed |

Adapted from Ref. [31] (*With permission of Wolters-Kluwer Health, Inc.*)

efficacious and do not improve patient safety [12]. Green, Mason, and Krauss conducted the first systematic review of published pulmonary aspiration incidence during sedation anesthesia and analgesia in patients of all ages. Nearly 3 percent of the identified records described one or more occurrences of pulmonary aspiration during sedation anesthesia and analgesia. The gastrointestinal endoscopy suite was found to have a significantly higher incidence of aspiration morbidity and mortality [13]. Observational studies have indicated the nil per os (NPO) status and the prevalence of aspiration during sedation is relatively infrequent, and even rare [13–15]. Despite the ongoing debate to rethink the current NPO guidelines, the ASA Task Force recommends the following guidelines to be used in sedation, general and regional anesthesia, and analgesia (Table 14.5).

## Sedation and Monitoring

Serious adverse events have been reported related to monitored anesthesia care. Cardiovascular decompensation, respiratory depression, and arrest, permanent neurological brain injury and death are associated with surgical and diagnostic procedures during and after sedation in both adults and children [3]. The severity of sedation anesthesia adverse events is comparable to those of general anesthesia (Figure 14.2). Nearly half of these MAC-associated adverse events were deemed preventable with better monitoring.

The monitoring of patients undergoing surgical and diagnostic procedures with sedation requires the same level of vigilance for measuring and recording physiologic parameters as with patients administered general anesthesia. Patient monitoring described by the ASA Task Force consists of five measured parameters; (1) Level of consciousness (2) Oxygenation and ventilation (3) Hemodynamic monitoring (4) Recording of monitored parameters (5) Availability or presence of an individual for patient monitoring.

Although there is insufficient evidence to support that qualitative monitoring of a patient's level of consciousness improves patient safety or decreases adverse events, the ASA Task Force recommends a five-minute interval monitoring of a patient's response to verbal commands and tactile stimulation. Some studies have shown no conclusive evidence to support the use of depth of sedation monitoring

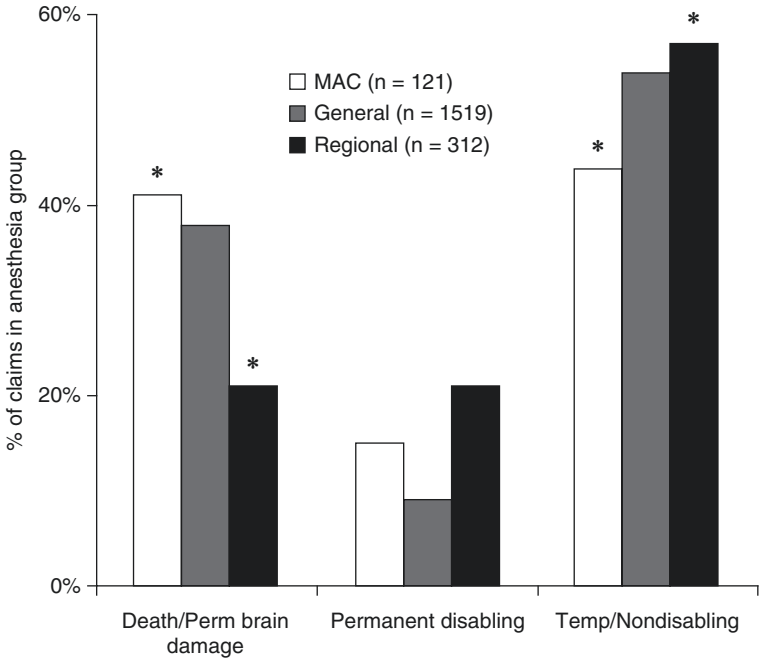


**Figure 14.2** The severity of injury in monitored anesthesia care (MAC), general, and regional anesthesia claims. The proportion of claims for death (14%) and permanent brain damage (7%) was reduced in regional anesthesia compared with MAC (33% death and 8% brain damage). In contrast, the severity of the injury was similar between MAC claims and those associated with general anesthesia (27% death and 10% brain damage). $* P < 0.025$ MAC versus regional. (Figure from Bhananker et al. [16]. (*Used with permission of Wolters Kluwer Health, Inc.*))

devices such as the processed electroencephalogram (EEG) monitor, bispectral index (BIS) monitor, or the Anesthesia Responsiveness Monitor. A systematic review and meta-analysis (total of 16 clinical trials; 2138 participants) of the depth of monitoring devices used in sedation and analgesia, found no substantial evidence to support improved patient outcomes and decreased adverse events in patients monitored with processed EEG compared to those who were not. However, the total dose of Propofol used was significantly lower in the group of patients monitored with EEG compared to those who were not [16]. Other studies have also found no correlations with BIS monitoring and the level of sedation.

Oxygenation monitoring via pulse oximetry has been a staple for patient care for all levels of sedation and general anesthesia practices.

Capnography, the measurement of the concentration or the partial pressure of carbon dioxide via infrared spectroscopy, has proved beneficial in improving patient safety during sedation.

The respiratory function may become impaired and inadequate, during moderate and deep sedation secondary to opioids and benzodiazepines.. The marked decrease of the genioglossus nerve activity demonstrated by electromyography during the

transition from consciousness to deeper levels of sedation may lead to airway obstruction, and aspiration secondary to pharyngeal dysfunction [17, 18]. Depression of the central nervous system leading to hypoventilation theoretically precedes hypoxemia. It's hypothesized that the early detection of respiratory compromise may lead to earlier clinical interventions. Although the review of literature regarding the safety and effectiveness of capnography during sedation is scarce, current research demonstrates that the addition of capnography does reduce the incidence of hypoxia-related events [19–21]. Deitch showed that by using capnography during procedural sedation, inadequate ventilation was identified before the onset of hypoxemia by an average time of sixty seconds [19]. Another essential benefit of capnography, which is the graphical waveform measurement of the respiratory ventilation cycle, is that it can provide clinical diagnostic information to the clinician, which is otherwise unavailable with only a numerical $ETCO_2$ value by capnometry. The height, width, and shape of the capnography waveform verify the quality of the patient's ventilatory status. Understanding the four phases of the $CO_2$ waveform and associated disease patterns such as hypopneic hypoventilation, bradypneic-hypoventilation, central apnea, obstructive apnea, and bronchospasm, the sedation provider can more readily treat the underlying cause. Use of capnography for continual monitoring of ventilatory function to supplement standard monitoring by observation and pulse oximetry is one of the new recommendations in the recently updated the guidelines on sedation and analgesia by the American Society of Anesthesiologists (ASA) Task Force by in March 2018 [2].

## Summary of the Updated Guidelines

The updated guidelines specifically address moderate sedation/analgesia, and separate guidelines for deep sedation are underway. The guidelines were developed by a multidisciplinary task force of physicians including dental surgeons with the intent of addressing moderate procedural sedation provided by any medical specialty in any location. These guidelines do not specify certification requirements for providers.

The guidelines suggest that ASA Standards, Guidelines, and Policies should be adhered to except when not applicable to outpatient care. The facility should have a medical director or governing body that establishes policy and is responsible for the activities of the facility and its staff. The facility must comply with the local, state and federal laws and regulations with specific reference to the ASA "Statement on Nonoperating Room Anesthetizing Locations."

### Preoperative Care and Patient Evaluation

Patient and procedure selection should be such that duration and complexity of the procedure will permit the procedure to be completed under sedation, will not require general anesthesia and the patient be recovered and discharged from the facility. Preprocedure patient evaluation should preferably be done well ahead in advance.

Before the procedure, patients or legal guardians should be informed of the benefits, risks, and limitations of sedation/analgesia and possible alternatives. Providers of sedation/analgesia must elicit patient preferences and verify that patients are adequately fasted as per the facility's guidelines. There must be appropriate education, training and licensure, by the facility when non-anesthesiologist physicians are administering or supervising the administration of sedation/analgesia.

## Personnel

When administering moderate sedation, it is likely that the level of intended sedation may be exceeded. Therefore, a designated individual, not from the team performing the procedure, should be present to monitor the patient throughout the procedure. There must be adequate training for the responsible individual in recognition and treatment of apnea and airway obstruction and this individual must be authorized to seek additional help.

## Monitoring and Equipment

At a minimum, all facilities should have a reliable source of oxygen, suction, resuscitation equipment and emergency drugs. When providing deep sedation, an ECG monitor and a defibrillator should be readily available. Patients should be monitored for level of consciousness assessed by the response of patients; adequacy of ventilation assessed by clinical signs, capnography and pulse oximetry and hemodynamic stability assessed by measuring blood pressure, heart rate and electrocardiography. There should be a recording of monitored parameters and availability/presence of an individual responsible for patient monitoring. The frequency of monitoring depends on the depth of sedation, the type and amount of medications administered, the length of the procedure and the general condition of the patient.

## During the Procedure

Studies show that the use of supplemental oxygen during the procedure reduces the frequency of hypoxemia. Therefore, supplemental oxygen should be administered unless specifically contraindicated for a particular patient or procedure. The name, route, site, time of administration and dosage of all drugs administered should be documented.

## Recovery

Decreased stimulation after the procedure, delayed drug absorption after nonintravenous sedation and slow drug elimination may contribute to residual sedation during the recovery period. The facility must have appropriate staff and an equipped

area to monitor the patients at regular intervals until (e.g., every 5–15 min) they are at the baseline level of consciousness and are not at increased risk of cardiorespiratory depression. Providers must design discharge criteria to minimize the risk of central nervous system or cardiorespiratory depression after discharge from observation by trained personnel. In the event of an emergency or need for extended care, written protocols should be in place to safely transfer patients to a prespecified facility in a timely manner.

### Creation and Implementation of Patient Safety Processes

Facilities should have quality improvement processes and emergency preparedness plans to ensure patient safety. Quality improvement processes should be based on national, regional or institutional reporting protocols and should be periodically updated to keep up with the advances in sedation practices and technology. Team training, simulation drills and regular education of personnel should be utilized to prepare for rare events. An emergency response plan (e.g., activating the "code blue" team or activating the emergency medical response system: 911 or equivalent) should be created.

## Sedation by Oral Route

With the intent of providing cost-effective medical care, there has been a tremendous increase in office-based medical and surgical procedures [22, 23]. This has changed the administration of anesthesia with increased use of sedation techniques and local anesthesia. Dental surgeons, faciomaxillary, and cosmetic plastic surgeons in office-based settings frequently administer oral sedation for office-based procedures [24, 25]. More recently, ophthalmologists have performed cataract surgery using oral sedation in combination with topical anesthesia [26]. However, the literature on the practice of oral sedation is very sparse.

Oral sedation offers the advantages of better patient compliance, efficiency, decreased cost for patients and affords more control. Oral sedation is easy to administer, convenient and painless. There is minimal downtime and recovery is quick. Unlike intravenous sedation, an effective level of sedation is not guaranteed, nor can a deeper level of sedation be prevented. Therefore, patient safety must be the prime consideration [25].

Though the level of sedation is independent of the route of administration, the goal of oral sedation is usually to provide minimal sedation along with reduced pain, anxiety and reduced patient-recall of the procedure [27]. According to the American Dental Association (ADA), administration of a drug by enteral route usually provides minimal sedation as long as the maximum FDA-recommended dose is not exceeded. When the maximum recommended dose is exceeded or more than one enteral drug is administered to achieve the desired sedation effect, guidelines for moderate sedation must apply [28].

Dental surgeons frequently perform oral sedation in their office. The ADA has guidelines for minimal sedation stating that patients considered for minimal sedation must be suitably evaluated preoperatively by a thorough history, focused clinical examination, and appropriate consultation with their primary care physician or medical specialist [28]. Informed consent for the proposed sedation must be obtained from the patient, parent or legal guardian. They must also be advised regarding the procedure associated with the delivery of any sedative agents. As it is likely that depth of sedation may increase more than the intended level, an adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be available. Preoperative dietary restrictions must be considered, based on the sedative techniques. In addition to the physician/dentist performing the procedure, at least one additional person trained in Basic Life Support for health care providers must be present. The patient must be monitored by either the physician/dentist or an appropriately trained individual under the direction of the physician/dentist during the procedure. Monitoring should include the level of consciousness, pulse oximetry, respiratory rate, chest excursions, blood pressure, and heart rate. There should be full documentation of drugs used, dosage, vital signs monitored, adverse drug reactions, and if applicable emergency measures were employed during the procedure and in the recovery period.

A qualified physician must determine and document satisfactory recovery of the patient prior to discharge from the facility. The patient, parent, legal guardian, or caregiver must receive postoperative instructions.

## Safety of Oral Sedation

As the volume of office-based medical and surgical procedures continues to rise, so does the use of oral sedation for these procedures [24, 25]. It is important to ensure that patients receive a level of anesthetic care comparable to that provided in a hospital. There is a lack of studies to show how this affects patient morbidity and mortality [26].

Butz et al. studied the safety of oral sedation in facial aesthetic surgery in an office-based facility from 2008 to 2014. This retrospective analysis studied 199 patients undergoing 283 surgical procedures using oral sedation and local anesthesia. All patients received a combination of diazepam, diphenhydramine and hydrocodone/acetaminophen or acetaminophen alone. Tramadol was substituted as an analgesic in patients with hydrocodone allergy. The investigators reported no major complications related to oral sedation and attributed their success to careful patient selection and appropriate medication and dosage selection. They state that patients with ASA physical status III or greater are not ideal candidates for office-based procedures. Patients with poorly controlled hypertension should not be offered this option. Also, patients with obstructive sleep apnea, history of a difficult airway and prior anesthesia complications should be cleared medically prior to considering the sedation protocol. They also stress the importance of titrating medications to presenting vital signs, avoiding large doses of opioids, liberal use of local anesthetics

and that the surgeon must discuss the procedure with the patient at appropriate times and reassure the patient throughout the procedure [25].

Routinely, cataract surgeries are performed as outpatient procedures under topical anesthesia. Successful outcomes require not only precision with surgical techniques but also patient cooperation at appropriate times. Intravenous sedation is commonly used during the procedure. Chen et al., in a prospective randomized control trial compared oral diazepam with intravenous midazolam for conscious sedation during cataract surgery under topical anesthesia. Outcomes studied were undesired movement, pain, anxiety, and the inability of the patient to cooperate with surgeon instructions. There were no significant intraoperative complications in any case. Undesired movement was statistically significant in the IV midazolam group. There was no statistically significant difference in any other primary outcomes between the two groups. Based on this and the relative cost difference, the authors' institution has changed to oral diazepam as the first-line agent for sedation during cataract surgeries. They do reiterate that careful patient selection is crucial for successful outcomes [27]. Improvements in care can be made with national standardization of care, safety checklists, and development and adherence to professional practice guidelines.

## Conclusions

Sedation and analgesia can be provided for ambulatory procedures without exposing the patient to the risks of general anesthesia. However, the incidence of adverse events including death and permanent brain damage in patients receiving MAC for predominantly elective surgeries mostly in outpatient settings were similar to that undergoing general anesthesia. Respiratory depression from oversedation was stated as an important mechanism of injuries [3]. There is always a possibility of unintended escalation of depth of sedation. Different scientific societies have offered guidelines with respect to appropriate patient selection, skilled personnel administering the sedation, appropriate drug selection, careful monitoring of the patient during and immediately after the procedure and regular evaluation of practices with the aim of providing sedation while maintaining patient safety. Implementation of these guidelines into regular practice has the potential to reduce adverse events and improve outcomes in providing sedation and analgesia.

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# PACU Management: Unique Concepts to ASCs

15

Fatima Ahmad and Niraja Rajan

The Post Anesthesia Care Unit (PACU) is a highly specialized unit where a group of specially trained nurses provide care for patients in the immediate post-operative period: a critical period of high acuity. The efficiency of an Ambulatory Surgery Center (ASC) depends heavily on the Post Anesthesia Care Unit (PACU). With the current emphasis on cost cutting in all aspects of medicine, it is the responsibility of the perioperative care team to ensure patient safety while maintaining efficiency. In an ambulatory surgery center, the PACU is the final point where necessary post-surgical care is provided and patients are safely discharged. With the emphasis on early discharge after ambulatory surgery, there need to be definite protocols and criteria to determine when patients are suitable to be discharged to the care of non-medical caregivers such as friends and family members.

## PACU Design

A PACU should be located contiguous to the Operating Rooms in order to provide immediate access to anesthesia and surgical staff if necessary. Another consideration is ease of access from the most distant OR to PACU with a straight wide hallway leading from the OR to PACU being most ideal. The current recommendation for the number of PACU slots is one and a half to two PACU slots for each

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operating room in the ASC. This ensures that there are no delays in receiving patients into the PACU and allows for high volume days with short cases and rapid turn-overs. The PACU must be oriented so as to facilitate unidirectional patient flow which means the entrance to the PACU must be from the OR and the exit should lead to the parking lot via Phase 2 recovery. This allows for seamless and efficient patient flow with no cross traffic. The usual floor plan for a PACU is an open square with the nursing station, medication storage, cabinets, desk and dictation areas on one wall and patient slots on the remaining walls permitting a clear line of sight for patient monitoring. There are other plans as well including the pod design with four beds at 90 degree angles with one or more nurses and supplies at the center. The PACU should also include a storage area for a ventilator, emergency carts, Malignant Hyperthermia carts and resuscitative equipment. There should also be one closed off patient care slot for patients requiring isolation. Consideration should be given for family members to access the PACU via a designated route so as not to disrupt patient throughput. Other considerations include: synchronized clocks easily visible from all parts of the room, hand wash sinks every six patient slots, hand sanitizers in every patient slot, separation of clean and dirty storage, three separate sinks in the dirty area, blanket warmer in the clean area, staff storage space and adequate desk space. The PACU is under the supervision of the anesthesiologist and daily operations are determined by the charge nurse. Detailed information on PACU design may be obtained from OR design manuals or Life Safety manuals [1].

## Phases of Recovery

Postoperative recovery is a similar process, both in hospital based inpatient procedures and ambulatory surgical procedures. However, what makes ambulatory surgery unique is that patients have to return to their preoperative physiological state and be discharged home or to other living arrangements in the care of a family member, while inpatients admitted in hospital are not expected to reach this state in the immediate postoperative period. This process of full recovery is divided into three phases [2]:

### Phase I

Phase I recovery is the process of immediate recovery from general anesthesia or deep sedation to a level where the patient can be safely transferred to Phase II recovery or a step-down unit. Phase I recovery requires close monitoring. The ASPAN and ASA recommend that patients have their vital signs monitored every five to fifteen minutes in this phase. Most centers use some modification of the Aldrete score for determining when a patient can be safely transitioned to Phase II care (Table 15.1). The criteria include an assessment of oxygenation (SPO2), circulation

**Table 15.1** Modified Aldrete Score

| Patient Sign | Criterion | Score |
|---|---|---|
| Activity | Able to move 4 extremities | 2 |
| | Able to move 2 extremities | 1 |
| | Able to move 0 extremities | 0 |
| Respiration | Able to deep breathe and cough | 2 |
| | Dyspnea | 1 |
| | Apneic or obstructed airway | 0 |
| Circulation | BP +/−20% of pre-anesthesia level | 2 |
| | BP+/−20–49% of pre-anesthesia level | 1 |
| | BP+/−50% of pre-anesthesia level | 0 |
| Consciousness | Fully awake | 2 |
| | Arousable (by name) | 1 |
| | Non responsive | 0 |
| Oxygen Saturation | SPO2 > 92% on room air | 2 |
| | Requires supplemental O2 to maintain SPO2 > 90% | 1 |
| | SPO2 < 90% with supplemental O2 | 0 |

(blood pressure), respiration (rate and depth), consciousness and activity (ability to move extremities). A patient with a score of 8 with no zeros in any category may be discharged to Phase II recovery. Regarding staffing ratios in Phase I, ASPAN recommendations state: "Two registered nurses, one of whom is an RN competent in Phase I post anesthesia nursing, are in the same room/unit where the patient is receiving Phase I level of care" [3].

## Phase II

Phase II recovery is achieved when patients are considered ready to be discharged from PACU to home or other residential facility. This is dependent on a set of well-designed discharge criteria. Various scoring systems and tools are available to determine appropriate discharge criteria. There are limitations to these scoring systems when different patient populations and anesthetic techniques are considered. A simple and easy to use discharge criteria scoring system is the Post-Anesthetic Discharge Scoring System, PADSS, for home readiness after ambulatory surgery described by Frances Chung and her group [4]. It consists of an evaluation of vital signs, mental status, nausea/vomiting, pain, surgical bleeding and intake and output. However, the American Society of Anesthesiologists has stated in its Practice Guidelines for Post Anesthetic Care [5] that tolerating oral fluids and voiding should not be routine discharge criteria for all patients; rather, these should apply to selected patients. Considering these recommendations, the discharge criteria have been modified as shown in Table 15.2. When the patient is back to baseline mental status, a score of 9 or above is considered safe for the patient to be discharged home. ASPAN recommendations based on expert opinion indicate that in Phase II, vital signs are obtained every 30–60 minutes and include admission and discharge vital signs.

**Table 15.2** Modified PADSS

| Criteria | 2 | 1 | 0 |
|---|---|---|---|
| Vital signs | Within ±20% of baseline | Within ±20–40% of baseline | Greater than 40% of baseline value |
| Activity | Steady gait, no dizziness | Able to ambulate with assistance | Unable to ambulate |
| Nausea and vomiting | None or minimal and controlled with PO medications | Moderate and treated with IV medications | Severe and poorly controlled |
| Pain | Minimal (0–3) | Moderate (4–6) required treatment | Severe (7–10) requiring treatment |
| Surgical bleeding | None or minimal | Moderate | Severe |

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The most important thing to consider here is the current evidence based trend of determining Phase II recovery by clinical based discharge criteria rather than the traditional time based discharge criteria [6]. There is no reason to have a mandatory minimum stay in PACU according to current evidence. Discharging patients based on objective criteria rather than time, improves PACU efficiency while maintaining patient safety.

### Phase III

This is the late recovery phase that may last from several days to weeks and is completed at home or other residential facility. Both Phase I and Phase II recovery require clinical and logistical planning to ensure rapid discharge to home.

## Fast Tracking

Fast tracking is the process whereby a patient is directly transported to Phase II recovery from the OR, bypassing Phase I, if they meet certain criteria. Fast tracking allows for earlier discharge of suitable patients thus improving perioperative efficiency and throughput after ambulatory surgery. Effective and reliable fast-tracking criteria have been designed that allow anesthesiologists to rapidly assess patient suitability for direct discharge to a step-down unit. One of these is the White's fast tracking criteria. It includes an assessment for postoperative pain and nausea in addition to the criteria assessed in the modified Aldrete score. The maximum possible score is 14. Patients must score 12 or above with no zeros in any category to be eligible for fast tracking [7].

PACUs in most ASCs do not have a rigid distinction between Phase I and Phase II recovery areas but instead provided blended levels of care which improves efficiency and patient comfort.

## ASC Staff

It has been shown that a specialized group of anesthesiologists practicing evidence based ambulatory anesthesia could contribute to decreased PACU length of stay [8]. This group should also be well versed in basic regional anesthesia techniques as applicable to the type of procedures performed at the specific ASC. An individualized anesthetic plan for each patient and procedure, keeping in mind fast-tracking and discharge goals go a long way towards reducing PACU length of stay, increasing efficiency and improving patient safety and satisfaction.

## Factors Predicting Extended Length of Stay in PACU

Phase II recovery is complex, as it involves multiple interactions between patient co-morbidities, surgical factors, anesthetic factors and post-anesthesia side effects. If a prolonged PACU stay is anticipated, it may be prudent to schedule these cases earlier in the day to avoid nursing overutilization and staffing issues at the end of the day. Some of the common predictors of prolonged PACU stay are listed here [9]:

1. Morbid obesity (increased risk of sleep apnea and postoperative airway obstruction)
2. Hypertension
3. Type of surgery (ENT, gastroenterology and ophthalmology had decreased odds for extended PACU length of stay)
4. Primary anesthetic type (general anesthesia)
5. Scheduled case duration (due to more complex surgeries and increased anesthetic utilization)

Other predictors of prolonged PACU stay are not known ahead of time [10] and include volume of intraoperative fluids, postoperative pain, intraoperative arrhythmias, delayed emergence and prolonged intubation, and nausea and vomiting.

Although the geriatric population may have more co-morbidities than their younger counterparts, generally healthier elderly patients are considered for ambulatory surgery so age is not considered a predictor of prolonged PACU stay.

## Hypoxia

A commonly observed fact that is infrequently mentioned in ambulatory anesthesia literature is post-operative hypoxia after interscalene block in patients with obesity and/or moderate pulmonary dysfunction.

Shoulder surgeries in ASCs usually do not require muscle relaxation and are performed with LMA/spontaneous ventilation. As there is a high incidence of

phrenic nerve blockade when interscalene blocks are done for shoulder surgeries, these patients can be significantly hypoxic in the PACU secondary to atelectasis due to prolonged spontaneous ventilation under GA. For longer cases it may seem prudent to intubate these patients so they can be adequately ventilated or provide assisted modes of ventilation with an LMA. Incentive spirometry and early ambulation should be encouraged to improve pulmonary excursion in the PACU. Patients should be seated in recliners rather than in the bed during Phase II recovery. Supplemental oxygen, if needed, should be just enough to maintain oxygen saturation in an acceptable range (92–94%), and patients should be motivated to cough and take deep breaths frequently. Applying high flow oxygen via face mask that arbitrarily brings up saturation to 100% may not correct atelectasis and patients will continue to be hypoxic when supplemental oxygen is removed. Ideally these patients should be scheduled earlier in the day to provide ample time for recovery.

## Hydration

Early discharge from PACU is highly dependent on an overall feeling of wellbeing. Planning for this starts way ahead of the procedure. Both adult and pediatric patients should be well hydrated and allowed to drink clear liquids as recommended by ASA Practice Guidelines for Preoperative Fasting [11]. This is especially important for patients scheduled later in the day, particularly diabetic patients. Intraoperatively patients may require more intravenous fluids when the procedure is scheduled later in the day.

## Hypothermia

Hypothermia in the PACU can also discourage patients from early ambulation. An active warming regimen should be started on arrival to pre-operative area. Patient carts and beds should be warmed actively and warm blankets should be provided early. Every effort should be made for intraoperative warming.

## Pre-operative Medications

Chemical homeostasis is very important and patients should be advised to continue their routine essential medications such as antihypertensive, cardiac, respiratory and anti-epilepsy medications till the day of surgery. Similarly, patients with psychiatric conditions should continue their medications unless a drug interaction is expected. Patients with chronic pain should continue all of their pain medications and bring them along on the day of surgery.

## Pain

Patients on chronic pain medications should be specially advised to take all their medications till day of surgery as prescribed by their physicians. Otherwise it becomes very challenging to treat their post-operative pain. Inadequate pain management can delay discharge. Planning for this should start in the surgeon's office when surgery is being planned. Patients should have realistic expectations that in some situations the pain score will not be zero in the immediate post-operative period.

In addition to pain there may be discomfort from pressure dressings and casts. Regional anesthetic techniques are most helpful for acute post-operative pain. Multimodal analgesia should be strongly considered including acetaminophen, conventional NSAIDS, COX-2 inhibitors and anticonvulsants such as gabapentin and pregabalin. A multimodal regimen also helps to reduce opioid requirements and the associated undesirable side effects such as sedation, respiratory depression and nausea. Non pharmacological techniques such as acupressure, cold-hot treatments and Transcutaneous Electrical Nerve Stimulation (TENS) are also some options to relieve pain. Adequate control of acute pain requires an individualized pain plan for each patient and procedure and can help prevent progression to chronic pain.

## Post-operative Nausea and Vomiting

Post-operative nausea and vomiting (PONV) is another challenge faced by PACU staff. In addition to significant patient discomfort and delayed discharge, it can also lead to unplanned admission. Prevention of PONV is closely related to anesthetic management and pain control techniques. Considering patient risks factors such as history of motion sickness/PONV, female gender and non-smoker status, attempts should be made to minimize dose and duration of emetogenic agents such as inhalational agents, and opioids. Alternate techniques such as total intravenous anesthesia and regional anesthesia, should be considered for high risk patients. Some surgeries such as laparoscopic, ear and gynecological surgeries can be particularly emetogenic. Although there are various algorithms to determine the number of antiemetic drugs recommended for a particular patient, compliance may be poor [6]. Since the side effect profile of most antiemetic drugs is quite safe, administration of a combination of antiemetics could be cost-effective in all ambulatory patients. Commonly used antiemetics include dexamethasone, 5-HT3 antagonist, scopolamine transdermal patch, droperidol, phenothiazenes and metoclopramide [12]. In some extreme cases of PONV, a subhypnotic dose of intravenous propofol titrated carefully to level of consciousness and respiratory rate is also effective [13].

Sometimes, nausea and vomiting also occurs after the patient has left the ambulatory surgery center. This is known as Post Discharge Nausea and Vomiting

(PDNV). PDNV is a big concern in ambulatory patients as it potentiates dehydration and renders the patient unable to take their pain medicine resulting in an emergency room visit. Statistically significant independent predictors of PDNV include female gender, age less than 50 years, history of PONV, opioids in the PACU, and nausea in the PACU. Long-acting prophylactic antiemetics like dexamethasone, aprepitant, palonosetron, and transdermal scopolamine, either alone or in combination, appear to significantly reduce PDNV [14].

## Recovery Room Nurses

The PACU at ASCs is usually staffed by nurses who frequently cross cover between the preoperative areas and sometimes the OR. The American Society of Anesthesiologists recommends that PACU nurses should be trained in airway management, basic life support and managing the special needs of postoperative patients [5]. In addition to this an ACLS trained health care professional should always be available when a patient is recovering. In free standing surgery centers, this means that a physician (anesthesiologist) must remain on the premises until the patient is discharged. According to the American Society of PeriAnesthesia Nurses (ASPAN), 2017–2018 Perianesthesia Nursing Standards, Practice Recommendations, and Interpretive Statements, "The perianesthesia registered nurse providing Phase I level of care will maintain a current Advanced Cardiac Life Support (ACLS) and/or Pediatric Advanced Life Support (PALS) provider status, as appropriate to the patient population served" and "It is strongly recommended that the perianesthesia nurse providing Phase II level of care will maintain a current Advanced Cardiac Life Support (ACLS) and/or Pediatric Advanced Life Support (PALS) or Pediatric Emergency Assessment Recognition and Stabilization (PEARS) provider status, as appropriate to the patient population served."

The ASPAN standards regarding Phase I patient care state that two competent personnel should be available in the same room as a patient receiving Phase I level of care, one being an RN competent in Phase I nursing. In many facilities the second competent personnel is often a nurse's aide or other non-RN personnel, including the LPN [3].

PACU staffing considering nurse patient ratio has been described in the ASPAN Standards with an emphasis on elements of acuity. The general ratio of 1 nurse to 2 patients in Phase II allows for appropriate care based on the complexity and requirements of a particular patient. Acuity in a postanesthesia patient often revolves around the stability of an airway, level of consciousness, pain management requirements, interventions for hemodynamic stability, PONV, restlessness and anxiety and may require a change in staffing ratio to 1 nurse to 1 patient [3].

## Patient Escort

American Society of Anesthesiologists in its Practice Guidelines for Post Anesthesia Care recommends that all patients should be required to have a responsible person accompanying them home and to receive discharge instructions. This can be a family member, friend or a caregiver from nursing home or extended care facility [5]. It is required that the ASC inform patients that they will need a responsible adult to remain with them for the first 24 hours after surgery. A responsible individual needs to be able to comprehend the discharge instructions, perform the necessary tasks to care for the patient, and recognize and call for help in case of postoperative complications. If it appears that the individual accompanying the patient will not be able to perform these tasks, it is necessary to make alternate arrangements for patient care which may sometimes include transfer to a hospital. The ability to drive is not a requirement for the responsible individual. It is acceptable to discharge a patient with the responsible individual to take a taxi or other means of transportation home. In the case of patients that live in nursing homes or assisted living facilities, who are transported to the surgery center by a driver, the information about who will be caring for the patient after surgery needs to be obtained prior to patient admission. The PACU nurse then gives instructions to this individual over the phone and discharges the patient. There is currently some debate about whether patients receiving mild to moderate sedation really need an escort for discharge. There is no definitive evidence yet on this subject. Discharge planning needs to begin at the time of scheduling the procedure at the ASC. Depending on their living or caregiver arrangements, some patients may not be suitable for outpatient surgery.

## Handoff and Communication

The handoff provided by the anesthesia team to PACU is an important component of patient care and is a potential point for communication failures that could compromise patient safety. While there are no widely accepted guidelines for a standardized PACU handoff, institutions have adopted several different measures to ensure complete transfer of information from the anesthesia team to the PACU nurse. One of these is the SBAR (Situation, Background, Assessment, and Recommendation) approach. Another is to develop a standardized checklist which could be customized by the ASC to best fit their needs. Any standardized checklist has to be balanced between being too comprehensive or too efficient. There is no evidence at present to suggest that a standardized PACU checklist improves patient outcomes but the use of a checklist does increase the amount of information transferred from the anesthesia team to the PACU nurse [15].

## Post Anesthesia Evaluation

In accordance with CMS standard §482.52(b)(3)[16]: Post-anesthesia Evaluation: all patients must have a post anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, no later than 48 hours after surgery or a procedure requiring anesthesia services. The post anesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with ASC policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care. The practitioner completing the evaluation need not be the same practitioner who administered the anesthetic for the patient. This evaluation should not be performed at the time of handoff, but at the time when the patient is sufficiently recovered from anesthesia, and in the case of same day surgery, may be completed after the patient is discharged from the ASC, but no later than 48 hours post discharge. The elements of an adequate post-anesthesia evaluation should include:

- Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
- Cardiovascular function, including pulse rate and blood pressure;
- Mental status;
- Temperature;
- Pain;
- Nausea and vomiting; and
- Postoperative hydration.

## Summary

The phase of recovery is a vital part of the perioperative period especially in an ASC. A well run PACU can contribute immensely to patient safety and satisfaction while maintaining cost-effectiveness and efficiency. Having a dedicated ambulatory anesthesia team, time based discharge criteria and an individualized anesthetic plan to circumvent the factors leading to delayed discharge all contribute to PACU efficiency.

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# 16 HR Issues: Sexual Harassment, Workplace Diversity, Cultural Sensitivity, Privileging, Credentialing, Denying Privileges, Difficult Conversations

Marjorie P. Brennan and Niraja Rajan

## Introduction

Health insurance companies are increasingly encouraging health plan enrollees to use ambulatory surgery centers (ASCs) instead of hospital outpatient departments for common procedures. An analysis of health insurance claims found that ASC prices are significantly lower than hospital outpatient prices for the same procedures throughout the U.S and can lower the cost of outpatient surgery [1]. These lower prices translate to ASCs being driven to closely manage costs. Further challenging for ASCs, the way they are reimbursed is changing. Bundled pricing — the act of grouping together facility and other fees — is an increasingly used practice by ASCs. ASCs must pay careful attention to all expenses, especially those related to human resources. Practice managers must assess staffing levels to ensure they are adequate for the given case volume levels and optimize scheduling to ensure proper utilization of the ASC while maintaining a culture of safety.

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## Human Resource Management

There is a growing body of evidence on the importance of human resource management (HRM) in the quality of services that healthcare workers are able to deliver. A successful ASC is dependent on healthcare professionals to deliver services. Leaders must recognize the heterogeneity of service capabilities within any given employee over time and among different employees [2]. Jim Collins used research and analysis to identify the most important factors that shape organizational success. In "Good to Great" he speaks of the importance of the right people in the right seats on the bus:

> *"The executives who ignited the transformations from good to great did not first figure out where to drive the bus and then get people to take it there. No, they first got the right people on the bus – and the wrong people off the bus – and then figured out where to drive it"* [3]

Human resource management (HRM) is an approach to ensure that an organization effectively mobilizes its people to accomplish its mission, goals, and strategic plans. Following industry best practices, an organization can be positioned for better results by optimizing key aspects of the hiring process. Implementing effective HRM means that requirements for positions must be determined, qualified persons must be recruited and selected, employees must be trained and developed to meet future organizational needs, job performance must be evaluated, and adequate rewards must be provided to attract and retain top performers. A human resource manager needs to be a visionary and have the future of the facility in mind during this process. Despite substantial theoretical evidence, scholarly review of how HRM actually enhances performance in health care organizations remains underdeveloped.

Strategic human resources management is the process of formulating HR strategies and implementation tactics that are aligned with and reinforce the organization's current mission and future direction. It requires development of a comprehensive set of managerial activities and tasks related to developing and maintaining a qualified workforce. This workforce, in turn, contributes to organizational effectiveness, as defined by the organization's strategic goals. Strategic HR management emphasizes consistency among individual HR practices (horizontal fit) and between HR strategy and overall strategy (vertical fit) [4]. In strategic HR management, HR's primary role is viewed as influencing workforce mindset, competencies, and behavior, while enabling its employees to carry out the organization's strategy and mission.

Much of the research in HR is still concentrated on the traditional personnel functions such as ability, job satisfaction, employee turnover, and performance. This focus continues to observe the individual as the main point of evaluation. Some HR researchers have begun questioning the relevance of traditional HR as it leads to an "activity trap" in which HR activities are aligned neither with each other nor with organizational goals and priorities [4]. Strategic HR in health care, like any other service industry, can be achieved through the cultivation of an external orientation to customers' demands (excellent patient care and patient satisfaction) and a commitment to employee development. Poorly trained staff, high employee turnover

and negative work environments undermine patient satisfaction [5]. Paawe asserts that there are three dimensions to HRM: (1) strategic; (2) professional; and (3) societal. To ensure long-term organization effectiveness, HRM must focus on relational as well as economic factors [6]. Human resources add value to an organization, but HRM should also appreciate the need for professional development for their employees.

Studies have shed light on the process through which employees' perceptions of HR systems are linked to organizational performance outcomes. A study on HR system perceptions on civility towards patients determined that employees' civility towards patients is negatively affected by employees' intention to leave, an essential attitudinal HR outcome [7].

HRM in health care is more complex than many other service industries because of its intensive reliance on labor, and the presence of well-established separate professions with their own control [8]. For most health care organizations, the nursing staff is a major HR component. Research demonstrates that nurse staffing is significantly associated with organizational outcomes such as clinical outcomes, nurse turnover, nurse burnout, nurse job satisfaction, patient satisfaction, and patient safety [9].

The successful ASC has leaders that work with employees effectively, and are knowledgeable about the numerous systems and practices available to put together a skilled and motivated workforce. Proactive work behaviors such as self-initiated, anticipatory action and proactive problem solving improves quality of patient care [8]. Identifying approaches to improve performance and customer service, and rewarding employee success are very relevant to ASC managers.

A successful strategic plan focuses on developing a strong recruitment base, a career pathways compass, and an ongoing leadership pipeline [10] (Figure 16.1). Another key strategy is talent development. New hires should undergo a robust orientation program. Managers should seek to implement programs for leadership development and formulate pathways for succession planning.

With consolidation of the healthcare system and the rise of managed care, along with its demands for efficiency, fewer financial resources are available [11]. Changes in the organization and financing of healthcare services and technological advances have expanded job opportunities for healthcare providers and extenders. With the advent of managed care, greater reliance has been placed on non-physician practitioners. As a result, healthcare organizations may be pressured to replace highly trained and more expensive professionals with unlicensed support personnel. The use of unlicensed support personnel poses concerns for inadequate oversight and increased potential for adverse outcomes [11]. Professionals are pressured to perform more tasks and are required to supervise more assistants who are functionally trained for specified organizational roles. Staffing an ASC is confounded by the fact that ASC staff members must be cross-trained to manage several functions. A circulating nurse may need to scrub if the scrub nurse is on vacation or sick. Unclarified expectations regarding cross covering can be stressful for employees, breed conflict and erode morale. Well-developed collaborative practice models of ASC staffing—all with a clear understanding of the professional's roles on the health care team—are essential for improved healthcare outcomes for patients. Roles and responsibilities should be clarified at the time of hire and reinforced on a regular basis.

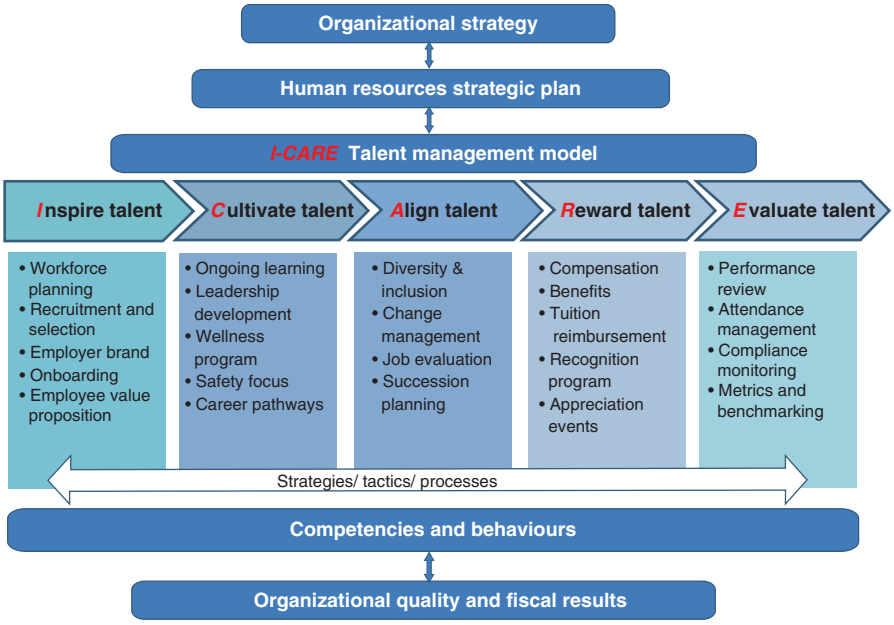


**Figure 16.1** Lewis R. Building Capacity and Enhancing Engagement – Innovative Approach at The Scarborough Hospital. GSTF Journal of Psychology Vol.1 No.2, October 2014. (*Adapted with permission of Rhonda Lewis, Scarborough Hospital.*)

A unique aspect of HRM in ASCs is the fact that ASC staff members have to interact or liaise with professionals from multiple walks of life including surgeons, anesthesiologists, CRNAs, physician assistants, nurse practitioners, representatives from various equipment companies all of whom are involved in patient care but not directly employed by the ASC. This can sometimes lead to tricky management situations. This is unlike the hospital model where everyone is employed by the hospital.

## Organizational Mission and Culture

Healthcare is a highly competitive job market, and organizations are constantly competing for the best talent. In this environment, developing an attractive HR brand is extremely important. A brand embodies the values and standards that guide employee behavior. It indicates the purpose of the organization, the types of people it hires, and the results it recognizes and rewards. Barker asserts that when trying to avoid pitfalls of organization failure, it is important to directly engage staff, have a diversified management team that shares viewpoints, and seek outside advice on major issues and problems [12].

First, organizations should have a vision statement capturing their view on how the organization should view and conduct itself. Development of these ideals and communicating to staff the importance the organization attaches to these aspirations

are key. Next, the organization must implement and endorse mentoring schemes. Last, they should consider offering staff regular career development opportunities. A positive learning climate and a work culture that recognizes and rewards staff encourages innovation and improvement. Evidence also points to the importance of hospitals' HR systems as determinants of the interpersonal aspects of care, such as treating patients with courtesy, dignity and respect [7].

An environment that values teamwork and fosters a culture of safety is crucial to employee satisfaction. Staff is very aware of the perceived level of focus and commitment on patient safety. Employees must feel that there is a mechanism to discuss errors with a sense of psychological safety in a confidential manner in a non-punitive environment. Hospital work environment has powerful effects on the quality and safety of health care delivery and on traditional employee satisfaction variables and turnover [13]. The Institute of Medicine, in one of the first comprehensive reports on medical errors, To Err is Human, proposed that most medical errors are the result of unavoidable human error [14]. Medical accidents can provide a form of information about a system and represent places in which the system failed with resulting harm to a patient [14]. Errors, therefore, can only be reduced through system changes. ASC leaders must provide an overt, clearly defined, and continuing effort on patient safety programs. These programs should implement non-punitive systems for reporting and analyzing errors and evidence-based methods of team management and process improvement. Employee perceptions about inequity, or a management team that does not follow up on errors can impact how employees interact with the rest of the team and impact safety. Leadership support is paramount for safety culture creation and maintenance.

## Sexual Harassment

Sexual harassment is unlawful, and is defined as unwelcome conduct, on the basis of gender, such as sexual advances or offensive verbal harassment [15]. ASCs need to adopt policies and procedures for reporting of sexual harassment and for the investigation of misconduct. Prevalence of sexual harassment is influenced by supervisory relations, levels of interaction, appearance and personality [16]. Healthcare organizations have high rates of sexual harassment. More than one third of female physicians [17] and 69% to 85% of nurses [18] perceive that they have been sexually harassed. Sexual harassment in the workplace and in educational settings erodes morale and may have a negative impact on individual performance and effectiveness as well as organizational productivity.

Rulings by the U.S. Supreme Court provide legal incentive for clear policies. The Supreme Court's landmark decision, Meritor Savings Bank, FSB v. Vinson in 1986, held that plaintiffs could establish violations of the Title VII of the Civil Rights Act of 1964 "by proving that discrimination based on sex has created a hostile or abusive work environment" [19]. The court expanded this by ruling in 1993 by ruling that "so long as the environment would reasonably be perceived, and is perceived, as hostile or abusive... there is no need for it also to be psychologically injurious (in order to find that it violates Title VII)" [20]. In June, 2004, the Court held that an

employer is not strictly liable for sexual harassment by supervisory-level employees when the harassed employee resigns if there are effective procedures for the employees' reporting of sexual harassment and if the employee unreasonably failed to take advantage of those procedures. The 2004 ruling provided clear legal guidance for organizations to adopt policies and procedures to protect themselves from liability, but does not address changing the culture that fosters sexual harassment. Organizations with culturally ingrained discrimination discourage many victims from voicing concerns, or victims may face obstruction to having grievances investigated without the risk of punitive consequences.

Sexual harassment in the workplace is mitigated by understanding the factors that lead to harassment and by developing a suitable organizational culture. Important steps include fostering a climate of dignity and integrity, clearly and forcefully opposing gender discrimination, providing open and safe channels for addressing and voicing grievances, enforcing a code of conduct and implementing an effective sexual harassment policy [16]. It is incumbent on the ASC to establish the rules of conduct within the organization, and outline the responsibilities of both employees and employers. Clear and enforced policies and procedures protect the rights of the ASC workers as well as the business interests of the employer.

## Human Resources Information Systems (HRIS)

The Human Resource Information System (HRIS), or Human Resource Management System, is a software or online solution for the data entry, data tracking, and data information needs of the human resources. Data on recruitment and performance management can provide health leaders with crucial information for efficient capacity planning and resource allocation.

HRIS have received very little attention in the health informatics literature, and their development and implementation in health organizations are inadequately understood. Human resource information systems have the potential to improve organizational efficiency and effectiveness by facilitating workforce planning, financial and operational administration and staff training. However, the evidence base regarding HRIS in health care has been limited in scope.

The majority of studies describing HRIS implementation are not in the health sector and are driven by expected benefits or goals. The most common goals are related to strategic orientation of the organization, improving staff performance, and gaining evidence to inform decision-making and planning. Other expectations driving implementation include standardization of systems, processes, or data; empowerment of managers and/or employees; and compliance with statutory requirements for data on the health workforce [21, 22].

The most commonly realized benefits of HRIS implementation, related to *strategic orientation* and *operational efficiency improvements,* followed by *empowerment of managers and employees,* improvements in *service delivery, standardization, and compliance* with regulatory requirements (Figure 16.2). Another realized benefit was improvement in patient care by facilitating minimum standards of nursing care [21].

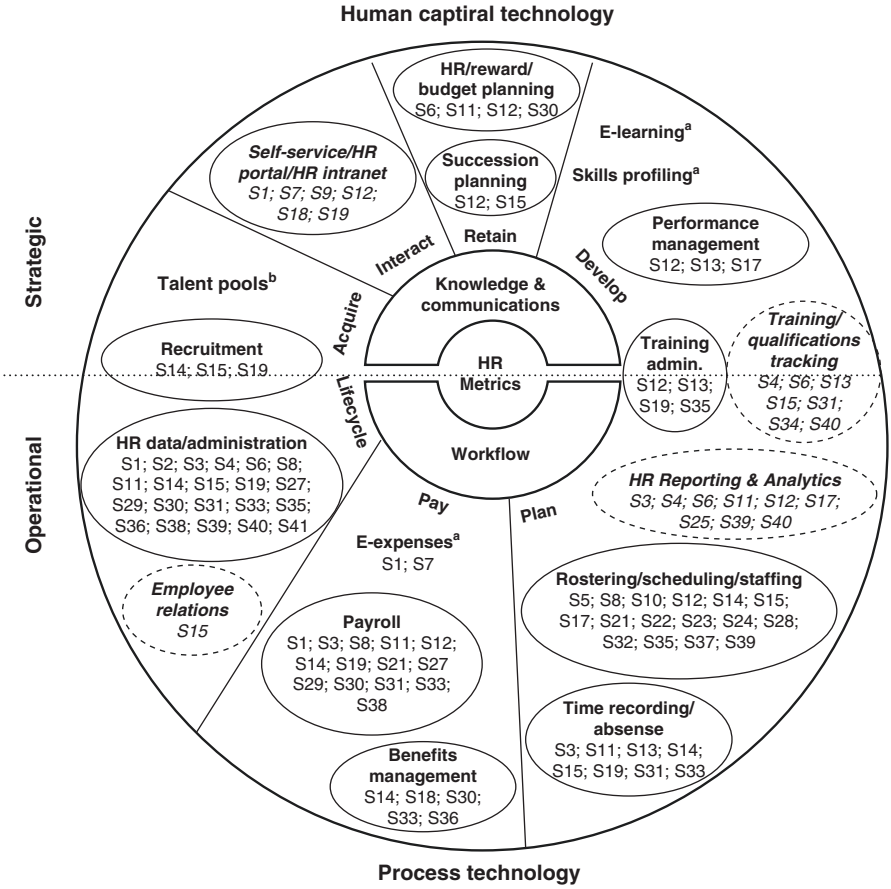


**Figure 16.2** Scope of Practices in HRIS – Tursunbayeva, et al., 2017. (Open Access article: Tursunbayeva A, Bunduchi R, Franco M, Pagliari C. Human resource information systems in health care: a systematic evidence review. *Journal of the American Medical Informatics Association: JAMIA*. 2017;24(3):633-654. Doi:10.1093/jamia/ocw141. 2016-10-05; Copyright © 2016, Oxford University Press. Creative Commons.)

The electronic capabilities of the system provide the opportunity to have necessary HR information readily accessible. An ASC can track information such as upcoming recertification dates, payroll data and timekeeping. Online training can also be incorporated into the system. The system places all training information in one location, which can be easily monitored.

When choosing an HRIS tool, a homegrown system achieves better quality of patient care than an outsourced one [23]. An interdisciplinary team should be actively engaged in development of an HR information improvement initiative. Successful rollout requires clear vision from the chief information officer, professional expertise of the information technology staff, and support of ASC leadership.

## Workplace Diversity

With our country growing more diverse each year, natural progression would suggest that so too should our fundamental institutions, such as our healthcare facilities. Women dominate health care jobs, comprising 75% of the workforce [24]. This includes healthcare providers, administrative and management roles. Workforce projections for the future show significant growth in fields that are currently predominately comprised of women (Figure 16.3) [25].

Registered nurses, home health aides, and personal care aides are among the occupations nationally projected to have the largest job growth between 2010 and 2020, adding more than 2 million jobs and with another 700,000 job openings due to vacancies from attrition.

In 2013, the Institute for Diversity in Health Management, an affiliate of the American Hospital Association (AHA), conducted a national survey of hospitals to determine the actions that hospitals are taking to reduce health care disparities and promote diversity in leadership and governance. In a review of 1,109 hospitals, the AHA's Institute for Diversity found that minorities represent 31 percent of patients nationally, but constitute just 14 percent of hospital board members, 12 percent of executive leadership positions and 17 percent of first- and mid-level management positions [26].

Health care organizations are aware of the benefits of a diversified work force, but the divide between diversity in healthcare leadership and the populations they serve persists. When turnover rate is low, employee diversity takes a very long time to change, even in the absence of any bias [27]. "Missing Persons: Minorities in the Health Professions," a report from the Sullivan Commission on Diversity in the Healthcare Workforce, an initiative of the W.K. Kellogg Foundation, goes so far to state: "The fact that the nation's health professions have not kept pace with

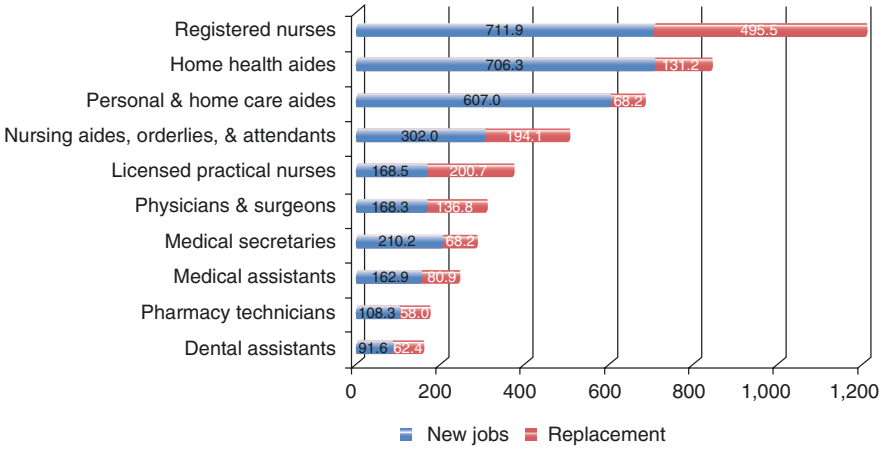


**Figure 16.3** Selected Health Occupations with Greatest Need for New Workers between 2010 and 2020

changing demographics may be an even greater cause of disparities in health access and outcomes than the persistent lack of health insurance for tens of millions of Americans" [28].

Cultural competence refers to the knowledge, skills, attitudes and behavior required of a healthcare professional to provide optimal care and services to patients from a wide range of cultural and ethnic backgrounds. It's important for students and professionals to study and understand cultural diversity to help reduce health disparities. With the number of minority citizens on the rise, future healthcare professionals will be tasked with caring for many patients whose backgrounds differ from their own. It is becoming more and more critical that providers maintain a firm understanding of how and why different systems of belief, cultural biases, ethnic origins, family structures and other culturally determined factors influence the way patients experience illness, heed medical advice and respond to treatment plans. The outcome of care is dependent on cultural factors such as these.

The most effective healthcare professionals are those who maintain a steady commitment to continually learn and progress in their field. Some impactful first steps toward a more diverse healthcare workforce have been taken, but the work has only just begun. It will take active participation from health organizations such as ASCs to ensure a diversified, more culturally competent team of caretakers and providers.

## Privileging and Credentialing

Credentialing is a critical function of the ASC. Credentialing is as process to ensure the ASC's independent practitioners (physicians, nurses, physician assistants, etc.) are qualified and licensed.

Credentialing and privileging of healthcare professionals protects patients and the ASC by minimizing the risk of medical errors that may result from unqualified providers.

The number of ambulatory surgery centers has increased in number dramatically over the past decade. In 2016, over 40% of outpatient surgery was performed in ambulatory surgery centers (ASCs) [29]. Some ASC's are physician owned and some are jointly developed by an established hospital and physicians. A 2009 study suggested that physician ownership is associated with the increasing use of ASCs. New owners, the authors stated, frequently altered their procedure-mix to include a greater share of financially lucrative procedures [30].

Challenges can be evident in privileging in ASC's regardless of ownership. ASCs may have less oversight and less-well-developed policies for credentialing and privileging. A survey of 139 freestanding ASCs with two or more specialty services in 2007 revealed that only 54 % of their physicians were board certified at any time during their tenure [31]. The Accreditation Association for Ambulatory Healthcare (AAAHC) and the Joint Commission have extensive credentialing and privileging requirements.

The Comprehensive Accreditation Manual for Ambulatory Care (CAMAC) contains the set of standards that defines performance expectations to evaluate ambulatory care settings, including ambulatory surgery centers (Table 16.1).

The Standard delineates the structures or processes that must be in place in order for an organization to provide safe, high-quality care. They address the

**Table 16.1** Joint Commission Standards and Guidelines for Human Resources in Ambulatory Care Settings

| Standard | Elements of Performance |
|---|---|
| **Standard HR.01.02.07** The organization determines how staff function within the organization. | All staff that provide patient care, treatment, or services possess a current license, certification, or registration, as required with law and regulation.<br>Staff who provide patient care, treatment, or services practice within the scope of their license, certification, or registration and as required by law and regulation. (See also HR.01.02.05, EPs 1 and 2)<br>Staff oversee the supervision of students when they provide patient care, treatment, or services as part of their training. |
| **Standard HR.01.06.01** Staff are competent to perform their responsibilities. | The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.<br>An individual with the education background, experience, or knowledge related to the skills being reviewed assesses competence.<br>Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.<br>Staff competence is initially assessed and documented as part of orientation.<br>Staff competence is assessed and documented once every three years or more frequently as required by organization policy or in accordance with law and regulation.<br>The organization takes action when a staff member's competence does not meet expectations. |
| **Standard HR.02.02.01** The organization provides orientation to licensed independent practitioners. | The organization determines the key safety content of orientation provided to licensed independent practitioners.<br>Note: Key safety content may include specific processes and procedures related to the provision of care, the environment of care, and infection control.<br>The organization orients its licensed independent practitioners to key safety content before they provide care, treatment, or services. Completion of this orientation is documented.<br>The organization orients licensed independent practitioners on the following: Relevant policies and procedures. Completion of this orientation is documented.<br>The organization orients licensed independent practitioners on the following: Their specific responsibilities, including those related to infection prevention and control and assessing and managing pain. Completion of this orientation is documented. (See alsoIC.01.05.01, EP 6 and RI.01.01.01, EP 8)<br>The organization orients licensed independent practitioners on the following: Sensitivity to cultural diversity based on their specific responsibilities. Completion of this orientation is documented. |

organization's responsibility to establish and verify staff qualifications, orient staff, and provide staff with appropriate training. HR must also provide for the assessment of staff competence and performance. Finally, the organization is responsible to credential and privilege licensed independent practitioners and provide them with orientation and a fair hearing and appeal process. A center is evaluated as either "compliant" or "not compliant" with a standard. Accreditation decisions are based on simple counts of the standards scored "not compliant."

The Joint Commission requires healthcare organizations to assess their staffing effectiveness by continually screening for issues that can potentially arise as a result of inadequate staffing. Staffing effectiveness is defined as the number, competency, and skill mix of staff related to the provision of needed care, treatment, and services [32]. The Joint Commission's focus is on the link between HR strategy implementation (i.e., adequate staffing) and organizational outcomes (i.e., clinical outcomes).

Understanding of these standards is crucial for ASC managers. In 2014, half of the organizations surveyed were not in compliance with the standard of privileging. 50% did not meet the standard that states that the organization grants initial, renewed, or revised clinical privileges to individuals who are permitted by law and the organization, to practice independently [33]. ASCs who receive Joint Commission accreditation have proved that they provide the highest level of performance and service to their patients.

ASC leaders realize that accreditation surveyors expect a high degree of updated and complete information in human resources files. Yet, they may feel challenged to have the expertise to navigate the process. Outsourcing the credentialing process may be a viable option to support the ASC's credentialing staff. If there is insufficient staff to handle the workload, identifying a reliable credentialing partner may provide an efficient and cost-effective solution [34].

It is important for administrators to maintain complete and up-to-date records on all staff credentialing and privileging. Practitioners must only apply for the privileges they intend to practice. The process of credential verification and privileging needs to be clearly defined in the ASC's policies and procedures. The process requires the oversight of the Medical Director, the Medical Executive Committee and the Governing Board of the ASC. All appointments are usually for a period of one to two years and reviewed and renewed at the time of re-appointment. ASCs must also have clearly stated procedures for denying of privileges or re-appointment if the situation arises.

## Difficult Conversations

An administrator, medical director or nurse manager in an ASC is usually the person called upon to resolve conflict. As such, it is important that they receive training in conflict management and in how to have difficult conversations. According to Deborah Frances Tannen, an academic and professor of linguistics at Georgetown University in Washington DC, "Every time we open our mouths to speak, we are taking a leap of faith –faith that what we say will be understood by our listeners, more or less as we mean it" [35]. An organization's success depends on effective communication by its leadership.

Take the following examples:

1. *You are the director of nursing at the ASC. KC, an OR nurse meets with you at the end of the day. She alleges inappropriate behavior by a high volume surgeon at the ASC. The behaviors include inappropriate contact, verbal harassment, and that he followed her after hours in the parking lot.*
2. *You are the Medical Director of the ASC. SR, a PACU nurse* reports *inappropriate remarks of a racial nature made by an attending anesthesiologist in the PACU within earshot of patients and families.*
3. *You are the administrator of the ASC. JT, a scrub technician, complains about off color humor in the operating room and derogatory statements against women made by the surgeon, CRNA and OR nurse.*

It is important during a difficult conversation or conflict resolution process to remain neutral and accept that conflict is a natural consequence of different personalities at work. Ensure that the existing policies and procedures for the type of situation are being followed. If there is not a policy already addressing the issue, consult with the rest of the management team to develop one. It is critical to maintain documentation at every step of the conflict resolution process. Gather data by meeting with both parties, in the presence of other management leaders if necessary. While gathering information, engage the individual by asking open-ended questions and avoiding accusatory questions. Remain solution focused, avoid hyperbole and be willing to negotiate. Expect the accused party to become defensive, deny or discredit their accuser. Be prepared with what changes you expect in the accused party's behavior after this process and what actions you will take if no resolution is achieved [36].

## Conclusion

The contribution that human resources management makes to an organization's ability to provide safe, quality care cannot be overemphasized. A cohesive and motivated team can handle many challenges in these rapidly changing times for healthcare. There are initiatives under way to reduce the cost burden on ASCs. A bipartisan bill, the Ambulatory Surgical Center Quality and Access Act of 2017, was introduced in the U.S. House of Representatives on March 30, 2017. The act aims to ensure that the Medicare program maintains high levels of care and cost savings by introducing a series of measures including moving the ASC reimbursement update from the Consumer Price Index for All Urban Consumers (CPI-U) to the hospital market basket update. The hospital market basket update, currently used by hospital outpatient departments (HOPD's), better measures the cost of practicing medicine. These measures would achieve greater reimbursement parity between ASCs and HOPD's [37].

Like other healthcare organizations, ambulatory surgery centers face the same challenges when it comes to hiring quality talent. A positive relationship has been

demonstrated between high-performance work systems and quality of care. ASC managers must also develop policies to encourage multiculturalism as many more people from a variety of backgrounds are in the workforce. Optimized recruiting processes and effective employee retention programs are critical for providing quality care and ensuring patient safety. In addition managers must also be prepared to act as mediators to resolve the inevitable conflicts that arise in the workplace.

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# Culture of Safety

# 17

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## Creating a Culture of Safety in Ambulatory Surgery

In 2016, over 40% of outpatient surgery was performed in ambulatory surgery centers (ASCs) [1]. With exceptional outcomes and exceedingly high patient satisfaction scores at substantially lower costs, ambulatory surgery centers (ASCs) are arguably one of the greatest values in medicine. In 2014, over 5,400 ASCs treated 3.4 million fee-for-service (FFS) Medicare beneficiaries. Medicare program and beneficiary spending on ASC services was over $3.8 billion [2]. This drive toward outpatient surgery can be attributed to several factors: (1) Improvements in anesthetic care, including innovations such as shorter-acting anesthetic agents and improved cardiopulmonary monitoring, have allowed for fewer adverse anesthetic effects and rapid recovery; (2) Innovations in minimally invasive surgical techniques have decreased the need for inpatient hospitalization; (3) Economic pressures have also influenced increased adoption of outpatient surgery. Estimates have determined charges per visit for surgical procedures to be approximately five times less for outpatient *versus* inpatient surgery although unadjusted for length-of-stay or procedural complexity. Patient selection and these advances in perioperative care have allowed outpatient surgical procedures to be performed at an exceedingly low rate of morbidity or mortality [3].

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While the overwhelming majority of ASC procedures are done safely and without incident—as with surgeries in any health care setting—complications can result. These include healthcare-associated infections (HAIs), such as surgical site infections (SSIs) and other safety problems. The more than 2,100 freestanding ambulatory care organizations accredited by The Joint Commission are required to comply with rigorous standards and National Patient Safety Goals (NPSGs) that focus on problems in the ambulatory setting and how to solve them, including those related to: identifying patients correctly, using medicines safely, preventing infection, and preventing mistakes in surgery [4]. A lot of these topics are covered in other chapters in this book.

Concern over patient safety remains, as the outpatient surgical population has increased not only in volume but also in age and complexity, necessitating improved preoperative screening. In addition, the growth of ASCs has created a need to identify patients suitable for receiving surgical procedures on an ambulatory basis. Unfortunately, at this juncture, risk factors for major morbidity and mortality from outpatient surgery are not clearly defined. There are no national, prospectively collected data regarding optimal patient selection for ASC procedures. Current knowledge is limited to case series, single-center data, and administrative data analyses, and this continues to create a demand for evidence-based research to direct future initiatives. Patient selection is largely guided by administrative data, focused on risk of "readmission" or incidence of complications [3]. Developing appropriate ambulatory surgery clinical pathways will have an impact on safety, unplanned admissions, readmissions, delayed discharge home, post discharge complications, efficiency, and patient satisfaction.

## ASC Safety Begins with Patient Selection

The importance of monitoring outcomes in ambulatory surgery has gained CMS attention due to increasing numbers of Medicare beneficiaries having outpatient surgery. Outcomes of interest include appropriate patient selection, minimizing side effects, avoidance of unanticipated admissions to support an early return to functional status and avoidance of serious adverse events [5].

According to CMS Interpretive Guidelines for ASC Coverage 416.42(a) Standard: Anesthetic Risk and Evaluation: **"A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. The purpose of the exam immediately before surgery is to evaluate, based on the patient's current condition, whether the risks associated with the anesthesia that will be administered and with the surgical procedure that will be performed fall within an acceptable range for a patient having that procedure in an ASC, given that the ASC does not provide services to patients requiring hospitalization. The assessment must be specific to each patient; it is not acceptable for an ASC to assume, for example, that coverage of a specific procedure by Medicare or an insurance company in an ASC setting is a sufficient basis to conclude that the risks of the anesthesia and surgery are acceptable generically for every ASC patient"** [6]

With the advent of the perioperative surgical home, the emphasis on safety, quality, efficiency, cost-effectiveness, and patient satisfaction has led to the expansion of the anesthesia preoperative clinic. However, for those ASCs that do not have access to an anesthesia preoperative clinic, screening tools should be implemented to avoid catastrophic events and case cancellations.

There are many factors that determine if a patient surgery should undergo procedures/surgery at an outpatient ambulatory surgery center:

- Type of procedure
- Anesthetic technique
- Patient preoperative health (ASA status)
- Probability of significant blood loss
- Post op pain not manageable by oral medications
- Probability of post op admission
- Length of procedure
- Anticipated length of recovery
- Anesthesiologist & surgeon expertise
- Suitability of surgical facility (ASC or office based)
- Patient social factors

The American College of Surgeons (ACS) and the National Surgical Quality Improvement Project (NSQIP) database from 2005-2010 (n = 244,397), revealed that predictors of 72 hour perioperative morbidity included [3]:

- High BMI
- COPD
- Previous percutaneous coronary intervention/cardiac surgery
- Hypertension
- H/o TIA/CVA
- Prolonged operative time

In 2012, a retrospective case-control study by Whippey et al, found that the incidence of unanticipated admission following ambulatory surgery was 2.67%. The most common reasons for admission were surgical (40%), anesthetic (20%), and medical (19%). The following factors were found to be associated with an increased risk of unanticipated admission:

- Length of surgery more than one hour
- High (≥3) ASA physical status classification
- Advanced age (>80)
- High BMI

No specific comorbid illness was associated with an increased likelihood of unanticipated admission. These findings support continued use of the ASA classification as a marker of patient perioperative risk rather than attributing risk to a specific disease process [7].

Most ASCs develop patient selection guidelines based on local considerations including their state DOH restrictions, expertise of the anesthesia and surgical teams at the center, equipment availability at the center, proximity to a hospital with whom they have a transfer agreement, and resources available at the ASC.

Though patients with significant medical histories may undergo surgical procedures at ASCs, according to patient selection guidelines established by the Cleveland Clinic Foundation, in general, the following list serve as contraindications to general anesthesia in the ambulatory setting: [8]

- Highly suspected or a history of known difficult intubation
- Cases in which blood or blood products may be required
- ASA 4 physical status
- Total care nursing home patients or uncooperative patients
- Patients who may require extended recovery
- Patients with history of severe postoperative nausea and vomiting
- Patients with implantable cardioverter defibrillators who are pacemaker dependent
- Duration of surgery greater than 6 hours
- Emergency surgery
- Body mass index (BMI) greater than 50
- Patients with severe cardiac and pulmonary disease
- Patients who cannot be discharged to the care of a responsible adult
- When the patient's primary language is not English, and an interpreter is not available or present

## Evidence on Patient Selection

Researchers reviewed the evidence on the risk of ambulatory anesthesia for patients with significant coexisting diseases. In many cases, there is little evidence on outcomes, and they suggested more trials. Their findings:

- Elderly patients: May safely undergo ambulatory surgery but are at increased risk for hemodynamic variation in the OR. However, age >80 is an indicator of increased perioperative risk [7].
- Obstructive sleep apnea patients: patients with known OSA who have optimized co-morbid conditions and are able to use CPAP after discharge are candidates for ambulatory surgery. Those with a presumptive diagnosis of OSA based off STOP-BANG scoring, with optimized co-morbid conditions and postoperative pain that can be managed predominantly by using non-opioid analgesic techniques are also candidates for ambulatory surgery. OSA patients with non-optimized comorbid conditions are not suitable for ambulatory surgery and may benefit from diagnosis and treatment. It is important to remember that OSA patients are at increased risk of difficult tracheal intubation and respiratory events (i.e. oxygen desaturation, need for prolonged oxygen supplementation, stridor/laryngospasm, and airway obstruction) [9].

- Diabetes mellitus: Has not been linked with adverse events following ambulatory surgery. There is no evidence of any particular blood glucose level that is level that is harmful for outpatients. However, those pts with severe dehydration, keto-acidosis and hyperosmolar non-ketotic states are at increased risk for complications and should be postponed [10].
- Morbid obesity patients: At increased risk for minor respiratory complications in the preoperative period, but these events do not increase unanticipated hospital admissions. Patients with a BMI of 40-49 with optimized co-morbid conditions can undergo ambulatory surgery safely. Patients with a BMI >50 are generally not candidates for ambulatory surgery [11].
- Ex-premature infants: May be considered for ambulatory surgery if postconceptual age is >60 weeks and hematocrit is >30%.
- Children with upper respiratory infection: At increased risk for perioperative respiratory complications, particularly if endotracheal intubation is required.
- Malignant hyperthermia patients: May safely undergo outpatient surgery as long as a non-triggering anesthetic is used.
- Cardiac Disease: Elective non-cardiac surgery should be delayed 30 days after bare -metal stent implantation and optimally 6 months after drug -eluting stent implantation [12].

## In Summary

Patient selection for surgical procedures at ambulatory surgical centers is a complex and dynamic process. The first step in determining appropriate patient selection includes a preoperative assessment and identification of any comorbid conditions, which should be optimized to minimize risks. The development and implementation of clinical pathways should improve the process of appropriate patient selection in order to maximize patient safety and satisfaction while helping to decrease same day cancellations.

**Resources for Calculating Surgical Risks:**

1. ACS/NSQP Surgical Risk Calculator: https://riskcalculator.facs.org/RiskCalculator/PatientInfo.jsp
2. Gupta Perioperative Cardiac Risk Calculator: https://www.evidencio.com/models/show/961

## Limitations of a Freestanding ASC Versus Hospital Ambulatory Department

Thirty years ago, almost all surgery was performed in a hospital. It was not uncommon for patients to wait weeks to months for an appointment and to spend several days recovering in the hospital and several weeks out of work in recovery. This is still the case in many countries today, but not in the United States. The first ASC was opened in 1970 by two physicians who saw an opportunity to establish a high quality,

cost effective alternative to inpatient hospital care for surgical services [asge.org]. Ambulatory surgery centers are defined by Medicare as distinct entities operating exclusively to furnish outpatient surgical services to patients that do not require hospitalization and do not require more than a 24-hour length of stay. The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services. The ASC must: (1) have a written transfer agreement with the hospital and (2) ensure that all physicians performing surgery in the ASC have admitting privileges at the hospital.

Medicare recognizes two classes of ASCs: independent or freestanding ASCs, and hospital-based ASCs, which are owned or controlled by a hospital (CMS 2008b). Hospital based ASCs may be located on a hospital campus or at some distance in a separate building. Originally ASCs were competitors of inpatient surgery units. Now, ASCs are the primary competitors of hospital outpatient departments [13]. Sixty percent of hospitals now have an ASC within a five-minute drive from their campuses. As hospitals and health systems accelerate population health models, such as accountable care organizations, ASCs and their lower prices will become more critical competitors [14].

Free standing ASCs come with their own set of safety concerns and unique challenges:

- The lack of a diverse group of physicians to consult in the case of an urgent or emergent situation. It is not uncommon for ASCs to only have one anesthesiologist on site with multiple OR's running at the same time. This can result in serious consequences if an emergency situation arises.
- Lack of long term monitoring facilities necessitating transfer of patients requiring higher level of care to a hospital.
- Inadequate supply of emergency medications and equipment due to cost constraints.
- Unavailability of certain types of emergency medications or equipment.
- Inadequate nursing/support staff to assist in the case of an emergency.
- A lack of laboratory and radiological services in the case of an emergency.
- Lack of blood bank or transfusion capabilities.

It is important for physicians to create workable solutions to the issues listed above when they are working at ASCs to avoid poor patient outcomes and possible litigation, and most important—maintain a culture of safety.

## Communication Gaps

Effective communication is a cornerstone of providing safe and effective patient care. Communication breakdowns are the second most common cause of surgical errors and adverse events after technical errors [15]. (Arriaga) The Joint Commission concluded that failures of communication are the root cause of nearly every reported unexpected death and catastrophic injury [16].

Communication breakdowns have also been associated with increased overall morbidity [17, 18].

Critical lapses in communication can occur between providers such as physicians and nurses, between attending physicians and trainees, and between providers and patients. Barriers to effective communication between health care providers include environmental factors such as high workload, perceived lack of support, staff conflict, or unfamiliarity with communication tools. Barriers between providers and patients can include language differences, cultural differences, and low health literacy. A positive safety culture in organizations is only achieved with an intentional commitment to clear communication founded on mutual trust and shared perceptions of the importance of safety.

## Anesthesia to Nursing Communication

Several factors may impede good communication between anesthesia providers and nursing providers. Distractions in the postoperative care unit (PACU) environment during handoff can contribute to miscommunication or omission of patient information. The anesthesiologist and the PACU nurse may have differing expectations of the content and timing of information transfer. An effective handoff has several objectives. Handoff coveys key information regarding the patient's medical history and intraoperative course, and represents transition of care and responsibility to the PACU team. It can also serve as a key 'audit point' in management to review and plan further care [19].

An ASC should implement a protocol using clear and consistent language so that key information cannot be misinterpreted [20] (Figure 17.1).

Failure of this transition of roles and care can impair safety. Handoff protocols enhance communication while decreasing errors among nurses, anesthesiologists and surgeons during the transfer of patients from the operating room to the PACU [21]. Handoff improvements and smooth transitions between care settings should be tailored to the specific ASC.

## Attending to Resident Communication

Effective communication between residents and attendings regarding patient status is essential for patient care. Communication barriers may exist due to confusion regarding what to communicate, stress and fatigue, or lack of clarity regarding expected degree of resident autonomy.

A policy driven intervention at four teaching hospitals at Harvard University to improve surgical communication resulted in significant reductions in the percentage of critical events not conveyed to an attending physician [14]. A review of over 400 malpractice claims determined common characteristics of cases with communication breakdown. The authors endorsed a set of communication standards that have the potential to prevent 45% to 73% of cases of patient harm because of communication failure [22]. First, communication to attendings should include updates on patient condition and prompt notification of significant changes to status. Second,

| | | |
|---|---|---|
| Patient | Patient identification (nameband check) | |
| | Time in | |
| | Allergies | |
| | Surgical procedure and reason for surgery | |
| | Type of anesthesia (GA, TIVA, regional) | |
| | Surgical or anesthetic complications | |
| | PMH and ASA scoring | |
| | Preoperative cognitive function | |
| | Preoperative activity level (METs) | |
| | Limb restriction | |
| | Preop vitals | |
| Procedure | Positioning of patient (if other than supine) | |
| | Intubation conditions (grade of view, airway, quality of bag mask ventilation, bite block?) | |
| | Lines/catheters (IVs, a-lines, CVSs, foley chest tubes, surgical drains, Vp shunt) | |
| | Fluid management | Fluids=<br>EBL=<br>UO= |
| Medications | Analgesia plan - during case, postop orders | |
| | Antiemetics administered | |
| | Medications due during PACU (antibiotics, etc.) | |
| | Other intra-op medications (steroids, antihypertensives) | |

**"Do you have any questions or concerns?"**

**Figure 17.1** PACU Handoff Protocol. Ambulatory Surgery Center Survey on Patient Safety Culture. Content last reviewed January 2019. Agency for Healthcare Research and Quality, Rockville, MD. (*Adapted with permission of the Agency for Healthcare Research and Quality*.) http://www.ahrq.gov/sops/surveys/asc/index.html

direct attending to patient communication must occur. Third, attending-to-attending communication should occur if there will be a transfer of care [22]. Successful interdisciplinary teams with a culture of safety use teamwork skills and practice in a climate that fosters effective teamwork [23].

## Caregiver to Patient/Family Communication

Communications gaps in conveying health information can be expected with patients and families with low health literacy or low proficiency in the English language. In a 2003 evaluation of adult health literacy, the majority of Americans, 53%, had *Intermediate* health literacy. 22 percent of adults had *Basic* health literacy, 14 percent had *Below Basic* health literacy, and 12 percent had *Proficient* health literacy [24].

Populations at most risk for low health literacy are older adults, ethnic minorities, people with low-income levels and non-native English speakers [24].

Healthcare encounters should incorporate communications techniques known to enhance comprehension among patients. A key element is use of plain language:

- Organize and limit information so that the most important points come first
- Break complex information into understandable chunks
- Use simple language and define technical terms. Use drawings or models.
- Use the active voice [16]

"Teach back" techniques can assess and ensure patient understanding. The teach-back method is a communication tool for confirming accurate comprehension of health information by having patients state in their own words what was conveyed by the practitioner [25].

It is important as well to reconcile patient medications at each step along the continuum of care. Encourage patients to keep a list of all current medications and dosages updated [26].

Cultural and linguistic competency of health professionals can contribute to improved health literacy in patients. Cultural competence is the ability of health organizations and practitioners to recognize the cultural beliefs, values, attitudes, traditions, language preferences, and health practices of diverse populations, and to apply that knowledge to produce a positive health outcome. Competency includes communicating in a manner that is linguistically and culturally appropriate. To cultivate a culture of safety, ASC's must strive to make effective communications an organizational priority.

ASC staff need to feel empowered to speak up if they notice something awry and be able to "stop the line" if there is potential for patient harm. The ASC could also identify physicians who would act as a liaison between the leadership, ASC staff and medical staff to promote safe and effective patient care.

## Techniques to Implement a Culture of Safety

Joint Commissions standards refer to the Environment of Care [27]. As part of ASC credentialing, the facility must "promote a safe, functional, and supportive environment within the organization so that quality and safety are preserved." The environment of care includes the physical space, the equipment used and the people that work within the organization. All of these factors are to be considered when minimizing risks.

The Institute of Medicine, in one of the first comprehensive reports on medical errors, To Err is Human, concluded that most medical errors are the result of unavoidable human error [28]. Medical accidents can provide a form of information about a system and represent places in which the system failed with resulting harm to a patient. Errors, therefore, can only be reduced through system changes. The authors provided the following recommendation for performance standards to enhance focus on patient safety: [28] Health professional licensing bodies should:

(1) implement periodic reexaminations and relicensing of doctors, nurses, and other key providers; (2) work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action; and (3) make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. An effective ASC charts a course and finds a balance between a punitive culture that generally does not consider the systems issues that contribute to errors, and a culture without appropriate accountability for its staff. ASC leaders should provide training and establish systems and methods to report practice deviations, provide remediation for practice deficiency, and resolve systemic issues contributing to practice breakdown. Because many errors that impact patient safety are caused by system or process failures, understanding and adopting process-improvement techniques with agility is an important component to managing a complex ASC safety environment.

The National Academy of Engineering and the Institute of Medicine, in a novel report, recommended the application of systems engineering approaches for enhancing health care delivery [29]. Systems engineering is a disciplined approach to identify the components that meet the goals and requirements of an organization by integrating technology, personnel, and processes. Systems engineering approaches have been widely adopted in technology and service industries. The 2005 report *Building a Better Delivery System*, stressed the importance of the diverse participating elements of health care to recognize the interdependence of the influences of processes and people. The paper described that a systems approach to health is "one that applies scientific insights to understand the elements that influence health outcomes, models the relationships between those elements, and alters design, processes, or policies based on the resultant knowledge in order to produce better health at lower cost." [29]

These elements of the healthcare system can be stratified into four "nested" levels: (1) the individual patient, (2) the care team (physicians, nurses, pharmacists, etc.), (3) the organization (ASC, clinic or hospital) and (4) the political and economic environment (regulatory, health care payment methods).

Another well-studied implementation tool is the Translating Evidence into Practice (TRiP) model [30]. Steps in the TRiP model include:

1. Review the latest evidence;
2. Identify potentially effective and feasible interventions, test and refine practices with multidisciplinary team input, and implement interventions;
3. Measure performance; and
4. Spread and embed interventions into routine practice to meet the needs of all patients (Figure 17.2).

An approach to translating evidence into practice would focus on systems and processes, rather than care of individual patients. Care management teams are often composed of members from diverse medical delivery functions, and these teams must seek to integrate their expertise to contribute to the common safety goals. Each interdisciplinary team should be actively engaged in development of a safety

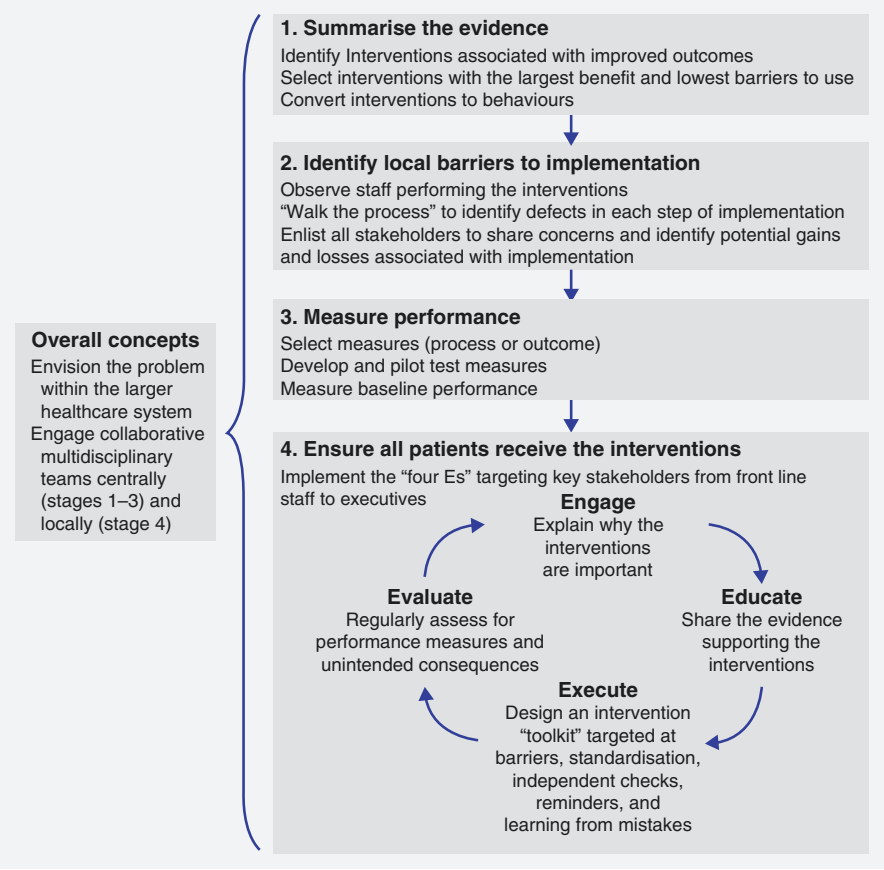


**Figure 17.2** Strategy for Translating Evidence into Practice

improvement initiative. A centralized support system should be created to support technical work for the team. Ownership is fostered when teams are engaged in development of protocols, and include team members that can implement adaptation of the intervention [30]. Ensure that team members understand the context surrounding the intervention and consider possible failure points and steps to improve compliance.

Performance measures are important to evaluate the intervention. Performance may be measured through process indicators or outcome indicators. Process indicators concern implementation issues, such as coverage, equity of distribution, and communication. Outcome indicators measure impact or measures of actual achievements intended by the intervention. Measuring indicators serves several important purposes. Indicators allow documentation of quality of care and benchmarking over time. Measuring indicators also supports accountability, ensures compliance with regulatory requirements, and supports quality improvement [31]. Outcome measures are preferred if feasible and reliable. When indicators are in

place, it is crucial to engage the ASC team in why the intervention is important for the safety of patients and the success of the ASC. Provide baseline data on complications such as postoperative infections, unplanned hospital admission, respiratory complications, etc.

Education and training of healthcare staff increases their knowledge and improves the quality of patient care, and is an important component of TRiP. Steps of knowledge transfer represent three major stages: (1) knowledge creation and distillation, (2) diffusion and dissemination, and (3) organizational adoption and implementation [32]. (Nieva) Knowledge creation *put*s the *products* of *research* into action by placing information and practice recommendations *into* the hands of practicing clinicians [33]. An ASC with a culture of safety is an organization where teams and individuals adopt and employ evidence-based research in everyday practice.

Execution is often the step of TRiP with the most barriers to implementation. Frequently, evidence from clinical research and treatment guidelines are not utilized in practice resulting in an evidence-practice gap [34]. The challenge is to find ways to improve the organization in a situation of shared power where the capacity for solving problems is widely dispersed. An effective implementation toolkit recognizes these barriers, standardizes care practices and creates independent measures of execution.

The Institute for Healthcare Improvement offers another model for improvement that focuses on setting aims. This model believes that an organization will not improve without a clear and firm intention to do so. The aim should be time-specific and measurable; it should also define the specific population of patients that will be affected. Getting consensus from staff on the aim is crucial. Then, the organization must allocate the people and resources necessary to accomplish the aim (Figure 17.3).

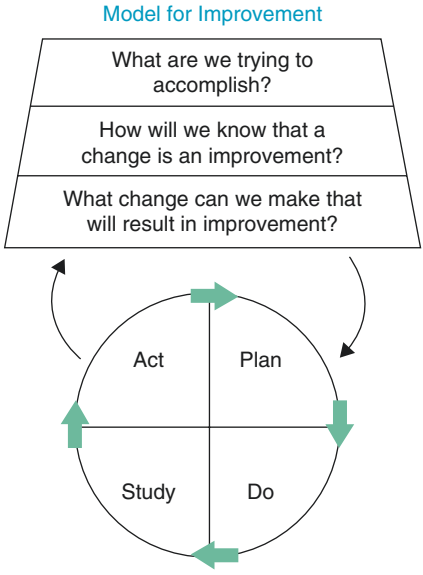


**Figure 17.3** Institute for Healthcare Improvement Model

The Agency for Healthcare Research and Quality (AHRQ) proposed a comprehensive program to implement an environment of safety in the ambulatory surgery setting. The goals were reduction in surgical site infections, improved patient safety culture, improved ASC patient experience of care and improved provider and staff satisfaction. The framework relies on a Comprehensive Unit-based Safety Program (CUSP), a culture change model that fosters collaborative interaction between physician, nurses, and the rest of the clinical team [35].

CUSP advances the mindset that it is crucial to develop a learning environment in which errors are treated as an opportunity to enhance learning for all team members and to reduce risk of future errors.

Key components of CUSP are Measurement, Safety Checklists, and Sustainability.

## Measurement

The collection and reporting of data is the cornerstone of any quality improvement initiative. Data allow you to benchmark current safety practices and guide future direction.

## Safety Checklists

The surgical safety checklist is an invaluable tool for optimizing patient safety culture through the use of teamwork and communication strategies, providing standardization across patient care, and decreasing the likelihood of complications.

Appropriately designed and executed checklists standardize practice in routine and emergency situations. Checklists provide a framework for adherence to regulatory and safety requirements, and an assurance that information is being cross-checked, particularly in high-stress environments [36].

Many health practitioners have resistance to checklists due to perceived inefficacy at improving patient care and inefficiency of implementation. Recommended steps to develop successful checklists with support of staff include the following: (1) review the existing literature; (2) engage a multidisciplinary team in design; and (3) tailor the tool to the users at your ASC. Checklists are powerful tools to standardize work processes and create independent checks for key processes. More details on checklists are provided in the Education and Training chapter.

The Surgical Care and Outcomes Assessment Program (SCOAP) provides another example of a surgical checklist for ambulatory surgery. It addresses what actions need to be taken during three steps: prior to incision, process control, and debriefing at case completion [37] (Figure 17.4).

Safety tools, such as checklists and standard communication protocols are beneficial to ensuring learned behaviors are executed on a daily basis. The most effective tools have staff input, and are customized for the specific ASC and culture of the staff. These protocols should be refined and updated regularly [38].

**Step 1: Prior to Incision**

**ALL TEAM MEMBERS STOP ACTIVITY AND BEGIN CHECKLIST**

- ❑ Team members introduce themselves (when personnel have changed)
- ❑ Introduce patient, verify consent, procedure
- ❑ Confirm site marked and if there is a single or multiple operative field

**Anesthesia Team Reviews**

- ❑ Airway issues or other patient-specific concerns (special meds, health conditions affecting recovery, etc.)
- ❑ Patient allergies reviewed ❑ N/A
- ❑ Antibiotics given within 60 mins before incision ❑ N/A

**Surgeon Reviews**

- ❑ Brief description of procedure and anticipated difficulties
- ❑ Describe implants needed, unusual instruments OR supplies ❑ N/A
- ❑ Confirm that essential imaging is displayed and correctly oriented ❑ N/A

**Nursing Team Reviews**

- ❑ Confirm that supplies and implants are available ❑ N/A
- ❑ If using an implant, confirm expiration dates ❑ N/A

**Step 2: Process Control**

IF PROCEDURE IS EXPECTED TO BE LONGER THAN ONE HOUR:

- ❑ Active warming in place ❑ N/A
- ❑ Glucose checked for diabetic patients ❑ N/A
- ❑ VTE prophylaxis ❑ N/A

**Step 3: Debriefing—At Completion of case**

- ❑ (Surgeon and Nursing) Before closure: Confirm that instrument, sponge, and needle counts correct
  - ❑ If counts incorrect, confirm x-ray negative
- ❑ (Surgeon and Nursing) Confirm specimen, label & instructions to pathologist ❑ N/A
- ❑ (All) Confirm name of procedure
- ❑ (All) Equipment issues to be addressed? ❑ No ❑ Yes, and response plan formulated (Who/When)
- ❑ (All) What could have been better? ❑ Nothing ❑ Something, with plan to address (who/When)
- ❑ (Surgeon and Anesthesia) Key concerns for recovery (e.g., plan for pain management, nausea/vomiting)

**Figure 17.4** Surgical Care Outcomes Assessment Program (SCOAP). *SCOAP Checklist*. 2012. Foundation for Health Care Quality, Seattle. (*Reprinted with permission of the Foundation for Health Care Quality*.)

## Sustainability

Quality improvement initiatives and patient safety processes should be part of the ASC's routine, day-to-day work. Key elements that foster sustainability are daily huddles, use of visual boards when possible, having a strong reporting system, and having clear escalation protocols [39]. It's important to realize that "checklist fatigue" can blunt the effectiveness of a safety plan [40]. Other key factors for a

sustainable safety culture include recognizing and celebrating success and improving teamwork and communication, which in turn promotes adherence to evidence-based practice. Innovative methods can be used to keep staff engaged in the process such as awards for "good catches", recognition for staff who prevented a serious event, empowering the staff to "speak up" or "stop the line" when they observe a potentially unsafe situation.

## Developing a Safety Culture Survey

Efforts to improve culture of safety need to be measured to demonstrate that organizational initiatives are resulting in the desired improvements to the ASC environment. The safety culture survey is a useful tool in tracking safety culture over time, and building a high-performance workforce at an ASC. Engagement of health professionals in a survey orients the organization towards viewing patient safety as the highest priority for the ASC.

The Joint Commission requires that hospitals measure the culture of safety within the organization using valid and reliable tools [41]. Some health care surveying organizations such as LeapFrog group require a culture of safety survey biannually as part of their certification. Valid surveys by Leapfrog's guidelines include: employees completing the survey should have familiarity with the facility; the survey must be administered to frontline clinical staff; there must be no coercion to complete the survey; it should include clinical and nonclinical staff; and high response rates are valued above high scores [42].

Surveys should include all clinical and nonclinical caregivers at the ASC, including physicians, nurses, technicians and schedulers. The survey should be anonymous, with no specific staff identifiers beyond their role in the organization. Questions should be aimed to identify opportunities for improvement and be able to generate information that will support specific action plans. AHRQ has an example of a validated survey [43] (Figure 17.5).

Administered regularly, a survey can help an ASC evaluate their processes, clarify opportunities for improvement, as well as examine trends in patient safety culture change over time.

## Summary

Safety culture as a concept originated in high reliability organizations but is now an increasingly important part of healthcare. Safety culture is the commitment made by the organization to maintain safety at all levels by fostering a blame-free environment, encouraging collaboration, allocating resources to safety initiatives and empowering staff to "speak up". Interestingly, the perception of safety culture in an organization varies considerably across job descriptions with nurses perceiving a punitive environment and physicians and non-physician providers perceiving lack of organizational commitment to a

**SECTION A: Working in This Facility**

▶ **How often do the following statements apply to your facility?**

| | Never | Rarely | Some-times | Most of the time | Always | Does not apply or Don't know |
|---|---|---|---|---|---|---|
| 1. Important patient care information is clearly communicated across areas in this facility | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 9 |
| 2. We feel comfortable asking questions when something doesn't seem right | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 9 |
| 3. We have enough staff to handle the workload | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 9 |
| 4. When we see someone with more authority doing something unsafe for patients, we speak up | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 9 |
| 5. Key information about patients is missing when it is needed | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 9 |
| 6. Our ideas and suggestions are valued in this facility | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 9 |
| 7. We share key information about patients as soon as it becomes available | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 9 |
| 8. There is enough time between procedures to properly prepare for the next one | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 9 |
| 9. Within this faclility, we do a good job communicating information that affects patient care | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 9 |
| 10. We feel rushed when taking care of patients | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 9 |

**Figure 17.5** Surgical Care Outcomes Assessment Program (SCOAP). *SCOAP Ambulatory Checklist*. 2010. Foundation for Health Care Quality, Seattle. (*Reprinted with permission of the Foundation for Health Care Quality*.) https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patientsafetyculture/asc/userguide/ascguide.pdf

culture of safety [44]. Commonly cited reasons for lack of safety culture in health care include: poor teamwork and communication, low expectations and steep authority gradients all of which have been associated with serious events and potential patient harm. It is these barriers that an organization needs to surmount in order to build a robust safety culture.

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# Education and Training: Staff and Facility

# 18

Catherine Chiu and Sakura Kinjo

## Introduction

As the scope of practice continues to grow for ambulatory surgery centers (ASCs), so does the potential for unintended adverse outcomes and events. The literature suggests anywhere from 0.5% to 25% of patients experience some complications from outpatient surgical procedures [1, 2]. Emphasis on education and training provided to staff is key to creating a culture of safety (Chapter 17) with proper emergency preparedness (Chapter 19).

While there is no "gold standard" for the education and training of staff, there are several practices that can be adapted from the hospital setting to improve patient safety in ASCs. These trainings include Crisis Resource Management and other team based approaches.

## Crisis Resource Management

Much can be learned from the aviation industry regarding education and training of staff employed in high stakes environments. What began in the 1970s as Crew or Cockpit Resource Management was adapted into Crisis Resource Management (CRM) in the operating rooms and in anesthesia curricula by David Gaba and his group at Stanford University [3, 4]. The tenets of CRM can be found in Table 18.1. Based on the idea that human error and poor communication are constant threats for most preventable adverse events, CRM emphasizes the importance of non-technical

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skills in the awareness and ability to use all resources when providing patient care [5]. Studies have shown that implementation of CRM principles improves patient safety, though admittedly it is difficult to show causality [6].

The use of cognitive aids (Table 18.1, Key point #11) in crisis situations has been specifically been shown to enhance interprofessional teamwork and performance in simulated situations [7–9]. Cognitive aids are meant to mitigate the errors that may arise from impaired memory and cognition during stressful situations and ensure

**Table 18.1** Principles of Crisis Resource Management

| Principles of Crisis Resource Management | |
|---|---|
| 1. Know the environment | Know what is available:<br>– Personnel, who can be called<br>– Equipment<br>– Supplies |
| 2. Anticipate and plan | What are the requirements to complete a case?<br>Anticipate what could go wrong |
| 3. Call for help early | Help may be needed when:<br>– Too many tasks need to be done<br>– Catastrophic or fatal situations<br>– Problems not responding to treatments<br>– You do not know what is going on |
| 4. Exercise leadership and followership with assertiveness | Leaders: planning, deciding, distributing tasks<br>Followers:<br>Get everyone to concentrate on *what* is right, not *who* is right |
| 5. Distribute the workload | 10 seconds for 10 minutes<br>– If a team can "slow down" its activities for 10 seconds, the benefit of rational decision making and planning can potentially save 10 minutes |
| 6. Mobilize all available resources | Utilize everyone and everything, including:<br>– Extra hands<br>– Extra technology / equipment |
| 7. Communicate effectively | Messages need to be received and understood by all parties |
| 8. Use all available information | |
| 9. Prevent and manage fixation errors | Obtain second opinions when possible |
| 10. Cross check and double check | Never assume anything |
| 11. Use cognitive aids | See below |
| 12. Reevaluate repeatedly | 1. Was the initial assessment or diagnosis correct<br>2. Is the problem getting better or worse<br>3. Does the patient have any side effects from previous actions<br>4. Are there any new problems or problems missed from before<br>5. What further developments can be expected |
| 13. Use good teamwork | It may be valuable to spend some time coordinating a team during a crisis (10 seconds for 10 minutes) |
| 14. Allocate attention wisely | Limit multitasking |
| 15. Set priorities dynamically | Always the paramount priority: good oxygenation and perfusion |

(Adapted from Miller's Anesthesia, 8th Edition, with permission)

adherence to practice guidelines [10]. They may range from simple checklists to organized flowcharts. Importantly, the utility of cognitive aids is dependent on the content, design, and training specific to proper use of the cognitive aid. Within the aviation industry, misuse or poor design of cognitive aids were attributed to several major airline accidents in the 1980s and 1990s. Since then, several tools to assess the quality of cognitive aids have been developed specifically for aviation, and some have been adapted and validated for the medical field [11, 12]. Without careful consideration of these three aspects, the literature does not support use of cognitive aids in emergencies [8]. Perhaps the most widely used and easily accessible cognitive aids in anesthesia come from the Stanford Anesthesia Cognitive Aid Group (Emergency Manual: Cognitive Aids for Perioperative Critical Events, http://emergencymanual.stanford.edu).

The actual practice of CRM requires appropriate training, and several validated programs are available for this purpose. These currently include Medical Team Training, TeamSTEPPS®, MedTeams®, and MOCA® Crisis Resource Management and among others.

- Medical Team Training (MTT): Implemented by the National Center for Patient Safety (NCPS) in Veterans Affairs Medical Centers in 2006, MTT has led to improvement in multiple areas of clinical practice such as teamwork, quality of patient care, operating room efficiency, and morale of staff and patient outcomes [13].
- TeamSTEPPS®: Developed by the Agency for Healthcare Research and Quality (AHRQ), TeamSTEPPS® aims to use evidence-based tools in improving patient outcomes through communication and teamwork [14].
- MedTeams®: Developed by the Dynamics Research Corporation, this system adapted teamwork strategies from the aviation world and applied it to emergency room teamwork [15].
- MOCA® Crisis Resource Management: Offered by the Center for Medical Simulation (CRM), workshops in Anesthesia Crisis Resource Management (ACRM) fulfill the Maintenance of Certification in Anesthesiology (MOCA) simulation requirement. More information available at harvardmedsim.org.

## Team Based Approach

A team-based approach to executing good ASC practices and providing the best care for patient safety is not a novel concept. As CRM dictates, patient safety requires communication and cooperation amongst all members of the healthcare team, regardless of technical skill. It is worth mentioning that the perception of teamwork can be misinterpreted by different members of the team, often based on an arbitrary level of hierarchy [16]. Several groups note the utility of validated questionnaires to bring out these differences in perception and instigate change in the workplace [16, 17]. One such available questionnaire includes the Safety Attitudes and Safety Climate Questionnaire [18].

Simulation of crisis-type situations is another useful tool to help establish teamwork and to practice specific center-based protocols [19, 20]. A comparison of high-stakes operating room simulation with and without CRM-type checklists found that checklists improved management of crises and improved teamwork during the crisis [21].

Some examples of emergency protocols to simulate include:

- Difficult airway protocol
- Malignant Hyperthermia
- Local anesthetic systemic toxicity
- Cardiovascular or pulmonary collapse requiring chest compressions

See the *Cognitive Aid* section at the end of the chapter for examples of cognitive aids that can be used during simulation training.

## Mandatory Training Protocols for Accredited ASCs

The accreditation process (Chapter 14) mandates training protocols be available for specific situations. While each accrediting organization will provide its own set of guidelines, the federal guidelines for compliance with the Medicare Conditions for Coverage are available to the public. Each protocol ought to include details on (1) Identification of the danger to patient or staff safety, (2) Potential mitigation of such dangers, (3) Preparedness for such dangers, (4) Response to such dangers, and (5) Recovery once a danger is deemed neutralized.

Mandatory training for ASCs include:

- Disaster preparedness, such as fire, flood, biochemical hazard, electrical failure, failure of the water supply, or failure of key operating room equipment.
  - ASCs are required to partake in two annual fire drills. One is preferred to be community-based, and the other can be facility-based.
- CPR training for appropriate staff
- Infection control
  - The Oregon Patient Safety Commission has a free and accessible "Oregon Ambulatory Surgery Center Infection Control and Prevention Toolkit" available online.

## Standard Healthcare Training

In addition to crisis simulation, it is important to utilize a team-based approach to preventing non-emergency adverse outcomes. Such practices may include:

- Avoidance of wrong patient, wrong site, wrong side, wrong procedure, wrong implant, and other adverse surgical events

– Standard safety precautions to prevent transmission of disease
– Cybersecurity
– Sexual Harassment

## Other Resources

Education and training of staff is not an easy task at hand. As such, there are several organizations that provide services to train groups of staff. These include, but are not limited to:

– Ambulatory Surgery Center Association (ASCA) Online Training Series
– AORN (Association of Perioperative Nurses) ASC Solutions
– HCCS Ambulatory Surgery Center Library Safety and Accreditation Courses

## Summary

Proper education and training of operating room staff to handle urgent and crisis situations is as important as having a trained anesthesiologist at hand. This chapter emphasizes the benefits of utilizing the tenets of Crisis Resource Management and developing a team-based approach to foster a safe and trusting environment. Cognitive aids can be used by properly trained staff and providers to improve patient outcomes in crisis situations. Finally, there are various structured training programs geared at standard healthcare training as well as mandatory training protocols for accredited ASCs.

## Cognitive Aids

The following section provides examples of cognitive aids for various emergent situations from different resources. It is not intended for use without proper training of staff and any updates to clinical practices should be incorporated at time of training.

## Cognitive Aid #1: Difficult Airway Algorithm (Figure 18.1)

The American Society of Anesthesiologists (ASA) published updated practice guidelines for management of the difficult airway in 2013 [22]. Perhaps most pertinent to the education of ASC staff includes the strong recommendation to "ascertain that there is at least one additional individual who is immediately available to serve as an assistant in difficult airway management." Although the difficult airway algorithm is primarily geared towards the trained anesthesiologist, staff knowledge of the algorithm is useful should the anesthesiologist need assistance with equipment or other maneuvers.

American Society of Anesthesiologists®

*DIFFICULT AIRWAY ALGORITHM*

1. Assess the likelihood and clinical impact of basic management problems:
   - Difficulty with patient cooperation or consent
   - Difficult mask ventilation
   - Difficult suprglottic airway placement
   - Difficult laryngoscopy
   - Difficult intubation
   - Difficult surgical airway access
2. Actively pursue opportunities to deliver supplemental oxygen throughout the process of difficult airway management.
3. Consider the relative merits and feasibility of basic managment choices:
   - Awake intubation *vs.* intubation after induction of general anesthesia
   - Non-invasive technique *vs.* invasive techniques for the initial approach to intubation
   - Video-assisted laryngoscopy as an initial approach to intubation
   - Preservation *vs.* ablation of spontaneous ventilation
4. Develop primary and alternative strategies:

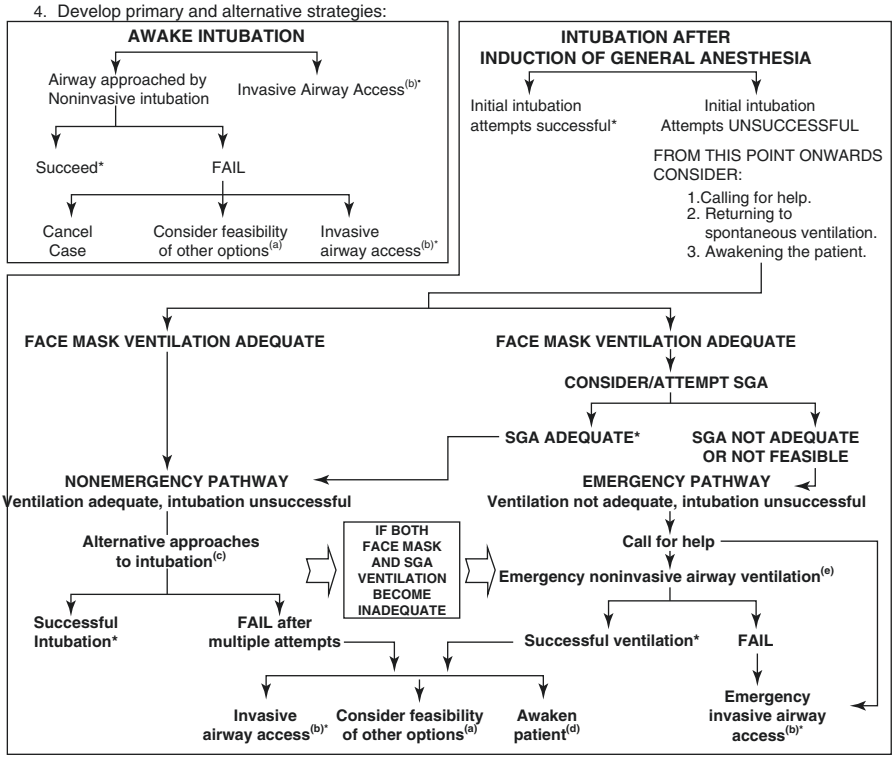


**Figure 18.1** Guidelines for Management of the Difficult Airway. LMA, laryngeal mask airway. (From Apfelbaun JL, Hagberg CA, Caplan RA et al, Practice Guidelines for Management of the Difficult Airway, Anesthesiology 2013;118:251–270, with permission.) [22]

## Cognitive Aid #2: Malignant Hyperthermia (Table 18.2)

Malignant hyperthermia (MH) is a rare but serious genetic disorder of metabolism that can be triggered by anesthetic drugs such as inhaled anesthetics and succinylcholine. The incidence of is reported to be between 1:10,000 and 1:250,000

**Table 18.2** Cognitive Aid for the Treatment of Malignant Hyperthermia

| Emergency Treatment for MH | |
|---|---|
| 1. Notify surgeon and stop procedure immediately | If surgery must be continued, maintain anesthesia with non-triggering intravenous anesthetics |
| 2. Get the dantrolene / MH cart | Call for help within the institution<br>Call the MHAUS hotline |
| 3. Hyperventilate with 100% O2 at 10 L/min | If available, insert activated charcoal filters into the inspiratory and expiratory limbs of the breathing circuit |
| 4. Give dantrolene 2.5mg/kg IV through a large bore IV | Repeat as frequently as needed until either:<br>– ETCO2 decreases<br>– Muscle rigidity decreases<br>– HR decreases |
| 5. Other considerations | 1. ABG to determine degree of metabolic acidosis<br>2. Cool patient to keep between 38-39C<br>3. If hyperkalemic, treat with<br>– Calcium chloride (10mg/kg)<br>– Glucose + insulin<br>– Sodium bicarbonate<br>– Consider dialysis, ECMO |

Adapted from the website of Malignant Hyperthermia Association of the United States (www.mhaus.org), with permission

anesthetic encounters; as such, very few anesthesia providers will have had experience treating MH if such a case were to occur [23]. As discussed above, simulation an MH crisis, as well as use of cognitive aids can greatly enhance teamwork and improve patient outcomes [9]. Table 18.2 is an adapted cognitive aid for treatment of MH [24].

Resources for Malignant Hyperthermia:

- Malignant Hyperthermia Association of the United States (MHAUS)
- www.mhaus.org
- Malignant Hyperthermia hotline: 1-800-644-9737
- Malignant Hyperthermia Australia & New Zealand (MHANZ)
- www.anaesthesia.mh.org.au

## Cognitive Aid #3: Local Anesthetic Systemic Toxicity (LAST) (Figure 18.2)

Local anesthetic systemic toxicity (LAST) is a potentially fatal complication characterized by seizures and cardiac arrhythmias that may lead to complete cardiac depression. The incidence of LAST has been reported to be 1:10,000 for epidural anesthesia and 1:1000 for peripheral nerve blocks [25, 26]. It is important for all staff to be trained in the recognition of signs and symptoms of LAST in order to respond timely and effectively. The American Society of Regional Anesthesia and Pain Medicine (ASRA) has published a simple checklist for treatment of LAST as well as practice guidelines [27].

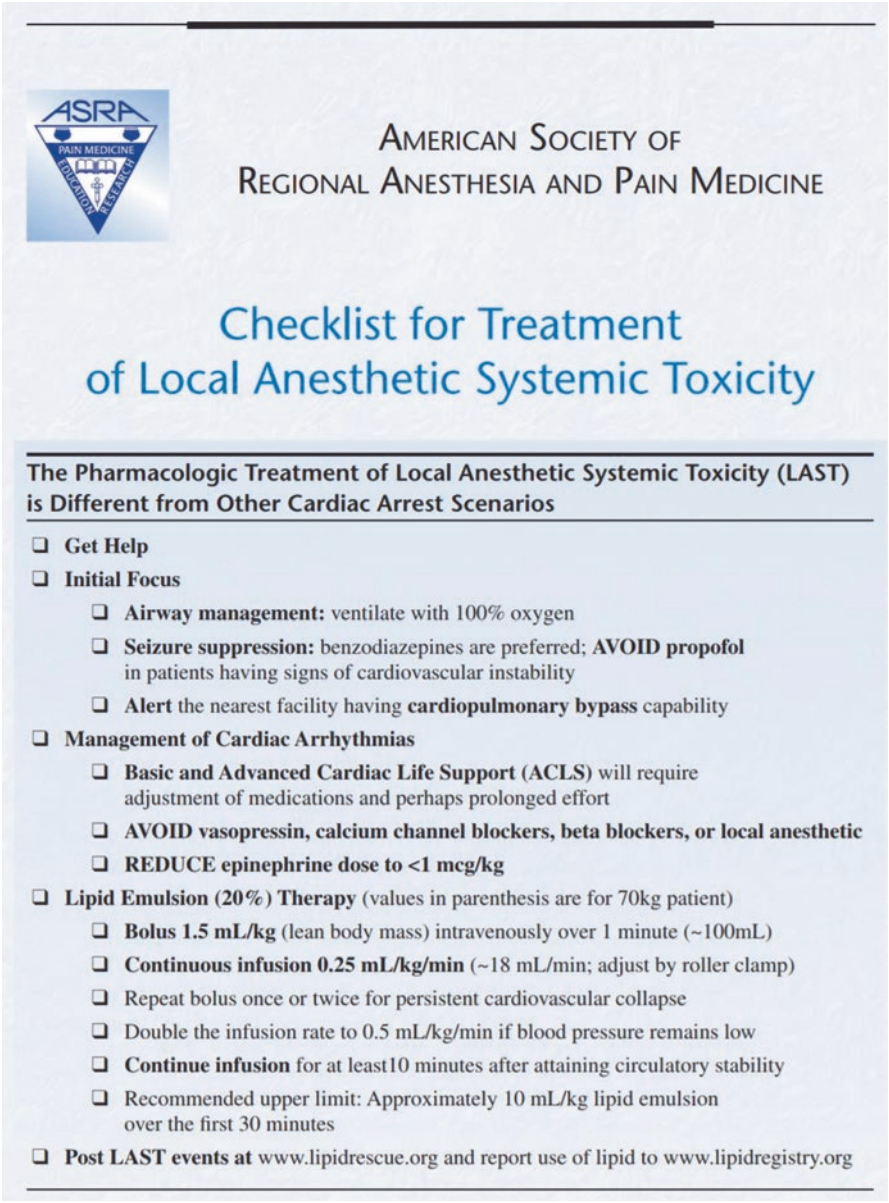


**Figure 18.2** Checklist for Treatment of Local Anesthetic Systemic Toxicity. (From www.asra.com, © 2011 The American Society of Regional Anesthesia and Pain Medicine, with permission.)

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# Emergency Preparedness in Ambulatory Surgery Centers and Office-Based Anesthesia Practices

19

Shaina Drummond and Michael O'Rourke

## Emergency Preparedness in Ambulatory Surgery Centers and Office Based Anesthesia Practices

In the past ten years, natural disasters and other emergencies have highlighted the shortcomings of healthcare systems to protect patients and healthcare team members during emergencies [1–3]. Ambulatory Surgery Centers (ASC) and Office Based Anesthesia Practices are unique healthcare environments that necessitate specific emergency planning for disasters and other emergencies. There is currently wide variability in emergency preparedness amongst Ambulatory Surgery Centers and Office Based Anesthesia Practices (OBAs). The Centers for Medicare & Medicaid Services (CMS) recently estimated that of 5,485 ASCs in the United States, 1,414 were accredited by some regulatory agency while 4,071 ASCs were non-accredited [4]. There is no standard for emergency preparedness in non-accredited practices. Even those ASCs with accreditation may have different levels of emergency preparedness as accreditation organizations can have different standards or no standards at all for emergency preparedness. It is important that healthcare providers at all ambulatory surgery centers and office based anesthesia practices are aware of existing regulations for emergency preparedness and work to ensure patients and staff as well as physical resources are protected during natural disasters and other emergencies.

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## Types of Emergencies

Emergencies and natural disasters stress a healthcare system and lead to challenges in protecting patients' and providers' welfare [2, 3, 5, 6]. Hospitals and other healthcare systems need to protect patients, employees, and physical resources during such events while continuing to provide care to those in need. Natural disasters can include earthquakes, tornadoes, hurricanes, floods, or tsunamis. Natural disasters generally affect a large number of people and can require coordination of both local and national resources to respond to healthcare needs [1]. The earthquake and subsequent tsunami that struck Japan in 2011 as well as Hurricane Katrina and the subsequent flooding in Louisiana in 2005 are examples of the widespread destruction that can be caused by natural disasters. In both of these cases, healthcare systems were disrupted and largescale resources were needed to respond to the subsequent healthcare emergencies [7, 8].

The dialysis community provides perspective on the importance of emergency preparedness. In response to an earthquake in Armenia in 1998 that disrupted dialysis services in the country, the International Society of Nephrology formed the Renal Disaster Relief Task Force. This task force provides expertise or resources to communities dealing with natural disasters. In response to an earthquake in Haiti in 2010, the organization provided 25 volunteers over a 2 month period to treat patients with both acute and chronic kidney injury [3]. Despite major organizational difficulties in Haiti, the task force organized renal care for patients in Haiti and arranged transfer of patients to the neighboring Dominican Republic when needed. The experience in Haiti highlights the efforts of an outside organization to organize dialysis care when the existing resources are not sufficient to adequately respond to a natural disaster. A major earthquake also struck the country of Chile in 2010 near the country's second largest city of Concepción. The earthquake disrupted dialysis care for 2500 people [3]. In Chile, local nephrologists were able to coordinate patient care including transfer of patients and adjustment in dialysis schedules. As a result, 100% of the affected patients had access to dialysis six days after the earthquake despite less than 60% of dialysis centers being operational [3]. In this case the Renal Disaster Relief Task Force served in an advisory role to the local nephrologists organizing care [3]. While it is difficult to compare earthquakes or other natural disasters, it is clear that having an emergency plan and resources in place prior to an emergency aids in patient care during an emergency.

Natural disasters are prototypical emergencies which can disrupt healthcare systems. However, numerous other emergencies exist. Infectious disease emergencies can be local or global in nature. Recent well publicized outbreaks of the Avian influenza, SARS and the Ebola virus are examples of infectious disease emergencies with global implications. However, a local outbreak of influenza could also require a response from an ambulatory surgery center. Acts of terrorism including chemical, biological, radiological, nuclear, or explosive attacks are a separate class of emergency. Active shooter events in the United States have prompted a greater awareness of these events and the need to create an emergency plan for such events. Local events that could disrupt ambulatory surgery centers or office based

anesthesia practices include severe weather or the loss of utilities or other services at the practice site. In addition to all these emergencies, surgery specific emergencies like local anesthetic systemic toxicity events or onset of malignant hyperthermia are patient emergencies requiring rapid responses. Due to the large and varied types of emergencies that can affect an ambulatory surgery center or office based anesthesia practice, it is important to assess a facility's need and ability to respond to various emergencies.

## Risk Assessment

The first step in emergency planning is performing a risk assessment for the particular practice. An "all hazards" approach is the preferred approach for risk assessment. The "all hazards" approach is used by a variety of organizations including the World Health Organization and the United States Federal Emergency Management Agency (FEMA) [9–11]. It is also the approach recommended by The Joint Commission for healthcare organizations in emergency planning [12].

In an "all hazards" approach the practice attempts to identify all emergencies which could occur at the facility and in the community in which the facility is located. This process should include consideration of the general geographical area and the practice's specific location in the community. It should also consider the patient and staff population typically present at the facility including consideration for children, the elderly, or patients with disabilities [4]. Once all possible emergencies are identified they are evaluated for the likelihood that they would occur. To use recent natural disasters as an example, it would be appropriate for an ambulatory surgery center in coastal Louisiana to prioritize planning for a hurricane or flooding whereas a facility in Los Angeles might more appropriately plan for an earthquake. In addition to natural disasters, emergencies that every ambulatory surgery center or office based anesthesia practice should assess are severe weather, active shooter in the facility or nearby area, loss of utilities at the practice, and medical emergencies like malignant hyperthermia, local anesthetic systemic toxicity, or an unresponsive patient.

## Development of an Emergency Plan

Once a risk assessment has been completed, an individualized emergency plan for the practice should be developed. To be meaningful and work effectively, the emergency plan must be individualized for the particular Ambulatory Surgery Center or Office Based Anesthesia practice and take into account the resources, staff, and patient population of a particular practice. Once developed, the emergency plan should be reviewed and updated annually.

Certain portions of an emergency plan may be very specific. For instance, if an office based anesthesia practice provided service for patients receiving local anesthetic injections as part of cosmetic or reconstructive procedures, it would be

recommended the practice have a specific plan for managing a patient with local anesthetic systemic toxicity (LAST). The emergency plan would be tailored to the particular resources and staff at the practice. This could include having assigned roles for staff in a LAST event such as bringing emergency airway equipment to the patient bedside, bringing lipid emulsion therapy to the bedside, or assisting with airway management. The plan could also ensure availability of lipid emulsion therapy and the American Society of Regional Anesthesia and Pain Medicine's Checklist for the Treatment of Local Anesthetic Systemic Toxicity for any such event [13]. The plan could include annual LAST drills with staff so resources and roles are well established prior to such an event. By having a specific plan for a specific LAST emergency identified in its risk assessment, an office based anesthesia practice might better provide timely and appropriate care to its patients during such an emergency.

The emergency plan should include a framework for managing larger or previously unidentified emergencies. This could include identification of leadership roles during the emergency, a plan for sheltering or evacuating patients and their families, a plan for sheltering or evacuating staff, and a plan for preserving physical resources at the practice. Large or unexpected emergencies are unpredictable in nature, but establishing a management plan for such events as part of a larger emergency plan provides a baseline level of expectations and responsibilities amongst staff for handling such events. Establishing this plan prior to the event allows for staff to know their role during an emergency. If a large or unexpected emergency event arises, leadership can adapt the plan as needed to that specific emergency.

## Key Elements of an Emergency Plan

Though emergency plans will differ depending on the type of practice, there are several key elements which should be included. CMS provided an outline of such key elements in its final rule on Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers in 2016 [4]. CMS identified three essential requirements for maintaining healthcare services during an emergency: safeguarding human resources, maintaining business operations, and protecting physical resources [4]. CMS requires that a facility's emergency plan include a list of services it is able to provide during an emergency [4]. Obviously, most ambulatory surgery centers and office based anesthesia practices that provide elective surgical care would not continue to provide elective care during a true emergency. However, CMS requires that the practice consider what services would or could be provided during an emergency [4]. CMS also requires the practice to attempt to collaborate with local, tribal, regional, state, or federal emergency officials [4]. In addition, an emergency plan should address the continuity of operations, including the delegation of authority and succession plan [4].

An emergency plan also needs to account for care of staff and patients during an emergency. An emergency plan should include a system to track the location of

staff and sheltered patients in an ambulatory surgery center during an emergency [4, 12]. A means to shelter in place for patients, staff, and volunteers should also be included.

When sheltering in place is not feasible, an emergency may require the evacuation of a facility. Hence, a safe evacuation plan is a necessary component of any emergency plan. The evacuation plan should consider the abilities of staff, patients, families, and volunteers typically present at the practice. The plan should include planning for care and treatment of evacuees both during and after evacuation. Means of transportation and evacuation locations should be documented in an evacuation plan. If on-duty staff or patients are transferred during an emergency, documentation of the receiving facility's name and location should be made at the ambulatory surgery center [4, 12]. Finally, a primary means of communication amongst staff and patients should be established as well as alternate means if the primary method is disrupted during the emergency.

Medical documentation is important at all times including during an emergency. Hence, an emergency plan should include a method to preserve patient information and protect patient confidentiality during an emergency. For example, during loss of utilities a facility should have a plan to maintain medical documentation and ensure those records are secure and available for patients and staff.

## Assessing Emergency Needs and Equipment

Planning for an emergency necessitates the creation of emergency preparedness checklists to address several key requirements: 1) Patient notification systems (in case of emergency or closure); 2) Staff notification system (in case of emergency or closure); 3) Medical records backup plan (e.g., cloud servers for electronic records, short term use of paper records); 4) Remote medical record access, 5) Billing services (continuity plan); 6) Security at the facility; 7) Utility emergency shut-off location and procedures; 8) Service availability (define available priority services); 9) Disaster planning for staff (who is expected to work and when) [5].

In times of crisis, staffing at an ASC can become a major issue. It is important to identify a variety of staffing strategies before an emergency to ensure that proper staffing levels can be maintained as staff may have difficulty reporting for work because of the incident [5]. A triage plan should be developed for use in time of emergency. For example, utilizing all members of the team, from the physician and nurses to the medical assistants and housekeeping staff to serve on teams in specific areas to better facilitate patient care. It is important for everyone available to play a role on a team.

If an ASC is affiliated with a larger hospital entity, it is possible that the ASC could be used to treat less acute surgical patients during an emergency situation if the main hospital is at capacity due to a mass casualty. Code carts and medications should be fully stocked, organized and maintained. In addition, emergency supplies (e.g., emergency airway kits, fiberoptic scopes, glidescopes, backup anesthesia machines, full oxygen tanks, extra batteries) and medications (e.g., intralipid

emulsion if applicable and dantrolene for treatment of malignant hyperthermia) should be kept up-to-date and checked regularly to ensure properly functioning equipment. It is also important for ASC leadership to know the location of suppliers and whom to contact if more supplies are needed. In the event that an ASC is in close proximity to a larger affiliated hospital system, a courier service between both entities for laboratory and equipment needs could be utilized.

The outbreak of the Ebola virus in Dallas, TX highlighted the importance of infection control planning in emergency preparedness. ASCs should have a staff person whose designated responsibility is infection control. Even though most ASCs are unlikely to face a largescale outbreak of an infectious disease, it is still important for ASCs to have procedures in place for the proper collection, holding, and disposal of biological waste and to establish systems in case disposal measures are disrupted. There should also be procedures in place for the isolation of a patient who is discovered to have an infectious disease along with procedures for the safe transfer of a patient to an appropriate facility [14]. Most ASCs do not electively take care of patients with certain types of communicable diseases due to their lack of isolation facilities.

## Communication

Communication is a critical component of any emergency operations plan. CMS requires facilities to have a written emergency communication plan that describes how the facility will coordinate continued patient care within the facility, with outside healthcare providers, and with state/local public health departments in the case of an emergency. Location specific considerations must also be incorporated, such as limited access to the internet or phone capabilities for those practicing in more rural locations. During an emergency situation, it is important for an ASC to have established methods to communicate with partner facilities and local emergency responders should there be a loss of landline and cell phone capabilities. Components of effective communication in a time of emergency include: 1) a functional audible paging system to announce clear text messages to alert staff, patients and visitors of the emergency; 2) procedures for calling staff back to the organization, when needed and also a process whereby staff report if they become aware of an emergency and landlines or cell phones cannot be used to contact staff; ASCs should have a phone tree or another method of rapidly communicating with all their staff in case of an emergency. 3) a method to communicate with patients to cancel procedures when necessary [14].

Administration and the governing body of the ASC are responsible for the development and approval of the disaster preparedness plan. The ASC should designate and clearly communicate with their staff, the person responsible for the emergency operations plan. This designated person should have this responsibility listed in their job description. Other examples of responsibilities that should also be included in the job description include: 1) maintain current knowledge of changes to environment of care and emergency management standards; 2) establish and implement safety and emergency preparedness policies appropriate for the ASC; 3) coordinate emergency

preparedness plan with partner organizations and other emergency response partners; 4) ensure safe environment for patients, visitors, and employees; 5) evaluate safety and emergency preparedness orientation and annual education and training programs for employees and ensure compliance with all applicable standards including Centers for Medicare and Medicaid (CMS), Joint Commission (or other accrediting agency); 6) recommend and monitor trends for improvement opportunities related to employee, visitor, and patient incidents; 7) plan, implement and evaluate environmental rounds; 8) monitor and evaluate timely and thorough completion of Emergency Preparedness exercises and complete the After Action Report (AAR) for all exercises, including identification of Corrective Actions; 9) evaluate and up-date the Safety and Emergency Preparedness Programs annually [14].

Physicians working in the ED the night of the recent Las Vegas mass casualty shooting revealed that many lives were saved due to the ability of physician leaders and nurses to effectively organize patients into clear physical zones by communicating clearly with their staff to avoid wasting time that could be better spent on resuscitating patients. In any emergency situation, effective communication is key to saving lives. One effective communication method is the SBAR mnemonic: **S**ituation, **B**ackground, **A**ssessment, **R**ecommendation (Figure 19.1). It was first developed by the military then adapted to the aviation industry to combat communication barriers

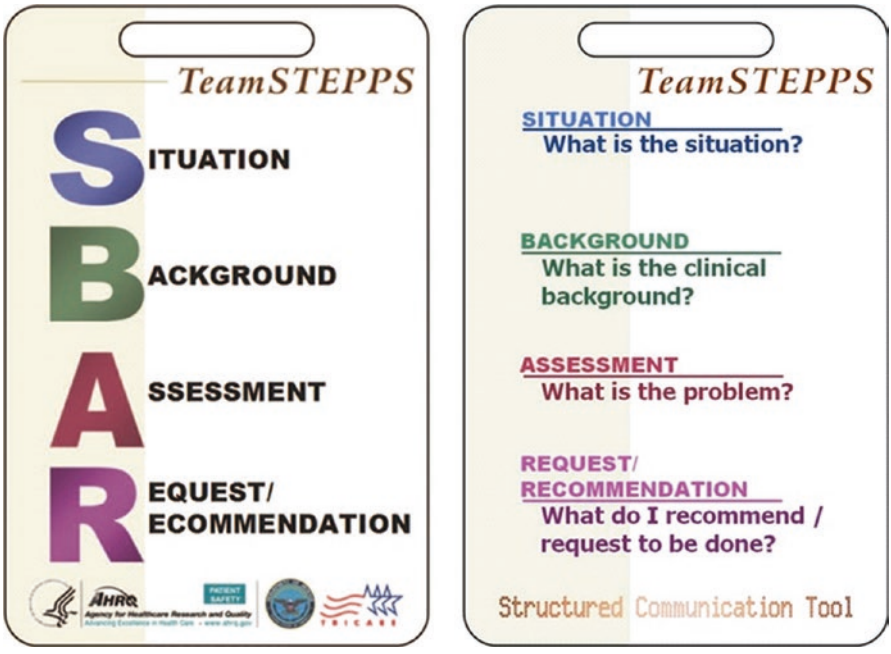


**Figure 19.1** "SBAR" TeamSTEPPS® 2.0 Pocket Guide. Team Strategies & Tools to Enhance Performance & Patient Safety (TeamSTEPPS®) 2.0. Agency for Healthcare Research and Quality, Rockville, Maryland (USA). December 2013. http://www.ahrq.gov/teamstepps/instructor/essentials/pocketguide.html. (*Reprinted with permission of the United States Agency for Healthcare Research and Quality.*)

inherent in the work environment, which were causing life threatening crashes. In 2002, it was introduced into the healthcare system by Kaiser Permanente after the realization that there are fundamental similarities between healthcare and aviation/military environments--both are high stress, high risk, time sensitive environments, where wrong decisions can be life threatening. It was initially introduced into rapid response teams with the goal of improving patient safety by having a standardized process for early intervention before a patient's condition deteriorates. The goal of SBAR is to overcome communication barriers by providing a standard concise framework for conveying pertinent information between members of the healthcare team, which is essential for fostering a culture of patient safety [15].

## Training and Testing

Centers for Medicare and Medicaid have mandated that ASCs take part in two annual emergency preparedness tests to assess an emergency plan's effectiveness. The first exercise should be a community based drill, if available. If this is unavailable, then the ASC is required to conduct an individual facility-based drill. For the second exercise, an ASC would be required to conduct either a facility based drill or a tabletop exercise. While the drill does not have to test the response to every identified hazard, it is expected to test a significant portion of the plan. Drills and exercises should be conducted to practice policies and procedures, evaluate the effectiveness of the emergency plan, and identify areas of improvement. In addition, it is important for an ASC to maintain documentation of all emergency training completed by staff [4, 14, 16].

Implementation of emergency organized drills and testing is a complex task requiring significant resources in terms of cost, manpower, training, and time commitment. Given the fact that the process of preparing healthcare professionals to manage emergencies is both complicated and costly, it is important to optimize the emergency preparedness program by investing resources in the common components that may improve preparedness for different emergency scenarios. This is where simulation based drills could play a very important role. Simulation based training can increase emergency preparedness by exposing healthcare staff to real world emergency situations. Benefits of team based simulation include assessment of the current internal emergency disaster plans and the team's readiness to deal with the situation at hand, development and application of clinical and critical thinking skills, promotion of team based collaboration and communication skills, discovery of flawed processes, and problem solving through corrective action plans [17].

## Development of a Corrective Action Plan

While drills and testing are necessary components of disaster planning, it is equally important that team members debrief at the end of an exercise by creating an after action report. The report should identify and document deficiencies

and recommendations for improvement otherwise known as "corrective actions". A corrective action plan (CAP) includes: 1) the purpose of the drill or exercise, 2) participating agencies 3) scenario overview, 4) exercise objectives (e.g., communications, resource mobilization), 5) areas for improvement. The plan should also include a full description of the deficiency; the action that should be taken; the resources required to address the deficiency; and justification for the need to correct the deficiency. Prioritization of corrective actions is helpful because funding and time are usually limited [18]. Prioritization can also identify significant deficiencies that should be reported to management and corrected as quickly as possible. Criteria or categories for corrective action may include the following: 1) hazards to health and safety, 2) regulatory compliance, 3) hazards to property, operations, the environment or the entity 4) conformity to national standards. Action on deficiencies should be assigned to the person or department best able to address the issue. A due date should be assigned and the corrective action database reviewed regularly to track progress. If there are changes in processes or practices as a result of the corrective action plan, they should always be clearly communicated to staff, physicians, and governing bodies prior to implementation [17–19].

## Recovery

Following an emergency situation that results in major disruption of services or evacuation, recovery measures are required to restore the facility to baseline level of operations. Major facility disruptions are required to be reported to the state Department of Health (DOH) and patient care activities may only resume after an inspection by the DOH.

## Conclusion

Over the past decade, the need to respond to emergencies, natural disasters, and mass casualty events has been highlighted in the United States and throughout the world. Ambulatory Surgery Centers and Office Based Anesthesia Practices are unique healthcare environments that necessitate specific emergency planning for disasters and other emergencies. Such practices typically do not have rapid response or code teams on site and often have leaner staffing than other parts of a health system. CMS has developed a series of guidelines to establish consistent emergency preparedness requirements for healthcare providers specifically in the ambulatory surgery setting. Components of emergency preparedness consist of planning, organizing, communicating, equipping, training, and exercising (Figure 19.2). While the development of an emergency plan is an important first step in the process of emergency preparedness, it is also important to continuously reevaluate the emergency plan through drills, simulation, and corrective action plans. Without periodic maintenance, the emergency plan will


**Figure 19.2** Preparedness. Courtesy of Timothy Riecker, Emergency Preparedness Solutions, LLC, Utica NY. https://triecker.wordpress.com/

become outdated and ineffective. Emergency preparedness is an ongoing process in which leadership, commitment, action, funding, and partnerships at all levels must be sustained.

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# Risk Management and Quality Improvement

# 20

Jeffrey W. Lee

Patient care is a reason that most healthcare providers choose their career, but recently, the improvement of patient safety has been added to the responsibilities for all health care providers. In particular, physicians are in a unique position where they direct medical attention to address a patient's issues and ailments. However, along with these responsibilities, a physician must practice in a manner that abides by a spectrum of medical, legal, and ethical parameters that may complicate the situation.

More than ever before, providing patients with safe, high-quality medical care is of the utmost importance. Aside from the obvious priority placed on a patient's well-being, physician compensation has begun shifting away from the antiquated fee-for-service model where production alone is the main driver of payment. Instead, quantifiable measures meant to increase the quality of health care and practice improvement are being emphasized and calculated into the physician compensation formula. Following governmental approval in 2015, the Centers for Medicare and Medicaid Services (CMS) developed new compensation regulations to modify physician compensation called the Medicare Access and CHIP Reauthorization Act (MACRA). The goal of MACRA is to ensure that physician payment is not solely based on volume, but rather also improved value and patient care [1]. As a result, it is imperative that anesthesiologists incorporate a new system of practice that continually delivers safe patient care of the highest quality possible.

Although daunting, this new paradigm of compensation has required anesthesiologists to evaluate their daily practice in a relatively unfamiliar manner. Anesthesiologists are now looking for various aspects in their practice that they can identify as potential weaknesses and implement novel measures in hopes to reach

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their stated goals. These quality improvement projects provide a platform for practitioners to continually improve their medical practice, workflows, and patient outcomes.

Risk management and quality improvement are two aspects of healthcare delivery that focus on patient safety and satisfaction. Although they traditionally operate independently, the increasing importance of safety and efficiency naturally allows their efforts to intertwine with one another. The World Health Organization estimates that for the 234 million surgeries performed globally per year, 50% of surgical care errors are avoidable [2]. While this statistic highlights the pressing need for organizations to improve patient safety, another consequence to this is the amount of wasted health care spending used to make up for those errors. A conservative assessment of medical waste was estimated to be near $550 billion, but realistically may even top $1 trillion annually [3]. In addition to the patient harm incurred and the medical resources needed to treat these patients, billions of dollars are used annually to pay for these additional medical expenses as well as the litigation costs and lost productivity [3].

## Risk Management

### What Is Risk?

Risk is a function of (1) the likelihood of a given threat triggering or exploiting a particular vulnerability, and (2) the resulting impact on the organization. Therefore, risk is not a single event or factor, but rather a combination of threats and vulnerabilities that may have an adverse impact on the organization if they occur [4]. In order to quantify risk for a given situation, one can look at a risk matrix to assess the severity of the threat. Depending on the likelihood of an event occurring and the severity of the potential impact, the resulting risk of that event can be quantified (see Figure 20.1). For events that may pose minimal to low risk, they may be assumed or accepted where they may not need any addressing or action. However, as risks increase along the spectrum, they may require further intervention or resource expenditure to prevent them from occurring. Considering risk should be essential when designing and developing various aspects of an ambulatory surgery center (ASC).

## Risk Management in Ambulatory Surgery Centers

In order for an ASC to effectively provide services for patients, it is imperative that a culture of efficiency and safety be established. A risk management team would ideally be assembled with knowledgeable stakeholders to oversee the daily operations of the ASC to ensure that the facility and its employees adhere to this mission. The primary objectives of risk management include detecting, reporting, and

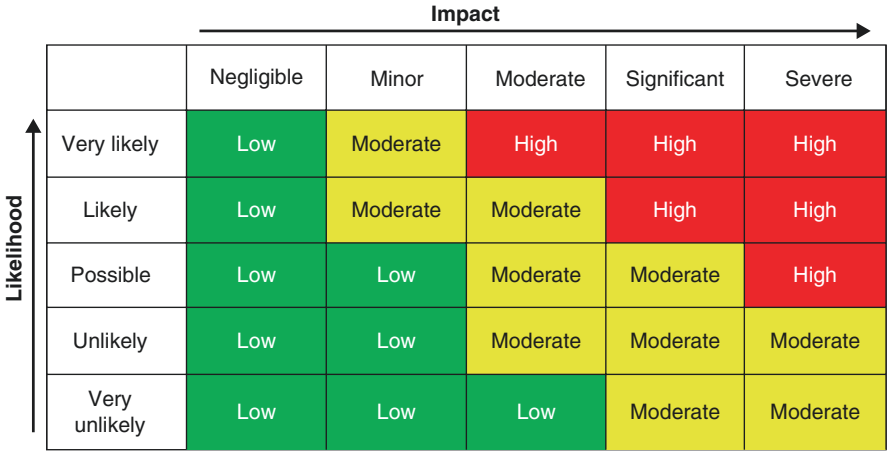


**Figure 20.1** Risk Matrix. *(Used with permission from © 2018 Burns Engineering, Inc.)* From: https://www.burns-group.com/blog/2017/01/time-within-budget-using-risk-assessments-deliver-complex-infrastructure/

correcting actual or potential deficiencies in the process that could lead to significant or costly errors. This applies to all aspects of the business operation, including work, production, and personal interactions

Depending on the organizational composition of the ASC, whether it be an entity of a larger hospital or an independent facility, the team should be comprised of personnel (physicians, nurses, managers, or administrators) that aim to limit the risk of undesirable outcomes. Ideally, risk management applies a program of well-designed policies and actions that ultimately yields error-free healthcare service and places patients in the safest practice environment possible. Having a risk management plan is a vital component to any facility. It provides an accessible outline that can minimize risk and reduce exposure to financial and operational losses. CMS also requires that the written plan be approved by the governing body and evaluated on an annual basis in order to be compliant with its regulatory standards.

There are vital qualities that effective risk management teams should exhibit. Generally, there should be proactive policies implemented to preempt adverse events with an emphasis on open retroactive reporting to record events. Instituting comprehensive policies that are sensible and forward thinking, will help the facility in providing a foundation for effective patient care delivery. Policies may describe how legal documents, correspondence, and potential events are handled. This includes clearly addressing a system of tracking and investigating such events or errors.

However, ASCs must avoid complacency when dealing with the continuously changing landscape of health care. In order for an ASC to continue its relentless efforts toward risk management, it must also be able to learn from any adverse events or violations of its policies. This requires stake holders to accurately and

honestly report events in a timely manner. To accomplish this, an ASC must create a nurturing environment that does not reprimand those who report events; but rather, it should support and encourage a culture of enhancing patient safety. When reporters can document incidents without fear of judgement or retaliation, ASCs can learn from these errors and strive for reconciliation and improvement. Administrative leadership must demonstrate a commitment to optimizing its risk management plan and prioritizing changes that will reduce risk exposure.

## Steps of Risk Management

In order to accomplish an effective risk management program that aims to optimize the functions of an ASC, a general process must be identified that governs the process. This includes establishing a series of actions that identify possible threats, analyze these issues, permit the formulation of corrective or preventive actions, and review the implemented measures.

***Establishing Context of Risk*** For ASCs, the first step in risk management is to establish the appropriate context of such efforts, namely one for an outpatient surgical facility. Rules and risks may differ from those that are applicable to a hospital or a primary care clinic. Although maintaining accreditation by national regulatory bodies remains a goal, each ASC should institute independent policies that are sensible and facility-centered. This includes planning the objectives of stakeholders and defining a framework for the process. For example, an ASC may find value in adopting appropriate patient selection criteria that maximizes patient volume yet prevents high-risk patients from having procedure performed and potentially having adverse outcomes occur. Conversely, it may not be beneficial to address central line-associated blood stream infections (CLABSI) at an ASC given the lower acuity of presenting patients and the rare need for central venous catheterization in this setting.

***Risk Identification*** The next step should include identifying possible risks. Successful risk identification requires a thorough understanding of the ASC. Extensive knowledge of the business components of the ASC, including legal, economic, social, and managerial factors are necessary to anticipate potential risks and effectively address these concerns. This is a key process providing the foundation of risk management. The failure to foresee and prevent such events from occurring can equate to damaging loss for the facility. Risk identification can be accomplished through group meetings, retrospective reviews, patient feedback, and regulatory reporting such as CMS or Accreditation Association for Ambulatory health Care (AAAHC) site visits. An online resource list provided by the Agency for Healthcare Research and Quality (AHRQ) can assist ASCs in improving patient care [5]. Although this resource may not be comprehensive, it provides a starting point for facilities to use when initiating risk management efforts.

***Risk Analysis*** Once a particular risk has been identified, an organization must fully understand the reasons why the potential risk exists. This can include clinical practices, staffing, procedures and workflows, as well as equipment issues. Organizational discussions among stakeholders can help identify possible underlying causes. While facilities should attempt to preempt any events from occurring, this may not be possible. Adverse events that take place offer opportunities for the organization to analyze and improve processes. A systematic approach to such events can include the conduction of a root cause analysis whereby contributing factors are identified and modified with the intention of improving the process.

***Risk Evaluation*** Once risks have been assessed, a facility must evaluate them and determine its approach to addressing the risks. This involves determining the likelihood of an event happening as well as the severity of impact from a potential event. The product of these two factors, also known as the risk score, can help an organization evaluate a risk and prioritize efforts to mitigate its threat of occurring. Threats with a high risk score warrant attention as they represent either a serious and/or frequent concern. If, however, the risk score of a particular threat is on the lower end, it may be considered a lower priority to work on this issue while more serious risks are addressed.

***Risk Treatment*** Once risks have been identified and assessed, the techniques to manage the risk can be placed into four categories [6]. Risk transfer refers to the organization transferring all or part of the losses to another party (i.e. insurance company). Risk avoidance means that the facility does not participate in any activities that may place itself in a position where an event may occur. This may include refusing to schedule a procedure secondary to a patient's preexisting medical history or surgical risk. Risk retention means that the facility retains the entirety of the losses accrued by an event. Parties that are self-insured may elect to proceed in this manner. Risk control refers to the redesign of policies and procedures in hopes that future exposures are mitigated. How an ASC decides to proceed in treating a risk depends on the its unique setting and the circumstances surrounding it. The risk management team must consider factors including staffing, resources, and competencies while understanding various limitations when determining which treatment to apply. A free-standing surgery center remotely located from emergency medical services may opt to refuse a surgery while an ASC in close proximity to a large hospital may elect to perform the procedure or accept patients with a higher acuity. There are no decisions that universally apply to ASCs. The role of a risk management team is to decide what issues are the most threatening and pertinent to its practice and plan accordingly.

Risk management plans aim to cover and prevent all potential risks, but the dynamic nature of health care delivery systems make this nearly impossible. Based on experience, feedback, and process reviews, organizations must implement appropriate changes and adapt their risk management plans to ensure the safety of their patients and provide high quality care. Active monitoring and review throughout the

risk management process is essential for consistent tracking and evaluation of potential risk. Tools like incident reporting, satisfaction surveys, patient/staff complaints, and clinical audits can be used to guide novel interventions to reduce risk.

## Areas to Address

As the number of surgical cases performed in ASCs and their complexities grow, it becomes increasingly vital for facilities to minimize risk and ensure patient safety [7]. While it is inherently assumed that patient-centered risks are of vital importance, there are other aspects that must be addressed. These additional categories of risk are as equally integral to the proper functioning of the ASC and its prospective success. Table 20.1 illustrates various categories of risk that ASCs may encounter and identifies examples of such risk. Clearly, risk extends simply beyond clinical patient care. ASCs assume responsibility for safety, financial, and managerial factors that threaten its viability.

## Quality Improvement

Quality improvement (QI) is a combination of prospective and retrospective measures that aim to create or modify systems that lead to measurable improvements in products or services. Pioneered by W. Edwards Deming and his 14 key principles for management, this ubiquitous principle has been applied globally to industries and businesses to adapt to a changing marketplace and continually push for high-quality results. When used in healthcare, efforts are made to construct methods that lead to desirable outcomes with relation to patient care. The Institute of Medicine's

**Table 20.1** Types of Risk Commonly Encountered by Ambulatory Surgery Centers

| Categories of Risk | Examples of Risk |
|---|---|
| Financial | Profitability<br>Cost analysis<br>Reimbursement<br>Insurance coverage |
| Managerial | Facility/employee credentialing<br>Staff training<br>Job descriptions/staffing |
| Facility/Equipment | Building safety<br>Disposal/waste systems<br>Equipment sterilization process |
| Safety | Disaster/Emergency planning<br>Discharge criteria<br>Emergency protocols |
| Clinical | Surgical/anesthesia risk<br>Patient consent<br>Falls/injuries<br>Postoperative infections |

report, Crossing the Quality Chasm, defines 6 areas of improvement in healthcare quality which are as follows: patient safety, care effectiveness, timeliness, patient-centeredness, efficiency, and equity [8]. Common issues that an ASC may address are reducing the rate of medical errors, improving outcomes, or process refinement. With more emphasis being placed on medical quality, efficiency, and safety, QI has become a vital practice used by organizations to address shortfalls and identify areas for improvement. Effective QI practices position a health care practice for success by preparing for value-based payment models, reporting physician-quality data, and allowing for participation in QI incentive and national recognition programs [9]. Creating a work environment that encourages QI processes will highlight its significance and promote employee participation toward improvement.

## Basic Principles of Quality Improvement

While QI can be utilized in a variety of scenarios in healthcare, there are several key components that should be consistently followed to achieve the desired results. The first task should be to clearly establish the aim of the QI effort with an aim statement. This goal or measure of what is to be accomplished should be well-defined and address an issue that is pertinent to the organization. At this stage, barriers to the project and a study time frame should be identified. Furthermore, the aim statement needs to specifically define what population it will study, the time frame in which the study will occur, and identify the amount of change it hopes to see. Without clearly identifying the objective or having stakeholders understanding the purpose of the project, any QI efforts may lack definitive direction in their relation to improving patient care. Avoiding broad project boundaries may allow the project to appropriately focus on the objective and prevent divergence from its goal. In an ASC setting, an example of an aim statement could be decreasing the rate of case cancellation by 50% within the next six months. There are numerous sources of tools and worksheets readily available that can assist with the development of an aim statement. The Institute of Healthcare Improvement (IHI) is a comprehensive resource that provides valuable tools such as information, references, case studies, and videos to help start and navigate through a QI project. By using such aids, an ASC should personalize its own work tool that will facilitate this initial step and customize efforts that are pertinent to the practice.

When the goal of a QI effort has been determined, the focus should shift towards developing measures and defining improvement. Although this may drain time and resources, it provides the groundwork by which organizations can find success. During the course of a QI project, a variety of data can be collected. However, only a fraction of the data may be valuable and applicable to the scope of the study. A practice should delineate what data points are going to be collected from the project. In doing so, information yielded will show factual results toward the stated goal and eliminate the subjective element of measurement. This can provide insight to current patterns and trends that may be occurring in a practice. It may also highlight relationship strengths and deficiencies between different departments and

stakeholders. Methods of data collection must be determined at the outset of the project. Guidelines addressing the frequency, process, and responsible parties of data collection should be outlined to eliminate ambiguity.

Creating possible changes that will lead to improvement is another important facet to the QI process. In order to achieve this, the QI team must fully comprehend the existing process in place. One exercise that may prove beneficial is to perform a *gemba walk*, which is a thorough, on-site observation of workflows that allows for personal interaction with employees and inspection of the entire process [10]. Since this is more of a fact-finding exercise, efforts should be made to withhold scrutiny and judgement during the gemba walk. When done correctly, areas for improvement can be identified and reflected upon so that possible change ideas can be formulated at a later time. Once areas for change have been identified, QI teams must develop change concepts that address the aim statement and lead to improvement. These proposed changes are based on theories and predictions of the particular change concept and its potential to generate a positive outcome in the existing workflow.

Once this has been accomplished, the change should be tested with the notion that it will yield pertinent feedback. As with change in any situation, there may be prohibitive roadblocks that pose challenges. In the case of healthcare quality, these would be factors such as limited resources and staff resistance. Thus, it is advised that testing initially occurs slowly at first, one change at a time. As data is collected over time, knowledge can be built sequentially and modifications can be made. When testing, it is important to consider personnel feedback and to confirm that the information being collected is the intended data applicable to the aim of the QI project. Data collection and analysis are then conducted so that successful changes can be identified and prepared for implementation. Once these changes are adopted as a part of the process, there must be continuous study and review to ensure that the change is still benefitting the organization.

## Plan-Do-Check-Act (PDCA)

A widely-endorsed method that encompasses the principles of the QI process is the PDCA cycle (see Figure 20.2). Based on theories by QI innovators such as Deming and Walter Shewhart, this model for improvement can be used when starting a new project or repeated for continuous improvement efforts [11]. PDCA has many uses that validate its popularity. It can help predict the effectiveness of change, revise change to adapt to the patients' or practices' needs, and anticipate potential implementation barriers. Once a QI team has identified an area to address, the PDCA cycle can help navigate improvement efforts.

*Plan* The planning phase provides the guidance for a team's efforts. At this stage, teams must acknowledge the purpose of the project. This includes the development of an aim statement and ensuring that the activities align with the goals of the study.

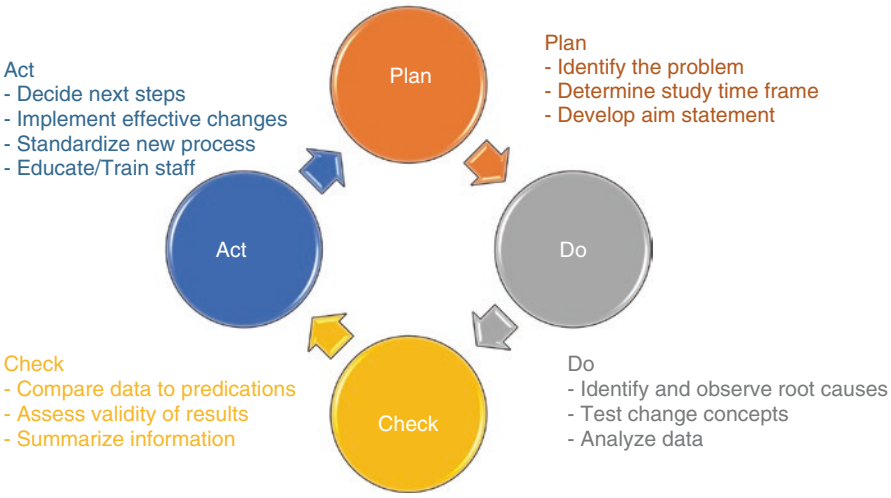


**Figure 20.2** Plan-Do-Check-Act (PDCA) Cycle

It should comprehensively outline facts pertaining to the study, including key players, timing, and location. Predictions of outcomes should be made to hypothesize the results of these efforts.

*Do* Once the plan has been detailed, the change concept is carried out to see if there are any improvements made. In doing so, any observations or problems with the proposed change are identified and recorded. At this point, data can be collected preliminarily with performance of general analysis.

*Check* Once the test has been completed, the entire data set may be analyzed and compared against any predictions you made in the planning phase. Examining pertinent data will help determine if the results are appropriate and adequately addressed the aim of the project. Upon conclusion of the study, a summative report describing observations and results may be warranted.

***Act*** Now that the study has been performed and results have been analyzed, decisions must be made about the next steps to take. What may help guide further efforts are observations and data generated in the report that identify factors that positively (or negatively) impact improvement efforts. Organizations can opt to simply permanently implement these tested changes if they are satisfied. This requires educating staff on the newly implemented changes and tracking whether the improvement efforts are sustained. However, often times, the yielded changes can be further improved. Therefore, another PDCA cycle can be initiated with the intention of testing other change concepts in hopes of attaining a certain level of change in the practice. If the results encourage further improvement efforts, incorporating learned

information can lead to wider change. Continuous monitoring and QI efforts rely on the repeated utilization of the PDCA cycle to sustain improvement measures and persistently look for ways to enhance the healthcare experience.

## Challenges to QI Efforts

While quality improvement may be desirable in today's healthcare environment, there are significant challenges that may impede the drive towards valuable change. Generally, they can be categorized into personnel issues, work culture, and study design [12]. An organization should make a concerted effort to prevent these factors from limiting its QI efforts.

QI efforts require an ardent commitment from every person involved. This may start by motivating people to make changes. People may be skeptical about whether there is a problem or if proposed changes may work. With such reluctance and apathy, it may be difficult to effectively carry out a change plan. In order to persuade the involved parties, using hard data and presenting a well-conceived change plan can provide objective motivation. Having buy-in from everyone involved will facilitate efforts. Project leadership must also assume responsibility and proactively confirm that testing is occurring correctly.

A corollary to the personnel challenges is the culture of the work environment. The ambition of improving quality may be erroneously perceived as judgement or scrutiny of a person's work. This notion may intimidate employees from accurate reporting or QI participation. To eliminate personnel reluctance, there should be a culture that encourages quality enhancement and communication. People need to understand that the QI process is not personally threatening, but rather that the process review is aimed towards improving the delivery of healthcare. Organizational leaders need to modify the work culture as such to establish an environment conducive to QI studies and provide support for staff. Sharing results of the project and providing feedback on a continual basis also keeps staff engaged and motivated.

Creating a QI initiative that is simple and successful is the ideal goal for every team. Unfortunately, this is often the exception as projects may seem arduous and complex. The varying stages of QI should be carefully designed as efficiently as possible to reduce loss of motivation from key players and staff. Project goals should be realistic and concise so that people feel like change is possible instead of overwhelmed (and possibly unmotivated) by potentially unattainable goals. Data collection is an important aspect of the process, but can consume valuable staff time and resources. Having a study that yields pertinent measures will increase the efficiency of the study without the clutter of unnecessary data. Depending on staffing, it may be overly burdensome to collect and analyze data. Realistically allotting resources for data collection is imperative for a successful study.

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# Office-Based Anesthesia and Surgery: Unique Aspects

# 21

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## Abbreviations

| | |
|---|---|
| OBA | Office-Based Anesthesia |
| OBS | Office-Based Surgery |
| ASA | American Society of Anesthesiologists |
| ISOBS | Institute for Safety in Office Based Surgery |
| AAAHC | Accreditation Association for Ambulatory Health Care |
| AAAASF | American Association for Accreditation of Ambulatory Surgery Facilities, Inc |

## Introduction

Since 1915, when one of the earliest office-based anesthesia (OBA) practices was established by anesthesiologist Dr. Ralph Warters, there has been a steady rise, especially in the past few years, in the number of surgical procedures performed on an outpatient basis in the office. In the mid-1980s, the number of procedures performed in the office increased from 2% to 5% and then to 8.5% in the mid-1990s [1]. Advancements in technology, improved available equipment, and decreased overhead costs make it possible for more and more procedures to be performed in a freestanding office. Advantages of office-based surgery (OBS) include ease of

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scheduling procedures, convenience for both the patient and the surgeon, decreased costs, and increased patient privacy [2]. Despite the advantages of OBS, there are some drawbacks to using such facilities. Patient safety in these facilities has been a major concern over the years. Rules and regulations have been set in place to ensure patient safety in these facilities. Vila et al. found a ten-fold increased risk of adverse events and deaths in a review of surgical procedures performed in the office compared to ambulatory surgery centers with most of the deaths occurring in unaccredited offices [3]. When discussing patient safety in OBS, several factors need to be taken into consideration, including the office location, accreditation of the facility, patient selection, available personnel, and the surgical procedure. Vila also states that adherence to standards in these facilities and not just being accredited is what drives safety [4]. The American Society of Anesthesiologists currently has guidelines in place for the administration of moderate sedation by practitioners who are non-anesthesia professionals [5].

## Patient Safety in the Office-Based Setting

A low number of office-based cases are reported in the ASA Closed Claims Database [6]. The most frequent claims are ophthalmic (21%) and facial plastic surgery cases (26%). The most common cause of injury was severe respiratory depression (21%). A large number of these claims (46%) may have been prevented by improved patient monitoring and vigilance, especially in the postoperative period.

The majority of observational studies on safety at accredited OBA facilities conclude that office-based surgery is not inherently unsafe [6, 7]. Risk of injury and mortality in procedures performed by board-certified specialists at accredited office sites have been shown to be on par with hospital surgical facilities [8]. The results of studies assessing the safety of anesthetic techniques in office-based settings have reported varying results. For example, Hoefflin et al. saw no cases of mortality after reviewing 23,000 office-based procedures which were performed under general anesthesia [9]. On the contrary, Coldiron et al. concluded that there was an increased risk of mortality in patients undergoing tumescent liposuction under general anesthesia [10]. More research into the safety of office-based anesthesia is required to draw definitive conclusions.

Depending on the state in which they are located, office-based facilities may not be as strictly regulated as ASCs or hospitals. There may be a lack of quality measures to ensure patient safety [2]. With increasing pressure for regulation of OBS, the Institute for Safety in Office Based Surgery (ISOBS) was formed. ISOBS consists of a group of experts from different professional backgrounds charged with the mission of improving patient safety in OBS. ISOBS developed an OBS surgical checklist that can be used to promote safe practice [11]. Patient safety can be enhanced by adherence to rules and regulations, maintenance of accreditation, ensuring that surgeons and anesthesiologists are credentialed to perform specified procedures, and ensuring that the offices are adequately equipped to perform procedures and resuscitate patients in the event of an emergency.

Certain factors need to be considered when performing procedures in the office setting. Facilities should be carefully selected to ensure that they are up to standard. Properly functioning equipment must be available and qualified personnel should be employed to staff these practices. Careful patient selection should be employed as comorbid conditions can affect patient outcomes.

## Patient Selection

Careful patient selection for OBS is important for safe practice. A detailed preoperative assessment should be performed on all potential patients to assess for comorbid conditions such as heart disease, obstructive sleep apnea, diabetes mellitus, asthma, COPD, uncontrolled hypertension, kidney disease, obesity, history of difficulty airway and past history of anesthetic complications which can lead to postoperative complications. A preoperative evaluation also assists the team in choosing the appropriate facility for the procedure. Ideal patients for OBS are American Society of Anesthesiologists (ASA) physical status I or II [5].

## Accreditation

Office-based practices are by far less stringently regulated than hospitals or ambulatory surgery centers. They are not subject to oversight by Centers for Medicare and Medicaid Services (CMS). Lin et al. states that acquiring accreditation allows an office to be objectively evaluated by a third party monitoring and validating office procedures, thus providing a national acknowledgement of quality [12].

Regulation of office-based practices is on a state-by-state basis. Facilities need to familiarize themselves with the regulations for their specific state. To ensure patient safety, facilities must comply with imposed rules and regulations. Currently, the rules and regulations specific to each state with regard to OBS can be found on the Federation for State Medical Boards [2].

There are currently three outside organizations that provide accreditation for OBS. These include the Joint Commission (JC), Accreditation Association for Ambulatory Health Care (AAAHC), and American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF). The Joint Commission is a non-profit organization founded in 1951 that accredits health care organizations in the United States. To earn and maintain a Joint Commission accreditation, an organization must undergo an onsite evaluation every three years [13]. AAAHC was founded in 1979 and offers accreditation for office-based practices, ambulatory surgery centers, endoscopy centers, college student health centers, and health maintenance organizations. AAAHC surveyors are usually professional volunteers who are involved in ambulatory health care. Accreditation by AAAHC is usually for a three year term [14]. AAAASF is a non-profit outpatient accrediting organization that was established in 1980. AAAASF accreditation is granted for a three year term [15]. More details on these organizations can be found in a separate chapter.

## Credentialing and Privileging

It is important that all practitioners in the office based setting be credentialed and only perform procedures for which they have privileges at the office.

## Office-Based Dental

Many office-based dental procedures are performed under analgesia administered by the performing dentist. The American Dental Association publishes guidelines for the use of sedation and general anesthesia by dentists and includes deep sedation and general anesthesia if the dentist has completed an advanced education program accredited by the Commission on Dental Accreditation [16]. Those who go by the title of "dental anesthesiologists" comprise dentists who have completed a 2-year training in dental anesthesiology. The relative safety and methods of these practitioners is out of the scope of this chapter.

Other dentists recognize the safety and advantages of having a dedicated board-certified anesthesiologist in charge of the patient's anesthetic for any at risk population (young children or adults with developmental disabilities) or while they perform more complex dental procedures. While these procedures are sometimes performed in hospitals, the vast majority take place in the office-based setting. As with all OBA, careful patient selection is imperative to ensure safety. ASA 4 patients should receive only local anesthesia in the office, while a subset of ASA 3 patients are candidates for additional anesthesia in the office [17].

Any procedure performed in the office-based setting may require anesthesia, from simple cleanings in adults with special needs to bony-impacted wisdom tooth extraction in healthy individuals. As such, the level of sedation needed can vary greatly also. While most Americans have seen an improvement in their oral health in preceding decades, the incidence of dental caries in primary teeth in 2–5 year olds has risen – early childhood caries is the most common chronic childhood disease [18]. As such, very young children will especially need the services of an anesthesiologist to ensure cooperation during dental procedures.

Patients who require anesthesia for dental treatment should receive the same standard of care as for any other procedure, including standard ASA monitoring and following NPO guidelines. The main considerations are the "shared airway"; the potential for secretions, blood or debris to pool in the back of the pharynx; and stimulation of the trigeminal nerve increasing the chances of arrhythmia during surgery. A throat pack is sometimes used to absorb blood or particulate matter and must be remembered to be removed prior to awakening. Secretions can be minimized with anti-sialagogues, and anti-emetic agents should be employed for certain patients and considered whenever opioids are used. The positioning of the patient in the dental chair should also be considered in the case of an emergency requiring resuscitation.

The mainstays of intravenous sedation for dentistry are midazolam, propofol, ketamine, dexmedetomidine and opioids [19]. When endotracheal intubation is

needed, nasal intubation is often preferred by the dentist. In patients who have a contraindication to nasal intubation or in young children to avoid trauma to adenoidal tissue, pre-formed oral tubes are useful. Maintenance of anesthesia is by either inhalational or intravenous anesthetic depending on the equipment available in the setting (portable ventilators) and the left lateral position is useful for extubation when possible to avoid aspiration of secretions or debris. Irrespective of the length of the procedure, the standards for recovery and discharge after anesthesia for dental surgery remain the same as for any other procedure under anesthesia. A post-anesthesia care unit staffed by a designated nurse with the appropriate resuscitation certification (BLS, ACLS and PALS) must be available to recover patients from anesthesia [20].

## Office-Based Gastroenterology

An office-based setting for gastroenterology procedures offers advantages for the patient and the endoscopist. In response to the shift of endoscopy services into the physician office setting, the American Gastroenterological Association published a set of guidelines to ensure that patients remain as safe as in a hospital or ambulatory surgery center setting. The guidelines include a list of procedures deemed inappropriate for the office-based setting and reiterate that ASA 4 patients should not undergo endoscopy in the office [21].

Specific considerations for office-based gastroenterology procedures are the "shared airway" during endoscopy and the risk of aspiration with anesthesia. Patient factors, such as symptomatic gastroesophageal reflux disease, as well as conditions for which endoscopy is performed that are associated with a high risk of aspiration must be evaluated.

Meeting discharge criteria quickly is an important goal for office-based endoscopy where the procedures may be very quick, leading to fast turnover and multiple cases scheduled in a short period of time. Propofol is an excellent drug choice in this setting where patients are not expected to have post-endoscopy pain. Propofol's rapid onset and effect site equilibration, anti-emetic profile and quick recovery without psychomotor effects have led it to be the preferred drug for this situation, with even patients having a preference for propofol over fentanyl and versed combination [22]. Despite propofol seeming to be the ideal drug for office-based endoscopy, there is evidence to suggest that the use of propofol for endoscopy results in an increase in adverse events [23]. A strong association was demonstrated between propofol use for sedation and various patient factors and the frequency of adverse events. The cause of this association is not known, but the use of propofol and depth of sedation in the office-based setting for endoscopy should be carefully titrated to avoid over-sedation and inadequate oxygenation/ventilation, which have shown to be the leading reason for claims made in remote locations from the Closed Claims database [24]. More details on the continuum of sedation and providers administering sedation are discussed in a separate chapter.

Recovery should entail adequate personnel, equipment and, most importantly, time to ensure full recovery from anesthesia. Bloating from the gas used during insufflation and possibly nausea from stomach distention are common complaints post-procedure, and anti-emetics can be given routinely to try to prevent these issues.

## Office-Based Gynecology

Rising healthcare costs have led to the migration of several gynecologic procedures to the office-based setting [25]. In promoting the safety of office based obstetrics and gynecology, the Presidential Task Force of the American College of Obstetricians and Gynecologists highlights anesthesia safety as one of its main recommendations [26]. The task force recommends that the type and level of anesthesia should be dictated by the procedure with input based on patient preference.

Mild (Level 1) to moderate (Level 2) sedation is typically considered safe in the office based setting. Procedures that cannot be safely or comfortably performed under these levels of sedation should be referred to an outpatient surgical center or hospital. For level 1 sedation, personnel with training in Basic Life Support should be immediately available until all patients are discharged from the facility. Emergency equipment, oxygen, and suction must be readily available. For level 2 sedations, two members of staff must be on the premises, one of whom shall be a licensed physician or licensed health care professional with current training in Advanced Cardiac Life Support (ACLS). Emergency drugs including all ACLS drugs and their delivery systems (i.e. infusion pumps) should be readily available. According to the recommendations of the Malignant Hyperthermia Association of the United States (MHAUS), all facilities including ambulatory surgery centers and offices, where MH triggering anesthetics (isoflurane, desflurane, and sevoflurane) and depolarizing muscle relaxants (succinylcholine) are administered, should stock dantrolene, along with the other drugs and devices necessary to treat an MH reaction (https://www.mhaus.org/faqs/who-should-stock-dantrolene/). If none of these agents are ever in use in the facility, then dantrolene need not be kept on hand. Additionally, at least one physician must be present or immediately available any time patients are present in the facility.

Procedures performed in the office-based setting include hysteroscopies, endometrial thermal ablations, biopsies, laparoscopies, and tubal ligations. Speculum placement can be uncomfortable, and studies have shown significantly lower pain scores with lubricating gel, compared to water [27]. For cervical manipulation, cannulation and dilation, a recent metanalysis demonstrated that the use of a paracervical block with lidocaine resulted in lower pain scores during placement of the tenaculum and passage of the hysteroscope through the external and internal os [28]. It should be noted that paracervical blocks may be associated with an increased risk of systemic local anesthetic toxicity, and the supervising physician should be prepared to recognize and treat any such symptoms.

With regard to the choice between oral or intravenous analgesia, a randomized controlled trial comparing intravenous sedation to oral analgesia for trans-cervical

sterilization did not demonstrate a significant difference in overall pain scores between women who received intravenous conscious sedation (fentanyl 2 mg/kg and midazolam 2 mg) versus oral analgesia (oxycodone 5 mg and naproxen 500 mg) [29]. No significant difference emerged at the time of speculum insertion, cervical injection of lidocaine, insertion of the hysteroscope, placement of the first device, and removal of the hysteroscope. Average procedure time and time in the recovery area was not different between groups. When oral analgesia was utilized, oral medications were typically administered one hour before the procedure. On the other hand, intravenous analgesia was initiated after positioning of the patient for hysteroscopy. Regardless of the choice of analgesia, all patients received 8 mL of 1% lidocaine injected to the cervix at the 4 and 8 o'clock positions.

With regard to endometrial thermal ablations (EA), non-resectoscopic techniques are technically easier to perform than resectoscopic techniques, have shorter operative times, and allow the use of local anesthesia rather than conscious sedation or general anesthesia. Conscious sedation may be required for resectoscpic EAs. Potential complications include uterine perforation, fluid overload, hematometra, cervical lacerations, nausea/vomiting, uterine cramping, and pain [30]. Adequate intravenous access is essential, and arrangements for transport of patients to a hospital should be in place. Transfer regulations vary from state to state. However, written guidelines outlining arrangements for ambulance services and transfer of medical information is recommended. For facilities performing advanced surgical procedures, it is recommended to have a written transfer agreement with a local hospital, and all physicians performing surgery in the facility should have admitting privileges at a designated hospital.

Office-based laparoscopic procedures are typically performed with a combination of oral or intravenous sedation and infiltration of local anesthetic for trocar placement. Precautions similar to those carried out for EAs should be followed for these procedures. Bradycardia may occur during insufflation, and atropine should be readily available.

## Office-Based Otolaryngology

Office-based otolaryngology procedures include laser procedures, vocal fold injections, transnasal esophagoscopy, transnasal tracheoscopy, endoscopic sinus procedures, insertion of pressure equalization tubes and biopsies.

Procedures are typically performed with local anesthesia and minimal to no sedation. To prevent discomfort during passage of the endoscope, topicalization of the nasopharynx with 4% lidocaine and 0.05% oxymetazoline hydrochloride may be followed by topicalization of the vocal cords and trachea with 4% aerosolized lidocaine. Topicalization of the vocal cords and trachea may not be necessary for very brief procedures [31]. Regardless of the depth of sedation, the responsible provider should be prepared to treat complications such as upper airway obstruction and laryngospasm. Equipment to facilitate manual positive pressure ventilation such as bag valve masks should be readily available. Airway fires are of great

concern when monopolar electrocautery is utilized. Bipolar electrocautery should be utilized when possible, and oxygen delivery should be interrupted before the use of monopolar electrocautery and laser thermoablation.

## Office-Based Plastic Surgery

The increased popularity of aesthetic surgery has been associated with a large number of procedures being performed in office-based settings. Simple procedures such as blepharoplasty may be performed under local anesthesia (2% lidocaine with epinephrine 1: 100000) and oral sedation (diazepam 10 mg and propoxyphene with acetaminophen 100 mg/650 mg) [32]. However, the increasing complexity of other plastic surgery procedures also means a large number may need to be performed under conscious sedation or general anesthesia [9]. Standard preoperative, intraoperative and postoperative procedures should be followed when utilizing general anesthesia. An adequate depth of anesthesia is especially important during operations on the face and eyelids.

Minimizing blood loss is essential for hemodynamic stability and preserving aesthetic effect. Antihypertensives such as labetalol and nitroglycerin may be necessary. Excessive bucking may not be favorable, and prophylaxis against nausea and vomiting is essential. A deep extubation may be preferred under certain circumstances.

Breast surgery is one of the most common plastic surgical procedures. Postoperative pain management can be particularly challenging after this procedure. In a prospective randomized controlled study of patients undergoing reduction mammoplasty, patients who received 10 ml of 0.25% bupivacaine into their Jackson-Pratt drains were discharged home an hour earlier and required fewer opioids at home [33]. When added to a multimodal analgesic regimen, intravenous dexamethasone (16 mg) has been shown to provide postoperative analgesia from 24 to 72 hours in patients undergoing breast surgery [34].

Tumescent liposuction involves the infiltration of large volumes of lidocaine with epinephrine into subcutaneous tissue, of up to 4 L or more of dilute lidocaine ($\leq$1 g/L) and epinephrine [35]. The infiltration of such large volumes of lidocaine raises the possibility of lidocaine toxicity. In a recent study of patients undergoing facelift surgery, the use of lidocaine with epinephrine, at doses of lidocaine 3.1 times higher than the currently recommended dose (7 mg/kg) yielded plasma concentrations below the levels considered safe (5 mcg/ml), and there were no lidocaine-related adverse effects [36]. However, the authors note several limitations to their study including the small number of patients and the variable surface area and vascularity of the area infiltrated. Therefore, lidocaine toxicity remains a potential complication after such procedures.

Fires are of particular concern when procedures are performed in the region of the face and neck. Compared to a standard nasal cannula, oxygen delivered through a nasopharyngeal tube may be associated with lower oxygen concentrations of the surrounding air [37].

## Office-Based Interventional Pain Management

Interventional pain management includes a variety of procedures, some of which are routinely performed in office-based settings. The relative lack of information regarding best practices for sedation during office-based interventional pain procedures have resulted in heterogeneous periprocedural management protocols [38, 39]. According to the guidelines of The American Society of Anesthesiologists, minimally invasive procedures including epidural steroid injections, epidural blood patch, trigger point injections, injections into the shoulder, hip, knee, facet, sacroiliac joints, and occipital nerve blocks, may be performed without the need for supplemental sedation in addition to local anesthesia. The physician performing the interventional pain procedure(s) may provide moderate (conscious) sedation as part of the procedure, but a second provider may be required to manage deep sedation or, in selected cases, other anesthesia services. Examples of procedures which may require moderate sedation include but are not limited to, sympathetic blocks (celiac plexus, paravertebral and hypogastric), chemical or radiofrequency ablation, percutaneous discectomy, spinal cord stimulator generator and lead implantation, and intrathecal pump implantation. Major nerve/plexus blocks such as brachial plexus block, sciatic nerve block, and continuous catheter techniques could be performed under moderate (conscious) sedation, but may require deep sedation or general anesthesia.

The use of sedation during nerve blocks has been shown to vary from 5% to 82% [39]. The most commonly used sedatives are benzodiazepines (97%) and opioids (77%). A few practitioners (36%) use Propofol. While intravenous sedation is typically reserved for spinal cord stimulator placement and cervical or lumbar discography, oral sedatives may be utilized for procedures such as peripheral nerve blocks, bier blocks, and intercostal nerve blocks [38]. Infrequently, intravenous sedation may be used for epidural steroid injections, stellate ganglion blocks, intercostal nerve blocks and peripheral nerve blocks. A neurological assessment may be required during these procedures. It is therefore essential that patients are able to communicate either during or shortly after the procedures.

There is a lack of uniform fasting guidelines during office-based pain management procedures. Surveys indicate that 47 to 74% of practices have fasting guidelines for procedures without sedation [38, 39]. More importantly, not all facilities have fasting guidelines for patients requiring sedation. The degree of monitoring has also been shown to vary. Standard ASA monitoring is typically used during intravenous sedation. However, non-invasive blood pressure monitoring and pulse oximetry are frequently the only monitors utilized during nerve blocks. Most practitioners send their patients to a recovery area after the procedures, with longer recovery times in patients with spinal cord stimulators, and in those who have undergone discography. Not all patients are discharged home with a designated driver.

As illustrated above, sedation practices in office-based pain management settings vary, and it is incumbent upon the practitioners to follow the ASA guidelines for sedation.

## Summary

OBS offers many conveniences to both patients and practitioners. It is important to recognize the wide variation in Office based anesthesia practices and follow the ASA Guidelines for Office-Based Anesthesia [40] at a minimum. It is important to take into consideration the governance, organization, construction and equipment, as well as policies and procedures, including fire, safety, drugs, emergencies, staffing, training and unanticipated patient transfers [40].

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