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## Pitfalls and Pearls

- Developing countries have recently adopted internationally recognized protocols and strategies aimed at increasing patient safety in surgery and reducing the incidence of adverse events in the perioperative setting.
- Adoption of a uniform institutional practice for antibiotic administration can decrease variations in performance, in both developed and developing countries.
- Prophylactic administration of antibiotics is not the only means for reducing infections at surgical sites: other means are antisepsis, optimal surgical technique, patient temperature maintenance, glucose control and the use of clippers instead of razors.
- Prophylaxis against venous thromboembolism remains the most appropriate strategy for reducing the sequelae described above, and primary thromboprophylaxis reduces the rates of deep-vein thrombosis, pulmonary embolism and fatal pulmonary embolism.
- Virtual consultations could improve patient safety by widespread dissemination and access to expert medical and surgical care.
- Routine intra-operative radiographic screening in selected, high-risk categories of procedures has been proposed for detecting retained foreign bodies.
- A positive, non-punitive reporting culture could build the basis for assessing the incidence and scope of surgical errors and allow the design of further measures to decrease the rate.

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- A systems approach should also emphasize team training and improved communication.
- Integrating patient safety and error reduction into the curriculum of medical education, postgraduate medical education, board certification, re-certification and continuing medical education could raise awareness about these issues and perhaps modify the practice of clinical care.

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## Outline of the Problem

*Greater longevity of population has created a greater need for essential surgical services worldwide. Health systems in all countries are now massively increasing the number of surgical procedures performed. As a result, the safety and quality of care has become a major issue everywhere.*

Surgical patients remain highly susceptible to preventable perioperative complications, despite the nationwide implementation of standardized patient safety protocols in recent years. Preventable adverse occurrences include so-called “never events,” such as wrong-patient and wrong-site surgery [1]. Recent publications emphasize the fact that our current patient safety protocols are indeed not safe in protecting our patients from suffering unintended and preventable harm [2]. We have inculcated a great deal of knowledge, nevertheless it is often unmanageable. The volume and complexity of what we know has exceeded our individual ability to deliver the benefits correctly, safely or reliably. Medicine has become the art of managing extreme complexity. New strategies to improve patient safety in surgery include the implementation of defined surgical safety checklists, standardized “readbacks” to improve communication in perioperative services, and medical team training programs [3, 4].

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## Limitations of the Current Practice

### Surgical Site Infections

Infections at surgical sites make a heavy contribution to patient injury and mortality and to health-care costs. Their prevalence in the United States is more than 2 % [5]. Mortality rates, length of stay, readmission rates, use of health-care services and the total cost of care are all substantially higher for patients with infections at surgical sites than for uninfected patients [6]. Reports from developing countries indicate an even higher incidence of infections at surgical sites than in developed countries, two studies showing rates of 12 and 26.7 % [7, 8]. Overall, infection control practices were considered to be poor as a result of deficient facilities, inadequate surgical instruments and lack of proper supplies

for wound care and personal hygiene. While records of surgical site infections are rare and few studies are available, rates of 40–70 % have been reported [9]. Lack of adequate decontamination, non-functioning sterilization equipment, reuse of limited sets of equipment and improperly reprocessed surgical drapes pose threats to hygiene [10]. The more pressing issue in healthcare systems in developing countries, however, is ensuring a constant supply of antibiotics for prophylaxis. Because of different hygiene and disinfection procedures and potentially different infectious disease profiles, the needs for specific types and classes of antibiotics might be different from that in developed countries. Research is needed to evaluate feasible supply channels and cost-effective application and distributions, taking into account the local culture and needs. The focus should be on establishing efficient, cost-effective, sustainable strategies for financing and implementation.

## Venous Thromboembolism

Postoperative thromboembolic events are among the main causes of morbidity and mortality after surgery [11]. Patients undergoing certain types of surgery, such as orthopaedic and abdominal operations, are at highest risk [12, 13]; postoperative pulmonary embolism is the single most important cause of death after surgery such as hip replacement. The extent of this type of complication in resource-poor settings is unknown and might be difficult to assess because of lack of consensus on diagnosis and because a substantial number of incidents occur after discharge from the hospital and are therefore not recorded. Even though most countries might not have access to advanced surgical interventions such as joint replacement, the preventable nature of venous thromboembolism as a post-surgical complication underlines the importance of raising awareness of prophylactic measures.

Most hospitalized patients have one or more risk factors for venous thromboembolism, which are usually cumulative [14]. Without prophylaxis, the incidence of objectively confirmed, hospital acquired deep-vein thrombosis is 10–40 % among medical and general surgical patients and 40–60 % after major Orthopaedic surgery [15]. In many of these patient groups, venous thromboembolism is the commonest serious complication [16] and about 10 % of hospital deaths are attributed to pulmonary embolism [17], making it the commonest preventable cause of hospital death. Although better patient care might attenuate some of the risk factors for venous thromboembolism, hospitalized patients might now be at greater risk than those studied in the past because of more advanced age, a greater prevalence of cancer and intensive cancer therapy, more extensive surgical procedures and prolonged stays in critical care units.

While groups at high risk for venous thromboembolism can be identified, it is not possible to predict which patients in a given risk group will have a clinically important thromboembolic event. Furthermore, massive pulmonary embolism usually occurs without warning, and patients with this complication often cannot be resuscitated. Routine screening of patients for asymptomatic deep-vein thrombosis is

logistically difficult and is neither effective in preventing clinically important venous thromboembolism nor cost-effective [18, 19].

The objective of thromboprophylaxis is not only to prevent fatal pulmonary embolism but also to prevent symptomatic deep-vein thrombosis and pulmonary embolism, which are associated with considerable short- and long-term morbidity and use of resources [20].

Most cases of symptomatic venous thromboembolism associated with hospital admission occur after hospital discharge. When symptomatic hospital-acquired venous thromboembolism is suspected, extensive diagnostic testing is necessary. If the condition is confirmed, therapeutic anticoagulation therapy, with its potential for serious bleeding complications, must be initiated, resulting in a longer hospital stay or readmission. In resource-poor settings, early mobilization of patients and cheaper alternatives, such as intermittent pneumatic calf compression, might also be useful.

## **Infrastructure**

In many developing countries, the quality of surgical care is often constrained by lack of trained staff, poor facilities, inadequate technology and limited supplies of drugs and other essential materials. Basic supplies for preoperative disinfection at standards considered acceptable in developed countries are often lacking, probably resulting in higher rates of preventable infection. In order to formulate sustainable, feasible approaches to these issues, it is important to understand the local infrastructure. The different levels of infrastructure in developing countries also affect use of newer surgical techniques with potentially better outcomes, lower complication rates and lower use of resources in the long run. Aside from the initial investment in equipment and training for these techniques, a new infrastructure for care support might be required for successful implementation. The resistance from local surgeons might be substantial barriers to safer patient treatment and care. Use of some techniques, however, might be feasible even in settings lacking the optimal infrastructure [21].

Adequate infrastructure includes not only equipment and facilities but also qualified medical personnel and specialists, who are lacking in vast regions of developing countries, representing a major cause of morbidity and mortality in those areas. The impossibility of being seen by a qualified surgeon in a timely manner almost surely contributes to death and disability across the world. Improved training and more surgeons are the solution but are costly.

## **Wrong-Site Surgery**

Although rare, cases of surgery at the wrong site receive wide media coverage when they occur. Surgery at the wrong site can be defined as surgery on the wrong person, on the wrong organ or limb or at the wrong vertebral level [22]. The incidence of such errors has been difficult to assess. In a review of 10 years of data from medical

malpractice insurers, claims related to surgery at the wrong site comprised 1.8 % of all orthopaedic surgical claims. In an analysis of the causes of 126 cases by the Joint Commission on Accreditation of Healthcare Organizations in the United States, surgery on the wrong patient accounted for 13 % of cases, use of the wrong procedure for 11 % and surgery on the wrong body part or site for 76 % [23].

Possible risk factors include emergency operations, unusual time pressures to start or complete a procedure and the involvement of many surgeons or procedures at a single surgical visit. Surgery at the wrong site is unacceptable but rare, and serious injury attributable to it is even rarer. No single protocol will prevent all cases. An optimal reduction in the number of cases requires safe, simple, efficient, pragmatic measures, and various systematic approaches to prevention have been proposed [24]. Communication failure has been identified as a leading cause of operations at the wrong site [25]. Teamwork is central to a culture of effective communication in the operating room and is a surrogate marker for patient safety [26]. A number of team-based approaches have been proposed over the past few years, which could be used in tackling this and other sources of surgical errors [27]. Effective team communication can provide an additional safeguard against surgery at the wrong site. Even if multiple layers of checks and controls are in place in a coordinated health-care team, however, the ultimate responsibility for ensuring the correct site of operation in every case is that of the surgeon.

## Unintentionally Retained Foreign Objects

Like surgery at the wrong site, leaving sponges or instruments inside patients is rare but can result in major injury [28] and often results in wide media coverage and lawsuits. The incidence of these errors has not been determined, but estimates suggest that they comprise one case out of every 1,000–1,500 intra-abdominal operations [29]. It is unclear why these incidents occur and how to prevent them. As is the case in wrong-site surgery, the lack of information on this error makes it difficult to assess the prevalence of this error in resource poor settings accurately. The possible catastrophic consequences and readily preventable nature of this error merit an evaluation. The established standards require that only sponges detectable on radiography be used for surgery; they should be counted once at the start and twice at the end of surgery. Instruments should be counted in all cases involving open cavities. If the count is incorrect, radiography or a manual search should be performed. Some reported incidents appear to have resulted from failure to adhere to these standards [30]. In most cases, however, foreign bodies go undetected, despite proper procedures. Even if counts are done properly, one-third of the time they are not documented because of the emergency nature of an operation or an unexpected change in procedure. It has been proposed that hospitals should monitor compliance with the existing standard of counting sponges and counting instruments in every operation involving an open cavity. Radiographic screening of high-risk patients before they leave the operating room should be considered even when the counts are documented as correct.

## Communication Breakdown

Surgery at the wrong site or with the wrong procedure, retained sponges, unchecked blood transfusions, mismatched organ transplants and overlooked allergies are all potentially catastrophic events, which, in certain circumstances, can be prevented by improved communication and safer hospital systems. In the analysis of causes submitted to the Joint Commission on Accreditation of Healthcare Organizations in the United States, communication was identified as the commonest cause of sentinel events [26]. Creating a culture of safety is therefore a high priority for surgeons and hospitals. Several interventions to improve patient safety in surgery have been introduced, including additional checks to confirm procedures and new policies for operating rooms. In addition, many hospitals are investing in safety training programs for their staff. System factors have been identified that change the expected course of care and compromise patient safety. Some relate to communication and information flow, particularly in the context of handover of patients, competing tasks and a high workload. Like other complex systems, operating rooms rely on information: performance and safety depend on how information is forwarded between phases, physical locations and providers.

Team instability—for example, different scrub nurses—can result in inferior outcomes in terms of care, indicating the importance of human resource management to ensure good team work, where members know and understand each other well. Organizational and team policies for communication are also important [9]. A policy that disallows distraction in the operating room appears to be beneficial, probably because of the inevitable effects on communication.

Another systemic cause, which is often ignored by researchers, is resources. If there is more than minimal staffing—known in highly reliable organizations as ‘redundancy’—people have time to communicate properly. Communication is not simply transmitting but also receiving, including confirmation that the transmission has been understood in the way intended. Team meetings can engender rapport and improve communication [31]. Personality may also be a factor: leaders should foster active communication among team members even when it results in constructive criticism of the leader.

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## Where Is the “Golden Bullet”?

Indeed, many complications and errors in surgery can be prevented. A study in the United States in 1999 showed that 54 % of surgical errors were preventable. The Harvard Medical Practice Study showed that adverse events in the operating room accounted for 48 % of all adverse events, occurred in about 2 % of all hospitalized patients and were preventable 74 % of the time [32]. The most effective strategy might be to plan interventions for the operations most likely to result in adverse events: the study of surgical adverse events in the United States in 1992 showed that 15 types of operations accounted for 58 % of surgical adverse events and for 37 % of all hospital adverse events [33]. Guidelines for the prevention of surgical site infections such as those established by the United States Centers for

Disease Control and Prevention might be useful. These issues should be addressed in conjunction with adequate perioperative antibiotic prophylaxis. The effectiveness of preoperative administration of antimicrobial agents to prevent infection has been established and confirmed [34]. Therapeutic levels of antibiotics must be present at the time of the incision to achieve effective prophylaxis, and the timing of administration is critical. Despite the existence of guidelines, however, adherence is frequently inadequate as evident in inadequate timing of antimicrobial administration, inappropriate choice of antibiotics and inadequate duration of prophylaxis [35]. Few studies have been reported on prophylaxis for infections at surgical sites in developing countries, and a quality improvement program to reduce the incidence of these infections in low- and middle-income countries has been proposed [36]. Although an estimated 40–60 % of infections at surgical sites could be prevented by administration of proper prophylactic antibiotics, over-use, under-use and misuse of antibiotics have been estimated to occur in 20–50 % of operations [6]. The timing of administration is critical, and both early and late administration is associated with increased rates of infection.

Improving adherence to evidence-based practice, as determined by national experts and representatives of major surgical professional organizations, can reduce the incidence of surgical infections. The guidelines include three main performance measures for antibiotic administration: selection of appropriate drugs, administration 60 min before incision to achieve therapeutic levels, and discontinuation within 24 h of surgery. In one study, anesthetists were identified as the practitioners most likely to administer antibiotics within 60 min of the incision. Changes were made accordingly in ordering, documentation and antibiotic preparation, and education sessions were held with all operating-room staff at meetings and grand-round presentations. The results of these changes were prominently displayed, and feedback was provided. The surgical site infection rate was significantly reduced [37]. For a lasting reduction in the rate of infections at surgical sites, the process of antibiotic prophylaxis administration must be analyzed, and all departments providing care must participate in implementing change [38]. Appropriate use and administration of prophylactic antibiotics can also be improved by standing orders, computerized reminders, defined location of antibiotic administration, proper documentation and identification of accountable providers [39]. A local response to restricted supplies of standard preparations from developed countries can be to use cheaper, locally available preparations that are equally effective. This would be a cost-effective option, and the funds saved could be used to improve preoperative antibiotic administration or hospital infrastructure [40].

Prophylaxis against venous thromboembolism remains the most appropriate strategy for reducing the sequelae described above, and primary thromboprophylaxis reduces the rates of deep-vein thrombosis, pulmonary embolism and fatal pulmonary embolism [41]. In a systematic review by the Agency for Healthcare Research and Quality in the United States, in which interventions for patient safety were ranked on the basis of the strength of the evidence [42], the safety practice with the highest rank was appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk. The recommendation was based on

overwhelming evidence that thromboprophylaxis reduces adverse patient outcomes, while, at the same time, decreasing overall costs [43]. Prevention of thromboembolic events with anticoagulants, early mobilization and mechanical devices (i.e. compression stockings) are also known to be effective. Many of these treatments, such as warfarin and compression devices, are known to be cost-effective in high-income countries. Whether they are readily available, cost-effective and likely to be used in middle- or low-income countries is not known. The limited publications available for review indicated that the rate of postoperative thromboembolic complications is higher in developing than in developed countries. As in developed countries, there appears to be no clear consensus about prevention strategies [44]. The same issues and barriers as those described above with regard to a sustainable supply of antibiotics apply to pharmaceutical thromboprophylaxis.

Modifiable risk factors for surgical and anesthesia errors should be identified in order to design targeted interventions to improve patient safety. The focus of the challenge is the WHO Safe Surgery Checklist. The checklist identifies three phases of an operation, each corresponding to a specific period in the normal flow of work: Before the induction of anesthesia (“sign in”), before the incision of the skin (“time out”) and before the patient leaves the operating room (“sign out”). In each phase, a checklist coordinator must confirm that the surgery team has completed the listed tasks before it proceeds with the operation. The WHO safe surgical checklist was first employed in eight hospitals across the globe as a pilot study [5]. The final results of the study showed that the rate of major complications fell by 36 % after introduction of the checklist. Deaths fell 47 % by following a few critical steps; health care professionals can minimize the most common and avoidable risks endangering the lives and well being of surgical patients.

Advances in communication and information technology might extend specialist coverage to underserved rural regions, and telemedicine can provide local medical personnel with specialist advice on diagnosis, management and monitoring of treatment [45]. This concept could also be extended to include the participation of international experts.

The encouragement of open communication and constructive criticism has been used in aviation safety and could be applied to surgical teams as well. Miscommunication can also arise from the power relationships that exist in health care as a result of the traditionally different status of different professional groups. Effective teamwork is an asset in the operation theater. “Team briefing” before the surgery, wherein the team members including the surgeons, nurses, anesthesiologist are supposed to stop and take a moment simply to talk with one another before proceeding- about whether the patient has any risk factors or concerns that the team needs to be prepared for, how much blood loss is expected etc, can help the operating room be a safer place. Each one in the OR must not only perform their set of tasks but also help the team get the best possible results. Teamwork remains a critical component of success in surgery.

Reducing surgical errors and improving patient safety are essential for improving health care and should be included in research and implementation in this area.



Ideally, safe standards of care with a focus on better outcomes should be founded on the principles of evidence-based medicine. Implementation of and adherence to safety guidelines should be monitored, possibly with financial incentives.

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## Take-Home Message

- A systems approach to reducing surgical errors must take into account the highly complex, interdisciplinary, high-pressure environment of surgery.
- Adoption of a uniform institutional practice for antibiotic administration can decrease variations in performance, in both developed and developing countries.
- Prophylactic administration of antibiotics is not the only means for reducing infections at surgical sites: other means are antisepsis, optimal surgical technique, patient temperature maintenance, glucose control and the use of clippers instead of razors.
- Routine intra-operative radiographic screening in selected, high-risk categories of procedures has been proposed for detecting retained foreign bodies.
- One aim would be to modify the professional culture prevalent in surgery, addressing the leadership style of surgeons.
- A positive, non-punitive reporting culture could build the basis for assessing the incidence and scope of surgical errors and allow the design of further measures to decrease the rate.
- A systems approach should also emphasize team training and improved communication.
- Methods used in industry, aviation and the military could be applied to surgery, including human factor engineering, crew resource management and simulation training. Experience in improving reliability could be applied as well.
- Integrating patient safety and error reduction into the curriculum of medical education, postgraduate medical education, board certification, re-certification and continuing medical education could raise awareness about these issues and perhaps modify the practice of clinical care.
- Virtual consultations could improve patient safety by widespread dissemination and access to expert medical and surgical care.

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