Clinical Information Systems and Applications

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Caitlin M. Cusack, Veena Lingam, Christoph U. Lehmann, and Rachel Wong

Learning Objectives

- Understand settings in which clinical information systems are used.
- Describe the key functionality of clinical information systems.
- Understand the role of telehealth as a tool for healthcare delivery and how it integrates into the health information system.
- Describe the spectrum of clinical communication channels, the flow of information between users, and best practices.
- Understand the reporting of data to clinical registries for secondary use.
- Identify key considerations around medical device management in health information systems.
- Gain insight into innovations and future directions of clinical information systems.

Practice Domains

- K053. Health information technology landscape (e.g., innovation strategies, emerging technologies)
- K063. Types of settings (e.g., labs, ambulatory, radiology, home) where various systems are used
- K068. Functionalities of clinical information systems (e.g., Electronic Health Records, Laboratory Information Systems, Picture Archiving and Communications Systems, Radiology Information System, vendor-neutral archive, pharmacy, revenue cycle)
- K071. Clinical communication channels and best practices for use (e.g., secure messaging, closed-loop communication)
- K078. Clinical registries
- K083. Regulated medical devices (e.g., pumps, telemetry monitors) that may be integrated into information systems
- K085. Telehealth workflows and resources (e.g., software, hardware, staff)

Case Vignette

Ms. Jones was diagnosed with invasive breast cancer following a breast biopsy done in her rural community. Upon diagnosis, she is included in her state's breast cancer registry. Consultations, surgery, and follow-up care are 2 h from her home at the tertiary care center. Her care is documented in the local electronic health record, with data available to her care team electronically and to her primary care doctor via the regional health exchange. During her surgery, she suffers a cardiac event, resulting in post-op care in the cardiac care intensive care unit and a brief stay at a rehabilitation center. Imaging and post-op radiation therapy are completed at a radiology center closer to her home. Throughout her entire

C. M. Cusack (✉)
Insight Informatics, Washington, DC, USA
e-mail: cait@insightinformatics.com

V. Lingam
Clinical Informatics Fellowship, Department of Medicine and Biomedical Informatics, Stony Brook Medicine, Stony Brook, NY, USA
e-mail: Veena.lingam@stonybrookmedicine.edu

C. U. Lehmann
Clinical Informatics Center, UT Southwestern Medical Center, Dallas, TX, USA

Department of Pediatrics, UT Southwestern Medical Center, Dallas, TX, USA

Department of Population and Data Sciences, UT Southwestern Medical Center, Dallas, TX, USA

Lyda Hill Department of Bioinformatics, UT Southwestern Medical Center, Dallas, TX, USA

R. Wong
Department of Internal Medicine, Renaissance School of Medicine at Stony Brook, Stony Brook, NY, USA

Department of Pathology, Renaissance School of Medicine at Stony Brook, Stony Brook, NY, USA
e-mail: rachel.wong@stonybrookmedicine.edu

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course for her breast cancer, from diagnosis, treatment, and post-recovery care, her care is facilitated by clinical information systems (CIS) that support all facets of her care. Throughout this chapter, Ms. Jones' journey and her interaction with CIS will continue.

Introduction

Just as technology has become an everyday aspect of our daily lives, health information technology (health IT) has become a ubiquitous tool in healthcare delivery and continues to gain importance. However, the path to today's health IT state has been long. By 1965, electronic health records (EHRs) were used in 70 hospitals, and it wasn't until 1971 that Lockheed Corporation produced the first computerized provider order entry (CPOE) system. In the 1980s, the Veteran's Administration's Veterans Health Information System Technology Architecture (VistA) system was ready. The Master Patient Index (MPI, see Chap. 14) was first introduced in the 1980s. Later in the decade, personal computers and the Windows operating system brought more computing power into physicians' offices. In 1990 the world wide web was invented, and by 2004 President George W. Bush had pointed out the importance of EHRs for healthcare. However, until 2009, with the 35-billion-dollar investment in health IT under the American Recovery and Reinvestment Act (ARRA), the EHR reached a penetration of physicians' offices and hospitals of over 90% [1].

Health IT is now ubiquitous. It reaches out beyond clinical settings throughout the community. Even patients now are familiar with EHRs and patient portals; smart devices such as scales, glucose monitors, and blood pressure monitors are all capable of feeding data back to the EHR. Thousands of apps on smartphones purport to manage health and well-being.

Enterprise Clinical Information System Settings

Not long ago, the task of describing healthcare settings where technology had penetrated would have taken a sentence: some hospitals, fewer ambulatory settings, a scatter of pharmacies. The Institute of Medicine's (IOMs) 2003 landmark book *Patient Safety, Achieving a New Standard for Care* [2] identified only four settings that contained electronic functionality: "…hospital, ambulatory care, nursing home, and care in the community".

As technology adoption has drastically increased, particularly since the Health Information Technology for Economic and Clinical Health Act (HITECH) Act and Meaningful Use incentive program sponsored by the U.S. Centers for Medicare and Medicaid Services (CMS), technology has penetrated every aspect of our healthcare system. Health care delivery settings go well beyond hospitals and ambulatory settings into our homes, long-term care, rehabilitation centers, and even in the ambulances that transport patients to acute care settings. Taking advantage of computing power, systems have been developed to support, enhance, and create efficiencies in every aspect of health and healthcare. As a focal point in the large scope of these systems, consider the patient, as the consumer of these services, at the center of these settings (Fig. 11.1).

During Ms. Jones' care, she interacts with numerous healthcare settings that take advantage of clinical information systems to support that care: her primary care physician's office, the community pharmacy, a commercial laboratory, the mammography center, the local surgeon for her breast biopsy, the Breast Care Center 2 hour from her home for her consult, definitive surgery, the rehabilitation center, and her home.

Seen at a high level, settings include the home and the patient's community. The community contains urgent care facilities, clinics, private physician offices, free clinics at charity organizations, free-standing radiology centers, laboratories, physical therapy, and surgery centers; large chain and small independently owned pharmacies; long-term care facilities; and rehabilitation centers. Entry into some settings requires that the individual be part of a group with access, for instance, school clinics, university health centers, and clinics embedded into companies that provide care only for their employees.

Many of the high-level care settings contain sub-settings, all supported by the software. Using the hospital as an example, each facility is a collection of individual settings. Some areas receive patients: hospital-based clinics, the emergency department, and admissions. While smaller hospitals may have single inpatient settings, larger hospitals begin to segment patients into dedicated inpatient areas: medical, surgical, cardiac, antepartum, neurology, pediatric, physical therapy, and many others. For those in critical condition, intensive care units (ICU) provide care: smaller hospitals may have a single ICU, while larger facilities may segment critical care into medical-surgical ICUs, coronary care units (CCU), pediatric intensive care units (PICU), neonatal intensive care units (NICU), trauma intensive care, neurological intensive care, and burn care units. Surgery is performed within hospital and outpatient surgical suites, including pre-operative areas, operating rooms, post-anesthesia units, and recovery. Obstetric labor and delivery units may care for both healthy laboring and critically ill patients. Many units also have dedicated

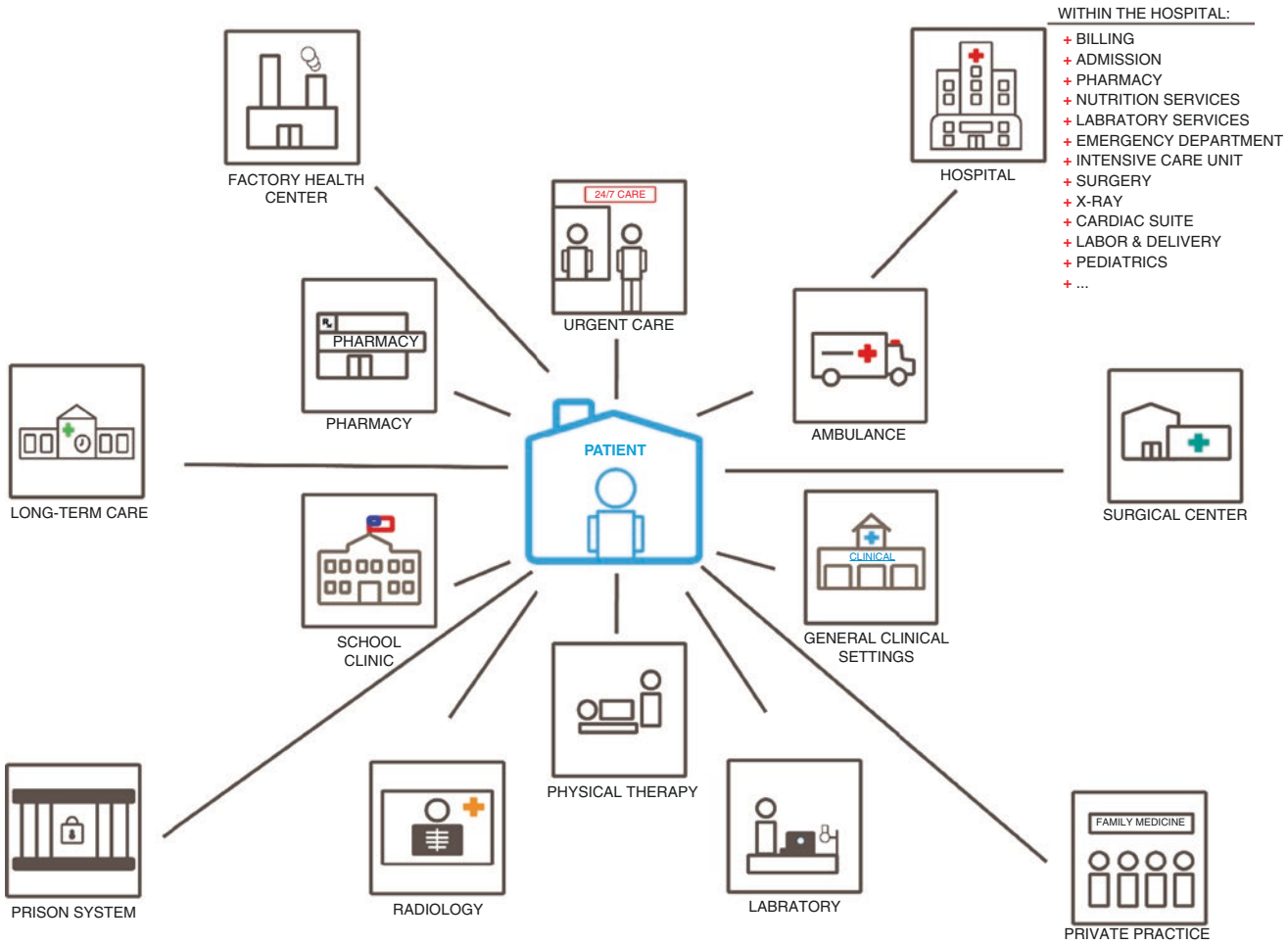

Fig. 11.1 Common settings for clinical information systems

surgical suites for cesarean deliveries, antepartum, and post-partum procedures. Cardiac suites may have capabilities to perform invasive procedures such as cardiac catheterization and relatively simple procedures such as echocardiograms and stress tests. Radiology suites include capabilities to perform x-rays, ultrasound, magnetic resonance imaging (MRI), computerized tomography (CT) scans, positron emission tomography (PET) scans, and more. Some also have active interventional capabilities that allow fluoroscopy guidance, vessels cauterization, and radiation treatment. Added to these settings are those that the patient may never physically visit but that are critical to care: pharmacy, laboratory, pathology, supply, and blood bank. Finally, there are the areas in the hospital that collectively ensure that the enterprise is functioning: the administrative suites, billing, medical records, pastor services, medical library, food and nutrition services, and housekeeping services. Today, many of these settings are computerized, with specialty software supporting unique needs and workflows.

Functionalities of Clinical Information Systems

Clinical information systems (CIS) are software systems coupled with necessary hardware that allow the capture, storage, and processing of clinical information to those making clinical decisions [3]. Considering the vast scope of settings highlighted above, the applications that make up a CIS have grown exponentially. Once the available range could be summarized into core functionality—electronic medical record (EMR), ancillary systems, scheduling, and billing—applications no longer fit into neat, discrete categories. To describe all that exists under the umbrella of CIS and the functionalities of each type of CIS is beyond the scope of this chapter. Still, the reader should be aware that there is technology behind it supporting health and healthcare (Fig. 11.2).

This section will describe the core systems that makeup CIS, highlight the vastness of functionality available, and address common challenges that informaticists face regarding all CIS, including issues of interoperability, integration, maintenance, and support of the end-user.

Fig. 11.2 Common clinical information systems

Electronic Medical Records/Electronic Health Records

Ms. Jones care is supported by numerous clinical information systems, including her primary care provider's EHR, the regional HIE connecting her various providers, ePrescribing that allows for more seamless prescription management, the patient portal that allows her to see upcoming appointments and receive patient education information, the LIS that supports the local lab, and the RIS that supports the mammography center.

While the terms **electronic medical record (EMR)** and **electronic health record (EHR)** are frequently used interchangeably, they are distinct entities. The United States Office of The National Coordinator for Health Information Technology (ONC) defines the EMR as a "digitized version of a patient's paper chart" [4], containing the "medical and treatment history of the patients in one practice" [5]. ONC states that EHRs "focus on the total health of the patent—going beyond standard clinical data collected in the provider's office and inclusive of a broader view on a patient's care" [5]. The key is that the EHR represents a real-time, single place for collecting health, wellness, and healthcare information on a given patient, across physical sites. An EMR contains all the capabilities that allow a given provider to capture, store, edit, and view information they have documented on their patients. An EHR allows for the incorporation of data from external sources. Ideally, everything representative of a patient's care would be contained within a single EHR, but with continued interoperability challenges, such a vision has not been achieved. Today's reality is that an individual's health is represented in many records in each place the individual has sought care with some islands of interoperability and data exchange. While recognizing the differences between an EMR and an EHR, for simplicity, we will only utilize the EHR term for the remainder of this chapter.

Core Functions of the EHR

As the healthcare landscape has evolved in the United States (US) over several decades, so too has its EHRs. Initially, medical records were developed as tools for a single department or use—repositories of patient demographics, laboratory information systems, and so forth. With time, they expanded in scope, with cross-departmental use and integration with other systems. As CIS has become more widely adopted into all clinical care and supporting systems, defining discrete categories of systems and applications within them becomes a difficult task. A review of any EHR vendor's website demonstrates dozens of capabilities within even a single given vendor system.

To simplify, we present two perspectives for categorizing EHR functionality: the first, as defined in 2013 by the Institute of Medicine (IOM) that focuses on end-user needs and functionalities; and the second as defined by the federal government's certification program requirements for EHR vendors and used to achieve incentive payments. Which vantage is of most use is dependent on one's role within a given healthcare organization: as a care provider, the IOM's perspective is of more value; as a vendor or purchaser, one's focus must be on certification criteria. These varying viewpoints elucidate the inherent conflict between providers and those with purchasing power within an institution.

Institute of Medicine

In 2013, the Institute of Medicine defined eight core functionalities of an EHR [6], representing one of the first attempts to categorize desired functionality.

These included:

1. Health information and data
2. Result management
3. Order entry/management
4. Decision support
5. Electronic communication and connectivity
6. Patient support
7. Administrative processes and reporting
8. Reporting and population health

Even today, this is a robust way to think through what functionality is needed by the end-user providing patient care. In a historical context, EHR functionality was primarily focused on replicating the patient's paper record, ensuring that these core patient care activities were accommodated. Continuing to the present day, it is possible to bucket every existing functionality under one of these eight categories. However, as broad categories, specificity around functionality is not well represented.

ONCs Certification Criteria

As with the software systems that support Ms. Jones care in the community, her entire hospital stay for her breast cancer surgery and recovery are supported by sophisticated clinical information systems. Technology allows her clinicians to document and monitor her care, track her movement through the surgical suite, support her care in the CCU, support the administrative functions of the hospital, tests, and their results, and even the food that she is provided.

With the HITECH Act and its incentives for adoption and implementation for those who used "meaningful" systems, it became necessary to define the term "meaningful". In 2010, ONC began defining certification criteria for EHRs and, to date, has released three editions providing needed definitions around functionalities. The most recent 2015 Edition Cures Update Base EHR definition includes the following base EHR Capabilities (on or after December 31, 2022) [7]:

1. Patient Demographic and Clinical Health Information
   (a) Demographics
   (b) Implantable Device List
2. Clinical Decision Support
3. Computerized Provider Order Entry
4. Capacity to capture and query information relevant to healthcare quality
   (a) Clinical Quality Measures—Record and Export
5. Capacity to exchange electronic health information with and integrate such information from other sources
   (a) Transitions of Care
   (b) Application Access
      (I) Patient Selection
      (II) Standardized Application Programming Interfaces (API) for Patient and Population Services
      (III) All Data Request
      (IV) Direct Project or Direct Project, Edge Protocol, and XDR/XDM

ONC provides significant detail around each of these capabilities, but this high-level list offers an excellent approach to defining the core functionalities of an EHR.

Beyond the EHR

To support the settings in which care takes place, the EHR as the focus of the patient record is surrounded by complex and diverse software systems including those critical to care, such as ancillary services, and software that supports the mechanics of care, such as scheduling, billing, and supply management. It would require volumes to delve into all the functionalities that support care. Instead, we will use the hospital setting as a core example of how systems and software interact in providing care and the challenges informaticists face.

Hospital Information Systems

The hospital's needs are specific enough that many apply the term **hospital information system (HIS)** to the range of software solutions available to them. Under this umbrella exist administrative, financial, clinical, and ancillary systems, in addition to the core EHR. Hospitals are certainly the most complex settings and largest consumers of CIS, with the broadest range of software tools to support them. Table 11.1 lists a sampling of HIS.

HIMSS Adoption Model

The Healthcare Information and Management Systems Society (HIMSS) Electronic Medical Record Adoption Model allows hospitals to track and categorize progress around implementing various EMR capabilities of a

Table 11.1 Examples of software solutions available to hospitals

Administrative	Financial	Clinical	Ancillary
Admission, discharge, and transfer (ADT)	Revenue Cycle	Clinical Documentation, physician, nursing, and others	Laboratory Information System
Patient registration	Inventory/Materials and Supply Chain management	Computerize Provider Order Entry	Radiology Information System
Master Patient Index (MPI)		Specialized systems for medical specialties (e.g., Anesthesia, Cardiology, Dentistry, Dermatology, Obstetrics, Ophthalmology, Oncology, Surgery, Emergency, Cardiology, ICU)	Picture Archiving and Communications System
Scheduling		Population-Level Reporting	Pharmacy Information Systems
Administrative Reporting		Infection Control Management	Specialized systems for common procedures (PFTs, EKGs, Echo, Endoscopy)
Quality Measuring and Reporting		Operating Suite	Anatomic Pathology System
Nutrition and Dietary Management			Medication Management including the electronic Medication Administration Record

health information system (also referred to as HIS) [8]. This model presents a progression of capabilities, from basic automation to a complete system capable of participating in data exchange. Of note, the HIMSS model has evolved as systems have become more widespread and sophisticated.

The model includes the following eight stages and cumulative capabilities:

- **Stage 0**: None of the three Ancillaries-Laboratory, Radiology, Pharmacy Installed
- **Stage 1**: Ancillaries-Laboratory, Pharmacy, and Radiology/Cardiology Information Systems: Picture archiving and communication system (PACS); Digital Non-DICOM (Digital Imaging and Communications in Medicine) Image Management
- **Stage 2**: Central Data Repository; Internal Interoperability; Basic Security
- **Stage 3**: Nursing and Allied Health Documentation; Electronic Medication Administration Record; Role-Based Security
- **Stage 4**: Computerized Provider Order Entry (CPOE) with Clinical Decision Support (CDS); Nursing and Allied Health Documentation; Basic Business Continuity
- **Stage 5**: Physician Documentation Using Structure Templates; Intrusion/Device Protection
- **Stage 6**: Technology-Enabled Medication, Blood Products, and Human Milk Administration; Risk Reporting; Full CDS
- **Stage 7**: Complete EMR; External health information exchange (HIE); Data Analytics, Governance, Disaster Recovery, Privacy and Security

This approach to categorizing EHR capabilities is of particular use to those creating strategies for implementation and stepwise approaches to that task.

The Traditional Ancillary Systems: "Lab/Rad/Pharm"

Long-held as core to healthcare and technology, laboratory information systems (LIS), radiology information systems (RIS), and pharmacy information systems (PIS) provide the ability to capture, store, and retrieve information related to diagnostic testing and medication orders. These ancillary systems were established early in adopting healthcare technology, forming the initial start of some of the largest EHR vendors today. These systems are generally considered "modules" that sit outside of, but interface with, the clinical record.

Laboratory Information Systems

LIS are also known as laboratory information management systems (LIMS) and laboratory management system (LMS) systems. As a natural evolution for automated systems, LIS were one of the earliest aspects of healthcare to become computerized, creating vast improvements over previously manual processes. The earliest computer terminals in the hospital wards generally performed the sole function of patient laboratory lookup using DOS roll-and-scroll functionality. These digitized systems allowed labs to increase laboratory reporting volume, efficiency, and speed and permitted exporting and storing historic patient results.

As LIS systems became more sophisticated, they evolved into today's offerings: end-to-end support for laboratory functions. These functions include receiving and processing orders, translating results into human-readable text with local reference ranges, allowing manual input of tests, stor-

Table 11.2 Laboratory information systems functionality

Pre-analytical	Analytical	Post-analytical
Orders	Results entry	Reporting
Collection	Review	Interpretation
Accession		Billing
Labels		Tracking

ing the results, pushing results out to patients and care providers, and making those results available for future viewing [9]. Today, patient portals also assist with the dissemination of results to patients.

In thinking about LIS, one useful construct is outlined by McCudden et al. [10] specifying three stages of modern LIS systems: pre-analytical, analytical, and post-analytical (Table 11.2).

Because various laboratory machines support specific laboratory tests, LIS modularity allows labs to customize their local needs, budgets, and capabilities through 'plug and play'. For instance, most labs have modules for basic chemistries and hematology and expand to microbiology, immunology, and genetics, as well as growing system functionalities within anatomical pathology. So sophisticated are these systems that large organizations have clinical informaticists dedicated to supporting them.

While LIS had the advantage of early adoption and iterations of improvement over the years, there remain challenges due to the continued variability in processing, labeling of results, and varying reference ranges between brands of laboratory devices. This lack of standardization early on continues to impede progress in areas such as interoperability. In 1994, to improve interoperability of laboratory values, Regenstrief Institute in Indiana created the logical observation identifiers names and codes (LOINC) standard that is widely used today [11]. Although codified laboratory values are critical, issues remain related to many legacy laboratory terms that exist for a single meaning.

Varying legacy terminology represents a major challenge for informaticists: a seemingly simple effort utilizing laboratory values in a CDS tool requires intensive upfront labor to map values from backend LIS systems. For example, to ensure that a hemoglobin result is incorporated into a given CDS, informaticists must include and exclude multiple values—include Hemoglobin, Hb, HGB; but exclude hemoglobin A1C and Hemoglobin S. To highlight the scope of the issue, a LOINC inquiry returns 445 hits on the term "hemoglobin".

Radiology Information Systems

RIS are the core systems for the input and storage of radiology reports, tracking images and patient flow, reporting notification to ordering providers, and billing. RIS systems typically have integrated voice recognition systems for providers to create reports quickly while attaching appropriate diagnostic and billing codes. These systems are used in concert with PACS, which stores the actual digital copy of the image. RIS/PACS were embraced early by radiologists because they created efficiencies and allowed them to be free from the constraints of reading and interpreting films within the four walls of a hospital or radiology center [12]. Radiologists began to work both at a distance from the site that used their services and asynchronously. Providers also benefited as the systems allowed for quick, ubiquitous access to previously viewable images only on physical film.

Standards have long been in use in the radiology space. Digital Imaging and Communications in Medicine (DICOM) standards allow for imaging and the resulting data communication. Although initially developed by the American College of Radiology (ACR) and the National Electrical Manufacturers Associations (NEMA) [13] for system interoperability, these standards are now used across all medical imaging. ACR has been active in pursuing standards for radiology, including the development of standardized coding schemes to represent imaging results, such as the Breast Imaging Reporting and Data System (BI-RADS) for mammography results allowing results to be codified used for reports and decision support. Recently the Radiologic Society of North America (RSNA) developed the new radiology lexicon called RadLex, containing a comprehensive set of terms to be used in reporting, CDS, registries, education, and research [14].

Over time as CIS became more robust, functionality that once was part of a RIS may now be housed elsewhere in the EHR, such as patient registration, order entry, decision support, the physician directory, and report storage [15].

Because of the large size of many images, storage and bandwidth for connecting can be more significant barriers in this space than many other areas of CIS. One solution is to have end-users tunnel into PACs for viewing or showing only thumbnails of an image within an EHR. Generally, RIS systems use inexpensive storage systems to store the vast amount of data and fast network connections to allow rapid access to images requested.

Pharmacy Information Systems

Pharmacy information systems (PIS), also known as pharmacy management systems, are central to medication management. Siska describes these systems as containing five core functionalities:

- Order management and communication;
- Order verification, confirmation, and fulfillment;
- Preparation, distribution, and inventory control, storage, and security;
- Administration; and
- Intervention and monitoring [16].

PIS interfaces with other systems integral to EHRs, including CPOE, CDS, medication reconciliation, medication dispensing,

and medication administration systems [17]. As an ancillary system, the need for tight integration leads to many challenges for PIS that are critical to patient safety. For instance, terminology must be consistent between PIS and CPOE. The ordering provider, pharmacist, those administering medications, and the patient must all see the same name when identifying the order, prescription, pill bottle, or intravenous (IV) bag. Consistency requires synching terminologies on the pharmacy system side as well as the provider facing the EHR side. Maintaining a medication catalog can be time-consuming and complex due to the vast numbers of available medications, matching generic and brand names, and the options for dose, route, frequency, duration, and indication. As medications are purchased, and formularies change, the medication catalog must be updated in the pharmacy and EHR side. What may seem to be a simple medication change results in a cascade of updates to provider-facing order sentences, medication picklists, and order sets. Failure to update across the enterprise risks providers ordering something that the pharmacy no longer stocks.

Although one would intuitively assume that information such as body mass index (BMI), age, gender, pregnancy, and lactation status would be viewable to the pharmacist when it exists in the EHR, this only occurs when these discrete data elements are explicitly mapped and coded to a pharmacy view. In the case of pregnancy status, many EHRs do not capture it as discrete data, and thus while it may be accessible on the EHR side, it may not display on the pharmacy package side.

In addition to building medication libraries and maintaining orders in the EHR, decisions around CDS also require frequent updating. It is imperative to implement CDS carefully to take advantage of its ability to reduce prescribing errors. It is worth noting that although prescribing errors are common, it is rare for an error to lead to direct patient harm [18]. Most organizations have purchased rules engines that conduct drug-duplication, interaction, dose, and allergy checking to enhance drug checking that considers patient weight, pregnancy, lactation, age, and laboratory results.

Frequently organizations make the error of activating all vendor-supplied CDS around medications in the mistaken belief this will lead to fewer errors, improve patient safety, and reduce medical liability. However, the resulting barrage of interruptive alerts of frequently clinically irrelevant information results in the opposite effect. The irrelevancy leads to clinicians reflexively overriding all alerts, commonly referred to as 'alert fatigue', and missing the rare critical alert that warranted attention and action. There is often tension between those believing that having all alerts turned on leads to legal liability protection and those attempting to constrain interruptive alerts to only those of clinical relevancy. As such, a critical role of an informaticist is to make careful, deliberate choices around which alerts to utilize and maintain. For example, alerts around known human teratogens and pregnancy have high utility. Alerts for medications with scant evidence of issues during pregnancy can create noise, are of little clinical value, result in high override rates, and cause many organizations to choose to turn off medication-pregnancy alerts altogether.

One approach that some organizations use today is to monitor override rates: a medication alert overridden most of the time is likely one that should not be used. A close look at these alerts, along with the overriding reason captured, allows the informaticist to decide how to alter the alert to add clinical relevancy or decide to retire the alert all together for lack of clinical value.

Beyond the Hospital Information System

With the core CIS representing the hub where most health data are generated, organized, and synthesized, several systems facilitate data exchange between the patient, community, and environment. To effectively communicate health information with patients, families, providers, and other stakeholders throughout and across health systems, there are multiple channels for data exchange in and out of the core CIS. Technology has enabled remote technologies such as telehealth, patient portals, and secure messaging systems to promote the flow of information between patients and providers. Registries populated with data from the CIS inform public health and healthcare systems in population health practices. As medical devices become ever more ubiquitous, essential patient and environmental data flow between devices and the CIS for diagnostic and therapeutic purposes.

Telehealth

Using telehealth, Ms. Jones has an e-consultation with a genetic specialist, who views a previously completed family history questionnaire and other history in the EHR, provide counseling, and order genetic testing. Based on test results and coordination with her surgeon, together they decide to proceed with a double mastectomy and lymph node dissection.

While telehealth is explored in greater depth in Chap. 18, we review aspects of telehealth that integrate within CIS. Telehealth uses electronic information and communications technologies to provide and support healthcare when distance separates the participants [19]. For HIS, telehealth offers a set of tools and processes that facilitate the synchronous and asynchronous exchange of information with patients and other providers. Telehealth can expand the reach of healthcare organizations and patient access to healthcare, with multiple factors affecting the integration of telehealth data into the HIS. Successful use of telehealth requires many factors, including the hardware and software for communication between patients and providers, equipment for capturing

remote patient data, and secure systems for data transmission. In addition to equipment and infrastructure, telehealth workflows are necessary to ensure support for patients and providers, documentation, and the appropriate use of data to provide clinical care. External factors that have limited telehealth adoption, including reimbursement, licensure, and geographic and practice setting restrictions, are evolving [20, 21].

Telehealth Models and Modalities

Telehealth was traditionally developed in a hub and spoke model, with large tertiary care centers as "hubs" providing specialty consultation to small rural hospitals in the periphery. Telehealth acts as a connector or "spoke" to increase access to specialty care [22]. Healthcare providers also act as hubs in providing remote care (spokes) to the patients in their preferred setting, such as their homes or primary care office. Telehealth offers a wide range of modalities that vary by synchronicity and identity of the hubs and spokes (Table 11.3). Examples of synchronous, patient-to-provider interactions, include live video interactions that use two-way audio-visual communication, such as tele-psychiatry and tele-primary care. Synchronous provider-to-provider telehealth can connect on-site providers to specialty expertise, such as tele-stroke or tele-ICU services in settings that lack specialists. Another form of provider-to-provider telehealth is tele-mentoring, where remote expert teams support primary care providers (PCPs) via videoconference. Models such as Project ECHO [23] provide tele-mentoring in various topics such as behavioral health, medication-assisted treatment, HIV care, and antimicrobial stewardship. Asynchronous or store-and-forward telehealth is defined as transmitting pre-recorded digital information, such as images, pathology slides, documents, audio files, or videos, that a patient or provider can send to another care provider or specialist. Examples include provider-to-provider e-consultation, such as tele-dermatology for remote diagnosis of skin lesions, tele-ophthalmology for screening of diabetic retinopathy, and tele-pathology for evaluation of pathology specimens. Remote patient monitoring refers to continuous assessment of patient data collected remotely, such as monitoring of vital signs, weight, or virtual exam recordings [22, 24, 25].

Telehealth Hardware and Software

Telehealth delivery requires patient and provider access to hardware and software that allows for virtual communication and secure Health Insurance Portability and Accountability Act (HIPAA)-compliant information exchange. The rise in consumer use of smartphones, tablets, and computers with high-resolution cameras has allowed personal devices for real-time audio-visual communication. Choices regarding software may be determined by practical issues, such as using previously purchased software, ease of use, familiarity for patients and staff for scheduling and technical support, integration with EHRs, and HIPAA compliance with the requirement of business associate agreements [24, 26]. Health systems with well-developed telehealth programs may have EHR-integrated tools, such as Kaiser Permanente's (KP) integrated telehealth software with their KP HealthConnect EMR, or utilize custom software applications such as the Veterans Affairs (VA) mobile VA Video Connect for video chat. In addition, these systems may have other mobile applications for patient reminders and chronic disease management [27, 28].

Outside of large healthcare systems, most telehealth programs are not integrated into the larger organizational EHR. With the need for rapid expansion of telehealth services due to the COVID-19 pandemic, the Office of Civil Rights loosened enforcement of the HIPAA rules during the nationwide public health emergency. This loosening of rules allowed health systems for the first time to leverage popular consumer virtual communication platforms for the rapid scaling up of telehealth services [29, 30].

The remote monitoring devices landscape is rapidly growing. Systems can capture various health data such as sensors to track physical activity, cardiac information through remote telemetry, heart, and lung sounds through virtual stethoscopes and vital sign information [31].

Telehealth Workflow and Integration

Telehealth implementation requires thoughtful mapping of workflow and system processes. For example, implementing remote continuous glucose monitoring (CGM) might require multiple steps: patient and device selection, scheduling and consent, delivery of equipment, training for patients and providers, processes for data review and integration, data acquisition, and appropriate documentation and billing [32, 33]. Patient selection will be affected by the level of patient engagement, insurance coverage, and the likelihood of benefit, such as patients with labile blood sugars on basal/bolus insulin or with type I diabetes. With various medical devices, customized device selection must be made to fit the patient's monitoring needs. Healthcare providers help patients obtain access to monitoring devices and provide training to patients and staff who need to download and interpret data.

With CGM devices capable of capturing glucose levels every 1–5 min, information overload can become a problem, with many data points potentially obscuring clinically meaningful or actionable information [34]. Data filtering

Table 11.3 Telehealth modalities

	Asynchronous	Synchronous	Remote patient monitoring
Patient-to-patient	Patient store & forward	Live video	Remote monitoring
Provider-to-provider(s)	E-consult	Videoconferencing Tele-mentoring	

and visualization can make interpretation easier. For example, glucose trends may inform insulin titration or reveal the risk of hypoglycemia. Data may show the duration of time that glucose values remain within the desired range or generate metrics such as the glucose management indicator or area under the curve that estimate HbA1c [35]. Integrating information obtained through telehealth and remote monitoring technologies into the CIS can vary depending on the interoperability of software, data sampling rate, and clinical workflows for data capture and documentation. Emerging technologies often have independent portals for data visualization. Integration of clinical information may depend on provider documentation or platform interoperability for data exchange. For CGM data, a remote monitoring program may download data by plugging a reader into an office computer or from the Cloud and subsequently printing a single-page ambulatory glucose profile report. These reports provide clinical care and billing documentation but may need to be scanned to integrate them into the EHR. Information may be reviewed with patients in person or through face-to-face or non-face-to-face telehealth and remote monitoring services [36]. While CGMs represent only one example, the growing use of telehealth and remote monitoring systems will vastly increase the amount of data that flows in and out of CIS.

Clinical Communication Channels and Best Practices

Ms. Jones care is greatly enhanced by the availability of electronic tools that not only allow her providers to communicate with one another—in the form of Direct messaging to providers from other organizations, messaging within the EHR, and text messaging using encrypted apps on their mobile phones—but also allow her to communicate directly with her care coordinator throughout her journey.

As healthcare delivery moves to a patient-centered, team-based approach and spreads over many locations, secure HIPAA-compliant communication channels have become critical for care coordination. This need is especially highlighted in care delivery models such as the Patient-Centered Medical Home, where care coordination is one of five essential functions. Per the Agency for Healthcare Research and Quality (AHRQ), effective care coordination can be accomplished through frequent communication and the free exchange of information with the effective use of electronic tools [37].

Accessible, timely, secure, bidirectional communication channels between the healthcare teams providing care in disparate settings are essential for patient safety during care transitions, such as discharge a patient from an acute care setting to return to the primary care team [38]. A survey showed that PCPs and hospitalists alike preferred direct communication around the Transition of Care (ToC) [39].

Communication channels between patients and members of their healthcare team are just as critical. Patient portals are currently the predominant electronic medium for such communication. However, paper, telephone, and fax still have their stronghold in healthcare, especially where access to technology is limited. Clinical informaticists should be aware of all possible channels for internal and external messaging in their institution. They will need to implement, evaluate, monitor, and optimize these channels to ensure effective and secure communication [40].

Regulatory Factors

Several regulatory factors impact clinical communication that the informaticist should be familiar with. The Meaningful Use (MU) Program incentivized the collecting and sharing clinical data in a structured format through progressive implementation stages. The program defined secure messages as "any electronic communication between a provider and patient that ensures only those parties can access the communication. This electronic message could be email or the electronic messaging function of a personal health record (PHR), an online patient portal, or any other electronic means." Meaningful Use Stage 2 (MU 2) required using a patient portal for Eligible Practitioners (EPs) and/or Critical Access Hospitals, summarized in Box 11.1 [41].

Box 11.1. Communications Using CIS Regulations

2015 Meaningful Use Core Objectives:

1. Use secure electronic messaging to communicate with patients on relevant health information.

2015 Meaningful Use Patient Access Objectives:

1. Provide patients the ability to view online, download, and transmit their health information within four business days of the information being available to the EP (for EPs only).
2. Provide patients the ability to view online, download and transmit their health information within 36 h after discharge from the hospital (for Eligible Hospitals/CAHs only).

The latest iteration, Promoting Interoperability [42], required the use of:

- Existing 2015 Edition certification criteria
- The 2015 Edition Cures Update criteria; or
- A combination of the two.

Specifically, the 21st Century Cures Act requires EP and CAHs to attest to Prevention of Information Blocking and requires that data part of the US Core Data for Interoperability (USCDI) be made available electronically upon request in all instances except for a few exceptions. It clearly states that the data be made accessible to patients via smartphones and modern software apps leveraging secure, standardized APIs.

The main mechanism for requesting and receiving health records is often a patient portal. Patient portals can be tethered or untethered. Tethered portals are those that are connected to an EHR vendor and a particular organization. These offer two-way communication. Untethered portals are EHR agnostic and have a range of capabilities, such as the ability to import and upload data from various sources. Currently, these untethered portals only allow for unidirectional data flow, that is, from the source to the portal, and cannot send health care data back to the source or update the source information.

Security

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 consists of several rules. The Privacy rule and Security rule are key components that apply to secure messaging in healthcare. The HIPAA Privacy rule defines Protected Health Information (PHI). The HIPAA Security Rule [43] protects a subset of information covered by the HIPAA Privacy Rule [44], in that all individually identifiable health information a covered entity creates, receives, maintains, or transmits in electronic form. The Security Rule calls this information "electronic protected health information" (e-PHI). Secure messages in healthcare by nature contain e-PHI and must comply with the standards outlined in the Security Rule. The rule requires covered entities to maintain reasonable and appropriate administrative, technical, and physical safeguards for protecting e-PHI. Specifically, covered entities must:

- Ensure the confidentiality, integrity, and availability of all e-PHI they create, receive, maintain or transmit;
- Identify and protect against reasonably anticipated threats to the security or integrity of the information;
- Protect against reasonably anticipated, impermissible uses or disclosures; and
- Ensure compliance by their workforce.

Channels for Communication

While traditional paper-based modalities, such as mailed patient letters and faxed laboratory results or discharge summaries, persist in many areas, here we will focus on available informatics tools.

Secure communication channels are required between,

1. Members of the healthcare team in one setting;
2. Across healthcare teams in different locations; and
3. Healthcare professionals and patients and their families.

Communication in Acute Care or Hospital Settings

In the acute hospital setting, while the healthcare team is generally part of one institution and geographically close, the pace of communication is rapid and occurs simultaneously in multiple directions. Often, communication channels are the primary connections between groups working together for one patient, but with different roles and responsibilities. The challenge to a clinical informaticist in this setting is to implement a technological solution that enables secure, rapid two-way communication between the appropriate personnel and allows for triaging of the messages to avoid alert fatigue.

Commonly the flow of communication is one-sided, interrupted across a variety of channels, and lacking standardization. Pagers still play a major role in this landscape, but several studies highlight this system's inefficiencies [45, 46]. For instance, pagers may provide a false sense of security, but unless encrypted and provided with a display lock, they are not a secure means to share PHI.

Consider the situation depicted in Fig. 11.3. Here, the patient reports a complaint to the bedside nurse. The nurse then contacts the on-call clinical team using a web-based text paging application with a call-back number. Confusion about which team member is the correct contact for the patient delays communication [46]. The receiving provider calls the number provided and waits for the clerk to contact the nurse, who may have moved on to other tasks. This process is fraught with delays and leads to wasted time for busy clinical teams. Furthermore, communication by the outpatient/ambulatory care team with the acute care/inpatient team is practically non-existent, as discussed later in this section. Often the care teams resort to text messaging (SMS) on personal devices for timely communication and risk ePHI being shared and stored in a non-HIPAA compliant manner [47].

The need for efficient closed-loop communications has led to the development of numerous EHR vendor-based and independent applications. These applications provide several layers of functionality and have been shown to improve the efficiency of interdisciplinary communication when compared to traditional pagers [48].

One case study classifies these into three tiers based on the functionality as follows [49]:

- Tier 1: Basic Secure Communication
- Tier 2: Secure Communication within an Existing Clinical System

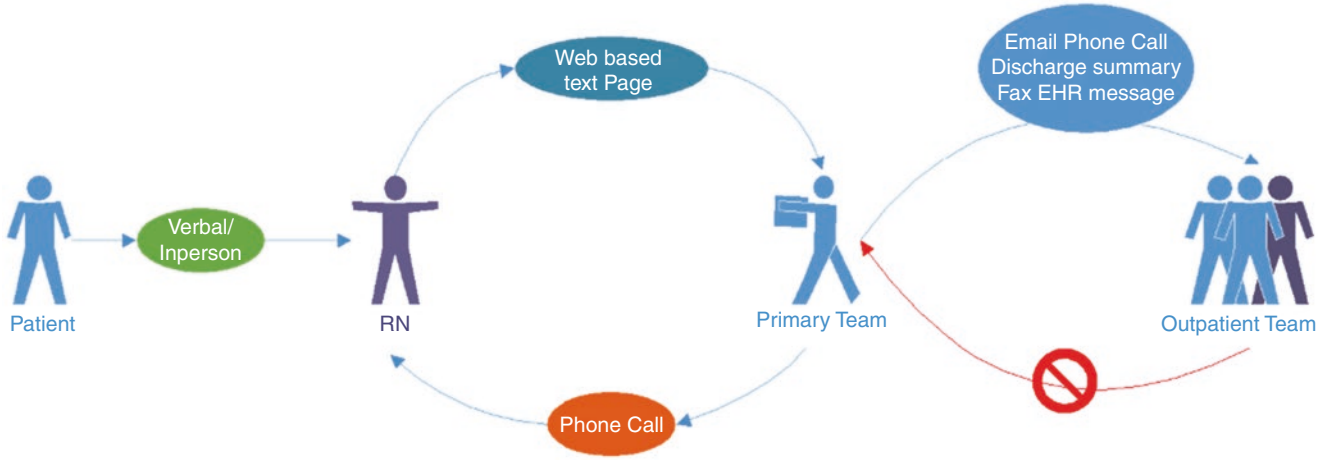

Fig. 11.3 Flow of communication between the patient and the care team

Table 11.4 Secure messaging application tiers: pros and cons

Tier and example applications	Pros	Cons
Tier 1		
HIPAACHAT Tigertext free edition	• Secure communication platform • Inexpensive/free	• No functionality to help with workflow • Minimal functionality to improve communication • Might be difficult to get full adoption due to minimal functionality
Tier 2		
CareAware Connect (Cerner secure messaging) Cores secure messaging Epic secure messaging Medisas miSecureMessages (AMTEICO) Mobile Heartbeat TeamStitch	• Secure communication platform • Potentially easier to implement if you already use native system extensively (i.e. Cerner or Epic) • Some offer functionality to help with hospital workflow and communication • Well integrated with existing native system • Vendors may have been in the health care sector for long periods of time	• Additional licensing costs for messaging functionality • Difficult to integrate across multiple different clinical applications • less advanced functionality (system-dependent) • Unclear how vendors will prioritize support and development of messaging functionality compared with native application • Ability to customize or integrate with third party systems uncertain
Tier 3		
Cureatr Doc Halo Imprivata Cortext PatientSafe Solutions PerfectServe Spok Care Connect Tigertext enterprise edition Voalte Vocera Zipit Wireless	• Secure communication platform • Intended to be integrated communication platform across entire health system • Solely dedicated to this area, offer good support • Offers extensive functionality to help with hospital workflow and communication • Offers the highest functionality, including integration with electronic health records, laboratory, scheduling, nurse call alerts, monitor alerts, etc. • Most customizable to meet specific • workflow needs or integrate with third party systems	• Most expensive option • May require additional time/expense to integrate with other clinical applications to leverage advanced functionality • Note: • Vendors in this space are relatively new. and the market is evolving (uncertain which vendors will thrive with market maturation)

Table adapted from [49]. Used with permission

- Tier 3: Dedicated Communication and Collaboration Systems

Within each of these tiers are pros and cons to the approach (Table 11.4).

For the acute care setting, the study summarizes essential requirements for system capabilities under several categories:

- Basic security and administrative functionality: Secure platform, Mobile Device Management (MDM) features, usage analytics, administrative controls, discoverable message logs, transparent message status updates with timestamps.
- Integrations and advanced functionality:
  - Active directories for secure login and recognition of users

ADT information
Staff scheduling software that can:
- Allow for role recognitions (Attending versus resident); and
- On-call personnel recognition (ex: primary nurses versus charge nurse to automatically forward unanswered messages)

- Communication and workflow functionality:
  - Inclusive and available for various roles such as doctors (primary team and specialists), nurses, physical therapists, social workers, etc.
  - Ability to have two-way messaging and group communication channels.
  - Ability to include various data formats such as pictures.
  - Quickly and automatically notify the correct personnel for hospital emergencies, Code Blue, etc.
- Technical: Wi-Fi, availability on multiple mobile Operating Systems (OS)

Some commonly available secondary features that commercial solutions advertise include integrating their content into the EHR and delivering alarms to the messaging application. These features seem useful at face value but only amplify the already noisy alarms in acute care settings with minimal enhancement to the workflows.

Clinical Informaticists must take a thoughtful approach when implementing communication platforms to optimize workflow efficiency as alert fatigue is a well-established issue in health informatics [50]. In the project planning phase, an interdisciplinary design discussion should occur to determine the alerts to be sent to the application and those that would add to the noise. Bring-Your-Own-Device (BYOD) is often a cost-effective approach to implementing secure communication platforms. Installation of Mobile Device Management software is vital in either strategy to mitigate the risks of loss of patient information if the device were to be hacked or lost. Detailed institutional policies addressing best practices for communication and escalation of care are critical.

Communication in Ambulatory Settings

Tethered—linked to the EHR—patient portals are the primary electronic communication tools between the healthcare team and the patients in the ambulatory arena. Communication is usually asynchronous and can be initiated either by the patient or the care team. The conversations can be saved to the patient's EHR for future reference. Most major EHR vendors offer a patient portal, particularly after it became a required feature for becoming a Certified EHR under the MU Use program. Non-Tethered communication solutions have also been gaining traction, especially among small independent practices. These are primarily in the form of two-way secure texting and calling solutions that can protect the personal mobile number of a practitioner. Some popular platforms offer additional features such as performing video visits and sending and receiving fax communication and are comparatively inexpensive compared to the prominent EHR vendors.

Communication Between the Clinical Teams Across Healthcare Venues

There is a significant gap in the availability of solutions focused on the area of inter-venue healthcare communications. There are two main channels available.

1. TOC using Continuity of Care Documents (CCD): Documents in this category range from dictated and transcribed discharge summaries to more structured electronic documents faxed or sent via direct messaging to primary care physicians. MU 2 leveraged HL7 standards; TOC documents were based on Clinical Document Architecture (CDA) following the implementation rules of C-CDA and sent via direct messaging or portals. While these standards aimed to improve semantic interoperability, the result did not translate to improved quality or uniformity of information available in these documents [51, 52]. Poor mapping of data elements often leads to missing information from the CCDs. As we move towards leveraging USCDI, Fast Healthcare Interoperability Resources (FHIR), and APIs, hopefully, the quality of TOC documents will improve.
2. Messaging between providers using the EHR tools or other secure communication channels tends to occur primarily within a healthcare institution where an existing communication channel can be leveraged. While there are EHR and institution agnostic independent communication applications available, these have not been adopted widely.

Clinical Registries

The cancer registrar at the institution where Ms. Jones had surgery to resect her breast tumor would collate her data including demographics, tumor staging, pathology report, and treatment record to the State cancer registry. The information is then reported to the National Program of Cancer Registries (NPCR) once a year. Her outcomes taken together with others in the registry will inform future research!

As EHRs and other means of collecting structured clinical data, such as LIS and Electronic Laboratory Reporting, have become widely adopted, the process of collecting

data for reporting to a clinical registry is also being automated. AHRQ defines a clinical registry as "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes" [53]. Clinical registries and their role in Public Health Informatics will be covered in more detail in the relevant (Chap. 25), but we will give a brief outline here. A clinical informaticist needs to understand the process of reporting data to registries electronically via flat-file reports or APIs and how this information is leveraged for various purposes.

National Quality Registry Network (NQRN) conducted a landscape survey that reported various registries based on the purpose and use [54]. The top five purposes were quality improvement, benchmarking, clinical effectiveness, safety and harm, and comparative effectiveness research based on the survey. The top five uses were clinical decision support development, education development, measure development, QCDR, and guideline development.

Some specific examples include:

1. Quality Improvement, CMS's Qualified Clinical Data Registry (QCDR) leveraged in the QPP programs;
2. Disease surveillance, such as the National Program of Cancer Registries (NPCR) under the CDC and the National Cancer Institute's SEER program. There are several other programs for specific diseases, including a rare disease registry, and a comprehensive list can be found on the NIH website;
3. Procedure or Device surveillance, such as medical device registries or surgical procedure outcome registries; and
4. Population Surveillance, such as Vital Statistics and National.

Registries can be sponsored by national organizations with mandated reporting or voluntary sharing of information initiated by patients. Registries can also be created locally at an institution level for the population under its management for reporting purposes in Alternate Payment Models (APMs), for example, a QCDR.

Uses and Value

Clinical registries can be leveraged not only for research but also for quality improvement and performance measurement, participation in payment programs, benchmarking, guideline development, clinical decision support, public reporting, hazard reporting, population health, and so forth. NQRN published a registry maturation framework to evaluate the capability and use of clinical registries [55].

Mechanism of Data Entry and Interfaces with EHR and Other Sources

Data is transferred from the EHRs via push or pull certification model (eCQMs) or manual chart abstraction. Some registries are also linked to external databases such as vital statistics and other CIS such as laboratory or pathology reporting. Increasingly, there is a focus on incorporating patient-reported outcomes such as quality of life or depression scales into registries.

To support data collection for reporting to registries, institutions often need to employ trained clinical registrars and invest in Clinical Registry Management Systems. Lack of adequate standards leads to incomplete data and requires time-consuming manual chart abstraction and resubmission. Incomplete data will ultimately affect any conclusions drawn from the data [56]. Each registry has specific formatting requirements for successful reporting. There is a significant need to leverage informatics principles to design interoperable clinical registries to minimize this inefficiency burden [57, 58]. HL7 Common Clinical Registry Framework Domain Analysis Model and FHIR standards may provide this much-needed interoperability.

Regulated Medical Devices

The definition of a regulated medical device in Section 201(h) of the Food, Drug, and Cosmetic Act is [59]:
An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).
In addition to the multiple interacting electronic information systems, many integrated medical devices exchange information within the health system. Medical devices are omnipresent, from diagnostic devices such as telemetry, vital sign machines, and glucometers to therapeutic devices such as infu-

sion pumps, medication dispensing systems, and implanted devices including pacemakers and insulin pumps. The Internet of Medical Things (IoMT) concept describes networks of physical objects embedded with sensors and software that connect and exchange medical data over the internet [60]. In healthcare delivery organizations, the management of medical devices is challenging. It can encompass everything from pre-procurement processes, purchasing, installation, network configuration, workflow design, ongoing maintenance and support, and device decommissioning. Many skillsets are necessary for integrating, managing, and operating medical devices that will often require a collaborative effort between manufacturers, IT experts, biomedical engineering, and end-users.

During Ms. Jones' surgery, multiple medical devices are used including IV pumps, monitors, and the ventilator. All data from the devices are incorporated into her medical record.

Medical Device Integration

Integration of medical devices into HIS is a multi-step, complex process that requires multidisciplinary collaboration. The implementation of new regular infusion pumps, for example, requires simultaneous changes to the ordering system and the pharmacy information system. Using integration of patient-controlled anesthesia (PCA) infusion pump as an example, several parallel processes must occur. After procuring the pumps, IT may work with the manufacturer on-device installation, testing, and optimization. They will need to make network configuration decisions based on whether data is stored on the device or server, the directionality of information flow, and which site-specific systems the device interacts with. The PCA pump may need to interact with the EHR for recording medication administration and CDS, with the pharmacy system for interaction alerts and medication inventory, and communicate with nursing displays to show pump performance information. Based on the device use case, workflow models must be developed that account for clinical, patient, and provider needs and quality control and billing documentation. For the PCA pump, a team representing nursing, informatics, and the acute pain service may be tasked with developing the protocols and training materials for patients and providers who will use the devices. As part of the implementation process, the project team also needs a long-term maintenance plan for the device. Factors they may consider include the degree of manufacturer versus on-site support, frequency of support needs (24/7 versus sporadic), device utilization, risks associated with device failure, designated contact for device updates and support, and device storage. The types of networked-enabled medical devices are currently limited, e.g., patient monitors, infusion pumps, imaging. Still, as the percentage of connected devices grows, health delivery organizations will need to develop EHR-medical device integration strategies. Organizations such as the American Society for Testing and Materials (ASTM) guides standards such as the Integrated Clinical Environment (ICE) standard to promote medical device interoperability [61–63].

Medical Device Management Systems

Given the vast spectrum of medical devices and the settings where they are used, the scope of work involved in medical device informatics is staggering. For healthcare delivery organizations, it is essential to have a high-level framework to inventory, organize, manage, and secure medical devices. Medical device management is often dictated by care settings, workflows, and the physical environment in which they are used. Relatively "fixed" devices in an operating room with sporadic use may have different requirements than continuous-use equipment that travels with a patient to multiple care settings. Inventory management systems can capture data about medical devices and organize the information to support maintenance and operational optimization. A critical function of these systems is to identify and locate devices due for updates or patches or medical devices that have been subject to recall. Utilization data can also inform operations. For telemetry equipment frequently utilized at capacity, managers can consider purchasing additional units or reviewing the appropriateness of use, whereas devices that are rarely used may be retired. In addition to physical and utilization tracking, medical device management systems must also monitor information traffic. Network access should be limited to the extent where devices can access the information they need to function appropriately but limited to avoid the risk of exposing patient data or affecting other systems in the event of a device malfunction, downtime, or cyberattack.

The landscape of medical devices presents a significant cybersecurity risk to organizations; managing the growing number of connected devices is a daunting task. This was highlighted by a safety communication from the US Food and Drug Administration (FDA) in 2017 regarding potential concerns of malicious interference with the programming in several St. Jude pacemaker models [64]. With the explosion in medical devices, vulnerability management involves identifying and prioritizing exploitable vulnerabilities for cyberattacks. Depending on the risk severity and impact on the organization, healthcare delivery organizations may apply increasingly effortful measures to patch, mitigate, or segment networks to reduce vulnerability from medical devices [65].

Medical Device Standards Organizations

Standards organizations guide the integration and management of medical devices in healthcare delivery organizations. The National Institute of Standards and Technology (NIST) provides an example implementation and best practice guide in its *Securing Wireless Infusion Pumps* publication [65]. This resource is targeted towards business decision-makers, IT

professionals, and project managers. It guides the approach and architecture for developing security platforms, life cycle issues, risk assessment, and functional evaluation. With a focus on medical device cybersecurity, the non-profit MITRE Corporation published a playbook with guidance on device procurement, inventory management, vulnerability analysis, and cybersecurity support [66]. Standards development organizations have also published tools to address security issues related to medical devices. The Manufacturer Disclosure Statement for Medical Device Security (MDS2), jointly developed by HIMSS and NEMA, is a voluntary standard for manufacturers' disclosure of security-related features of integrated medical devices [67, 68].

Regulation of Medical Devices

The US FDA Center for Devices and Radiological Health is the operating division of the Department of Health and Human Services responsible for assuring the safety and efficacy of medical devices. Medical devices are classified as Class I, II, and III based on the level of risk, indication for use, the population being diagnosed or treated, and manufacturer claims. The FDA ensures that devices are safe and efficacious when they enter the market and for a duration of time on the market as the uses of medical devices evolve. The FDA recognizes selected standards, parts, or standards as appropriate for addressing medical device product testing as listed on the agency's website [69–71].

Emerging Trends

Ms. Jone's daughter Courtney delivers a 30-week infant named Benjamin, who is transferred to the NICU at the tertiary care hospital. Wishing to breastfeed her infant, Courtney uses a pump at home and freezes the breastmilk. The hospital gives Courtney preprinted labels for the bottles from their new innovative breastmilk barcoding system. The system will track the age of the milk, how long it has been out of the freezer, and disallow milk to be put back if it has been out for 15 min or more. Prior to be given to Benjamin both he and the bottle will be scanned to ensure that the breast milk is from the correct mother and not beyond its expiration date.

As in all technology areas, CIS continues to evolve rapidly with many new innovative approaches to its development and use. Exciting emerging trends include expansion into pediatrics, improvements in documentation tools, machine learning (ML) and artificial intelligence (AI), expansion of patient-facing technology, and further infiltration in areas such as supply chain and blood bank systems. Even management of breast milk has been made safer with innovative technology. Below we present several of these new areas of innovation.

Pediatric Functionalities

Historically outpatient EHRs had failed to support pediatric functionalities needed to take care of children safely [72, 73]. These functionalities include weight-based or body surface-based dosing, age-appropriate development documentation and reminders, immunization tracking, and forecasting, to name a few [74, 75]. The 21st Century Cures Act addressed this issue by introducing voluntary pediatric certification currently being developed by the Drummond Group [76].

Documentation

Notes in US EHRs are substantially longer than in other countries [77]. The most likely cause includes a more litigious society with a higher risk for malpractice in the US with documentation as a prophylactic approach. However, note length may also largely be driven by requirements from the 1997 CMS's Documentation Guidelines for Evaluation and Management Services that described in great detail how many systems had to be reviewed, and physical exam systems had to be documented to be reimbursable for care. The resulting checkboxes within EHRs that generated normal physical exam findings, for example, contributed substantially to note length [78]. In addition, the use ease of "copy and paste" has substantially contributed to longer, 'bloated' notes. While convenient for providers, copy and paste has propagated errors, making important information hard to discover and notes much harder to read and digest. Fortunately, tool kits for managing the use of copy and paste have been developed [79]. Some recommendations include (1) to "provide a mechanism to make a copy and paste material easily identifiable"; (2) to "ensure that the provenance of copy and paste material is readily available"; (3) to "ensure adequate staff training and education regarding the appropriate and safe use of copy and paste"; and (4) to "ensure that copy and paste practices are regularly monitored, measured and assessed".

Use of Artificial Intelligence

AI is increasingly used in health care. Radiology imaging systems have been a prime target for ML and AI in diagnostic decision support. AI can provide a more efficient workflow, shorten the reading time, reduce radiation dose and contrast agents, and permit earlier diagnosis of disease. However, examples of bias have been noted in AI, which has generated further study [80]. These include referring black people less than white people with similar clinical complexity to patients with complex medical needs [81] and flagging

people from poorer neighborhoods with more African Americans as being less ready for hospital discharge.

Innovation in Portal Use

Another effect of EHR use has been the increased use of patient portals, especially for diseases that require frequent but not in-person contact between patients and providers [82]. Portals have reduced the need for phone calls to physicians and reduced unscheduled visits [83].

While interoperability and health information exchange from EHRs have to date failed to deliver the effect and value that had been hoped for [84], novel legislation in the 21st Century cures bill will make most content in the EHR available to patients immediately after it has been created, further engaging patients into their care. This requirement is likely to drive further innovation in this area.

Laboratory Information Systems

The recent emergence of SARs-COVID 2 and the subsequent world pandemic exposed weaknesses in our current systems and presented opportunities for innovation. Laboratories had to adjust to increased testing volume and develop new approaches for that testing. Many laboratories introduced pooled testing, where multiple samples are combined in a pool and are tested jointly. If a pool tested negative, then all samples were considered negative. If a sample tested positive, all samples would be rerun individually. Using this approach saved valuable resources which were limited during the pandemic.

Pharmacy Information Systems

Automation of pharmacy functionality is expected to grow by 11% between 2018 and 2025 [85]. Reducing labor costs and medical errors are driving this development. Automated medication dispensing systems are one example of this trend. With medication and dispensing errors being a major risk factor for hospitals, these systems aim to remove the inherent human risk factor of dispensing while providing an auditable trail. These systems are integrated with the PIS and allow institutions to dispense accurate doses at the point of care, reducing the possibility for error and reducing labor [86]. Other areas of automation in pharmacies include tabletop tablet counter systems, automated medication compounding systems, automated storage and retrieval systems, and automatic packaging and labeling systems.

Supply Chain Systems

Other newer CIS systems include inventory tracking systems, blood bank managing systems, and supply chain management systems. The recent pandemic highlighted the criticality of supply chain managing systems to ensure adequate supplies. For example, they keep track of the supply of personal protective equipment, ensure the rotation of supplies to be used before expiration, and flag items needing reordering [87]. Supply chain systems are dependent upon accurate measures to ensure adequate supply [87]. Failures in supply chains can lead to a slowdown or halting of operations. One example of a supply chain failure was caused when dispensing cabinets failed to report withdrawals in inventory to the central supply chain system, failing to reorder supplies, resulting in shortages of medical equipment.

Blood Bank Systems

Blood bank systems collect, manage, and store data related to blood donations, aliquots, testing results and use them to assure safe transfusion practices. These systems can manage inventory and predict demand for blood, and monitor transfusion practices of providers [88]. One area of development is using genotyped transfusions [89].

Summary

The rapid growth and adoption of CIS has meant that they are now found in all areas supporting and delivering the care of patients. While the EHR is the foundation of these systems within clinical practices and hospitals, portals, telehealth, and mobile technology have weaved the patient into these systems. Exciting, innovative developments mean that these systems will move far beyond where they are today. The role of the informaticist has become increasingly critical to the success of both the implementation and optimization of CIS, as these systems have become increasingly complex and integrated throughout society.

Questions for Discussion

1. List and describe two clinical information systems. How do these CIS contribute to patient care?
2. What are the three criteria for a regulated medical device according to the U.S. Food and Drug Administration (FDA)?

3. The hospital is considering replacement of pagers, yet some of your colleagues strongly wish to keep their pagers in opposition of the plans to adopt an electronic communications tool. How would you convince them to ditch the pager and use a new unified communications platform?
4. Name and describe three hospital information systems beyond the EMR.
5. Discuss the difference between patient-to-provider and provider-to-provider forms of telehealth. Name at least one modality for each type of telehealth system and describe how it supports the delivery of care to patients.

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