Chapter 9
Electronic Health Record and Patient Safety

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Introduction

Over two decades ago, the Institute of Medicine (IOM) released two reports that laid the foundation of the patient safety movement in the US. The reports identified the Electronic Health Record (EHR) as an important tool for improving patient safety in the care continuum. The first report in 1999 "To Err Is Human—Building a Safer Health System [1]" concluded that preventable medical errors were one of the leading causes of death. In 2001, in a subsequent report "Crossing the Quality Chasm," the use of information technology was recommended as playing a central role in the redesign of the entire healthcare system preventing errors, improving healthcare quality, efficiency, and enhancing the overall care experience [2].

In spite of the publication of these reports, EHR adoption in both hospitals and ambulatory care settings remained very low. This lag in the healthcare industry's EHR adoption was significantly remediated by the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act under the American Recovery and Reinvestment Act of 2009 [3]. As illustrated in Fig. 9.1, only 9% of the hospitals and 17% of the office-based physicians had adopted even a basic EHR in 2008 but as of 2019, this number increased to 96% and 72%, respectively (https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records).

The HITECH Act authorized nearly $30 billion toward Medicare and Medicaid incentive programs to encourage the adoption, implementation, upgrade, and

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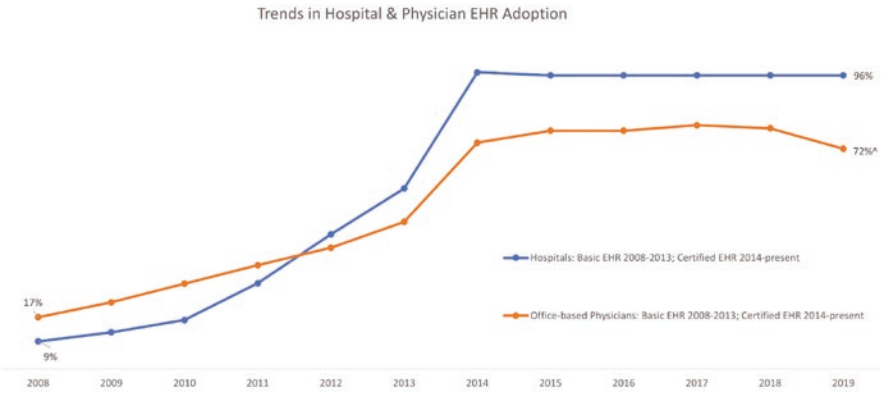

Fig. 9.1 Percentages of hospitals that adopted at least a basic electronic health record system. (Source: HealthIT.gov at https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records. Last accessed September 3, 2022)

demonstration of meaningful use of certified EHRs by hospitals and eligible medical professionals. The HITECH Act also created support programs to provide technical assistance and help build the enterprise-wide systems to enable the full use and potential of EHRs. The HITECH Act further required that meaningful use of EHRs include electronic reporting of data on the quality of care. Hence, the EHR meaningful use rule struck a balance between acknowledging the urgency of adopting EHRs to improve healthcare quality and recognizing the challenges that adoption posed to health care providers.

The EHR Meaningful Use or Incentive Programs were envisioned as a three-stage process that would encourage EHR adoption, promote interoperability, and ultimately the quality of care:

- **Stage 1** set the foundation by establishing requirements for the electronic capture of clinical data, including providing patients with electronic copies of health information.
- **Stage 2** expanded upon the Stage 1 requirements with a focus on advancing clinical processes, the use of EHRs for continuous quality improvement at the point of care, and the exchange of information in the most structured format possible.
- **Stage 3** focused on using EHRs to improve health outcomes.

To continue the commitment toward promoting and prioritizing interoperability and exchange of health care data, the Centers for Medicare and Medicaid Services (CMS) renamed the EHR incentive programs to Promoting Interoperability Programs in April 2018 [4]. This change moved the programs beyond the existing

requirements of meaningful use to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information.

The EHR plays a transformative role in healthcare by improving medication safety, making patient health information available at the point of care, facilitating care coordination, optimizing efficiency, and engaging both patients and caregivers [5]. A 2011 literature review by Buntin et al. (2011) concluded that 92% of the studies on health information technology (HIT) demonstrated net benefit [6]. Outcome measures were positive for efficiency of care, effectiveness of care, patient and provider satisfaction, care process, preventive care, and access to care (Fig. 9.2) [6]. Similarly, a recent systematic review by Kruse et al. (2018) also concluded that HIT continues to show positive effect on efficiency of care and medical outcomes [7].

As the adoption rates for HIT in clinical settings increased, the potential for unintended consequences increased alongside. While consequences can be positive or negative, we will focus on the unanticipated negative consequences that can arise and provide insights into how they can occur and how to avoid adverse impact on patient outcomes.

In this chapter, we present two case studies that illustrate some unintended adverse consequences of EHRs and what can be done to prevent them. These case studies identify the flawed workflow, processes, or systems leading to an EHR-related adverse event and recommends strategies to mitigate potential safety hazards.

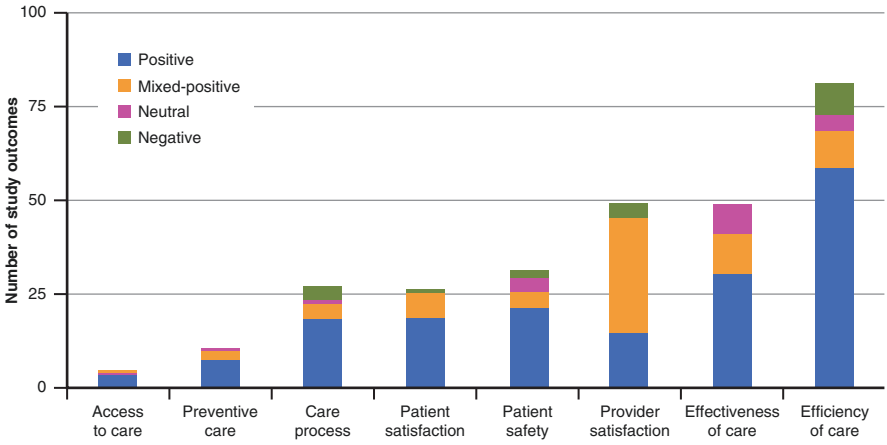

Fig. 9.2 Evaluations of outcome measures of health information technology. (Adapted with permission from Buntin MB et al (2011) (6))

Case Studies

Case Study 1: Medication Error Related to Pediatric Weight Entry Issues

Clinical Summary

A 2-year-old patient was admitted to the hospital's pediatric ward with fever. The admitting physician ordered acetaminophen in the hospital's CPOE (computerized physician order entry system) which provides a field for weight-based dosing (expected to be expressed in mg/kg). The child's weight was 27.5 pounds (lbs). Prior to the medication order, the nurse inadvertently entered the patient's weight as 27.5 kg (in the kilogram field as opposed to in the pounds field of the EHR). The ordering physician, unaware of this problem, assumed the entered weight was accurate and ordered about 2.5 times the recommended dose of the medication. The built in CPOE decision support did not provide any alert that this dose is excessive for a child of this age because the systems decision support computed the dose based on the incorrectly entered weight. The patient received one incorrect dose before the nurse realized the documented weight error, corrected it, and alerted the physician to discontinue and reorder the acetaminophen with the correct dose.

Analysis

The unique characteristics of the pediatric patient population inherently add significant variability and complexity to medication prescribing due to the need for weight-based dosing [8, 9]. A 2006–2007 analysis of the United States Pharmacopeia's MEDMARX database illustrated the risk inherent in weight-based dosing by revealing that one-third of pediatric medication errors were the result of "improper dose/quantity" and 2.5% of those pediatric dosing errors ultimately led to patient harm [10].

The adoption and implementation of EHRs with CPOE have drastically enhanced pediatric medication safety [11] but careful consideration must still be given to workflow. CPOE tools help providers determine the proper dose by pre-populating the patient's weight and performing the pre-determined calculations helping to alleviate the need to perform extensive manual calculations that are often complicated and error prone. The use of these tools eliminated guesswork, sped up the process, and assisted clinicians in prescribing the proper dose. However, as identified in the clinical summary above, a simple data entry error can lead to perpetuation of the error in the downstream workflow as automation provides a false sense of security among users that since the system is calculating the dose, it must be correct.

Corrective Actions

A collaborative team of pediatricians, nurses, and pharmacists was formed and based on an extensive review of the hardware, software, and workflow configurations, the following changes were made to the system:

(a) Implementation of a pediatric weight alert system: an extensive system of alerts to identify and alert multiple professionals in the medication management workflow if an abnormally high or low weight is encountered in a pediatric patient as detailed below.
(b) Modification and replacement of all scales in the institution to weigh only in kilograms.
(c) Additional staff training and reporting of any future errors.

Pediatric Weight Alert System (Figs. 9.3, 9.4, and 9.5) [12]

The trigger for the alert is based on the patient's age-based weight being outside the standard deviation (3% and 97%) of the growth chart. In this situation, if a potentially inappropriate weight is entered by a nurse, the system will trigger a "soft stop" requiring a reason to be acknowledged. If the nurse proceeds with the entered weight, the physician on any subsequent order entry or the pharmacist during any subsequent medication verification for this patient will be presented with an alert to review all active orders for accuracy. This closed loop system of prompts ensures

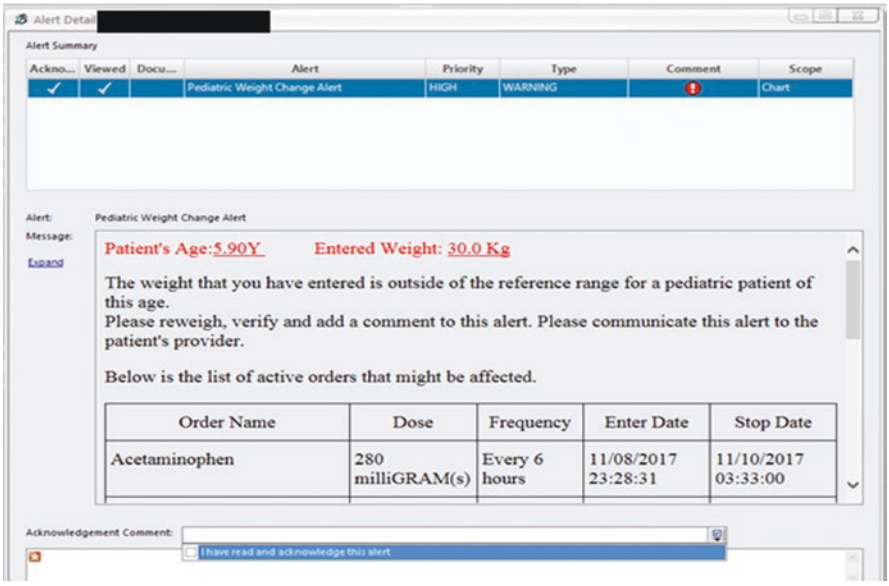

Fig. 9.3 "Soft stop" requiring a reason to be acknowledged

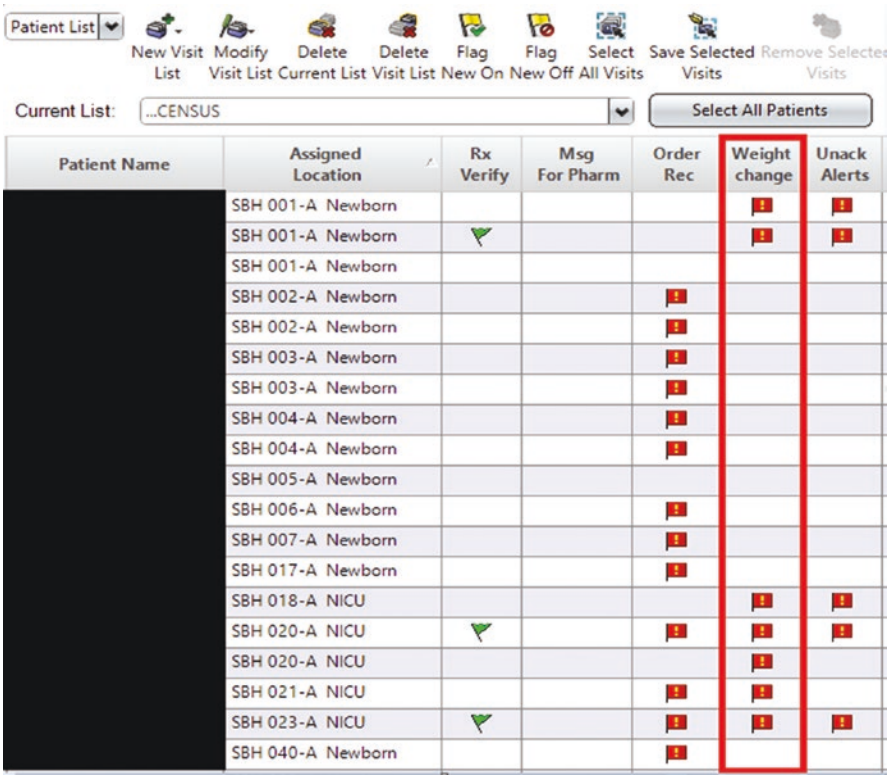

Fig. 9.4 Alerts for any weight changes outside the reference range to the physician

that alerts are reviewed and acted upon by nurses, physicians, and pharmacists collaboratively as redundant safety checks.

In addition to the medication process, these weight-based alerts are also displayed in the other areas of the EHR generating an audit trail each time an alert is triggered:

- Structured notes (admission pediatric profile, ED triage note, newborn/NICU admission profile)
- Flow sheets for pediatric patients

This abnormal pediatric weight alert is fired when all of the following is true:

- Patient is located on one of the neonatal or pediatric floors
- Patient's age is less than or equal to 15 years
- Patient's weight falls outside the standard pediatric weight based on the CDC weight-for-age chart for pediatric patients aged 0–15 years old

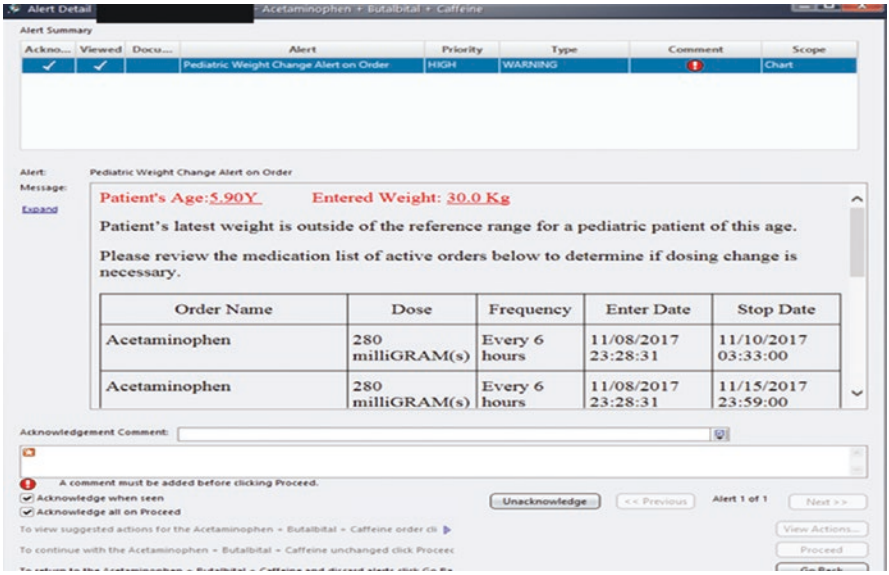

Fig. 9.5 Alert to physician or pharmacist on any subsequent order entry or medication verification

Case Study 2: Incorrect Medication Administration

Clinical Summary

A patient admitted to an inpatient floor of the hospital, with an extensive medication profile documented on their EHR, was scheduled to receive her next round of medications during regular nursing rounds. Unfortunately, she suffered a medication error as she was administered the wrong medication. Ropinirole (used to treat symptoms of Parkinson's disease), intended for a different patient on the floor, was incorrectly administered to this patient instead of the properly prescribed risperidone (used to treat the symptoms of schizophrenia). This administration error occurred during a busy lunch time shift where the administering nurse had pulled multiple medications for multiple patients on the floor, thereby allowing for the incorrect medication to be picked up from the medication tray. Most critically, the nurse did not follow the hospital's standard safety system, called bar-coded medication administration (BCMA), of scanning the patient's wrist band as well as the medication to ensure both the patient's identity and the medication match the order placed by the physician.

Analysis

Medication administration is a busy and complicated time for nursing staff who are often responsible for multiple patients, many of which are prescribed multiple medications to be administered over a narrow timeframe. Additionally, obstacles such as staffing shortages, technology, and poorly designed or implemented workflow can make the process even more prone to errors. When utilized correctly, HIT systems such as BCMA are critical to ensuring the five rights of medication administration—the right patient, right medication, right does, right route, and right time and at the same time provide a proper documentation of the administration process [13]. With scannable barcodes ubiquitous to the pharmaceutical industry, placed on most medication packaging, electronic systems can readily identify an individual, patient-specific drug, its dosage form and the strength to be administered. Closing the medication administration loop with processes and workflows incorporating barcodes printed on patient wristbands, EHRs can quickly and accurately validate the right patient. Matching the ordered medication's frequency in the EHR with previous administrations of the drug or with future scheduled administrations with the time of day the last "right" of time for administration can be assured. In this case, the nurse bypassed protocol by not scanning the barcode on the medication or the patient's wrist band and manually administered the incorrect medication outside of identified best practices leading to a medication error.

Corrective Actions

Implementation of a BCMA system, process, and workflow is not the end of the story but a beginning to the journey. Medication errors can occur across multiple pathways beginning with a medication order through to its administration to the patient. A culture of safety must be pervasive, encouraging participation at all levels and be grounded within training and continued monitoring of the entire system including a robust culture of compliance reporting, review, and action. A multidisciplinary team of physicians, nurses, pharmacists, and information technology professionals must convene regularly to monitor processes and adverse event reporting providing feedback to end users, clinical stakeholders, and leadership in a continued effort to drive toward patient safety. In this case, the BCMA workgroup identified the following issues that potentially prevent users from adhering to safety practices:

- Batteries powering computers and or scanning devices run out of charge
- Computers locked out due to password issues preventing users accessing software
- Scanners not working properly requiring reprogramming or replacement

Another source of medication errors that cannot be corrected with BCMA is the issue of providers entering orders, medication or otherwise, on the wrong patient. To detect and correct this type of error, the team undertook an assessment of current "near miss" error rates using a "retract and reorder" tool [14]. This tool identified

and reported on orders first placed on one patient then canceled with the identical order added to another patient's chart by the same clinician within a 10-min time frame. This assessment was taken as a proxy for those incorrect orders with a high likelihood of ultimately reaching the patient. Data review identified approximately 1 near miss per day [14]. A solution to this problem was identified requiring configuration changes to the EHR to produce a series of provider-based alerts at the beginning of order entry. Providers were required to enter the patient's initials and year of birth at the start of the order entry session (Fig. 9.6) [12] which are then validated against the patient's chart before being allowed to proceed. This not only aligns with the Joint Commission's national patient safety goal of using at least two patient identifiers when providing care, treatment, and services but also proved to reduce the prevalence of this type of error. If the prescriber enters the wrong patient identifier when starting order entry, a second alert is presented allowing for a correction to be made (Fig. 9.7) [12]. A subsequent third error (Fig. 9.8) [12] prevents the provider from proceeding with order entry requiring a new order entry session be initiated to proceed. An analysis comparing near misses before and after the alert configuration showed approximately a 35% decrease in near miss events in the emergency department of the hospital [12].

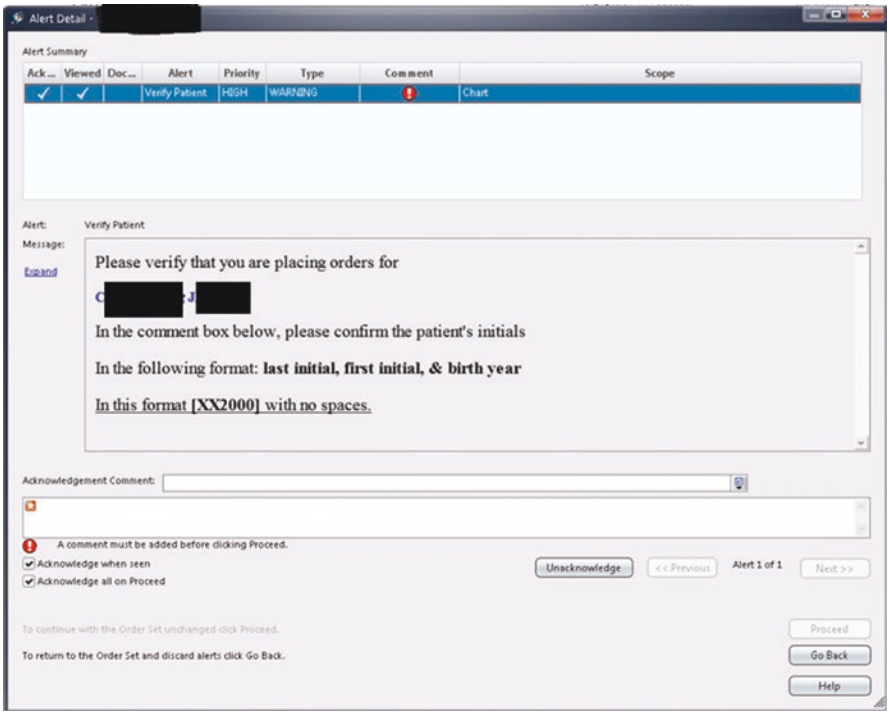

Fig. 9.6 Alert to the prescriber to input patient initials and year of birth. If the prescriber correctly inputs this data, then the ordering process can proceed. If the data is incorrect, then a second alert is activated

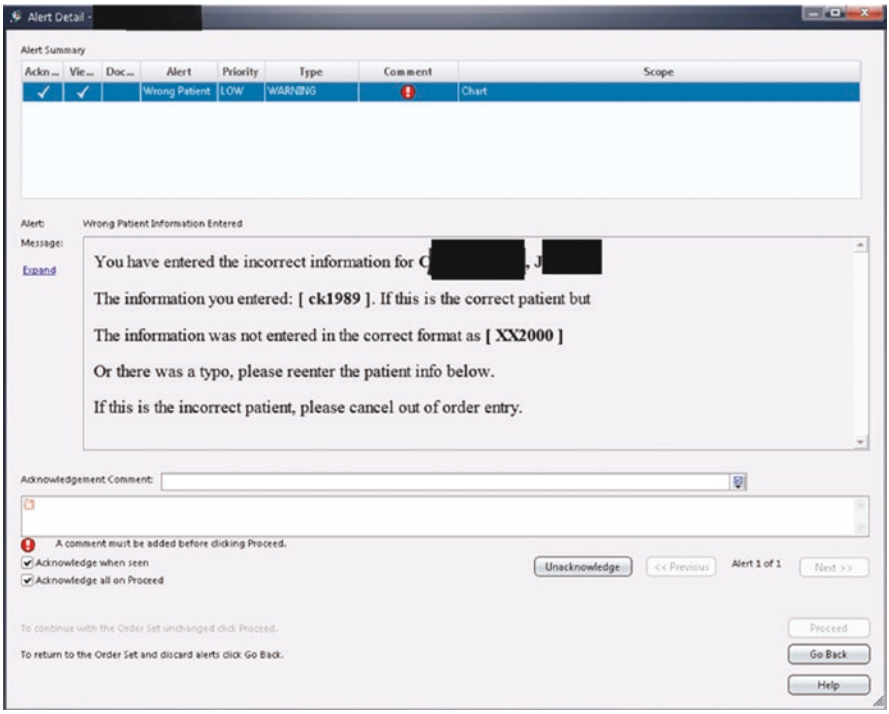

Fig. 9.7 This allows for typographical errors that may not be related to a patient ID error. If the prescriber enters the correct patient identifiers, then he or she can proceed normally with the order. However, if the prescriber again enters the wrong patient identifier, a third and final alert is generated

Discussion

Potential Benefits and Safety Concerns for Health IT

Health information technologies (HIT), such as EHR, CPOE, and clinical decision support system (CDSS), may enhance the safety, quality, patient-centered care, and increase efficiency. However, a growing body of research and user reports reveal many unintended adverse consequences of implementation that often undermine patient safety practices and occasionally harm patients [15]. Figure 9.9 [16] describe the potential benefits and safety concerns for CPOE, clinical decision support system (CDSS), BCMA, and patient engagement tools as reported in the book titled *Health IT and Patient Safety* published by the Institute of Medicine [16].

Ash et al. (2004) have described two major kinds of implicit EHR-related errors: those related to entering and retrieving information and those related to

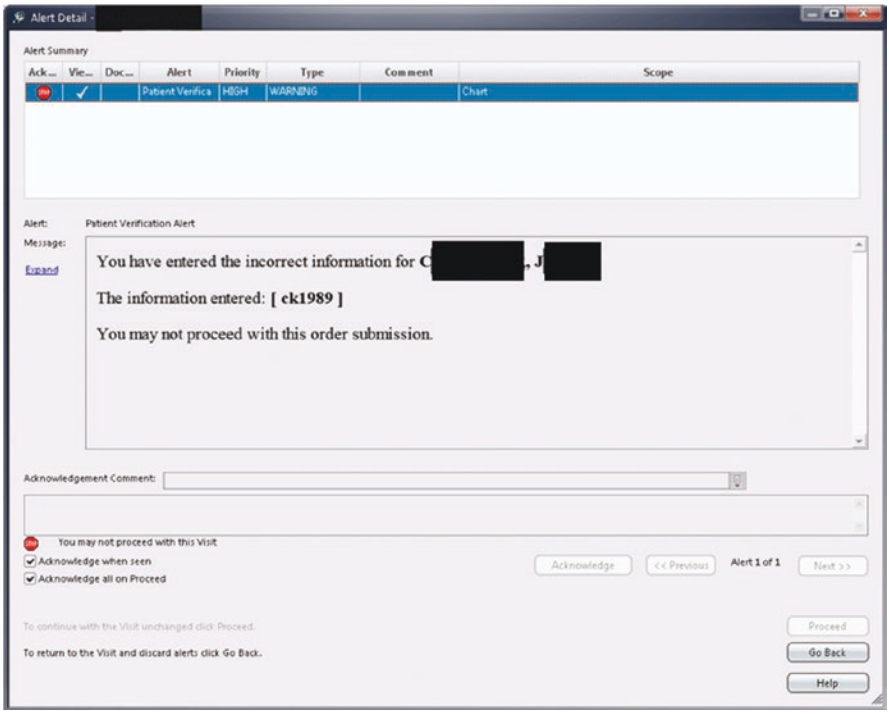

Fig. 9.8 The EHR system will see this second, failed, attempt as a true error in patient ID and will not allow the prescriber to proceed with the order

communication and coordination. As the potential causes of these errors are subtle but insidious, the problems need to be addressed in a variety of ways through improvements in training, education, systems design, implementation, and research [17].

The Sociotechnical Model

Although technical flaws often cause problems, many harmful or otherwise undesirable outcomes of HIT implementation arise from sociotechnical interactions—the interplay between new HIT and the provider organization's existing social and technical systems—including their workflows, culture, social interactions, and technologies. The "Sociotechnical" model is also an instrument for root cause analysis (RCA) that describes various factors and processes that can cause adverse events and a systems approach is necessary to reduce or eliminate future adverse events. As described by Meeks et al. (2014) [18], the sociotechnical model has the following

eight dimensions: clinical content, human–computer interface, people, workflow & communication, internal organizational features, external rules & regulations, measurement & monitoring, and hardware & software. These eight dimensions are processed through a three-phase patient safety model (safe technology, safe use of technology, and use of technology to improve safety) to help various stakeholders understand anticipated risks about patient safety and HIT.

The sociotechnical model of identifying unintended adverse consequences of HIT can assist software developers and end users become more aware of the flawed workflows and processes, which in turn will help deployment of HIT more effectively to improve overall healthcare safety and quality.

EHR-based interventions to improve patient safety are complex and sensitive to who, what, why, when, and how they are delivered. Current reporting guidelines do

Computerized Provider Order Entry (CPOE)

An electronic system that allows providers to record, store, retrieve, and modify orders (e.g., prescriptions, diagnostic testing, treatment, and/or radiology/imaging orders).

Potential Benefits

Large increases in legible orders
Shorter order turnaround times
Lower relative risk of medication errors
Higher percentage of patients who attain their treatment goals

Safety Concerns

Increases relative risk of medication errors
Increased ordering time
New opportunities for erros, such as:
- Fragmented displays preventing a coherent view of patients' medications
- Inflexible ordering formats generating wrong orders
- Separations in functions that facilitate double dosing

Disruptions in workflow

Clinical Descislon Support (CDS)

Monitors and alerts clinicians of patient conditions, prescriptions, and treatment to provide evidence-based clinical suggestions to health professionals at the point of care

Potential Benefits

Reduction in:
- Relative risk of medication errors
- Risk of toxic drug levels
- Time to therapeutic stabilization
- Management errors of resuscitating patients in adult trauma centers
- Prescriptions of nonpreferred medications

Can effectively monitor and alert clinicians of adverse conditions
Improve long-term treatment and increase the likeihood of achieving treatment goals

Safety Concerns

Rate of detecting drug-drug interactions varies widely among different vendors
Increases in mortality rate
High override rate of computer generated alerts (alert fatigue)

Fig. 9.9 Potential benefits and safety concerns of Health IT

Bar-Coding

Bar-coding can be used to track medications, orders, and other health care products. It can also be used to verify patient identification and dosage.

Potential Benefits

Significant reductions in relative risk of medication errors associated with:

- Transcription
- Dispensing
- Administration errors

Safety Concerns

Introduction of wortkarounds for example, clinicians can:

- Scan medications and patient identification without visually checking to see if the medication dosing and patient identification are correct
- Attach patient identification bar-codes to another object instead of the patient
- Scan orders and medications of multiple patients at once instead of doing it each time the medication is dispensed

Patient Engagement Tools

Tools such as patient portals, smartphone applications, email, and interactive kiosks, which enable patient to participate in their health care treatment

Potential Benefits

Reduction in hospitalization rates in children
Increases in patients' knowledge in treatment and illnesses

Safety Concerns

Reliability of data entered by:

- Patients
- Families
- Friends or

Fig. 9.9 Continued

not capture the complexity of sociotechnical factors that control or confound or influence interventions. Singh et al. propose a methodical framework for EHR interventions targeting patient safety building on an eight-dimension sociotechnical model for design, development, implementation, use, and evaluation of HIT [19]. This Safety-related EHR-based Research (SAFER) reporting framework enables reporting for patient safety focused EHR-based interventions needed to reduce or eliminate preventable harm, while accounting for the multifaceted sociotechnical context affecting intervention implementation, effectiveness, and generalizability.

Although, the sociotechnical model is a valuable tool for RCA after an error has occurred, there are two additional tools that can be used prospectively: Failure Modes and Effects Analysis (FMEA) [20] and EHR usage metrics. A comprehensive reference guide on FMEA is available online at the website of the Veterans Administration's National Center for Patient Safety (http://www.patientsafety.gov/SafetyTopics/HFMEA/HFMEA_JQI.html). EHR usage metrics can be monitored using "run charts" to find problems and track their resolution [21]. These metrics can include percent system uptime, mean response time (measured in tenths of a second), percentage of orders entered electronically, percentage of order sets used, percentage of alerts that fire, percentage of alerts overridden, system interface efficiency, and miscellaneous or free-text orders (which bypass clinical decision

support).The "Issues Log" is another tool to collect and manage unintended consequences of Health IT. A good sample issues log [22] can be downloaded from the www.HealthIT.gov.

Clinical Decision Support System (CDSS)

The Office of the National Coordinator for Health Information Technology (ONC) defines Clinical Decision Support as follows [23]: "*CDSS provides clinicians, staff, patients or other individuals with knowledge and person specific information, intelligently filtered or presented at appropriate times, to enhance health and healthcare.*"

CDSS encompasses a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients, clinical guidelines, condition-specific order sets, focused patient data reports and summaries, documentation templates, diagnostic support, and contextually relevant reference information. The ONC also asserts that CDSS "promotes patient safety", contributing to "increased quality of care and enhanced health outcomes" and "avoidance of errors and adverse events".

To achieve these patient safety goals across the clinical care continuum, it is essential CDSS tools succeed in getting the right information to the right people in the right intervention formats through the right channels at the right times in workflows [24].

An effective CDSS involves six levels of decision-making: alerting, interpreting, critiquing, assisting, diagnosing, and managing. Alerts are a vital component of a CDSS, and automated clinical alerts remain an important part of current error reduction strategies that seek to affect the cost, quality, and safety of health care delivery.

Systematic reviews of the impact of CPOE and CDSS across inpatient settings have reported significant reductions in medication errors, with modest reductions in length of stay and overall mortality [25].

Alert Fatigue

An important unintended adverse consequence of CDSSs is the overabundance of warnings and reminders which can result in alert desensitization and fatigue for clinicians. While notifications are meant to help clinicians by pointing out important information, EHR systems often produce excessive and unnecessary alerts that can lead to negative treatment outcomes, compromise patient safety, and even lead to clinician burn-out. To overcome this problem, software developers must design solutions using machine learning tools [26] that can aid clinicians' workflows without causing alert fatigue.

EHR Downtime and Patient Safety

Healthcare providers experience EHR downtime periods, when partial or all functions within the EHR are not available. Downtimes can be planned, when software upgrades to the EHR are performed, or unplanned, due to IT infrastructure or network outages. The unplanned ones have the potential to result in serious patient safety risks since critical information needed to provide effective care is not readily available [27]. Further, CDSS and safety alerts of EHRs that clinicians are dependent on are not available during downtimes. The Safety Assurance Factors for EHR Resilience (SAFER) guides [28] released by ONC—Health IT provides high level guidance and recommends that appropriate downtime procedures be put in place and practiced routinely to reduce patient harm.

Usability

Usability is a critically important consideration from the technology category that deserves elaboration. Simply put, usability is how easy a technology is to learn and use. Other related terms include human factors and user-centered design. Shneiderman promotes eight rules for human–computer interface design (Fig. 9.10) [29]. Ultimately, we believe that a more usable EHR is a safer EHR. While providers can change processes, training, and organization, rarely can they improve the usability of their EHRs. Complaints abound from clinicians about the poor usability of many EHRs. The concerns expressed include the excessive number of clicks to find information, non-intuitive graphic user interfaces, and lack of integration or interoperability between clinical systems. With the sheer volume and complexity of information in patient care today, poor usability can compromise decision-making and patient safety.

In order to minimize potential adverse impacts of EHRs on patient safety, the IOM report on patient safety and health IT made a number of significant recommendations [16] including:

- Specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety, culture, and usability.
- Establish a mechanism for both vendors and users to report health IT-related deaths, serious injuries, or unsafe conditions.

Additionally, the Office of the National Coordinator—Health IT (ONC) has proposed new EHR certification rules that would promote safety-enhanced design that mandate developers to adopt user-centered design, document software quality management [30], and in 2022 become certified with Real World Testing [31]. These rules are important steps in building more usable and safer EHRs.

Principles	Characteristics
Strive for Consistency	Samilar tasks ought to have similar sequences of action to perform, for example: • Identical terminology in prompts and menus • Consistent screen appearance Any exceptions should be understandable and few
Cater to universal usability	Users span a wide range of expertise and have different desires, for example: • Expert users may want shortcuts • Novices may want explanations
Offer informative feedback	Systems should provide feedback for every user action to: • Reassure the user that the appropriate action has been or is being done • Instruct the user about the nature of an error if one has been made Infrequent or maijor actions call for substant ial responses, while frequent or minor actions require less feedback.
Design dialogs to yield closure	Have a beginning, middle, and end to action sequences: Provide informative feedback when a group of actions has been completed
Prevent errors	Systems should be designed so that users cannot make serious errors, for example: • Do not display menu items that are not apprropriate in a given context • Do not allow alphabetic characters in numeric entry fields User errors should be detected and instructions for recovery offered Errors should not change the system state
Permit easy reversal of actions	When possible, actions (and sequences of actions) should be reversible
Support internal locus of control	Surprises or changes should be avoided in familiar behaviors and complex data-entry sequences
Reduce short-term memory load	Interfaces should be avoided if they require users to remember information from one screen for use in connection with another screen

Fig. 9.10 Eight golden rules for interface design. (Adapted from Shneiderman B, Plaisant C, Cohen M, Jacobs S. Designing the user interface: Strategies for effective human-computer interaction. Boston, MA: Addison-Wesley; 2009 (reprinted with permission))

This newest ONC requirement for 2022 of Real-World Testing, as outlined in the 21st Century Cures Act Final Rule, requires Certified Health IT Developers to document and publicly report out results of interoperability and functionality (Fig. 9.11) [32]. Functionality must now be tested in "real world settings" outside of traditional, in house, controlled test environments. This new requirement is designed

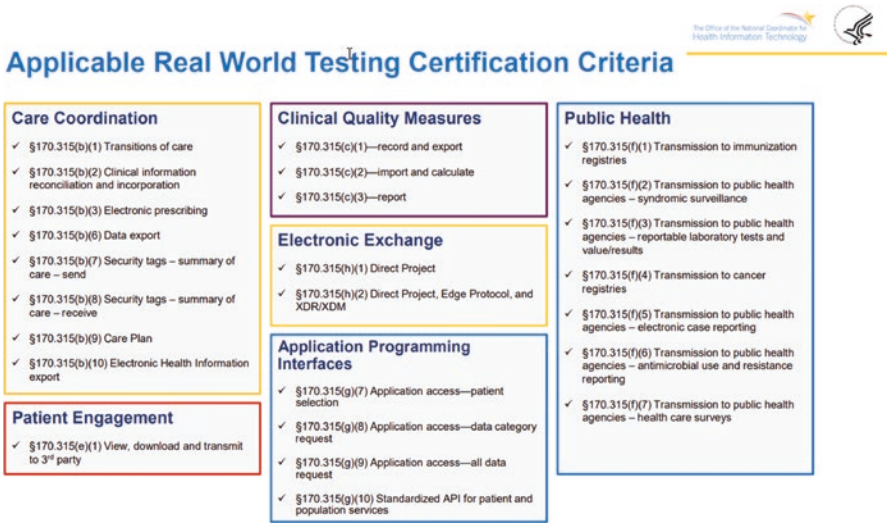

Fig. 9.11 Applicable real-world testing certification criteria

to force developers to demonstrate their software's ability to perform as intended in a transparent way to both the ONC and the public community.

Conclusions and Lessons Learned

- Healthcare is becoming a high-reliability industry with a mission of having zero harm during the care processes and continuum [33].
- Two decades ago, health IT was identified as an integral solution to improve clinical quality and patient safety. During this period, various legislative, incentive, and regulatory requirements have accelerated health IT implementation. However, adoption of these systems has burdened clinician users due to design, configuration, and implementation issues resulting in poor usability, challenges to workflow integration, and sub-optimal clinical documentation requirements. These must be addressed to ensure health IT provides maximum benefits for the healthcare professionals and their patients.
- There is mounting evidence of the role of EHRs in improving safety and quality of care. However, like any innovation, use of EHRs in clinical practice can lead to unanticipated and potentially adverse consequences on patient safety. These must be recognized and addressed.
- With the 21st Century Cures Act, there are opportunities for all stakeholders to work collaboratively in building various health IT solutions resulting in safer healthcare with improved health outcomes.

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