Guide to Reducing Unintended Consequences of Electronic Health Records

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Preface

The *Guide to Reducing Unintended Consequences of Electronic Health Records* is a resource designed to help you and your organization anticipate, avoid, and address problems that can occur when implementing and using an electronic health record (EHR). Our purpose in developing the Guide was to provide practical, troubleshooting knowledge and resources.

The Guide was developed with all types of health care organizations in mind—from large hospital systems to solo physician practices. We anticipate that the primary users will be EHR implementers such as Regional Extension Centers, chief information officers, directors of clinical informatics, EHR champions or "super users," administrators, information technology specialists, and clinicians involved in the implementation of an EHR. Frontline EHR users (such as physicians and nurses) may also find the Guide useful.

The Guide is based on the research literature, other practice-oriented guides for EHR implementation and use, research by its authors, and interviews with organizations that have recently implemented EHR. The Guide represents a compilation of the known best practices for anticipating, avoiding, and addressing EHR-related unintended consequences. However, this area of research is still in its infancy. Therefore, the Guide is a work in progress. We invite you to revise its tools and recommendations in keeping with your own experience and in response to emerging research findings.

Acknowledgments

Several organizations and individuals contributed to the development of this guide as members of the core research team, development sites, pilot testers, or advisors.

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(**External resources for each module are available electronically at http://www.healthit.gov/ unintended-consequences/content/external-resource.html**.)

Module 1. Introduction to Unintended Consequences

Electronic health records (EHRs) offer many advantages, but even the most experienced implementers can face unexpected difficulties. This module provides an overview of the kinds of issues that might arise during implementation.

Question 1: What Are Unintended Consequences?

EHRs can offer many benefits to health care providers and their patients, including better quality of medical care, greater efficiencies, and improved patient safety. However, even if these benefits are achieved, you will almost certainly face some unanticipated and undesirable consequences from implementing an EHR. Such consequences are often referred to as unintended consequences.

Unintended consequences can undermine provider acceptance, increase costs, sometimes lead to failed implementation, and even result in harm to patients. However, if you learn to anticipate and identify unintended consequences, you will be in a better position to make effective decisions, clarify tradeoffs, and address problems as they arise.

Question 2: What Are Some Examples of Unintended Consequences?

Here are some examples of common unintended consequences[1]:

1. **More work for clinicians**
   Example: After the introduction of an EHR, physicians often have to spend more time on documentation because they are required to (and facilitated to) provide more and more detailed information than with a paper chart. While this information may be helpful, the process of entering the information may be time consuming, especially at first.

2. **Unfavorable workflow changes**
   Example: Computerized physician order entry (CPOE) automates the medication and test ordering process by reducing the number of clinicians and clerical staff involved, but by doing so it also eliminates checks and counterchecks in the manual ordering process. That is, with the older system, nurses or clerks may have noticed errors, whereas now the order goes directly from the physician to the pharmacy or lab.

3. **Neverending demands for system changes**
   Example: As EHRs evolve, users rely more heavily on the software, and demand more sophisticated functionality and new features (e.g., custom order sets). The addition of new functionalities necessitates that more resources be devoted to HER implementation and maintenance.

4. **Conflicts between electronic and paper-based systems**
   Example: Physicians who prefer paper records annotate printouts and place these in patient charts as formal documentation, thus creating two distinct and sometimes conflicting medical records.

5. **Unfavorable changes in communication patterns and practices**
   Example: EHRs create an "illusion of communication," (i.e., a belief that simply entering an order ensures that others will see it and act upon it.) For example, a physician fails to speak with a nurse about administering a medication, assuming that the nurse will see the note in the EHR and act upon it.

6. **Negative user emotions**
   Example: Physicians become frustrated with hard-to-use software.

7. **Generation of new kinds of errors**
   Example: Busy physicians enter data in a miscellaneous section, rather than in the intended

8. **Unexpected and unintended changes in institutional power structure**
   Example: IT, quality assurance departments, and the administration gain power by requiring

9. **Overdependence on technology**
   Example: Physicians dependent on clinical decision support may have trouble remembering

Module II: Avoid Unintended Consequences

Unintended consequences are unpredictable, but much can be learned from the experiences of other EHR implementers and users. Adhering to best practices for selecting, implementing, and using your EHR will help you avoid unintended consequences. This Module is divided into two sections: the first section will be more useful to organizations that have not yet implemented an EHR, and the second section will be more useful to current EHR users.

For Future EHR Users

Implementing an EHR will dramatically change how your organization functions. To derive the full benefits of an EHR, your organization needs to be ready for these changes. A thorough and honest assessment of your organization's readiness should take place before you choose an EHR.

Question 1: Are You Ready for an EHR?

Careful consideration must be given to the question of whether your organization is ready for an EHR. An EHR is not a panacea—on its own it cannot solve problems with workflow, efficiency, staff training, or quality. In fact, if such problems exist, implementing an EHR may just make them worse.

CASE EXAMPLE: **Staff Readiness for EHR Implementation**[2]

Issues Encountered
Three independent orthopedic practices recently implemented the same EHR product. Each practice struggled with their implementation because they were unprepared in many respects to move to an EHR. Each of the practices identified the lack of basic computing skills among staff members as a major challenge. One of the practices reported that some of their longtime staff members were unable or unwilling to work with the new EHR system. Another practice reported that staff were upset because the new EHR actually created new work for them. For example, the office manager reported spending 95 percent of her time resolving IT issues, rather than fulfilling her other duties.

Finding a Solution
These practices recommended that organizations make sure that the necessary competencies are in place before proceeding with implementation. These practices found it helpful to hire new staff members who were proficient with IT to help existing staff get up to speed.

Lessons Learned
- Implementation should move at the pace that your practice is ready for. Make sure that the necessary competencies (e.g., basic computer skills) are in place before proceeding with EHR implementation.

- EHR implementation will have dramatic effects on how work is done. EHR implementation may result in more work for some members of your organization.

Before committing to acquisition of an EHR, it is wise to make a careful assessment of your organization's readiness for EHR implementation. If the assessment points to areas where your organization lacks minimum requirements for EHR implementation—such as a lack of basic computer skills among the staff—you can benefit by remedying these deficits before trying to implement an EHR.

USEFUL TOOL

Organizational Assessment Tools: The AHRQ National Resource Center for Health IT includes a number of tools that can help you assess your organization's readiness for EHR implementation. Interested users can search for such tools in AHRQ's Health IT Survey Compendium (http://healthit.ahrq.gov/Survey_Compendium). One useful readiness survey, the Primary Care Information Project's Evaluation Provider Survey, is available here http://healthit.ahrq.gov/PCIP_Evaluation_Provider_Survey.pdf .

Question 2: Why Do You Want To Implement an EHR?

Setting goals is a critical step in the EHR implementation process. Your organization's goals in implementing an EHR should be clearly stated, and the implementation plan should include strategies for achieving the goals as well as a way to measure your progress towards them.

USEFUL TOOL
Setting and Achieving Goals: The Doctor's Office Quality – Information Technology program has developed a useful document on goal setting (http://www.healthit.gov/unintended-consequences/sites/default/files/pdf/ModuleIIpdf1.pdf), and AHRQ has developed an HIT Evaluation Guide that can help you determine whether your project is achieving its goals and producing the desired results. The Guide is available at http://healthit.ahrq.gov/evaluation_toolkit.

CASE EXAMPLE: Conflicting Priorities: Regulatory Compliance vs. Clinical Workflow*

Issues Encountered

A large community hospital recently implemented a comprehensive EHR system. The hospital's nurses are some of the most vocal critics of the new system. In addition to generally slow response times, the nurses felt that the EHR's admission assessment form was too cumbersome and as a result took too long to fill out completely. The poor design of this form has resulted in many incomplete patient records.

Finding a Solution

Hospital administrators were reluctant to change the admission assessment form because in their view all of the items in the form were necessary in order to document the hospital's compliance with regulatory rules. After pressure from the clinical staff mounted, hospital administration made some efforts to streamline the electronic admission assessment form. However, the nurses still find the admission assessment form to be too long and too difficult to fill out.

The hospital's continuing problems with their EHR are a symptom of conflicting priorities among key stakeholders. In this example, the hospital administrators' priority appears to be the ability to document regulatory compliance, while ease of use is most important to the clinicians. Under the current arrangement, the needs of neither administrators nor clinicians are being met: the administrators are not getting the documentation they need because the clinicians are not filling out the form completely, and the clinicians are having difficulties using the EHR. However, the priorities of administrators and clinicians are not necessarily mutually exclusive. Trade-offs and compromise will be necessary; successful EHR implementations must incorporate and balance the preferences of all the relevant stakeholders.

Lessons Learned
- To enhance agreement about goals, involve all relevant stakeholders in the design, implementation, and governance of the EHR.
- Cooperation and compromise are necessary for successful EHR implementation and use.
- Some conflicts over priorities cannot be readily resolved. In these cases, management needs to inform all stakeholders why it favors one priority over another and actively solicit stakeholder support of the preferred course of action.

*Source: This material was derived from responses to a membership survey about unintended consequences that the American Health Informatics Management Association (AHIMA) conducted in 2009. For further information, contact Spencer Jones at the RAND Corporation at sjones1@rand.org.

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EHR Incentive Programs. The Medicare and Medicaid EHR incentive programs provide financial incentives to health care providers that are able to demonstrate "meaningful use" of certified EHR technologies.

⚒ USEFUL TOOL
Meaningful Use: CMS provides information about the Federal EHR incentive program at http://www.cms.gov/EHRIncentivePrograms/30_Meaningful_Use.asp.

Question 3: How Do You Select an EHR?

Functionality is only one factor in identifying the right EHR vendor. Other important factors include eligibility for Federal incentive programs, maintenance, support, privacy, ability to link with other systems in the facility, and data ownership. The Office of the National Coordinator for Health Information Technology (ONC) has established Regional Extension Centers across the United States to help health care organizations select, implement, and qualify for Federal EHR incentive programs.

⚒ USEFUL TOOL
Regional Extension Centers: To find your local ONC Regional Extension Center, go to http://www.healthit.gov/provider-professionals/listing-regional-extension-centers.

CASE EXAMPLE: **Choose Your EHR Vendor Carefully**[2]

Issues Encountered
Three independent orthopedic practices experienced several unintended consequences after purchasing their EHRs. These practices discovered that they needed to make costly customizations to the systems that were not covered in the original contract. They also felt that the vendor "nickel and dimed" them, charging them for phone calls, site visits, and interfaces with legacy IT. Additional costs for data conversion and hardware were not anticipated, and to make matters worse, after only a few months, a change in the software rendered some of the recently purchased hardware incompatible and unusable.

Finding a Solution
These practices recommended that practices work with vendors that have good reputations, pay close attention to the details of what is included in the contract and what is not, and build in penalties for vendors that do not meet deadlines and practice benchmarks. Practice leaders also felt that it was useful to hire an office manager or leader from a similar organization that had implemented an EHR, to serve as a consultant.

Lessons Learned
- Select a well-qualified vendor to avoid disappointments and unintended consequences.
- Carefully negotiate and understand your EHR contract to avoid unpleasant surprises.

Question 4: How Do You Conduct a Workflow Assessment?

The EHR will not magically improve your processes; in fact, preexisting problems can spread and worsen if they are not addressed prior to implementation. Assessment of your current processes, identification of inefficiencies or safety risks, and redesign of inefficient or unsafe processes should take place before you implement your EHR.

USEFUL TOOL

Workflow Assessment: AHRQ has developed a Workflow Assessment for Health IT Toolkit, available at http://healthit.ahrq.gov/workflow. In addition, the California Healthcare Foundation provides a tutorial on workflow analysis and process mapping at http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/W/PDF%20WorkflowAnalysisEHRDeploymentTechniques.pdf.

CASE EXAMPLE: **Redesigning Hospital Workflow**[3]

Issues Encountered

A two-hospital health system preparing to implement a new nursing documentation and ordering system assembled an interdisciplinary team to assess their current patient admission processes. They determined that there was significant duplicate documentation in the nurses' workflow. For example, according to hospital policy, nurses were required to fill out an electronic social functional assessment form within 24 hours of a patient's admission. The data collected by this form overlapped considerably with data collected on a paper admission form that was also filled out by nurses. Ancillary departments were being flooded with duplicate referrals via the paper and electronic systems. The departments wasted time reconciling paper referrals with electronic ones, trying to weed out the duplicates.

Finding a Solution

The team decided to address the problem by mapping out the admission data collection process using flow diagrams. They soon identified several ways to improve the process. First, they incorporated the functional assessment into the EHR's electronic admission form and implemented point-of-care documentation. Next, they made sure that data from previous visits and disparate systems could be incorporated into the central electronic record. Finally, they developed an automated referrals system to notify specific ancillary departments based on admission data from the EHR. Other existing policies and procedures were reviewed to ensure that they did not conflict with the new process. The process redesign, in combination with the new EHR, reduced duplicate documentation, improved communication, and increased nurse satisfaction.

Lessons Learned

- Duplication across paper and electronic systems or across disparate electronic systems can lead to unintended consequences.
- EHR implementation or modification provide an opportunity to reevaluate and redesign current processes.
- Process assessment should be conducted in a systematic way using tools such as flow diagrams.

Question 5: What Are the Recommended Practices for Avoiding Unintended Consequences of EHR Implementation?

As we've emphasized, implementing an EHR is a difficult process that may disrupt your organization's work and upset some colleagues and patients. The following is a list of implementation practices based on expert consensus that should help you avoid EHR-related unintended consequences during EHR implementation[4]:

- Project scope is defined, with clear, reasonable, measurable goals.
- Users are well-informed and engaged in the implementation.
- Initial milestones should produce early "wins" that will help maintain momentum toward more difficult long-term objectives.
- Plans are detailed but not overly complicated.
- Multiple mechanisms for collecting feedback from users are in place.
- The capacity to analyze and act on user feedback is in place.
- Leaders should work to develop consensus when disagreements arise.
- Use of consultants should be carefully planned with specific objectives before they are employed.
- A critical mass of users must be ready for the implementation.
- A plan for involving clinicians must be developed, followed, and evolved.
- Metrics for success should be determined beforehand and evaluated over time.
- The organization should hire and deploy staff where and when they are most needed.
- Maintenance routines and an environment to support ongoing quality improvement should be established.

 USEFUL TOOL

Health IT Journeys: ONC has compiled numerous success stories from early adopters of EHRs that are available at http://www.healthit.gov/providers-professionals/health-it-journeys.

CASE EXAMPLE: **Managing Expectations About How EHR Implementation Will Affect Workflow***

Issues Encountered
Clinicians at a college student health center complained that the introduction of an EHR significantly increased their workload. In particular, physicians and nurse practitioners complained that the additional time they had to spend learning to use the new system, combined with the additional burden of documenting patient visits in the EHR, reduced their capacity to focus on delivering patient care. One physician said: "In the EHR I have to click all these buttons, and when you see 20-plus patients a day all that clicking time really adds up." In addition to the time spent interacting with the EHR during the patient visits, the physicians were also unhappy with the additional time spent maintaining the patient record outside of the clinic. Another physician complained that he spent several hours each day documenting in the EHR and that the time he spent doing that was "totally uncompensated."

Finding a Solution
Changes in both the flow and distribution of work are natural byproducts of EHR implementation. The side effects described in the example above are very common. These are still open problems that do not have straightforward solutions. Some recommended practices for avoiding user dissatisfaction with the increased workload include being honest and upfront about the workload implications of EHR implementation (i.e., make sure you have "buy-in"). Organizations may also compensate for the increased documentation burden by scheduling fewer patients for a period after the introduction of the EHR. This approach will allow users to gain comfort and proficiency with the EHR.

Lessons Learned
- To foster buy-in, involve clinicians in the planning, selection, implementation, and maintenance of the EHR.
- Clinicians need to be aware of the workload implications of EHR introduction.
- Reduce the clinicians' workload during the learning period.

*Source: This material was derived from responses to a membership survey about unintended consequences that the American Health Informatics Management Association (AHIMA) conducted in 2009. For further information, contact Spencer Jones at the RAND Corporation at sjones1@rand.org.

For Current EHR Users

Unintended consequences are not limited to the initial implementation phase. They can occur at any time before, during, and even long after EHR implementation. Continuously monitoring the functionality and use of the EHR will help you anticipate and avoid adverse unintended consequences.

Question 1: What Are Some Recommended Practices for Avoiding Unintended Consequences of EHR use?

Unintended consequences result from complex interactions between technology and the surrounding work environment. Even if your EHR implementation was well planned and executed, some unintended consequences may emerge after the EHR is being used on a day-to-day basis. The following list of recommendations for improving EHR safety should help you avoid a range of adverse unintended consequences that may occur during day-to-day EHR use.[5]

- Actively involve clinicians and staff in the reassessment and ongoing quality improvement of technology solutions.
- Continuously monitor for problems and address any issues as quickly as possible, particularly problems obscured by workarounds or incomplete error reporting.
- Use interdisciplinary brainstorming methods for improving system quality and giving feedback to vendors.
- Carefully review skipped or rejected alerts.
- Require departmental or pharmacy review and sign off on orders that are created outside the usual parameters.
- Provide an environment that protects staff involved in data entry from undue distractions when using the technology.
- Continually reassess and enhance safety effectiveness and error-detection capability, including the use of error tracking tools and the evaluation of near-miss events.
- Use manual or automated surveillance techniques to continually monitor and report errors and near misses or close calls caused by technology.
- Pursue system errors and multiple causations through root cause analysis (finding the real cause of the problem and dealing with it rather than simply continuing to deal with the symptoms) or other forms of failure-mode analysis.

A systematic approach for identifying risks that are introduced by the EHR will help you anticipate and avoid unintended consequences. Useful tools have been developed that can help you systematically evaluate the risks associated with the use of your EHR.

USEFUL TOOL

Failure Modes and Effects Analysis (**FMEA**): FMEA is a systematic method used to proactively evaluate health care processes and to identify and assess potential vulnerabilities. The Department of Veterans Affairs provides a tutorial on how to apply the FMEA methodology in health care settings at http://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp.

CASE EXAMPLE: **FMEA + CPOE = Fewer Medication Errors**[6]

Issues Encountered
Pediatric chemotherapy is very complex, involves many risks, and leaves little margin for error. A Pediatric Oncology Department conducted a Failure Mode and Effect Analysis (FMEA) of their process for pediatric chemotherapy. Of the different chemotherapy steps (prescription, ordering, transcription, dispensing, and administration), the FMEA found that the modes of failure that were potentially the most severe and likely to occur took place during the ordering and administration (e.g., ordering/administering the wrong medication for/to the wrong patient).

Finding a Solution
In response to a sentinel event, and as part of a safety and quality improvement program, the Pediatric Oncology Department replaced their paper-based order entry system for pediatric chemotherapy with CPOE. They used the results of their FMEA to guide their CPOE implementation. For example, to address the risks associated with the misidentification of patients or patient variables (e.g., height, or weight) a multidisciplinary team from the hospital recommended that the CPOE incorporate the following functionalities:

1. Limit choices (i.e., menus instead of free-text)
2. Enforce entry of required data (i.e., user cannot navigate away until required fields are filled)
3. Alert users to abnormal values

After the FMEA-guided implementation of the CPOE system, the Pediatric Oncology Department observed a significant reduction in the number of orders with improper dosing, incorrect dosing calculations, and missing doses.

Lessons Learned
- Complex, multi-step processes are frequent sources of error.
- Systematic methods (such as FMEA) can be used to identify potential risks in clinical process.
- Prospective risk assessments can provide insights into which features and functionalities should be incorporated into the EHR.

Question 2: How Do You Monitor EHR Usage?

EHR Usage Metrics. Metrics can help you track the functionality and usage of your EHR. For example, the following list of metrics was developed to monitor the use of CPOE systems. These measures are useful as examples of what can be developed to assess and improve the usefulness of an EHR. The reporting and audit capabilities of EHRs will vary, but it may be

useful to evaluate potential vendors on whether their products will allow you to track these (or other similar) usage metrics.[7]

- **Percent system uptime**: calculated as the number of minutes the EHR was fully functional in a given month divided by the total number of minutes. Planned as well as unplanned downtimes should be deducted from the numerator. Downtimes should include any time period when systems that affect clinical use were not functioning properly.
- **Mean response time**: measured to the tenth of a second and calculated for any number of routine tasks (for example, accessing a patient's medication list).
- **Percent of orders entered**: the percentage of all orders entered electronically.
- **Percent order sets used**: the percentage of order sets (prefilled ordering templates or electronic protocols derived from evidence-based best practice guidelines) that have been used in the last 12 months; a similar measure could be calculated for other templates.
- **Percent alerts that fire**: the percentage of alerts that have fired in the last week, month, and quarter (a measure of the utility and sensitivity of the alerts).
- **Percent alerts overridden**: the percentage of alerts that are overridden by clinicians.
- **System interface efficiency**: measure of how well the EHR communicates with ancillary systems (e.g., pharmacy, lab, PACS, etc.). This could be calculated as the number of successful transmissions between systems divided by the total number of transmissions attempted.
- **"Miscellaneous" orders**: the number of miscellaneous or free text orders should be monitored. (Free text entry disables the capacity to provide decision support).

In order to qualify for Federal "meaningful use" incentives, health care providers must monitor and report the use of the EHR in their organization. The toolbox below provides links to the Federal meaningful use criteria.

USEFUL TOOL

Meaningful Use: CMS provides information about the Federal EHR incentive program at http://www.cms.gov/EHRIncentivePrograms/30_Meaningful_Use.asp.

Soliciting User Feedback. Make it easy for users to provide feedback or report errors and for the organization to respond to them. Module III describes strategies for error reporting. Module IV focuses on the remediation of EHR-related errors.

In addition to these strategies, regular surveys of clinicians can give you a sense of how the system is being used and what functions are the most or least useful. These surveys may also alert you to patterns of use that may be suboptimal or even dangerous.

Example User Survey: The New York Department of Health and Mental Hygiene and Columbia University developed a survey that can be used in whole or in part to assess how the EHR is being used in your organization. The survey is available at http://www.healthit.gov/unintended-consequences/sites/default/files/pdf/ModuleIIpdf7.pdf.

Auditing the Use of Copy and Paste. Copying clinical documentation can be a time-saver for busy clinicians; however it also can pose a risk to the integrity and utility of medical records and can even affect patient safety. Organizations that allow use of the copy and paste function in their EHR systems may need to audit its use in order to maintain compliance with State and Federal requirements.

Dealing With the Persistence of Paper After EHR Implementation. "Going paperless" in health care is a lengthy process, and it is likely that the use of paper records and forms will persist even after you implement an EHR. Paper does offer some features such as flexibility and tailorability that digital mediums presently do not. However, the persistence of paper records and paper-based information tools poses a problem when these tools are used as "shadow" medical records or are used to circumvent processes or checks that are enforced in the electronic systems. Best practices for using paper in an EHR environment are not available; however some research has described the reasons why paper persists in health care work environments and how paper might be used more safely and effectively.

 CASE EXAMPLE: **Paper Persistence after EHR Implementation**[8]

Issues Encountered
The Computerized Patient Record System (CPRS) is implemented throughout the Veterans Affairs Medical system. A recent study indicated that clinicians in the VA system consistently use paper to work around the limitations of CPRS. Some examples of the workarounds they identified include:

1. An emergency department physician feels that a paper form is more efficient than CPOE. He passes his paper-based orders to the nurse, who passes them off to the clerk, who then enters the order into the computer.
2. A pharmacist makes handwritten notes on printouts from the EHR and then enters the handwritten data back into the system later in the day. The pharmacist said, "The hand notes help me remember. I do this for discharges and inpatients. There can be 6 to 12 discharges per day. It is not possible to make these types of notes in CPRS [in real time]. I don't know how you would do this in the computer... We need paper to do our job."
3. A nurse uses a notebook to track patient lab values: "I add important footnotes — anytime the [international normalized ratio] INR is too high... The primary care provider will think the INR was too high only this one time but I have the data in my notebook to show that it was too high three times."

Finding a Solution
An EHR has many advantages over the paper record, including improved legibility, remote access, and the ability to integrate across information systems. However, don't be surprised if the EHR does not replace paper use entirely. Paper use may continue to the extent that clinicians perceive that it is more efficient than using the EHR.

How to best deal with the persistence of the paper record is still an open problem. However, the VA is carefully studying when, where, and why clinical users would develop these paper-based information tools to supplement or work around the EHR. They then use their observations to determine how the EHR applications could be altered to better suit the clinical users' work.

In some instances, paper-based solutions may be more efficient than a difficult-to-use EHR. However, these workarounds can create unanticipated risks or negate many of the benefits of having an EHR. If modifying the EHR to better suit the clinicians' work processes is not feasible, it might be most effective to develop standardized paper-based tools that can be used throughout your organization to supplement the EHR. While this solution may not be ideal, it is likely preferable to several different ad-hoc approaches floating around.

Lessons Learned
- Paper-based supplementation and workarounds are very common.
- Administrators should seek to find out why clinicians find paper records desirable and try to determine how the EHR could be modified to better suit clinical work so as to reduce the need for paper.
- In some instances, user preference for paper may be very strong. In these circumstances, it may be preferable to use both paper and electronic systems; approved paper systems should be standardized to avoid inconsistencies across the organization.

Question 3: How Do You Survive Updates?

No matter which system or vendor you choose, you will regularly be required to update your EHR software. When software updates do occur, you should be aware that such updates, by design, change the functionality of your EHR and therefore may also lead to unanticipated and undesirable changes in the way your EHR functions or is being used.

 CASE EXAMPLE: **User Frustration with Frequent EHR Updates***

Issues Encountered
A behavioral health and substance abuse facility implemented a new EHR. Many staff members were frustrated by the seemingly constant changes and updates to the system. One staff member said that she struggled to keep up with the "continual upgrades and modifications" and that she feels like the "target is always changing." Implementation of the EHR led to a decrease in staff morale, and a number of staff members left as a result.

Finding a Solution
An interdisciplinary group of clinicians, administrators, and IT staff worked together to make the implementation and maintenance of the EHR less taxing on the clinical staff. Their first solution was to focus on training and supporting users as they learned how to use the EHR. One user said that simply "having someone available to take calls and trouble shoot helped the most." Their second solution was to take a more gradual approach for updating the system. One member of the IT staff said: "We have learned to make changes in versions and we try not to implement any changes during some periods, so that staff members feel like they can manage the change." And his advice to future EHR implementers was: "Try to keep changes to a minimum. Improvements still mean change and that is the most common complaint — that staff cannot learn anything because the system is continually changing..."

Lessons Learned
- Training and support are essential to EHR success — beginning with implementation and continuing with each upgrade.
- Introduce system changes in versions (phases) and allow sufficient time between changes for staff to adapt to the new system.

*Source: This material was derived from responses to a membership survey about unintended consequences that the American Health Informatics Management Association (AHIMA) conducted in 2009. For further information, contact Spencer Jones at the RAND Corporation at sjones1@rand.org.

CASE EXAMPLE: **Despite Testing, Unintended Consequences Can Still Occur**[9]

Issues Encountered

After a year of testing at multiple sites, a large integrated health system was ready to roll out a systemwide software update for its EHR. Not long after the update, users reported that physician orders to stop medications had gone missing. The "missing" stop orders had caused some patients to receive intravenous medications longer than necessary.

Finding a Solution

Upon further review it was discovered that the stop orders were not, in fact, missing, but were simply displayed less prominently on a different portion of the computer screen. The nurses had grown accustomed to the stop orders being positioned at the top of the screen and did not see the orders once their position was altered. Once the problem was identified, it was quickly corrected.

To minimize unintended consequences of EHR updates, organizations need to ensure the following:

- The vendor and local IT have thoroughly tested the updated software
- The vendor or local IT provides documentation of all known ways the software update will change the EHR functionality
- Clinical users are aware of the changes in functionality
- The channels necessary to receive user feedback are open and users feel empowered to provide feedback
- Users are made aware of any unanticipated changes in functionality as soon as they become evident

Lessons Learned

- Despite lengthy testing of the software updates, problems may still emerge after implementation.
- Clinical users are the frontline for detecting unintended consequences that are not discovered during system testing.
- Be on high alert for changes in user behavior, which may reflect unintended consequences of software changes.
- If user behavior does change, carefully consider how these changes could impact patient care.

Module III: Understand and Identify Unintended Consequences

In the previous Module, we presented information and tools for choosing, implementing and using an EHR. The tools and information in Module II can help you avoid unintended consequences; however, even if you use these practices, there will still probably be unintended consequences associated with EHR implementation and use. In this Module, we present a framework that will help you understand why unintended consequences occur, in order to help you prepare to identify and address them.

Understand Unintended Consequences

Question: Why Do Unintended Consequences Occur?

Understanding why and how unintended consequences occur will help you identify and fix your current EHR-related problems and will also help you avoid future unintended consequences.

The management expert, Peter Drucker, called health care workplaces "the most complex human organization[s] ever devised." Interactions between these complex environments and increasingly complex EHRs can spawn subtle unintended consequences of EHR implementation. These consequences do not result from malfunctions within the EHR, but from the interactions between the EHR and the work environment or between the EHR and the technical and physical infrastructure.

In this section, we describe Interactive Sociotechnical Analysis (ISTA),[10] a framework to help you understand the types of interactions that can result in unintended consequences. The ISTA framework has four key elements:

1. The EHR (as designed), or how the developers envisioned that the EHR would be used
2. The work environment: The policies, priorities, hierarchies, and relationships within the organization.
3. The technical and physical infrastructure: Other IT, medical devices, building design and layout.
4. The EHR (as used): The product of interactions between the EHR and the work environment and the physical and technical infrastructure.

Figure 1. Elements of the ISTA Framework
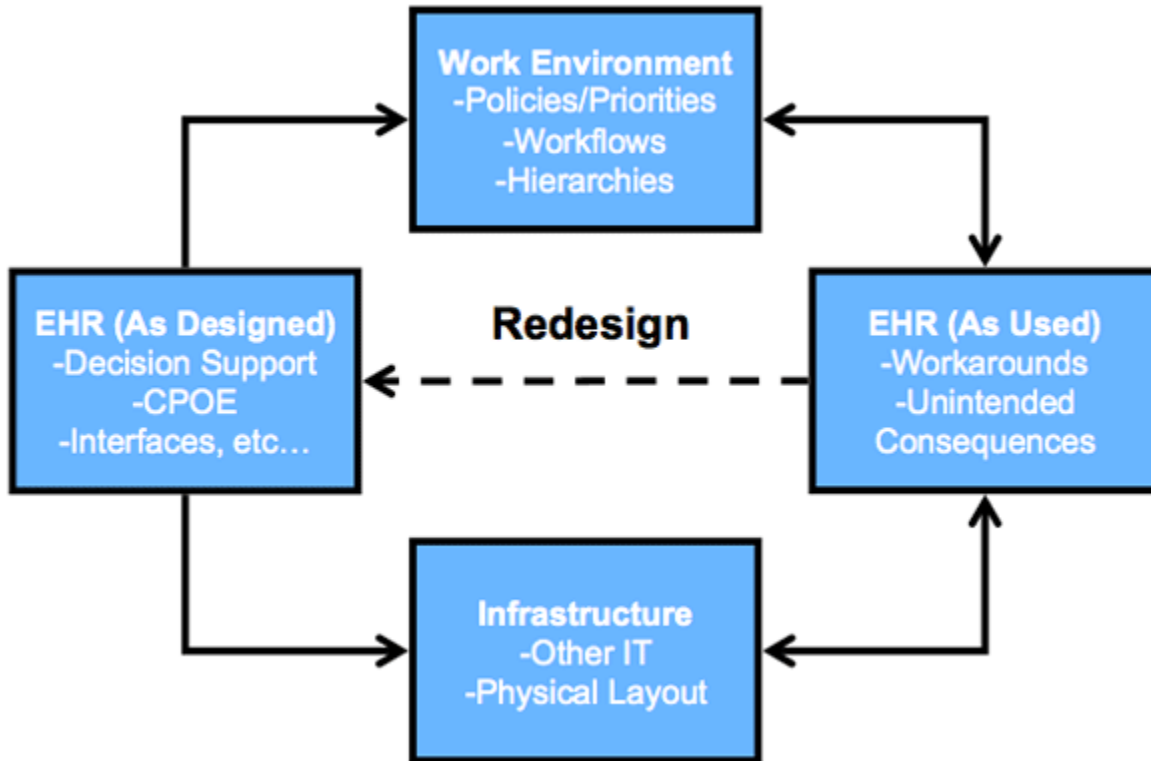
1. The EHR (as designed) interacts with the work environment

EHRs can alter communication and relationships among clinicians in undesirable ways, even while the EHR helps eliminate other problematic and dangerous forms of communication (such as illegible prescriptions).

CASE EXAMPLE: **Post-EHR Changes in Communication**[11]

Issues Encountered
A survey of commercial EHR physician users found that communication among clinicians, and between clinicians and their patients, benefitted from EHR features such as e-mail, instant messaging, improved access to patient information, and improved access to clinical guidelines. The survey also revealed that the introduction of an EHR resulted in some new communication barriers. Physicians indicated that some of the useful features of the EHR are distracting and prevent them from having meaningful personal interactions with their patients (e.g., physicians might get so wrapped up in simply filling in all the checkboxes on an EHR form that they don't take the time to ask their patients open-ended followup questions).

Some physicians also indicated that the EHR diminished communication with colleagues in some ways. Asynchronous communication via e-mail was viewed as problematic, particularly in the context of dealing with complex clinical cases. One cardiologist said: "If I am implanting a defibrillator, the primary care physician may have some thoughts about the patient's true life expectancy that might influence our decisionmaking process about whether the device is appropriate for the patient... We need to do a better job [of communicating orally], because we [cardiologists] can't do it without input from the physicians who understand the patient's complex chronic conditions."

Finding a Solution
Physicians identified some potential ways to overcome the clinician-to-patient communication challenges identified above. The primary recommendation was that strategic placement of the EHR workstation can allow the clinician to maintain eye contact with the patient. The clinicians should also engage the patient when they are reviewing relevant sections of the EHR, such as the problem list, or patient education materials. The patients can also be involved in checking the accuracy of the data in the EHR.

Physicians' primary suggestion for preventing the EHR from diminishing communication with other clinicians was to establish clear guidelines about the appropriate use of electronic communication at the organizational level. One physician respondent summed it up thusly: "The best way to ensure good coordination of care is for two physicians to speak with each other directly. You can't approach any technology solution, in as complex and risky a work environment as the practice of medicine, and have it be a substitute for appropriate human interactions."

Lessons Learned
- The introduction of the EHR can have negative effects on communications amongst clinicians and between clinicians and patients.
- The configuration of the EHR and organizational policies related to its use should facilitate interpersonal communications where appropriate.

2. The EHR (as designed) interacts with the physical or technical infrastructure

A poor fit between an EHR and other IT or the physical infrastructure is a common source of unintended consequences. Problems involving the interface with other health IT systems can lead to poor decisions, delays, data loss, errors, unnecessary testing, and system downtimes. "Dueling systems" can result if paper-based or legacy systems continue to be used after the implementation of an EHR. Features of the physical layout such as the ease with which computers can be accessed, noise, overcrowding, and illumination affect work performance and safety and may have unanticipated, negative effects on use of the EHR.

CASE EXAMPLE: **Conflicts Between Technology and Physical Layout**[12]

Issues Encountered

As a cost-saving alternative to installing computers in each patient room, a large academic hospital chose to invest in computers on wheels (COWs). The COWs were designed to roll anywhere they were needed and were intended to be especially useful at a patient's bedside. However, problems began to emerge after the COWs were put to use in the hospital. In rooms with two beds the COWs could easily be rolled to the bed nearest the door, but did not fit past the first bed to reach the second bed without having to move furniture. The nurses had several options for working around the problem. They could ask questions of patients from across the room, walking back and forth from the farthest bed back to the computer to enter information as they obtain it (e.g., blood pressure readings, pain levels), or they could speak to the patient privately and try to remember each of the answers so that they could enter the information on the computer at one time. Neither option was satisfactory. In addition to the challenges associated with getting the COWs into the patient rooms, the COW's batteries often failed without warning. This unfortunate feature led to the practice of the nurses plugging in the COWs whenever they were in use. This solution obviously negated one of the COWs most attractive features — their mobility.

Finding a Solution

Hospital staff brainstormed a couple of solutions to the problem. The first was to purchase laptops mounted on smaller carts, but these broke down constantly. To add to the problems, the laptops were unreliable and now form a small, lifeless herd in a corner of the hall and are often used as shelves for other items. The second solution was to modify the design of the COWs to make them slightly slimmer by removing the drawers under the computer, which hold the nurses' supplies and a sharps disposal bin (for disposal of used hypodermic needles and such). However, nurses said they need these supplies at hand to do their work. They felt that this solution was imposed without consultation of their needs as the users of the COWs.

This hospital struggled to find a satisfactory solution for the problem and encountered additional problems due to the approach used to try to address the original issue: The nurses felt that the proposed solution of the no-drawer cart was being imposed without consultation and without awareness of their needs. It probably would not have been difficult to solicit ideas from the nurses via e-mail, or just walking around with them. Hospital leadership could also have easily consulted with other hospitals of similar room design to consider their solutions. The IT department's response to the always-broken laptops appeared to be resignation. But efforts to solve the problem are ongoing.

In response to the problem with the battery failure on the COWs, the member of the hospital staff felt that the hospital could seek information about problems like these from users and might seek solutions from other hospitals and from vendors.

(Continued)

CASE EXAMPLE: **Conflicts Between Technology and Physical Layout** (*continued*)

Lessons Learned
- The physical layout of the hospital (i.e., patient room size and configuration) should be considered when purchasing any hardware for clinical use.
- Leadership should actively solicit ideas from end users and seek to understand how users' needs lead to workarounds.
- Failure to incorporate the ideas of end users leaves them feeling frustrated.
- Seek input from other organizations on how they have solved similar problems rather than approaching your problem by trial and error.
- To avoid making the same mistake twice, understand why previous "solutions" failed.

3. The work environment interacts with the EHR (as used)

Policies, priorities, hierarchies, and workplace relationships shape how the EHR is used and for which tasks. At the same time it is also possible that the way the EHR is used can lead to changes in organizational policies, procedures, and hierarchies.

 CASE EXAMPLE: **EHR Safety Check Results in a Potentially Dangerous Workaround**[13]

Issues Encountered

To reduce the risk of medication overdoses, a nursing home implemented "intentional blocks" in the order entry system. These blocks would not allow providers (most often nurses) to order medication doses that exceeded typical thresholds. To circumvent the blocks, nurses simply ordered multiple doses of the same medication in order to obtain the full dose that they desired.

A study of the use of an EHR in five nursing homes identified several other instances in which clinicians felt that they needed to work around the system in order to accomplish their work tasks. Examples of other potentially hazardous workarounds included:

1. A two-stage medication administration documentation system was designed to encourage staff to document preparation of the medication and then to return to document administration after it had taken place. The system was viewed as overly cumbersome, and most staff documented both preparation and administration in a single session—before actually administering the medications.
2. The EHR was designed to print out an individual sheet of paper for each medication order. Medication orders were then to be faxed to the pharmacy. The nursing home staff found that it was too time consuming to send multi-page faxes. Staff used two different approaches to work around this issue: (1) some staff would forgo faxing altogether and simply call the orders into the pharmacy and (2) some staff preferred to transcribe all of the medication orders onto a single sheet of paper and then send a one-page fax.
3. Many of the staff found that the EHR's response time was too slow. The slow response time, combined with the need to click through several different screens to access comprehensive patient information, led staff to employ other information-retrieval methods. For example, it was not uncommon for staff members to rely on handwritten notes or consult with other staff members to obtain the information that they needed, instead of looking it up in the EHR.

Finding a Solution

How to best deal with EHR workarounds is still an open problem. Workarounds may not necessarily be bad, and they may be preferable to expensive system modifications and upgrades. However, workarounds can be dangerous, and they should be monitored and, where possible, standardized. If you choose to incorporate a workaround into your workflows, you should carefully analyze the process to ensure that it does not put patients at risk. Systematic methods to study your processes are discussed in Module II.

Lessons Learned

*   Users will find creative ways to work around the system if it does not fit their workflows.
*   Workarounds should be carefully monitored and analyzed.
*   If a workaround is determined to be more effective or feasible than altering the EHR, then it may be advisable to ensure that the workaround is adopted by all users.

CASE EXAMPLE: **EHR-in-Use Alters Clinical Authority and Oversight**[14]

Issues Encountered

A hospital policy at an academic medical center required infectious disease (ID) fellows to review residents' CPOE orders of broad-spectrum antibiotics. However, no restrictions on residents' ordering privileges were implemented in the system. In order to avoid the hassle of dealing with the ID fellows, some residents would resort to "stealth dosing," that is, waiting until the ID fellows went off duty to prescribe the restricted medications. When they came back into work, ID fellows could demand medication changes. But changing antibiotic regimes can be problematic, so ID fellows let many such orders stand even if they were not ideal. Because ID fellows often take no remedial actions and residents can game the system, stealth dosing constrains the ID fellows' authority and weakens the oversight process.

Finding a Solution

Changes in organizational policy facilitated by the introduction of new clinical information systems can be a major source of unintended consequences. As we see in the example above, the unintended consequence of "stealth dosing" was not the result of any limitations or problems with the CPOE system; it was a response to a change in hospital policy. Just as is the case with the implementation of new clinical information systems, careful thought and consideration must be given to implementation of new EHR-related policies. After new policies are implemented, user response should be carefully monitored and user feedback about the policy changes should be regularly solicited.

Lessons Learned

- Changes in EHR-related organizational policy can lead to unintended consequences.
- EHR-related policies can motivate users to work around or "game" the system.
- User responses to policy changes should be carefully monitored.

4. The physical or technical infrastructure interacts with the EHR (as used)

There is also a two-way interaction between the EHR (as used) and the IT and physical infrastructure. The example below highlights some of the problems that can emerge when attempting to integrate an EHR with other IT systems.

CASE EXAMPLE: **System Integration Problems***

Issues Encountered
After implementing an EHR, a small hospital discovered that test results from an outside lab were not being loaded properly into the EHR. Lab results were being attached to the wrong patient records. Additional interface problems between the EHR and the coding and billing systems also began to emerge, which prevented claims from being processed in a timely manner.

Finding a Solution
Local IT staff developed an algorithm, which mostly succeeded in resolving the mismatched lab results. However, monitoring and updating the efficacy of their homegrown solution is a major burden on local IT staff. The problems with the EHR/billing system interface arose immediately after implementation of the EHR system, and the problems typically reemerge after an update to the billing system. Again, local IT staff members have developed solutions to the problems; however, the interface needs to be reprogrammed and tested for each billing system update.

Lessons Learned
- Missing or scrambled lab, pharmacy, or financial data in the EHR are signs of poor system integration.
- Integrating your EHR with your other clinical and financial systems can be a challenging, expensive, and labor-intensive process.
- Updates to your EHR and other systems are frequent sources of unintended consequences.
- Choosing systems that have worked well together in other practices or facilities and thorough testing of system interfaces will help you avoid system integration problems.

*Source: This material was derived from responses to a membership survey about unintended consequences that the American Health Informatics Management Association (AHIMA) conducted in 2009. For further information, contact Spencer Jones at the RAND Corporation at sjones1@rand.org.

5. User reactions to EHR features may require redesign

Finally, sometimes actual use of the EHR diverges so dramatically from the original design that it becomes necessary to reconfigure some EHR features. The next example illustrates some options for reconfiguring the system when "alert fatigue" sets in.

 CASE EXAMPLE: **Responding to Alert Fatigue**[15,16]

Issues Encountered
EHR systems often include decision support functionalities such as drug-drug interaction, drug-dose, drug-lab, and contraindication alerting. Several studies have identified "alert fatigue" (choosing to ignore alerts) as a common condition amongst clinicians using EHRs with decision support.

Finding a Solution
A review of the relevant research literature found that the majority of alerts are overridden. Multiple remediation options are available. The first option would be to deactivate the alerts entirely. A more measured approach might be to convene a panel of local physicians to determine which alerts should be turned on. Perhaps the most successful approach identified in the literature is implementing tiered alerts (e.g., minor, moderate, severe). Shah and colleagues found that this kind of approach significantly increased the acceptance rate of decision support alerts.

Lessons Learned
- Interruptive decision support alerts can be a major source of user frustration and system inefficiency.
- Careful consideration should be given to the type and frequency of alerts that are included in decision support systems.

 USEFUL TOOL

Other Resources for Understanding Unintended Consequences: Several other researchers have proposed frameworks for understanding EHR-related unintended consequences, including Sittig's sociotechnical model for studying health information technology in complex adaptive health care systems (http://www.ncbi.nlm.nih.gov/pubmed/20959322), Henriksen's Human Factors Framework (http://www.ncbi.nlm.nih.gov/books/NBK2666/), Vincent's Framework for analyzing risk and safety in clinical medicine (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1112945/), and Carayon's SEIPS model (http://www.ncbi.nlm.nih.gov/pubmed/17142610).

Identify Unintended Consequences

How Do You Identify Emergent Unintended Consequences?

Identifying unintended consequences is the first step towards remediating them. It is important to have the capacity to detect unintended consequences as they emerge, and not just retrospectively.

In Module II, we suggested a set of usage metrics and a user survey that can be administered periodically to assess the users' experience and satisfaction with the EHR. These tools are designed for periodic retrospective assessment, but they are not likely to be as useful for rapid detection of emergent unintended consequences.

An "Issues Log" is a tool for identifying emergent unintended consequences. The Log can take many forms and vary widely in its level of sophistication. A basic Log is simply a repository for collecting information about problems related to the implementation and use of the EHR. The Log should not be just a repository for software glitches or malfunctions, or even a log of incidents or "near misses" (where problems with EHR-disrupted patient care could have resulted in patient harm). These items should certainly be recorded in the Log, but it should be more expansive and include reports of more subtle issues that could conceivably lead to problems in the future. For example:

"A physician complains that the templated clinical notes generated in the EHR are bloated and virtually unreadable because they are filled with auto generated text and text copied and pasted from other sources"

OR

"Nurses report that since installation of the EHR they have less opportunity to talk with physicians about how patients are responding to medications."

Capturing issues like these that could potentially be hazardous will help address them at an early stage **before** they become serious problems.

There are a several considerations involved in creating and maintaining an Issues Log:

1. **Who maintains the log?** This might be a vice president of the hospital, an associate chief medical officer, the office manager at a medical practice, the chief quality officer, the risk management department, or others. The important thing is that the designated person has the authority to act on the information. For it to be complete and helpful, the log must be unbiased—not censored or filtered (even unintentionally) in favor or against the institution, the vendor, those implementing the EHR, or by one user group in the institution or practice. It's also important to avoid assuming that problems noted in the log

typically result from "user errors," rather than design problems, unintended consequences, or other factors.

2. **Who reports problems to the log?** Encourage all end users (doctors, nurses, pharmacists, technicians) and IT staff to report problems encountered when setting up or using the EHR. More reports are better than fewer reports. You can always reject a frivolous report, but you can't act on a report you've never received. Collect all issues, problems, and unexpected situations from all sources. All problems—even problems that are clearly "user errors"— have consequences. If confidentiality or anonymity will increase the number of people reporting, then be sure to offer it and strictly abide by your offer.

3. **How is information collected for the log?** This depends on the size and resources of your organization. In smaller organizations the most effective means to collect reports may be through face-to-face conversations or an anonymous suggestion box. Larger organizations may have the resources to support a dedicated help desk or an anonymous web-based reporting system.

4. **What information is collected in the log?** The Issues Log should include a detailed description of the issue as well as information about potential risks that the issue poses or incidents that have occurred as a result of the issue. The Issues Log can also include information about the issue and corrective actions that should be taken.

 USEFUL TOOL

Issues Log Template: The Issues Log is a central repository of information about EHR-related unintended consequences. For an example of what an Issues Log might look like, go to http://www.healthit.gov/unintended-consequences/sites/default/files/issue-log.xls. Your organization may wish more or less functionality (for example, the ability to query, or allow users to submit issues via the Web). This template should be adapted and modified to meet the needs of your organization.

This module sought to deepen your understanding of unintended consequences and the complex interactions that cause them. The next module will build on your understanding of unintended consequences and provide you with more information that can help you identify root causes and remediate unintended consequences in your organization.

Module IV: Remediate Unintended Consequences

Module III provided tools and information to help you understand and identify unintended consequences. In this Module, we provide you with tools and information that will help you pinpoint the specific causes of your EHR-related problems and that will help you remediate them.

Assess the Problem

A systematic approach will help you pinpoint the underlying causes of the most difficult-to-diagnose EHR-related problems.

Question: How Do You Pinpoint The Causes Of Unintended Consequences?

In some cases the Issues Log may contain all the information you need to identify the root causes of your EHR-related problems. For example, problems that stem from software malfunctions are likely to be diagnosable based on the information collected in the Issues Log. However, issues that arise from interactions between the EHR and other components of the work environment or infrastructure will likely require further investigation.

Pinpointing the Causes of Difficult-to-Diagnose Problems

Below we outline several steps that you can take to identify the root causes of EHR-related problems that result from interactions between the EHR and other components of the work environment and infrastructure. The process outlined below relies on the ISTA framework described in Module III, and uses the first issue reported in the sample Issues Log (available at http://www.healthit.gov/unintended-consequences/sites/default/files/issue-log.xls) as a case in point.

Step 1 — Define the problem. This should be a fairly concise description of the problem. The description captured in the Issues Log should provide sufficient information to define the problem. For example the first issue (ID=1) in the sample Issues Log reads:

"CPOE calculated incorrect heparin dose. Dosing error was not identified and patient received an overdose of heparin"

Step 2 — Gather evidence. The Issues Log should contain valuable information about the problem (for example, when and where it occurred, and the potential causes and impacts of the problem.) The evidence collected in the Issues Log will help you formulate hypotheses about why the problem occurred. In the case of the heparin overdose, the Issues Log indicates the date and time when the event took place and notes that the problem was associated with clinicians working with the computerized physician order entry (CPOE) module of the EHR.

Additionally, ask those who were directly involved in the incident or those who have knowledge of the problem to describe what happened. Ask probing questions and follow up with

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more specific questions to ensure that you are able to focus on the root causes of the problem, rather than just the symptoms. The questions you ask will vary with the context and characteristics of the problem you are facing. Below is a "starter set" of questions that can help you formulate questions to identify the root causes of your EHR-related problems.

<table>
<tr><td>🛠 USEFUL TOOL</td></tr>
<tr><td>Identify Root Causes: For a list of questions that you can use or adapt to identify the root causes of your EHR-related problems, go to http://www.healthit.gov/unintended-consequences/sites/default/files/starter-set.xls. In addition, AHRQ has made information and tools related to conducting available through its patient safety network at http://psnet.ahrq.gov/primer.aspx?primerID=10.</td></tr>
</table>

Step 3 — Construct a timeline. Your efforts to gather evidence should yield an extensive list of potential causes. For problems that resulted from a series of events that occurred over time it may be helpful to construct a timeline. (For other types of problems, a cause and effect diagram might be more useful). Carrying forward the example of the heparin overdose in the ED, several potential causes emerged after a review of the Issues Log and interviews with those involved in the incident. Figure 4.1 presents a timeline of events that led up to the adverse event that resulted from the error in the EHR entry.

**Figure 4.1 Timeline of events that led to the heparin overdose in the ED**
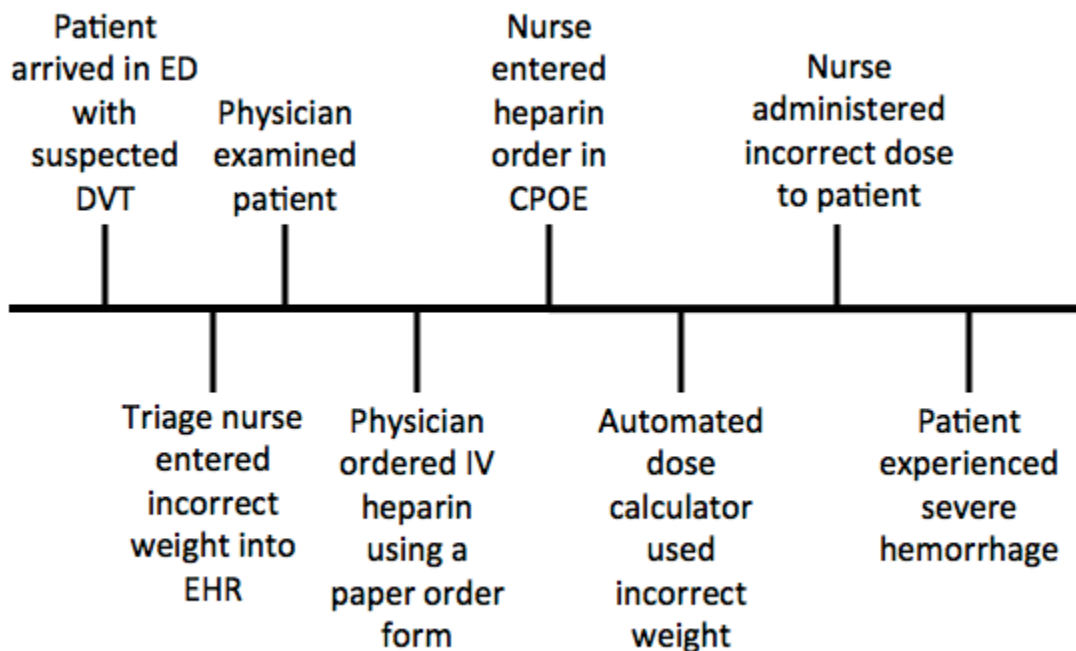
The timeline makes it possible to construct the chain of events that led to the adverse event. In this case a patient arrived at the ED with a suspected deep venous thrombosis (DVT). During

triage, the nurse entered an incorrect weight into the EHR. The physician did not notice the erroneous weight during her examination. Following the exam the physician used a paper form to place an order for heparin infusion. The paper form was picked up by the nurse, who entered the order via the EHR's integrated CPOE module. The system's automated dose calculator used the erroneous weight that was entered earlier to calculate the dose. This resulted in the system recommending a dose significantly higher than was appropriate for the patient. The nurse did not recognize the error and began the infusion using the CPOE recommended dose. Several hours later, the patient experienced severe hemorrhage.

Step 4 — Construct a cause and effect diagram: The cause and effect diagram is frequently used to classify the root causes of problems when many interacting factors are involved. Figure 4.2 illustrates an empty cause and effect diagram that is based on the ISTA framework in Figure 1. The cause and effect diagram consists of a horizontal line pointing to the unintended consequence, and four diagonal lines above or below the horizontal line that are each labeled with one of the ISTA interaction types:

- The EHR (as designed) interacts with the work environment.
- The EHR (as designed) interacts with the physical or technical infrastructure.
- The work environment interacts with the EHR (as used).
- The physical or technical infrastructure interacts with the EHR (as used).

**Figure 4.2 Example of an empty ISTA-based cause and effect diagram**
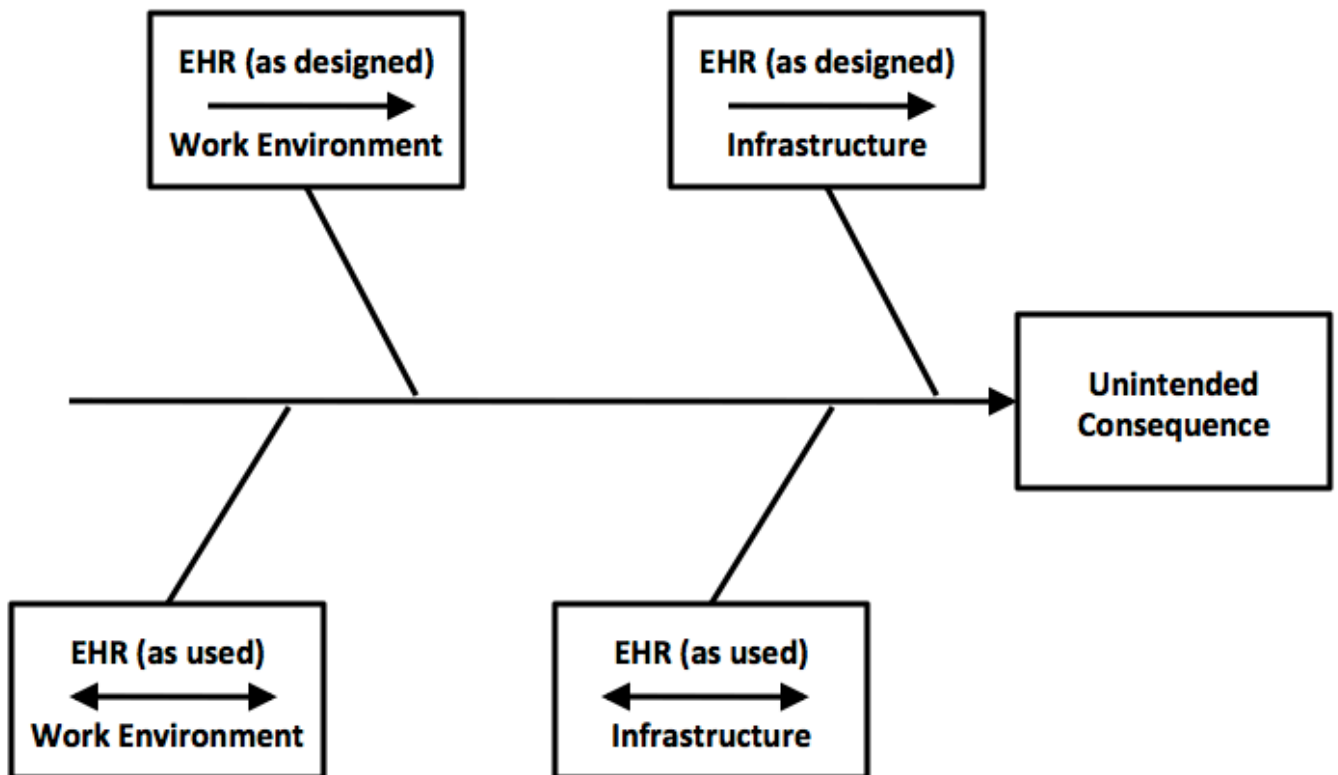
The cause and effect diagram can be used to graphically classify all of the potential root causes that were identified during your information gathering activities.

Turning back to the example from the Issues Log; the first potential cause of the adverse event in the ED was that a nurse entered an incorrect weight into the EHR during triage. This error was amplified when the system's automatic dose calculator used the previously entered weight to calculate the patient's heparin dose. At this point one might conclude that the adverse event was simply the result of a data entry error; however, the ISTA framework encourages further thought about what other factors might have contributed to this adverse event. For example, questioning those involved in the incident yielded several other potential causes of the adverse event:

- ED patient volumes have significantly increased; physicians and nurses often feel overwhelmed.
- Computerized order entry increases workload.
- Physicians were not mandated to use the order entry module.
- Paper-based order forms were still available in the ED.
- Physicians often had nonprescribers (nurses and clerks) enter orders.
- There was no policy or procedure that would ensure independent double checks on high-risk medications.
- Workstations were located in busy areas, where distractions were more likely to occur

All of the potential causes identified for the example case have been added to the cause and effect diagram displayed below. Each of the suspected causes has been assigned to one of the ISTA interaction types.

Figure 4.3 Example of a completed ISTA-based cause and effect diagram
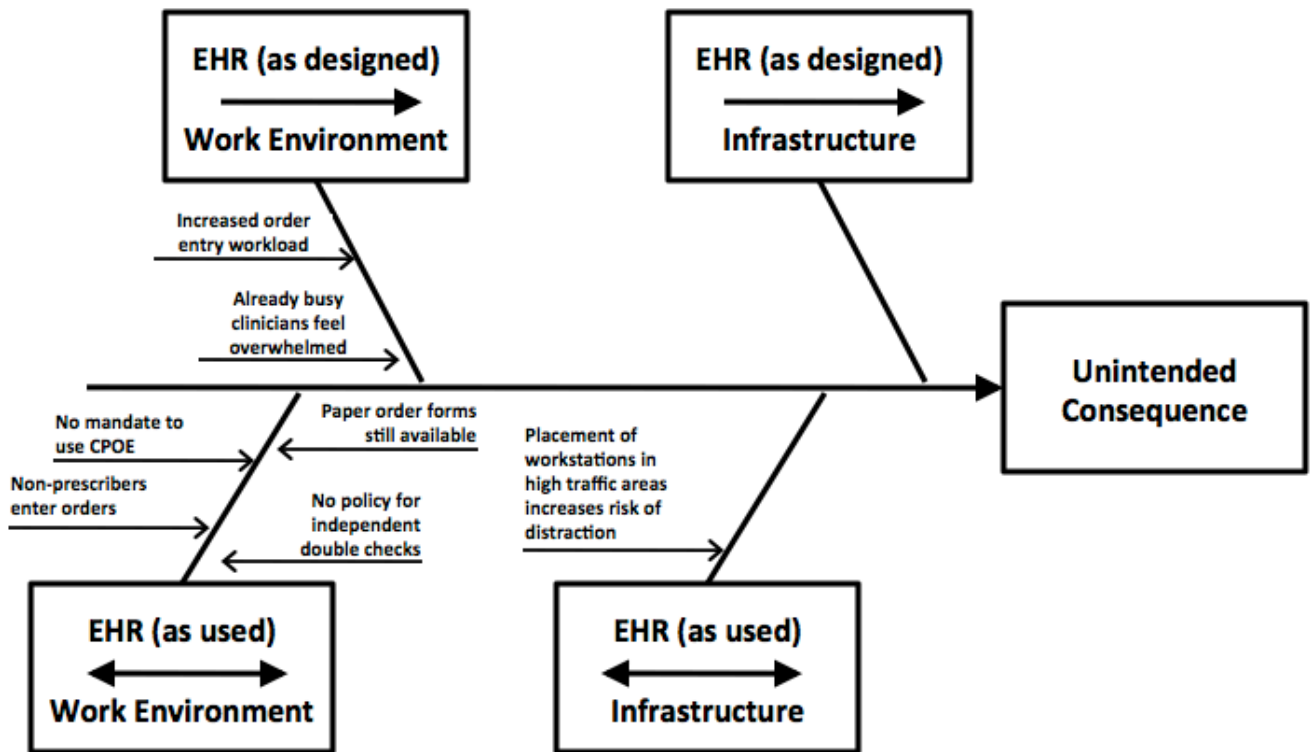
In this case it appears that CPOE in the ED created new work for an already busy ED physician. The physician's response was to exploit the lack of an appropriate organizational policy and find a way to work around the system (i.e., shift the order entry burden off to the nurses.) This workaround, combined with the nurse's overdependence on technology, made it possible for a relatively simple data entry error to be amplified into a serious adverse event.

Step 5 — Develop causal statements: The next step is to further refine the list of potential root causes illustrated on the cause and effect diagram. Developing a set of clear and concise causal statements will help you focus on the systemic vulnerabilities that led to the problem, and therefore help you design more targeted approaches to eliminating and managing similar problems in the future.

The National Center for Patient Safety (U.S. Department of Veterans Affairs) recommends five rules for developing usable causal statements:

1. Clearly show the cause and effect relationship. If you eliminate the root cause or contributing factor you will reduce the likelihood of similar problems occurring in the future.

2. Use specific and accurate descriptors for what occurred, rather than negative and vague words. Avoid words with non-specific negative connotations or that assign blame (e.g., careless, poor, sloppy, etc.)
3. Identify the preceding cause(s), not the human error. Focus on systemic vulnerabilities, not human error.
4. Identify the preceding cause(s) of procedure violations. Focus on the root causes, not the symptoms.
5. Failure to act is only causal when there is a pre-existing duty to act. In some cases the absence of policies and procedures is the root cause.
6. Based on the potential causes and contributing factors shown in Figure 4.3, we developed three causal statements for the heparin case.

Causal Statement 1: *High patient volumes and distractions in the Emergency Department increase the likelihood of data entry errors. In this case an erroneous weight was entered into the EHR during triage. The erroneous weight led to a miscalculation of the heparin infusion, which caused major bleeding.*

Causal Statement 2: *Some ED physicians feel that CPOE is slow and prefer to use paper prescription order forms. In this case a physician chose to use a paper order form and gave it to a nurse to enter into the CPOE. The nurse entered the order and the CPOE system recommended an inappropriate dose. The nurse did not recognize the error and initiated the heparin infusion, which caused major bleeding.*

Causal Statement 3: *Lack of a policy mandating independent double checks of high-risk medications increases the chance for error. In this case, a single nurse did not detect a dosing error and administered an excessive dose of heparin, which caused major bleeding.*

The causal statements should enable you to clearly articulate one or more root causes of your EHR-related problems.

Remediate the Problem

Prioritization and planning are necessary for effectively remediating your current EHR-related problems; extra care should be taken to ensure that corrective actions do not lead to other adverse unintended consequences.

Question 1: How Do You Identify and Prioritize Corrective Actions?

It's one thing to conduct the causal analysis, it's another to figure out when and how problems should be addressed. Corrective actions necessary to remediate EHR-related unintended consequences will vary across organizations; however corrective actions are likely to fall into one or more of the following broad categories:

1. Software Change
2. Training for Local IT Staff

3. Training for End Users
4. Configuration Change
5. Custom Programming
6. Care Process Change
7. Policy Change

Corrective actions should directly address the root causes outlined in the causal statements. Table 4.1 in the next section of Module IV provides a summary of causal statements accompanied by corrective actions for an illustrative case. In the toolbox below, we provide a link to a template that will allow you to keep track of your own causal statements and corrective actions.

USEFUL TOOL

Causal Statements and Corrective Actions: Download a Microsoft® Excel template for keeping track of your own Causal Statements and Corrective Actions at http://www.healthit.gov/unintended-consequences/sites/default/files/causal-statement.xls. In addition, consider the following factors as you prioritize corrective actions for unintended consequences.

Who is affected by the unintended consequence(s)?

- Clinicians
- Patients
- IT Staff
- Administrators
- Others (e.g., regulators, payers)
- All or some of the above

What issues does the unintended consequence create for them?

- Safety issue
- Quality issue
- Performance/productivity issue
- Financial issue
- Accounting issue
- Compliance/regulatory/legal issue

What types of activities or units are affected?

- Clinical
- IT
- Billing
- Ancillary services
- Facilities

What downstream processes are affected?

- Orders (ancillary services, medications, laboratory, radiology, referrals)
- Results (medication refills, laboratory, radiology, consults)
- Scheduling
- Billing/accounting
- Compliance reporting

How extensive are the effects?

- Limited — effects limited to a specific instance or specific activity
- Widespread — has recurring effects or affects several activities or entire departments
- Extremely widespread — affects many activities or departments

How serious are the effects?

- Not very
- Somewhat
- Serious
- Very serious

How urgent is remediation?

- Not very
- Somewhat
- Urgent
- Very urgent

Question 2: How Do You Develop a Plan To Remediate Unintended Consequences?

The earlier sections have primarily focused on identifying and understanding the root causes of unintended consequences. We have provided tools to help you identify corrective actions. However, these tools provide only high-level guidance for remediating unintended consequences.

Just as you need a careful plan for implementing an EHR, you should carefully plan any change in policy, processes, or technology designed to addresses an EHR-related problem. In this section we provide a tool you can use to develop a detailed plan for remediating unintended consequences.

Develop a Detailed Remediation Plan: The following template is adapted from the remediation planning process used at Kaiser Permanente of Colorado. This document is designed to help health care organizations of all types and sizes develop detailed plans for remediating unintended consequences. Download the remediation planning process plan at http://www.healthit.gov/unintended-consequences/sites/default/files/remediation-proposal-form.doc.

Track the Remediation Process

Monitoring the progress of your remediation plan will help ensure that you successfully resolve your EHR-related unintended consequences.

Question: How Do You Track the Progress of Your Remediation Plan?

The Issues Log can also be used to track the progress of your remediation plan. Table 4.1 provides an example of the tracking and remediation segment of the Issues Log. The tracking and remediation segment includes five columns.

Table 4.1 Example of tracking fields from the issues log

Corrective Actions	Steps taken to date	Assigned To	Date Assigned	Progress
Evaluate measures to reduce distractions while using the EHR. Removing Paper order forms from the ED within the month. Mandating MD CPOE use starting 6/12/2011. Providing 5 CPOE training sessions between the removal of the paper forms and the implementation of the CPOE mandate. Up staffing the ED for a month after the mandate and deskside support during peak ED hrs	3 of 5 CPOE training sessions conducted	CMIO	01/16/2011	On Track

In the Corrective Actions field (of Table 4.1), you can enter the plans outlined in your Remediation Plan (available at http://www.healthit.gov/unintended-consequences/sites/default/files/remediation-proposal-form.doc) or in the Causal Statements and Corrective Actions form available at http://www.healthit.gov/unintended-consequences/sites/default/files/causal-statement.xls.

In the Steps Taken to Date field, you can enter a brief overview of the parts of the remediation plan that have been carried out thus far.

In the Assigned to, Date Assigned, and Progress fields, you can indicate the person or group responsible for executing the remediation plan, the date they were given responsibility for remediating the issue, and whether or not the remediation is behind schedule, on track, or ahead of schedule.

Simply keeping tabs on and regularly evaluating the progress of your remediation plan will help ensure that your objectives are met.

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Appendix A: Glossary

A

Agency for Healthcare Research and Quality — AHRQ

>AHRQ's mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. The Agency has focused its health IT activities on the following three goals: (1) to improve health care decisionmaking; (2) to support patient-centered care; and (3) to improve the quality and safety of medication management. To address the mission, AHRQ has invested over $300 million in contracts and grants to over 200 communities, hospitals, providers, and health care systems in 48 States to promote access to and encourage the adoption of health IT.

Alert fatigue

>A commonly observed condition among physicians overwhelmed with large numbers of clinically insignificant alerts, thus causing them to "tune out" and potentially miss an important drug-drug or drug allergy alert.

Adverse drug event — ADE

>An injury resulting from the use of a drug.

B

There are no entries for this letter.

C

Cause and effect diagram

>A tool that can be used to graphically classify all potential root causes.

Clinical decision support — CDS

>Computer tools or applications to assist physicians in clinical decisions by providing evidence-based knowledge in the context of patient-specific data. Typically a decision support system responds to "triggers" or "flags" — specific diagnoses, laboratory results, medication choices, or complex combinations of such parameters — and provides information or recommendations directly relevant to a specific patient encounter.

Computerized physician order entry — CPOE

>A computer application that allows a physician's orders for diagnostic and treatment services (such as medications, laboratory, and other tests) to be entered electronically, instead of being recorded on order sheets or prescription pads. The computer compares the order against standards for dosing, checks for allergies or interactions with other medications, and warns the physician about potential problems.

D

There are no entries for this letter.

E

Early adopter

An organization or individual who embraces new technology or administrative practices before others typically do.

Electronic health record — EHR

A real-time patient health record with access to evidence-based decision-support tools that can be used to aid clinicians in decision making. The EHR can automate and streamline a clinician's workflow, ensuring that all clinical information is communicated. It can also prevent delays in response that result in gaps in care. The EHR can also support the collection of data for uses other than clinical care, such as billing, quality management, outcome reporting, and public health disease surveillance and reporting. EHR is sometimes used interchangeably with EMR (electronic medical record).

E-prescribe — electronic prescribing — eRX

A type of computer technology whereby physicians use handheld or personal computer devices to review drug and formulary coverage and to transmit prescriptions to a printer or to a local pharmacy. E-prescribing software can be integrated into existing clinical information systems to allow physician access to patient-specific information to screen for drug interactions and allergies.

F

Failure modes and effects analysis — FMEA

A widely-used risk assessment technique for identifying, prioritizing and fixing potential system failures before an adverse event actually occurs. Because FMEA is prospective — rather than retrospective — it focuses on systems rather than events. A common process used to prospectively identify error risk within a particular process.

Functionality

A set of capabilities associated with computer hardware, software or other electronic devices.

G

There are no entries for this letter.

H

Health information technology — HIT

The application of information processing involving both computer hardware and software that deals with the storage, retrieval, sharing, and use of health care information, data, and knowledge for communication and decision making. Applications of health IT include the electronic health record (EHR), the personal health record (PHR), computerized physician order entry (CPOE), and clinical decision support (CDS). In addition, health information exchanges (HIEs) are being developed to support sharing of information electronically among health care providers.

THe HITECH Act

The Health Information Technology for Economic and Clinical Health Act, signed into law on February 17, 2009, as a part of the American Recovery and Reinvestment Act (ARRA), amended the Public Health Service Act to codify the Office of the National Coordinator for Health Information Technology (ONC), required the national coordinator to establish a governance mechanism for a nationwide health information network (NIHN), and required the national coordinator to establish a voluntary program to certify health IT.

Through HITECH, Congress also amended the Social Security Act to pay incentive payments to hospitals and physicians to promote adoption and use of certified health IT technologies. It also reduces payments for those who are not meaningful EHR users, beginning in 2015.

I

Interface

Hardware or software that facilitates interaction between disparate components of a system.

Issues log

A tool for collecting information about problems related to EHR implementation that is useful in identifying emergent unintended consequences and in supporting corrective action.

Interactive socio-technical analysis — ISTA

A framework developed for understanding interactions among technology, physical behavior, and the work environment that lead to unintended consequences

J

There are no entries for this letter.

K

There are no entries for this letter.

L

Legacy IT

An existing health IT application or system that is in place when new IT is installed and may represent a significant prior investment. Compatibility with legacy IT is a major issue when considering acquisition of new applications or software.

M

Meaningful use

Requirements for obtaining certification and incentives for EHR usage, specified by the Department of Health and Human Services under the HITECH Act of 2009. See information provided by CMS about the Federal EHR incentive program at http://www.cms.gov/EHRIncentivePrograms/30_Meaningful_Use.asp.

Medicare and Medicaid EHR incentive programs

As a part of the HITECH Act of 2009, Congress created programs within Medicare and Medicaid to pay incentive payments to hospitals and physicians to promote adoption and use of certified health IT. Beginning in 2015, this program reduces payments for those who are not meaningful EHR users.

Multiple causation

When a combination (or alternative combinations) of causes are responsible for an outcome.

N

Near miss

An event or situation that did not produce patient injury, but only because of chance. This good fortune might reflect robustness of the patient (e.g., a patient with penicillin allergy

receives penicillin, but has no reaction) or a fortuitous, timely intervention (e.g., a nurse happens to realize that a physician wrote an order in the wrong chart).

O

Office of the National Coordinator for Health Information Technology — ONC

The principal Federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. The position of National Coordinator was created in 2004, through an Executive Order, and legislatively mandated in the HITECH Act of 2009.

P

Process mapping

A technique for making a graphic representation of work. It shows decisions, event sequences, and wait times or delays. A process map shows who is doing what, with whom, when, and for how long.

Q

There are no entries for this letter.

R

Readiness assessment

A tool designed to help organizations assess whether they are ready to undertake organization-wide practice or culture changes.

Regional Extension Center — REC

The Office of the National Coordinator for Health Information Technology (ONC), under the HITECH Act, has funded regional extension centers to provide technical assistance, guidance, and information on best practices to support and accelerate health care providers' efforts to become meaningful users of electronic health records (EHRs). The regional centers will support at least 100,000 primary care providers, through participating non-profit organizations, in achieving meaningful use of EHRs and enabling nationwide health information exchange.

Remediation plan

Plan for addressing a specific unintended consequence of EHR implementation.

Root cause analysis — RCA

A structured method used to analyze serious adverse events. The goal of RCA is to identify both active errors (errors occurring at the point of interface between humans and a complex system) and latent errors (the hidden problems within health care systems that contribute to adverse events).

S

System error

An error attributable to a combination of causes rather than to a single point of failure or a single individual.

T

There are no entries for this letter.

U

Unintended consequence

Unanticipated and unwanted effect of health IT implementation.

Usage metric

Measure for tracking the frequency and manner in which an EHR is used.

User interface

The display of computer information and the processes required to view and input information. How users must interact with the computer program.

V

There are no entries for this letter.

W

Workaround

An informal practice or temporary fix used by frontline heath care workers to deal with a perceived block or disruption to the normal work flow (for example, when personnel find ways of bypassing safety features of medical equipment).

Workflow analysis/workflow assessment

A process used to systematically analyze and evaluate how work tasks are accomplished.

X

There are no entries for this letter.

Y

There are no entries for this letter.

Z

There are no entries for this letter.