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*Anticipating Unintended Consequences of Health Information Technology and Health Information Exchange*

# The Role of Health IT Developers in Improving Patient Safety in High Reliability Organizations

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## Introduction

Health information technology (IT) has the potential to reduce and prevent health care hazards. When designed and implemented correctly health IT can dramatically improve patient safety in health care. As health IT systems continue to be rapidly adopted, both health care organizations and health IT development companies (health IT developers) must understand their roles in optimizing the safety and safe use of these systems. Even a well-designed health IT system has the potential to introduce new patient safety hazards if adoption, implementation, use, and maintenance are not optimized.[1,2] Close partnerships between health care organizations and health IT developers are essential to patient safety.

This paper will discuss the ways health IT and health IT developers can support health care organizations' efforts to become safer and more reliable. Like companies in other high-risk industries, such as aviation, nuclear power, and the military, health care organizations are striving to become high reliability organizations (HROs), characterized by high levels of safety under inherently risky, technologically complex, and demanding conditions.[3] Health IT has the potential to play a key role in a health care organization's journey to becoming an HRO and health IT developers support is critical to realizing this potential.

This paper provides a brief background on HROs from a system safety perspective, describes the impact that health IT can have on safety, and discusses how health IT developers can support health care organizations on their path to high reliability. To help health IT developers understand how they can partner with health care organizations to provide patients with the safest care possible, this paper describes specific examples, nested within the high-level HRO characteristics of leadership, a culture of safety, and robust process improvement.

## High Reliability Organizations

Patient safety is a long-recognized problem in health care that has received significant attention since the publication of the frequently cited Institute of Medicine report *To Err is Human.*[4] More recent evidence has shown that up to one-third of hospital admissions have an associated adverse event, a number ten times higher than previously reported.[4,5] Despite a significant effort by the health care community over the last decade to improve patient safety, there has been no significant improvement overall.[6–8]

The slow progress in patient safety has been attributed to several factors, including the complexity of the health care system and the focus on attributing blame to individuals. Other high-risk industries (aviation, military, and nuclear energy) have made significant improvements in safety despite their complexity. They have done this not by eliminating errors, which are inevitable, but by conscientious efforts to ensure that errors do not lead to harm. For example, recent evidence has shown that commercial airline pilots and air traffic controllers make approximately two errors for every hour flown, yet U.S. air travel is extremely safe.

These complex industries, with potentially catastrophic safety concerns, do not focus on blaming individuals when errors occur. Rather, these industries have adopted a *system safety approach,* which

optimizes safety by identifying and reducing hazards that can lead to harm.[10] These resilient industries are designed to prevent errors from leading to serious safety events. Health care organizations that aspire to become high reliability organizations are beginning to adopt the same system safety approach used in high reliability industries.[9]

## Key Characteristics of HROs

Health IT developers that understand the characteristics of HROs can support health care organizations as they strive to become HROs. HROs have key characteristics that this guide discusses in three areas: leadership, a culture of safety, and robust process improvement.[9] Each of these characteristics has elements that are important for health care organizations and health IT developers to understand and address.

### Leadership

Safety must be a top priority for a health care organization's leadership, including the governing authority and executive leadership. HROs must be committed to patient safety, including optimizing the safety and safe use of health IT and using health IT to improve care and patient safety. Important elements of leadership include:

- **Organizational commitment.** In HROs, leaders are clearly committed to safety and this commitment is consistently demonstrated through their day-to-day operational and organizational decisions. In HROs, this commitment is regularly communicated and is incorporated into organizational structures, such as board and management committee charters and job descriptions. Commitment is demonstrated through leadership activities so that everyone understands patient safety is a priority.
- **Dedicated resources.** HROs dedicate adequate resources to continuous progress on the path to high reliability. This includes providing the necessary personnel and a technology support infrastructure to ensure health IT is safe and is used safely. Health IT is seen as a resource that can be used to improve patient safety.
- **Monitoring and Oversight.** Leadership in HROs routinely monitors and oversees patient safety. In particular, leadership focuses on high-risk areas within their organization where change, , such as the introduction of complex health IT systems, can be expected to introduce new hazards. In HROs, monitoring by leadership, within the context of a culture of safety, is used to drive continuous attention to improvements in safety.

## Culture of Safety

HROs develop a culture of safety that is centered on recognition and reporting of potential safety threats. A culture of safety includes:

- **Collective mindfulness.** In a culture of safety, everyone in an organization, including crucial technology partners, understands and accepts that safety is their personal responsibility as well as a collective and shared responsibility. There is a clear understanding that small irregularities, hazards, or errors may lead to serious safety events and that each individual has a unique perspective and opportunity to notice these sources of potential harm.[9] Everyone in the organization is expected to remain mindful of potential hazards and respect insights provided by others.
- **Reporting.** HROs have reporting processes in place to track serious safety events, hazards, unsafe conditions, and small irregularities in process. The reporting systems direct attention to removing or mitigating aspects of the health care environment that could lead to errors and adverse events. HROs establish processes that make it easy and safe to report and that ensure reports are addressed, with follow-up.
- **Just culture.** HROs understand that errors are normal and unavoidable in any organization that involves people, especially in inherently risky and technologically complex health care settings. Overwhelmingly, these errors are unintended. Blaming good staff for unintentional errors does not improve patient safety; it undermines a culture of safety. Just culture recognizes that you do not improve safety by blaming staff for errors.[11] Instead HROs focus on removing hazards that contribute to errors and building care processes, including use of technology, so that errors are caught before they harm patients. Once individuals no longer worry about being blamed and potentially disciplined for unintentional errors and once the staff and leadership see errors as opportunities to identify and remove hazards, becoming an HRO can be more easily accomplished. Frontline clinical staff become willing to report hazards without fear of reprimand and the staff become empowered when leadership responds to their reports. Safety across the system can be greatly improved through just culture.

## Robust Process Improvement

HROs are continuously engaged in identifying process improvements and developing effective solutions to mitigate hazards. Such process improvements might include:

- **High reliability teams.** In complex systems, multiple factors impact quality and safety. HROs in healthcare create high reliability teams composed of individuals who can identify and address potential problems from multiple perspectives, including the complex social and technical factors surrounding health IT. Robust process improvement by high reliability teams can also be supported by external, independent safety organizations that have expertise in change management and risk management techniques. High reliability teams and the outside safety organizations that support them need technical expertise and practical experience in implementing and using health IT safely to improve patient safety.

- **Resilience engineering.** HROs employ system safety engineering principles to anticipate where hazards may arise and to develop processes and design changes to address these potential threats. This includes looking at processes that are successfully executed to understand why processes are working well.

## Impact of Health IT on Health Care Organizations Becoming HROs

Health IT and health IT developers can help health care organizations become HROs. For example, if used effectively, health IT can improve safety by providing decision support to clinicians during the care process, assisting providers avoid missed diagnoses, and improving compliance with evidence-based medicine. Similarly, reminders within an electronic health record (EHR) system and barcoding can help prevent medication errors, the common errors that lead to patient harm.

Health IT can also introduce hazards. For example, wrong patient selection errors might occur in computerized provider order entry (CPOE) systems, where the clinician selects the wrong patient and places an order that was intended for a different patient. This may occur due to juxtaposition issues, where there is minimal margin of error for selecting a patient or medication from a list, and a 1-pixel distance means the difference between a correct or incorrect order.[12] Poorly designed layouts can also contribute to wrong-sided orders for procedures or surgeries; this can happen when laterality is listed in a vertical orientation and must be selected from a list instead of in anatomic orientation. Other examples include errors of omission, such as forgetting to order a test or navigating away from the ordering screen before completing the order by signing it. To aid in understanding the types of health IT hazards, researchers have begun to broadly define categories of errors,[13] including:

- Inadequate data transfer from one health IT system to another
- Data entry in the wrong patient record
- Incorrect data entry in the patient record
- Failure of the health IT system to function as intended
- Configuration of the system in a way that can lead to mistakes

Health care organizations need help from their health IT developer partners as they work to predict, identify, and address these hazards associated with health IT systems. In order for health care organizations to reach their full potential as HROs, health IT developers must embrace shared responsibility for the safety and safe use of health IT and ultimately for patient safety.

## Role of Health IT Developers in Helping Clients Become HROs

The role that health IT developers play in supporting health care organizations on their path to high reliability may take many forms and will be unique to each health care organization. Just as health IT developers understand that clients have different needs when it comes to health IT products, developers need to understand that health care organizations have different needs when it comes to becoming an HRO.

## Responsibility of Health IT Developers

Health IT must be carefully integrated into health care organizations to avoid introducing new safety hazards and to support health care organizations' transition to high reliability. The safe integration of health IT to the existing work domain is significantly impacted by the developer's technology design, but it is also impacted by the choices made during implementation and post-implementation use of that technology. Three major stakeholders – the health IT developers, the leadership and administration[i] within the health care organizations, and the end users – share responsibility for the safe and successful development, implementation, and use of health IT.

## What Can Health IT Developers Do to Support High Reliability Organizations?

Health IT developers have the most extensive expertise in the technical aspects of their products as well as the implementation and use of their products and services across many organizations. Developers should leverage this expertise, with a focus on patient safety, when they support their clients' adoption, implementation, and use of health IT. To do this, developers can build on the foundations of HROs described above, by supporting leadership, helping to create a culture of safety, facilitating robust process improvements, and sharing best practices already learned from existing installations. Some specific practices that could help are suggested below.

## Support Leadership

- **Organizational commitment.** Health IT developers should be committed to supporting the leadership of their client health care organizations on the path to becoming HROs. This commitment should be a high priority for the health IT developer and should clearly be expressed to their client health care organizations. Embracing and acting on the Electronic Health Record Association's Code of Conduct is one way to demonstrate this commitment. The commitment should be demonstrated early in the relationship and sustained throughout the lifecycle of the health IT product.
- **Dedicated resources.** Health care organizations require adequate resources dedicated to the safety and safe use of health IT as they strive to become HROs. This means, among other things, adequate personnel and infrastructure support for pre-implementation planning, implementation, immediate post implementation, and ongoing maintenance. Health IT developers can provide personnel and infrastructure support in several ways:[ii]
  - *Clinical IT staff support.* Clinical IT staff within health care organizations often lack the deep understanding of a health IT system that the health IT developers

[i] As part of the leadership and administration of the health care provider, clinical IT staff are critical to implementation and maintenance of health IT.

[ii] There are likely to be differences between vendor health IT systems that are server-based and locally hosted, as compared with cloud-based systems. The important guideline is that dedicated resources must be provided to support the health care organization.

have. They will require assistance when addressing technical issues related to safe implementation and use of the health IT developer's technology. Health IT developers can directly support clinical IT staff by providing necessary training, certifying clinical IT staff members, identifying support staff from the health IT developer organization who work with the clinical IT staff, and having health IT developer experts as part of the clinical IT staff team responsible for optimizing the safe use of health IT to improve patient safety.

Health IT developers can also help clinical IT staff learn about industry-wide standards and incorporate these standards into the clinical IT staff's practices.

- ***End-user training.*** The users of health IT systems require training to ensure safe and effective use. Training is resource-intensive and health IT developers can reduce the costs and improve the quality of training by providing standardized training materials and experienced trainers to their clients. End-user training will not end after initial implementation, but will continue as part of efforts to optimize the safe and effective use of health IT functionality.
- ***Implementation resources.*** Implementation periods (which include implementation of clinically significant updates and upgrades) are critical times for identifying and mitigating safety hazards associated with use of health IT. Most health IT developers have extensive implementation experience and can provide guidance to the leadership and staff of health care organizations on critical safety issues leading up to and during the implementation process. Health IT developers can provide materials, such as checklists, testing procedures, work flow assessments, and training manuals and videos, that help health care organizations identify and avoid safety hazards before and during implementation. They can also help health care organizations use those materials.

- **Monitoring and Oversight.** Health IT developers can help the leadership of health care organizations monitor and oversee safe implementation and use of health IT by providing resources, such as measures of critical areas for safety and benchmark data that may allow organizations to compare themselves to other similar organizations. Health IT developers often have access to health IT usage data or other information that could be analyzed in real time, or retrospectively, to examine hazardous conditions. These data and analyses should be shared with health care organizations to allow for proactive identification of potential hazardous conditions. In addition, health IT systems (particularly EHR systems) should have methods for clinicians to easily report hazards and the results of such reports should be monitored by leadership.

***Recommendations to Support Leadership***

1. *Health IT developers should be committed to supporting the leadership of their client health care organizations throughout the lifecycle of the health IT product.*
2. *Health IT developers can support their clients' clinical IT staff by providing training, certifying clinical IT staff members, and fostering connections between the health IT developer support staff and the clinical IT staff.*
3. *Health IT developers can offer end-user training, both at initial implementation and on an ongoing basis, to optimize the safe and effective use of health IT functionality.*
4. *Health IT developers can use their extensive implementation experience to provide guidance, such as checklists, testing procedures, work flow assessments, and training manuals and videos, on critical safety issues leading up to and during the implementation process.*
5. *Health IT developers can provide information based on their access to health IT usage data, such as measures of critical areas for safety and benchmark data, so that organizations can evaluate their performance on health IT-related safety benchmarks over time and compare themselves to other similar organizations.*

## Facilitate a Culture of Safety

- **Collective mindfulness.** Health IT developers can be active participants in promoting both individual and collective responsibility for patient safety, including collective mindfulness of the potential of health IT to dramatically improve patient safety if implemented and used properly. Health IT developers can foster collective mindfulness about the impact of health IT on patient safety in several ways:
  - *Share information across organizations.* Health IT developers are uniquely positioned to observe common issues across multiple organizations. This information can be shared across organizations to improve awareness of potential hazards and to mitigate many health IT-related hazards. Health IT developers should do this proactively during design and implementation and should communicate with organizations regarding hazards with installed systems.
  - *Maintain collective mindfulness within the health IT developer organization.* The developer's organizational culture should emphasize commitment to safe use of health IT and to continuously improving patient safety. Each person within the health IT developer organization should be expected to remain mindful of potential hazards and to reduce those hazards. This could include sharing stories, within the developer organization, about how the developer's health IT is being used to improve patient safety and how individuals have identified ways to optimize the safety and safe use of the developer's health IT products and services.
- *Reporting.* Health IT can support health care organizations as they encourage their staff to identify and report hazards and adverse events. Doing so in a standard format allows aggregation and systematic analysis of reports both within organizations and across health care organizations through safety organizations. AHRQ has developed a standard format for hazard reporting called the Common Formats, including a specific format for health IT and devices.[14] The Common Formats can be supplemented by

other standardized reporting programs. Health IT developers should facilitate reporting using standardized methods, including the Common Formats. This might include:

- Automated methods for users to document safety hazards and adverse events through the health IT interface to reduce the burden of reporting;
- Methods to easily capture and report relevant information (including screen shots) surrounding a hazard or event to provide needed context; and
- A means for both the person submitting the report and risk management staff to track the report through the risk management process.

- **Just culture.** As part of a just culture, it is important for health IT developers to be responsive to the needs of the health care organization. It is often easy for the health care organization to blame the developer and the developer to blame the health care organization for safety issues that may arise. All stakeholders should strive to avoid blame and should focus on improving patient safety as a team. Health IT developers should work with health care organizations on implementing a written protocol for resolving concerns about the safety and safe use of health IT, consistent with just culture philosophy. By embracing an approach to patient safety based on just culture, health IT developers should focus on systematic reduction of hazards associated with the design, configuration, and use of health IT. Likewise, health care organizations must recognize that health IT developers are important partners on the path to high reliability, and should seek to work with developers as partners.

***Recommendations to Facilitate a Culture of Safety***

6. *Health IT developers can proactively share common issues across multiple organizations to improve awareness of potential hazards and to allow mitigation of hazards.*
7. *Health IT developers should promote an organizational culture that emphasizes commitment to safe use of health IT and to continuously improving patient safety using health IT.*
8. *Health IT developers should encourage their staff and their clients' staff to report hazards and adverse events and should facilitate such reporting using standardized methods such as the AHRQ Common Formats.*
9. *Health IT developers can work with their client health care organizations to implement written protocols for resolving concerns about the safety and safe use of health IT, consistent with a just culture philosophy which avoids blame.*

## Facilitate Robust Process Improvement

Many health care organizations have resources dedicated to patient safety and quality improvement. However, health care organizations may not have the expertise to recognize and address potential health IT-related hazards. Health care organizations will require developer support to implement robust process improvements.[9]

- **High reliability teams.** High reliability teams are most effective when they include a diverse set of experts from multiple disciplines. Health IT developers have an active role to play on health IT safety teams, given the unique expertise and valuable insight that developers can offer. Health IT developer involvement is particularly important when

health care organizations perform self-assessments of their readiness for health IT since developers are often familiar with the characteristics that make for a successful EHR implementation and use. The Office of the National Coordinator for Health Information Technology has supported the development of Safety Assurance Factors for EHR Resilience (SAFER) Guides.[iii] These guides provide a method for health care organizations to assess their practices to optimize the safety and safe use of EHRs. Many of the recommended practices in the SAFER Guides require the expertise of health IT developers during assessment and implementation phases.

Robust process improvement may also involve working with independent, outside safety organizations that provide support on safety-related change management and risk mitigation to high reliability teams. These safety organizations supplement the work of high reliability teams within HROs. The technical complexity of health IT in clinically complex health care environments poses new challenges to these safety organizations. They need the expertise and insights that health IT developers have as they develop resources and programs to avoid hazards and mitigate risks associated with health IT and to use health IT to improve patient safety. Health IT developers should establish relationships and collaborate with organizations dedicated to patient safety, including working with professional associations, patient safety organizations (PSOs), accrediting organizations (such as the Joint Commission), risk management organizations,[iv] and nonprofit organizations dedicated to improving patient safety.

- **Resilience engineering.** Health IT developers can support health care organizations by contributing to the organizations' resilience engineering processes to continuously identify and avoid safety hazards. Health IT developers can be involved in several ways:

  - ***User-centered design process.*** Health IT developers should employ a rigorous user-centered design (UCD) process to build a resilient health IT system that prevents errors from reaching patients. The UCD process should be integrated with the development cycles to ensure that users are engaged throughout development of the product. Through iterative design and testing, health IT developers should identify where safety issues may arise and redesign the system to avoid hazards. This includes assisting their clients in avoiding configuration and interface hazards. Further, testing should be conducted to examine how the developer's health IT interacts with other technology in a realistic environment. UCD should be a process that is employed not just during initial product design and development, but also during version improvements and updates.

  - ***Proactive identification and mitigation of hazards.*** Health IT developers should establish a method to actively monitor the health IT system at each of their client sites. The monitoring of health IT systems by the health IT developer and health care provider, and the reporting of hazards by the end users, provides the opportunity to identify existing hazardous conditions and to anticipate where hazardous conditions may arise. Health IT developers should use these data to drive future development, usability testing, and product refinement.

[iii] The SAFER Guides are available on the ONC website at http://www.healthit.gov/policy-researchers-implementers/safer (as of January 28, 2014).

[iv] This includes organizations such as the American Society for Healthcare Risk Management (ASHRM) and the American Health Lawyers Association.

– ***Responsive client support.*** Health IT developers should commit to work effectively and promptly with clients to reduce hazards associated with health IT use, concentrating in areas that have been longstanding, high risk safety challenges, such as medication errors and missed lab results. Health IT developers should implement policies and procedures that promptly warn their clients of safety issues, including issues with software design, interfaces with other products, and configuration/customization issues. Health IT developers should ensure that their client support and complaint processes are effective in supporting their health care client's safety processes. This is particularly important during critical safety periods in the lifecycle of health IT adoption, such as implementation, new version release, and downtime periods.

***Recommendations to Facilitate Robust Process Improvement***

10. *Health IT developers can identify individuals within their organizations who serve as representatives to health IT safety teams within client health care organizations and participate in health IT safety assessments, such as using ONC's Safety Assurance Factors for EHR Resilience (SAFER) Guides.*
11. *Health IT developers can establish relationships and collaborate with organizations dedicated to patient safety, including working with professional associations, patient safety organizations, accrediting organizations (such as the Joint Commission), risk management organizations, and other organizations dedicated to improving patient safety.*
12. *Health IT developers should employ a rigorous user-centered design process to build a resilient health IT system that prevents errors from harming patients.*
13. *Health IT developers should use iterative design and testing to identify where safety issues may arise and redesign the system to avoid the issues.*
14. *Health IT developers should conduct testing in a realistic environment to examine how the developer's health IT interacts with other technology.*
15. *Health IT developers should establish a method to actively monitor the health IT system at each of their client sites and to use these data to drive future development, usability testing, and product refinement.*
16. *Health IT developers should commit to work effectively and promptly with clients to reduce hazards associated with health IT use, concentrating in areas that have been longstanding, high risk safety challenges, such as medication errors and missed lab results.*
17. *Health IT developers should implement policies and procedures that promptly warn their clients of safety issues, including issues with software design, interfaces with other products, and configuration/customization issues.*
18. *Health IT developers should ensure that their client support and complaint processes are effective in supporting their health care client's safety processes.*

## Conclusion

Patient safety is a fundamental value and commitment of health care organizations. Many health care organizations are striving for safer care by leveraging a system safety approach, and are on the path to becoming HROs. As health care organizations increasingly adopt health IT, they need the understanding and support of health IT developers to ensure that health IT reduces hazards and improves patient care as an integral, foundational part of a high reliability patient safety program.

By understanding the elements of HROs and the system safety approach, health IT developers will be better equipped to support health care organizations on their path to high reliability. Although there are several ways to support health care organizations, health IT developers need to determine the individual needs of each health care organization in order to provide the right type of support. The health IT safety support can build on existing health IT developer-client support structures and on the safety-enhanced design practices that they already have in place. Ultimately, health IT developers and everyone involved in health IT-enabled health care delivery systems must take responsibility for optimizing the safety and safe use of health IT and for using health IT to make care safer, as they strive together on the path toward high reliability.

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