



A Clinically Integrated Outcomes Strategy for Health Systems Globally

Dr. Anne Snowdon RN, PhD, FAAN

Director of Clinical Research
HIMSS Analytics



Overview

Introduction	02
<hr/>	
The Prevalence of Medical Error and Adverse Events	04
<hr/>	
Factors that Contribute to Error	07
<hr/>	
Achieving Safe Health Systems	17
<hr/>	
The Clinically Integrated Supply Chain Strategy	22
<hr/>	
Summary	31

Introduction



While quality and safety have been the fundamental goals of all global healthcare systems from both a patient and a provider perspective, performance of North American healthcare systems remains far behind that of other OECD countries, ranking ninth for Canada and 11th for the United States (U.S.) compared to the other 11 countries in the OECD group.¹ Despite many well-funded initiatives to strengthen quality and safety, healthcare systems worldwide have not experienced significant improvement in these core areas. Patient safety is a particular challenge despite more than two decades of research and safety initiatives to define the problem, at both a country and global level. Medical error, a core element of patient safety, has now become the third leading cause of death in North

America, behind heart disease and cancer.^{2,3,4} Although there is growing awareness of the challenge of patient safety, there has been little evidence of improvement in the increasing rates of deaths and serious injury related to error and adverse events. Moreover, although the prevalence of adverse events and safety challenges has been widely reported related to hospital care, it is not well documented in community and long-term care settings. As Rafter³ identifies: “Patient-safety experts should question why, after 30 years, there has been so little evidence of overall improvement.” Not only are adverse events, particularly those that are preventable, devastating for patients and their families; they are very costly to the patient, to the organization and to the healthcare system.

Introduction

The purpose of this paper is to propose a strategy for addressing the seemingly intractable challenge of patient safety and the growing rates of death and injury associated with adverse events in healthcare systems. We first examine the occurrence of adverse events in healthcare across global jurisdictions to consider the magnitude and prevalence of this challenge. Lessons from other sectors, such as grocery, retail, airlines, banking and automotive, demonstrate how highly transparent systems that track and trace people, processes and products can be translated and applied to the health sector to advance safety and reduce error. We then reframe the challenge of patient safety in healthcare systems from one focused on types and rates of error, towards one that examines the features of health system environments that are able to measure the risk of error proactively, and enable clinicians to intervene to ensure the delivery of safe care.

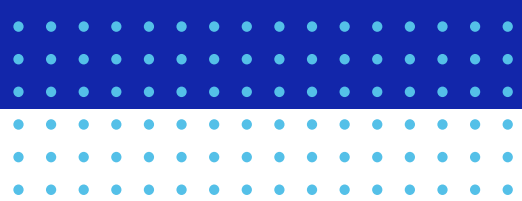
The term “transparency” in this paper is defined as *the ability to see or be seen; the quality or state of being known to the public, to providers, health system leaders and funders.*

It is a key strategy that not only offers healthcare systems greater clarity and accountability to the public they serve, but also guides how digital infrastructure in clinical settings can strengthen safety outcomes across health systems. The concept of transparency is an important strategy that provides the opportunity to strengthen system outcomes, create transparency for patients, provider teams, healthcare leaders, industry teams and the general public.

Finally, the paper examines the value proposition of restructuring clinical environments for health sector stakeholders including patients, providers, healthcare institutions, industry partners and health system funders and regulators. Ultimately, transforming clinical environments to adopt highly transparent supply chain tools and strategies will create environments for patients and practitioners that are safe and effective, and that make it nearly impossible for adverse events to take place.

The Prevalence of Medical Error and Adverse Events

The Growing Prevalence of Adverse Events and Medical Error in Healthcare Systems



Patient safety first emerged as a key health system priority almost two decades ago in 1999, when the Institute of Medicine published the seminal report, *To Err is Human*.⁵ Since then, many subsequent studies have reported on the prevalence of adverse events. Adverse events are defined as unintended injuries resulting from care processes or medical management, rather than from disease processes, that result in serious impairment, disability or death for patients.⁵

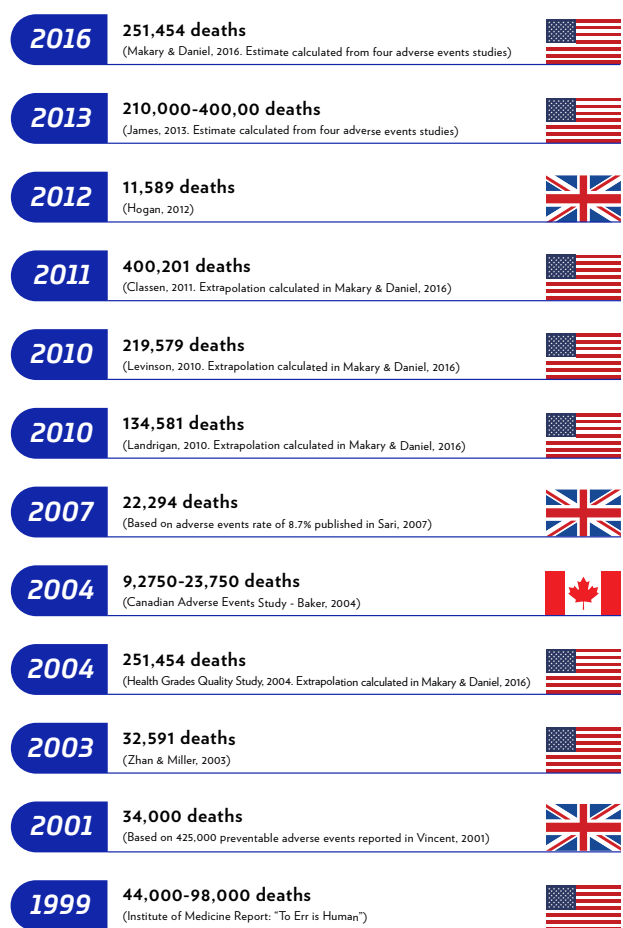
The Institute of Medicine report was the first to try to quantify the scope of the issue. It was estimated that 44,000 to 98,000 people die each year in U.S. hospitals due to potentially preventable adverse events.⁵ In the United Kingdom (UK), the report *An Organisation with a Memory* (2000) found that every year, 850,000 patients admitted to hospital in the National Health System (NHS) experienced an adverse event.⁶ The report further estimated that 60,000 to 255,000 cases (10.8% of patients admitted to hospital) resulted in permanent disability or death annually due to adverse events, nearly half of which (46%) were deemed preventable.⁷

Similar findings have emerged in Canadian studies. The Canadian Adverse Events Study revealed that patients experienced harm from adverse events at a rate of 7.5% of hospitalizations,⁸ with 36.9% of these events considered highly preventable. These findings revealed that 23,000 people annually (or 63 Canadians every day), *die* as a result of *preventable* adverse events.* More recently, a study by the Canadian Institute for Health Information identified that 1 in 18 patients admitted to hospital experience one or more adverse events.

More than two decades of research has provided evidence of the high rates of preventable deaths, demonstrating the growing prevalence of adverse events affecting thousands upon thousands of patients worldwide. Figure 1 illustrates a sample of studies that have reported the prevalence of deaths related to adverse events. These published studies are from Canada, the US and Britain from 1999 to 2016. All of these studies focus on rates of preventable deaths in hospital settings. There has been remarkably little focus on rates of preventable deaths or injury in other healthcare settings, such as long-term care or community-based care.

Of particular note is the most recent study by Makary and colleagues,² which estimates that 251,454 people experience preventable deaths every year in the U.S. This translates into 688 deaths every day in the U.S. health system. To put this figure into perspective, this is equivalent to two jumbo jet plane crashes every day. What is overwhelmingly clear is that adverse events are preventable, yet they continue to result in the deaths of far too many people within the U.S., Canada and the UK, among many other countries.

There are quite a few additional studies on patient safety outcomes (far too many to list), all of which provide growing evidence of the magnitude of the problem facing healthcare systems. While reports have made a variety of recommendations to achieve safer outcomes in healthcare, the rates of adverse events remain unchanged. If anything, deaths due to adverse events are growing over time, as healthcare services become more complex and patients experience increasing health challenges due to growing rates of multiple comorbidities. What is particularly notable is that this growing prevalence of



error is common across many global jurisdictions; no health system jurisdiction has “cracked the code” in terms of reducing preventable health errors.

The majority of these reports have focused their research efforts only on adverse events in hospital settings. What may be more alarming are the rates of error that are not captured in these reports—deaths and harm experienced by patients in the community (home care, long-term care, complex care and rehabilitation settings), whether from prescription drug errors, falls, neglected or incorrect diagnoses, and nursing home or community agency errors. These errors are less often captured or described in the current patient safety literature. Although there is limited evidence of adverse events in home care, long-term care or other community settings, the rates of adverse events suggest they are as high, if not higher, in these settings. Specifically, the rate of adverse events in the Canadian Adverse Events Study⁸ was estimated at 7.5% of hospital admissions; in the Canadian Patient Safety Institute’s Safety in Home Care study, the rate of error for 2009 was 13.31%,¹⁷ nearly double the rate in hospitals.

Figure 1: Preventable Deaths Due to Adverse Events,* 1999–2016

(Sources:^{5,7-16}) *The definition of adverse events varies across studies

Causes of Death, U.S., 2013

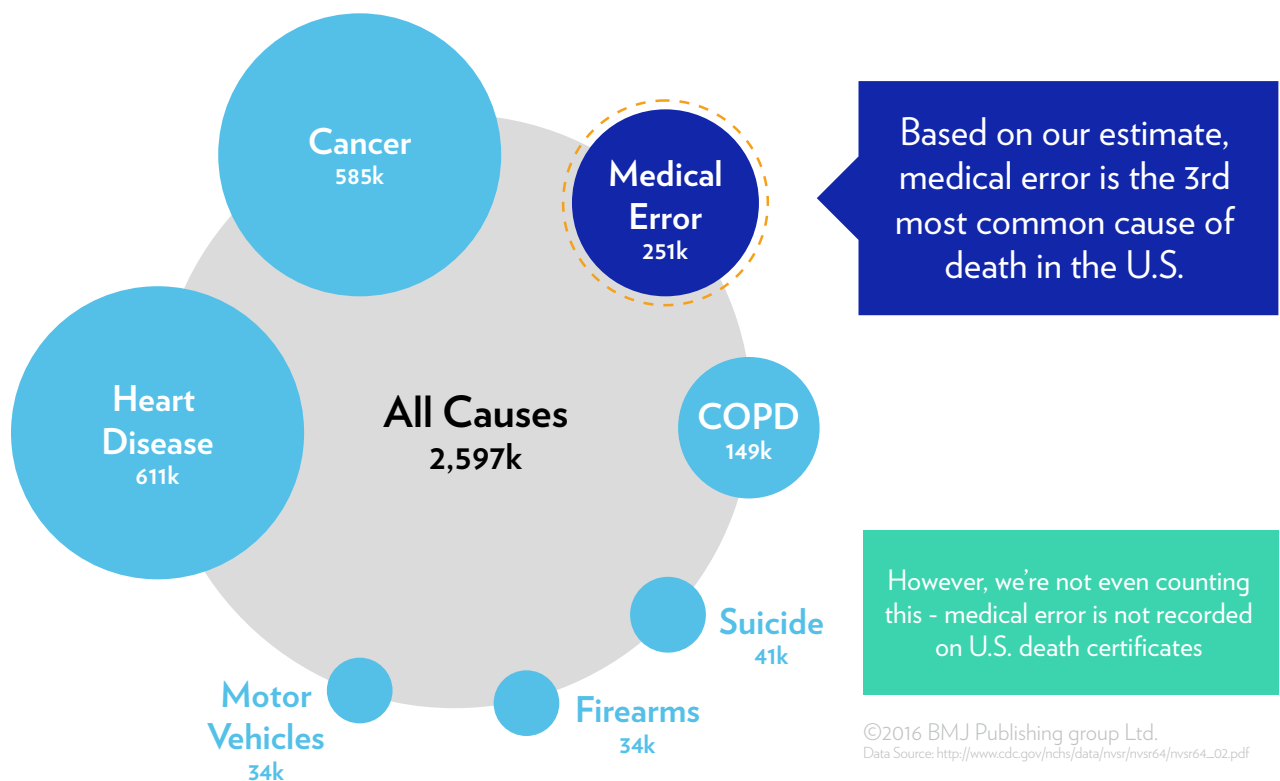


Figure 2: Causes of Death in the U.S.

In hospital settings there may be much more substantive documentation of care processes and adverse events than there exists for home, primary care and community care settings. The current estimates of adverse events are only able to capture adverse events recorded in patient charts, and these events are known to be under-reported as much as two-thirds of the time.¹⁸ Thus, not only are the rates and prevalence of reported adverse events growing; these estimates of patient harm or death may very well be only the “tip of the iceberg.” Nevertheless, the prevalence of death due to adverse events is now so high that it is reported to be the third leading cause of mortality in North America. This can be seen in Figure 2 as adverse events are third only to cancer and heart disease as causes of death⁴ (Figure 2).

In addition to research documenting the prevalence of adverse events in healthcare systems, there has been decades of research on how to improve safety in healthcare. The emergence of patient safety organizations (such as the Canadian Patient Safety Institute) following the early Institute of Medicine report and the Canadian Adverse Events Study, has resulted in a focus on safety education and awareness, and promoting a safety culture in clinical settings. Although these are very important steps in addressing patient safety challenges, we propose building on this work to focus on how the clinical environment infrastructure can be transformed by leveraging digital tools for tracking and traceability. Such direct support would enable clinical teams and administrative processes to reduce adverse events in healthcare settings.

Factors that Contribute to Error

Challenges in Current Health System Environments

There are at least four challenges in current health system environments that are contributing to the growing rates of adverse events and rising patient safety concerns.

01

EMRs are not Enough: Digital Infrastructure must Enable Clinicians to Proactively Manage the Risk of Adverse Events

There is very little “line of sight” or “transparency” in most health systems, one of the key conditions that contribute to adverse events. Although many health organizations have adopted electronic medical records (EMRs), EMR platforms are not designed to offer tracking and traceability of patient care outcomes in real-time. The tracking and tracing of outcomes allow clinicians to be alerted to potential risk of error. Specifically, when a patient is admitted to hospital, an electronic record is created for the patient and clinicians report their assessments and care processes in this digital record. The EMR is a data collection tool that creates a digital record of every patient’s care. EMR technologies are able to support retrospective studies or analyses by searching EMR data for key indicators of safety and then downloading these indicators into a database for further analyses, often used when conducting clinical trial research.

Current EMRs are not able to proactively analyze patient data at the point of care, and then signal clinicians if care processes are placing patients at risk (e.g. wrong patient, or wrong care procedure). EMRs are not designed to conduct analysis to inform clinician decisions. The major contribution of EMRs to date has been to digitize patient and hospital data which then enables researchers and quality and safety teams to conduct studies to advance and improve patient safety. The challenge remains to adopt digital tools able to analyze patient and care data in real-time, and then signal clinician teams of situations which are high risk to patients. Advanced analytics are needed (e.g. machine learning, artificial intelligence tools) to proactively track care processes and then cue clinicians when there is evidence of risk to enable preventive interventions that can mitigate the risk of adverse events. To date, in most countries, there is limited progress in adoption of digital infrastructure to evaluate the risk of adverse event outcomes for patients and then alert health system leaders to enable reduction in the risk of adverse outcomes for patients.¹

Registry infrastructure in the UK has shown significant risk reduction for populations by analyzing patterns or trends in adverse outcomes across patient populations. As registry data is analyzed, early evidence of poor outcomes of care procedures (e.g. joint replacement surgery) are identified, and then appropriate alerts are communicated to health organizations in order to prevent harm to thousands of patients if exposed to risk over prolonged periods of time.²⁷ Early warnings based on registry data analysis are advancing quality and safety outcomes, however a number of patients experience harm before clinicians are notified of the risks for future patients. Currently, there is little capacity to track and trace individual patients, care processes and product use across organizations, regions or jurisdictions to enable health systems to learn and disseminate data on care processes that work best for patients, and under what conditions best outcomes are achieved.

In stark contrast to the health sector, the majority of business sectors employ advanced supply chain infrastructure in their day-to-day operations, with embedded digital tools and technology that track processes to support high quality and safety across the organization. The tracking and tracing of products, processes and people creates transparency in these highly advanced systems, and the “ability to see and be known” to system stakeholders. This transparency creates strategic value that enables the entire system to measure the effectiveness, efficiency, performance and value of every step of the business process. For example, the retail and grocery sectors have sophisticated supply chain infrastructure systems able to track every food item from the farm it was harvested, to the home of the consumer who purchased the product. In the event of a food item being contaminated and potentially causing harm to consumers, alerts are issued and products are immediately removed from the store shelves and customers are alerted. ***There is no such system in health care.***

If digital technologies for health systems could be strengthened to identify individual patients and products used in care processes in near real-time, linked to the patient’s EMR to enable double-checking accuracy and effectiveness of care, then staff and clinical teams could apply their unique expertise and experience to identify and implement strategies to prevent adverse events. Such tracking tools could also enable and inform accountability structures to support quality and safety of patient care, ensuring that clinical teams are effectively managing safety and risk to protect patients. The potential to proactively identify risk for individual patients using automated tools at the point of care can be harnessed only if clinical environments provide clinician teams with the necessary digital infrastructure to enable complete transparency and traceability of care processes. An example of progress is the U.S. Food and Drug Administration (FDA) policy which monitors product recalls, whereby health plans and health systems are required to notify patients about the recalled device or implant. Currently, all medical devices are mandated to have Unique Device Identification (UDI). Although there has been progress in the U.S., the speed with which these notifications occur is limited; in some cases, recalled devices are still used for patient care because the notifications did not reach the providers quickly enough for them to retire products and thus protect their patient populations.¹⁹

02

Inadequate Reporting of Adverse Events: “You Can’t Manage What You Don’t Measure”

Healthcare systems have focused substantial effort on measuring utilization of services such as the number of annual emergency department visits, surgical wait times, patients’ experience and outpatient procedure wait times, which are tracked and reported publicly in most healthcare systems in North America and around the world. These same measures are captured in global performance rankings such as those published annually by the Commonwealth Fund.

The well-known phrase, “You can’t manage what you don’t measure,” captures one of the most substantial challenges related to health systems and contributes to limited progress in patient safety. After more than 20 years of research and best practice in patient safety, there remains a reliance on chart reviews and retrospective reporting to monitor adverse events, primarily in hospital settings.

Health system stakeholders use retrospective chart reviews to gather data to understand root causes of adverse events such as medication errors or falls. The key word here is “retrospective;” health teams rely on learning about adverse events after they have happened. The current evidence profiled in all of the patient safety studies identified (Figure 1) relies solely on estimates of adverse events in hospitals using retrospective chart

review data. This approach presents two significant challenges.

One challenge is the lack of evidence of the prevalence or root cause of adverse events in clinical settings such as primary care, long-term care or home care when adverse event outcomes (e.g., surgical infections) are most likely to be identified. Thus, provider teams or health system leaders have limited ability to prevent adverse events when they are not measured, reported or shared from one clinical setting to another.

A second challenge is the reliance on chart review methodology to determine the nature and prevalence of adverse events. While chart reviews are important to capture root cause analysis, this is a limited approach to day-to-day tracking, measuring and reporting of adverse events, compared to enabling clinicians to intervene effectively to prevent such events from happening during patient care. The advent of patient safety organizations (PSOs) has made important progress in providing the infrastructure for reporting, aggregating and disseminating safety information, yet adverse event reporting relies on providers to complete adverse event reports either manually, or by entering the adverse event information into the patient’s EMR. These retrospective reports do not capture details related to products and patients that are necessary to support root cause analysis across jurisdictions and healthcare organizations using automated tools and analytics.²⁰

Tragically, by the time evidence of the rates and types of errors or adverse events is published in empirical research, there are hundreds, if not thousands, of deaths (or preventable events leading to serious harm or death) across healthcare systems. For example, in the U.S., if a manufacturer receives an adverse event report, it is required to send the report to the FDA, as specified by that agency's regulations.²¹ The following excerpt from the UK illustrates the magnitude of the challenge of adverse event reporting for just one classification of healthcare products—joint implant devices:



When failures take a long time to develop, many faulty products can enter the market. In the case of the ASR and metal-on-metal implants it took 4–5 years before evidence was accumulated and reported. We are left with more than 500,000 patients with metal-on-metal prostheses in the USA and more than 40,000 in the UK who are at elevated risk of device failure, which will inevitably result in the burden of further surgical treatment as well as billions of dollars in costs to taxpayers.”²

To date, we can find no evidence of healthcare systems that have adopted and scaled digital infrastructure tools that offer clinically integrated tracking and traceability to document the risks to patients in near real-time, to inform clinician decisions to help prevent adverse events. Thus, clinician teams are unable to identify the risk of preventable events on their own clinical units, or across their organizations, and intervene quickly enough to prevent additional, similar events. Simply put, clinical teams cannot adequately address or prevent adverse events when they have no ability to measure them, accurately and objectively. If clinicians have no line of sight towards how, when and why these events happen, then there is little chance in determining what key changes in the clinical processes need to be addressed to prevent such events from recurring.

There can be no impactful strategy for reducing harm to patients due to error if clinical teams have no digital infrastructure capable of measuring adverse events that is flexible enough to enable them to prevent such events for future patients.

Traditional efforts to detect adverse events have focused on voluntary reporting and tracking of errors. However, researchers have established that only 10% to 20% of errors are ever reported and, of those, 90% to 95% cause no harm to patients, suggesting harmful adverse events are less frequently reported.²²

Hospitals need a more effective way to identify events that do cause harm to patients in order to quantify the degree and severity of harm, and to advance harm reduction strategies.³⁰ Community care settings need to develop adverse event reporting tools to support clinical teams to identify adverse event prevalence and severity across the continuum of care. Tracking adverse events over time is a useful measurement strategy to document whether changes being made are improving the safety of care processes. The Institute of Health Information has developed The IHI Global Trigger Tool for Measuring Adverse

Events to provide an easy-to-use method for accurately identifying and measuring the rate of such events over time. The Trigger Tool methodology relies on a retrospective review of a random sample of patient records using “triggers” (or clues) to identify possible adverse events.²³ Although the IHI tool offers an opportunity to better capture adverse events, it may also place additional burden on clinicians to complete the chart review data collection and to analyze outcomes that, in any case, offer limited scalability across entire health systems to advance patient safety outcomes.

The critical safety challenges in health systems today is the lack of transparency across healthcare systems regarding where, why or when adverse events happen, and very limited evidence to support clinicians in designing and testing prevention strategies to reduce the prevalence and impact of such devastating events for patients and families.

03

Lack of Standardization in Adverse Event Reporting Across Systems

Another infrastructure challenge in healthcare is the lack of standardization in adverse event reporting. Current adverse event reporting systems are predominantly focused on events in hospitals, with limited reporting in other settings, and no standardization of reporting across healthcare systems. In addition, reporting structures and systems vary widely and are not standardized, nor are they universal in terms of identifying processes, products or patient situations and outcomes. Summative adverse event reports are rare and do not account for the events, processes and products used in clinical care for patients across organizations or settings. The outcome of this lack of standardized reporting is that information cannot be shared across organizations and global healthcare systems.

One contributing factor associated with lack of standardization is that adverse events are typically reported by clinicians who most often manually complete an adverse event report (structured uniquely in each organization), either paper-based or online, to describe the events and the outcomes experienced by the affected patient and family. Adverse events are typically submitted to senior leaders in the organization responsible for patient safety. Although organizations are increasingly (but by no means universally) using electronic adverse event reporting systems, the lack of global standards for reporting has

resulted in a dearth of detailed information on products or care transactions that contribute to objective accounts of adverse event outcomes.

Given the limitations of current reporting, there are few opportunities for learning from error or adverse events across systems or organizations. The complexity of healthcare varies widely, as do the clinical environments and policy structures that underpin the operations of healthcare systems. However, dynamic reporting tools could enable clinical teams, particularly those working in highly specialized settings, to respond more rapidly and make changes in clinical processes that would decrease the risk of adverse events; but the current system offers few sources of systematic and objective evidence to support such learning. Similarly, there are no sources of patient-level information to assist manufacturers in informing the design and development of the next generation of products and technologies. As a result, all health system stakeholders (policy makers, clinicians and provider teams, manufacturers, regulation agencies) rely primarily on published research data describing rates and types of adverse events—sometimes years after the events have taken place—in order to learn about the magnitude and seriousness of safety events.

Another limitation is that few system-level adverse event outcomes are reported publicly by healthcare



systems. The UK has taken the bold move of publicly reporting safety and effectiveness of health services delivery, posted routinely on public websites,²⁵ to inform the population of safety and performance right down to the level of individual clinics or organizations. Such public accountability may be one reason that the UK is ranked first among all OECD countries in health system performance. The NHS has also made substantial investments in health system infrastructure to create the tools for use in clinical environments to track and trace patients, care procedures and processes, as well as products used in clinical settings. The NHS system has not yet linked traceability of processes and products to patient outcomes or safety events; however, they are well positioned to do so. The U.S. has implemented hospital rankings in the Hospital Compare reports on the Web and also has sites for nursing homes and other medical services, with physicians due to be ranked soon.²⁴ However, the information provides only high-level details on patient safety (for example, it identifies mortality rate as a ranking either above or below the national average) to assist patients and families in making informed decisions about accessing care services at these organizations.

To date, despite significant numbers of people experiencing harm or death due to adverse events, the public and other healthcare system stakeholders remain largely unaware of the nature of adverse events, their root causes and the environments in which they occur most frequently. The lack of internal reporting within organizations (such as hospitals) means there is no opportunity for learning across clinical units, organizations or healthcare systems. In the U.S., although there is greater uptake of digital technologies for reporting, substantial barriers to dissemination exist, related to challenges of legal liability and physician resistance.²⁶ We could find very few examples of external reporting strategies made publicly available so that consumers and taxpayers can better understand the nature of health system outcomes such as error or adverse events. There are few “scorecards” specifically for adverse events reporting that would provide incentives for healthcare organizations to implement safety tracking, tracing and reporting in clinical environments. Although many organizational performance scorecards contain safety indicators, there is no comparability across organizations owing to lack of standardization and insufficient detail to inform health system leaders on how best to improve patient safety across health systems and regional jurisdictions. In addition, because of the lack of public reporting, healthcare organizations are not able to identify and learn from the evidence of error in the system.

04

Outcomes of Healthcare Environments: The Emergence of “Never Events”

There are some adverse events that should just never happen in healthcare, when “never actually means never.” For example, a patient should never get the wrong medication that results in permanent harm or death. A patient should never receive the wrong surgery, such as replacing a healthy right hip instead of an arthritic left hip or placing a new lens in a healthy eye rather than the one that has the cataract. Figure 3 illustrates the number and diverse types of adverse events.

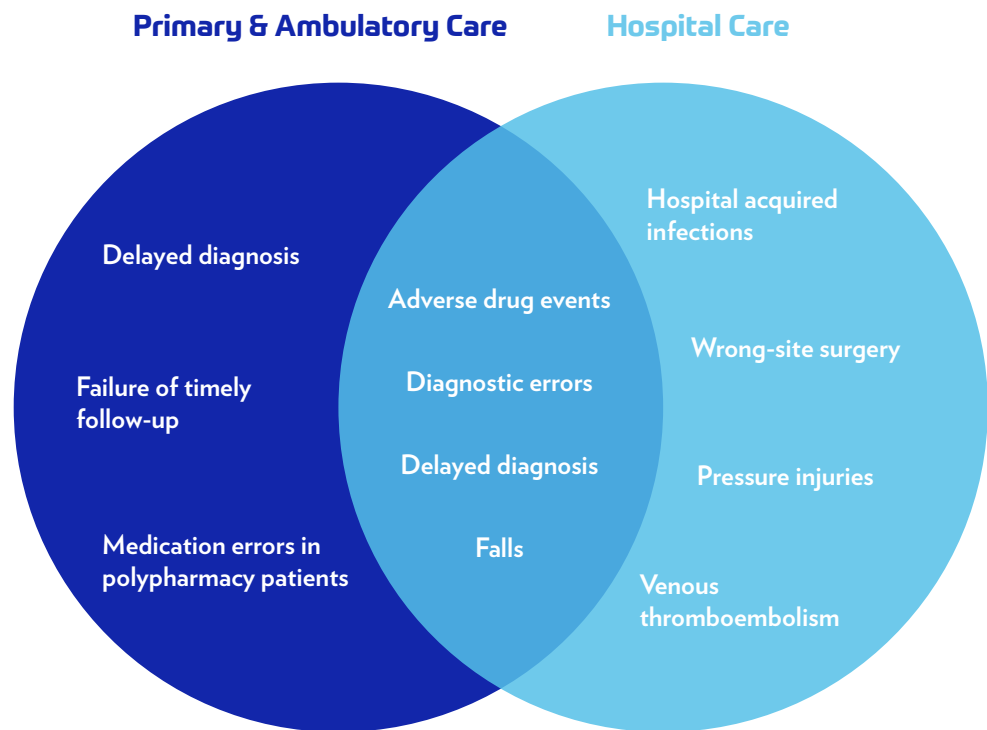
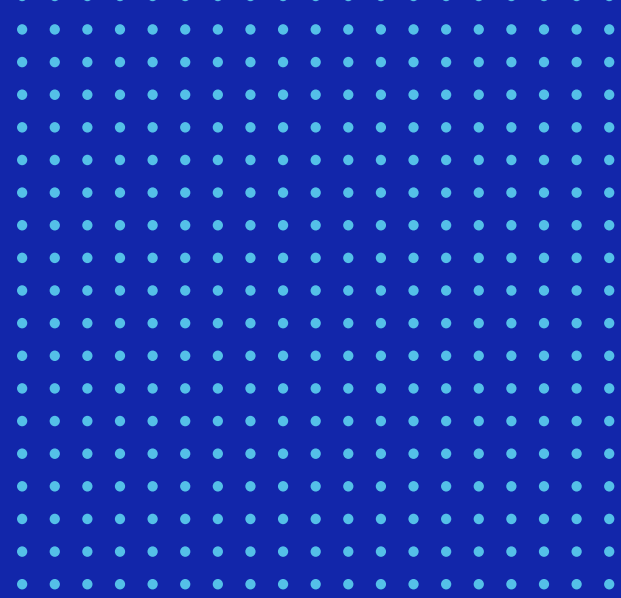
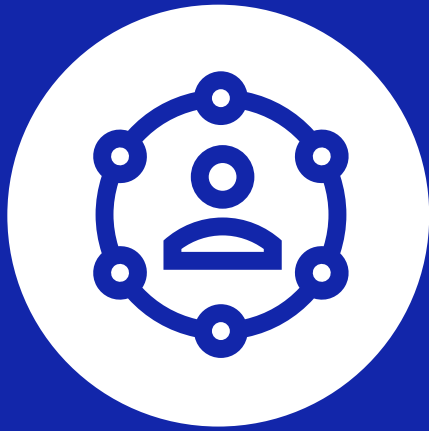


Figure 3: OECD Examples of Never Events

(Sławomirski, L. Aaraaen, A. Klazinga, N. 2017)

Never events have now emerged in the U.S., the UK and Canada as the most devastating adverse events that cause significant harm. They are defined as “patient safety incidents that result in serious patient harm or death and are considered preventable using organizational checks and balances.”²⁸ Never events may be the emerging “canary in the coal mine” that further illustrates the inadequacies of the clinical environment in supporting safe and effective clinical care for every patient.



In order to eradicate never events, health system environments require dynamic capturing of data, analysis and reporting of health system processes to proactively alert clinical teams to situations that are high risk for adverse events that have devastating outcomes for patients. Rethinking and redesigning the digital tools and processes of clinical environments, similar to advanced supply chain infrastructure in other sectors (e.g. grocery, food, manufacturing) that have been so successful, would offer a new approach to achieving safer patient care. Nearly every other business sector in the world has a well-developed digital infrastructure to advance supply chain traceability and transparency, a strategic asset that contributes directly to ensuring the safety of their products and services through highly transparent supply chain infrastructure. Business leaders have significant expertise in supply chain strategy, whereas health system leaders lack this expertise. The time has come for healthcare to learn from these other business sectors, leverage the existing knowledge of best practice translated for the healthcare context, and implement the infrastructure tools already in use in other sectors. There is emerging evidence that transforming digital infrastructure in healthcare environments can have a positive and lasting impact on protecting patients and delivering safe and effective healthcare.

05

Health System Environments: The Need for Digital Infrastructure to Create Transparency

There is a need for digital tools that offer transparency at the point of care to capture care delivery processes (e.g. scanning products at the point of care) making it possible for clinician teams to identify and proactively manage risks to improve safety outcomes. When products, or pharmaceuticals, are used and captured at the point of care, the data is entered into a patient's EMR to create a record of the care procedure. The EMR is often thought of as able to support safety and quality based on the fact that if clinical processes are recorded or captured digitally, then patient information would be more easily accessible by clinicians to inform their decisions and to adequately assess patient safety. Although the EMR can digitally capture and collect clinical care data points, it cannot analyze data to identify risks, or link data to outcomes to enable traceability. In order to advance quality and safety of patient care, the healthcare system must mobilize the EMR data, analyze it to identify risk, identify safety outcomes or risks, and then communicate to clinician teams so that they can address the risks and intervene to ensure patients are safe.

Currently, clinical environments have no “back up check list” or tools to identify gaps in information. As an example, pilots in the cockpit use a check list to double-check all systems are working on the plane. There is no such “double-check” in clinical systems to ensure the EMR data is fact-checked against other sources of data, such as the patient and family history, and other clinicians that may be involved in the case. EMRs need to be used in

conjunction with the automatic tracking and tracing of products and information. In addition, EMRs are not always seamlessly interoperable with all other technologies in hospitals. Most hospitals today have well over 30-40 different software/technology platforms, hand-held devices, and smart phones, all of various ages and stages of development. The EMR can work perfectly, but not be interoperable with the pharmacy software, the Enterprise Resource Management Program (ERP), or the doctors' order (CPOE) software. A clinically integrated supply chain strategy connects all of the data sources across the health system, tracks data for every patient, and then uses predictive tools to identify possible error or risks. A system at this level of sophistication is required to advance automated cues to clinicians who can then manage or improve patient safety. EMRs are only one part of an integrated system with all of the other technologies and data sources. When implemented most efficiently, this system would result in a seamless, integrated data infrastructure that makes it much less likely, maybe impossible, for errors to happen or for failure to rescue situations to occur. It means that the EMR data is mobilized, and tracked, and the use of predictive tools are embedded in the system to cue the clinician when an error could happen. Think of the airline travel. The boarding pass scanning is a system that identifies the passenger, links it to the reservation to make sure the right passenger is on the right plane, going to the right destination. If the wrong passenger is scanned, a big red X shows up on the screen to prevent the passenger from getting on the plane. If it is the correct person, then a big green checkmark appears as the double-check. We have no such system in healthcare. We need a clinically integrated supply chain strategy to increase the safety and quality of care for patients.

Achieving Safe Health Systems

Where to Begin? Current Features of the Health System Supply Chain

Healthcare is a highly complex system that delivers a wide range of specialized, knowledge-intensive services to patients (Figure 4). In order to deliver this wide range of services, healthcare systems procure tens of thousands of products, from medications to devices and consumables, that are used in hundreds of different services and procedures for patient care delivery. For example, there are often over 10,000 implant products in use in North American health systems that are all designed for essentially the same purpose.² In more than 20 other industry sectors, other than healthcare, automated supply chain processes are in place that use global standards to identify products accurately and highlight key attributes of the product, including the manufacturer, the ingredients, when the product was manufactured, when it was received, and when and where it was used or purchased by the end consumer.

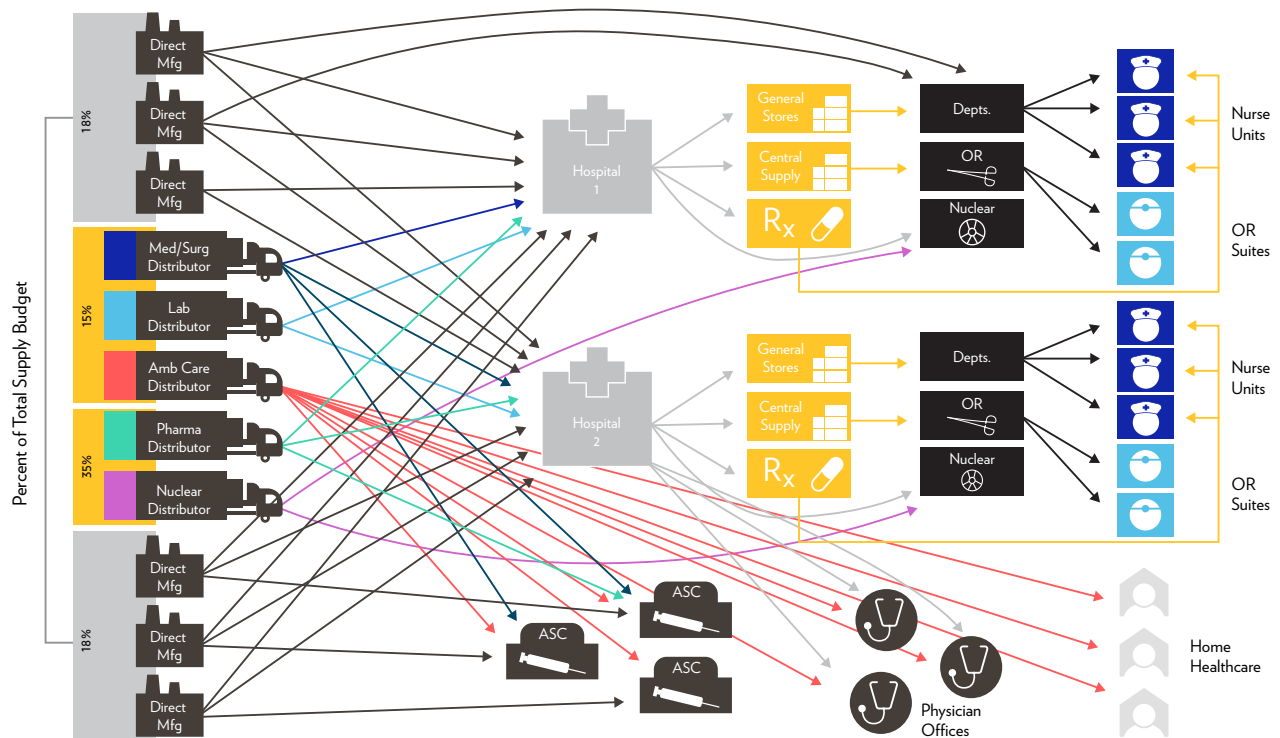


Figure 4: Complexity of Current Health System Supply Chain

(Snowdon, A. 2016. Original image, Cardinal Health Inc., 2016)

However, the health sector remains unable to track and trace products used in care processes across health system environments owing to the inability to identify products using global product identification standards (e.g. Global Standards 1, or GS1 standards are the only global standards across 114 countries). Standardized product identification allows for each health product to have its own identifying code that is recognized by all healthcare systems globally. In contrast, many healthcare products create their own code for manufacturing purposes, leading to duplication and lack of product information. Government regulation and policy have been slow to require the adoption of global standards (e.g. GS1) to guide supply processes or to support alignment with global jurisdictions. This presents challenges in managing inventory and procurement, and offers no ability to track product details as products move from manufacturer to the patient's bedside. Thus, hospitals and most clinical facilities cannot track or trace the medications, joint implants, pacemakers or any other products that patients receive during treatments or surgical procedures without standardized identification across the supply chain processes.

All pharmaceutical companies, retail pharmacies and distributors of “over the counter” products have already adopted GS1 product identification standards years ago. Yet pharmaceutical products still cannot be tracked or traced to individual patients in the majority of healthcare settings because health systems have not yet implemented clinically integrated supply chain infrastructure that enables point of care scanning tools in clinical environments to achieve product traceability. Thus, in most organizations in global health systems, there remains almost no ability to identify which individual patients have received

specific products in the event of a recall due to product failure. Inventory management processes have not been integrated into clinical settings in most organizations, making it challenging to align the demands for products and technologies with population health needs and demands for care. Manual inventory and supply chain processes are well documented to be associated with high inventory costs, frequent shortages of products and stock-outs, as manufacturers have limited ability to predict and manage surge demand for specific products²⁷ Further, many health systems in Canada and the U.S. rely on group purchasing organizations (GPOs), which offer some level of supply chain logistics, but only to the loading dock of the health organization. To date, no pathways have been described that map how supply chain processes operate in community-based health organizations.

A highly transparent healthcare system would create digital infrastructure in clinical care settings to reduce the likelihood of adverse events. Such a system would enable accountability for managing risk, informed by the near real-time reporting and analysis of adverse event alerts and clinician team interventions to manage risk. It would be characterized by a clinical environment where clinicians, provider teams, patients and their families have access to tracking and tracing reports (transparency) of all products, procedures and processes to inform decisions on the best available care processes that offer patients the best outcomes. Healthcare settings would have the infrastructure tools built right into the work environment. The tools would perform “double-checks” for accuracy and effectiveness of care processes, automating the tracking of the products or devices that patients receive during their treatments or procedures.

These automated tools enable accuracy and transparency across all components of the supply chain management process. For e-commerce processes, products are automatically reordered as they are used to ensure that stock-outs never happen and accuracy in product demand is captured, measured and reported. Tracking tools are embedded in clinical environments in a way that they are so intuitive that clinical teams use them as a routine part of care, with no need to manually check every step of care processes. All of this can be accomplished by changing existing environments so that care cannot happen unless the tracking and tracing tools are engaged. Data analytics offer the opportunity for analyzing organizational progress towards quality and safety goals, as well as accounting for clinician interventions to ensure safe care. Tools that measure and advance an organization's analytic capabilities can be essential in bridging the gap between data analytics and clinical care. A tool like this would use the analytics embedded in care processes to streamline the complex nature of healthcare environments, automatically track and trace patient care, as well as the involved providers and processes.

The data collected by the tool would support and inform accountable care models of service delivery and would be an essential step forward in using analytics to inform care. This, in turn, not only streamlines healthcare processes, but provides ways to improve patient safety and reduce medical error.

Highly transparent healthcare systems enable access to the patient record by providers when granted permission to do so by patients, who can use their own record of care to know exactly what care has been received, from whom it has been received, and what was achieved in terms of outcomes. Such details can inform patient and provider decisions in future phases of care. This high transparency in processes, products and patient outcomes essentially removes the unknown for clinicians, enabling an understanding of what has been offered to patients, the results that were achieved, the products that were used, whether or not a procedure offered value, and the long-term outcomes that were realized. Such a transparent system would also enable development of built-in algorithms to support best practice and evidence-based clinical decisions. For example, consider the patient described in the following patient story.



Helena Lambert's Story

Helena Lambert was prescribed 12 different medications for a variety of medical conditions. Mrs. Lambert was then also prescribed allopurinol for a gout diagnosis. She developed complications that led to her immune system shutting down, and eventually her death. It was subsequently concluded that the interaction between allopurinol and another one of her medications, mercaptopurine, was to blame. A physician at the hospital later said: “This should never have occurred; it was 100 percent preventable.”³⁷

Imagine the transparency in a health system that is supported and enabled by algorithms to detect and prevent such a catastrophic drug interaction that resulted in Helena Lambert's death.

As a patient presents with a complex record of interventions, built-in algorithms would notify patients that specific medications must never be taken with other medications. In highly transparent systems, the software uses the barcodes on medication labels to link, not only the physician orders, but also, the laboratory results and medication reconciliation of orders to prevent tragedies such as the one described in the example above. A transparent system would alert the pharmacist to ensure that such a toxic combination of medications could not be dispensed. Further, it would alert the physician or provider team of the potential for toxicity among the 12 different medications at the time they were prescribed. These types of alerts occur far too infrequently in current healthcare systems. What is needed is a system of tracking and tracing individual patient care processes (for example, medication prescriptions) across the continuum

of care that engages multiple provider teams and many distinct clinical settings.

Reducing medical error requires the integration of care processes that support informed clinical decisions, leveraging clinically integrated supply chain data on products, with patient data in EMRs, to enable traceability and analysis relative to patient outcomes. It requires data capture to be integrated automatically, in real-time, and at the point of care. EMRs can be helpful in these instances, but only as a way to collect data. They are a starting point, as there is a need for data to be collected and translated through analytic tools in a useful way for a clinician, or supply chain expert, to use. The more data that is collected, the more future risks can be identified and assessed to inform and enable clinicians to prevent error, manage risk, and improve quality of patient care for every patient.

The next section describes the opportunity for adoption of clinically integrated digital infrastructure strategy. Doing so can help organizations mobilize data from multiple sources in health systems, analyze data for risk at the point of care, inform clinicians of risks to patients, and thereby create the transparency of real-world data needed to reduce medical errors, and support and enable system learning. This ultimately advance and strengthen quality and safety of global health systems.

The Clinically Integrated Supply Chain Strategy for Health Systems

Many industries, other than health, have demonstrated the value in system infrastructure tools that provide the checks and re-checks in identifying processes and products accurately. This, in-turn, advances healthcare quality and safety. Clinically integrated supply chain infrastructure includes point-of-care scanning and analytic tools in the clinical environment to track and trace products, reducing healthcare spending and minimizing adverse events. The integration of supply chain and clinical care is becoming essential in a safe and quality driven healthcare system. The following are key steps for an integrated supply chain.

01

Adoption of GS1 Standards as the Global Language of Supply Chain in Healthcare Systems

The first and most critical step towards a highly transparent healthcare system is creating the policy framework to support tracking and tracing of healthcare products. This includes requiring every product and process in healthcare to use global standards that identify products used in care delivery, linking them to patients who receive care and to providers who deliver it. Over 20 industry sectors globally have adopted these standards, developed and implemented by a worldwide

network of GS1 organizations, currently operating in 114 countries. Every grocery item, every retail item and every pharmaceutical product currently use GS1 standards for identifying products accurately, tracking and tracing their movement from manufacturer and supplier to the organizations that purchase them. Leadership among policy makers is critical to implement regulatory frameworks that require adoption of GS1 standards for all products used in healthcare systems. GS1 standards are the only global product-identifying system common to 114 countries in the world.

“The starkest counterpoint to healthcare’s lack of transparency around error ... is offered by the aviation industry.”³⁶

The GS1 standards create a common language that every health system stakeholder knows and uses to identify, order and ship products to ensure they are available when and where they are needed, and then to track products and their use at the point of patient care. A number of product manufacturers have already adopted GS1 standards, and a number of retail organizations, such as pharmacies, already use fully automated systems for traceability of pharmaceutical products to individual consumers. Yet, the same capability has not been achieved in hospital pharmacies owing to the lack of policy mandates governing health systems. Once policy makers establish this requirement, healthcare organizations can leverage the many GS1-compliant barcodes to encode critical supply chain and clinical information, standardized to be read in any healthcare setting worldwide, to establish transparency in healthcare systems.

Adoption of GS1 standards enables the use of barcodes, allowing for a rich set of data to be encoded and then tracked in any health organization in any of the 114 countries (currently using GS1) in the world. Data tracked in GS1 barcodes of products includes product lot number, expiry date, serial number and shipping locations, which are then linked to unique identification of patients and individual providers who are assigned a Global Service Relationship Number (GSRN). For example, when a doctor prescribes a medication to a patient, the medication is dispensed by a pharmacist; a GSRN identifies the doctor and another GSRN identifies the

pharmacist who filled the prescription, which is then linked to the patient, who has their own unique GSRN. The medication has a global trade identification number (GTIN) that identifies the key attributes of the product to inform and ensure clinical teams and providers that they have the correct product information they need to make decisions. Unless, and until, policy frameworks governing healthcare systems require the adoption of GS1 standards for every product and clinical care process in healthcare systems, the value of global standards will not be realized.

The U.S. has made progress in policy support for transparency in healthcare systems. As of 2018, the Food and Drug Administration (FDA), the national body that regulates all food and drug approvals, has mandated that all health products (devices, drugs and consumables) must use GS1 or Health Industry Business Communications Council, or HIBCC, (for devices) for product identification to ensure that accuracy of product features and attributes are communicated for all stakeholders in healthcare systems.^{30,31} Similarly, the largest publicly funded sector of the U.S. healthcare system is considering mandating the use of global product standards (GS1 or HIBCC) for all claims submissions made to Medicare and Medicaid to include the unique product identification number in order for the claim to be considered for reimbursement. In combination, these two policies essentially mandate the adoption of GS1 standards by every manufacturer in the U.S. marketplace. More importantly, they require that health system organizations, such as hospitals, use the GS1 and HIBCC identification numbers to process reimbursement claims. This proactive policy leadership sets the stage for a highly transparent healthcare system in the U.S., one that will now be able to track and trace every product from manufacturer to patient (based on claims information) in the Medicare and Medicaid systems.

The European Union is poised to implement a policy requiring the adoption of GS1 standards for all health products procured across its healthcare systems with requiring all devices to be switched over by May 2027³². The NHS in the UK has already moved to incorporate GS1 standards and is implementing the concept of a fully transparent health system in a number of

NHS trusts. GS1 standards are now currently mandated in all NHS trusts with the due date to have everything switched over (including the use of international suppliers) by 2020³². One of the NHS leaders, Lorna Wilkinson (Director of Nursing, Salisbury NHS Foundation Trust), describes the impact the adoption of GS1 standards is expected to have in the UK health system:

“When implemented, the standards will enable clarity of the full patient journey including what clinical procedures have been performed, what equipment is being used, which devices are implanted, what medication is being administered and by whom, and all of this will be recorded in a comprehensive electronic patient record.”³³

02

Integrate ERP digital infrastructure with EMR platforms to enable Traceability and Risk Management at the Point of Care

EMRs are a digital platform tool that can enable clinical documentation to be entered by clinicians as they deliver care to patients. EMRs are an important tool to advance digital capture of patient data. However, EMR data is not integrated or interoperable with other data platforms in most hospitals or health organizations. For example, EMRs capture the progress notes, lab results, diagnostic imaging reports, and clinical assessment data for every patient, to enable clinicians to track patient health status. The limitation of the EMR is the isolation of this platform from other IT systems or software in organizations that measure finance, quality and safety. Advanced analytics tools (e.g. algorithms) have the ability to be used for decision support or to enhance inventory software to manage demand for products and supplies. These tools provide detailed product attribute data such as expiry date, lot number and batch number, all of which are required data points in the event of a recall. Typically, hospitals have a wide range of diverse software platforms operating at any given moment, estimated to be as many as 30-40 tools or applications

across the organization. The EMR platform is able to collect and store patient data. It is insufficient to advance quality and safety due to the limited interoperability of EMR data and other datasets such as product data, finance data and inventory software, which are typically housed in the ERP (Enterprise Resource Management) platform. To achieve a clinically integrated supply chain with the infrastructure able to support safety and quality for patients, there must be a fully integrated digital infrastructure. This infrastructure must be capable of traceability of every patient, the care processes they receive, the products used in care linked to patient outcomes to determine what care models and processes work best for individual patients, and under what conditions best outcomes are achieved. Clinically integrated supply chain infrastructure ensures all of the data platforms are interoperable and include embedded analytics able to support point of care capture of data, to serve as a “double-check” that the correct care processes are provided to patients. It allows data platforms to identify that the products used in care are safe (e.g. check expiry date and recalls), alerting clinicians in the event of risk to enable clinicians to intervene proactively to prevent adverse events and support the best possible outcomes for patients.

Clinically integrated supply chain infrastructure offers the ability to track and trace progress over the patient's journey of care, so that all provider teams can access data on care processes and decisions that all of the other clinicians have implemented. Clinical integration of data infrastructure makes it possible to access data across primary care, long term care, hospital care, home care, and other services or organizations providing care. This data infrastructure creates the opportunity to overcome the greatest risk and prevalence of error; during care transitions one provider team has no way to access the documentation of care across various clinician teams providing care to patients in different care settings.

Perhaps the most important opportunity in a highly transparent system, is the implementation of clinical safety tools to track and report the processes, procedures and products allocated to each individual patient to evaluate safety and effectiveness of care outcomes. Point of care capture of patient data (e.g. barcode or RFID scanning) generates alerts at the point of care for clinicians, and generates analytics profiled on dashboards for program teams to track quality and safety, in near real-time. The adoption of global standards enables traceability of

outcomes across organizations, regions and geographies to inform all health organizations of trending analyses for specific patient population segments, automated recalls of products with evidence of adverse outcomes, and segmentation of patient populations to reveal best outcomes linked to unique health needs and outcomes of individual consumers. Clinically integrated supply chain infrastructure integrates all data sources across the organization, links data to patient outcomes to determine value, and enables traceability of patient care across the continuum of care to inform decisions of patients and clinician teams to ensure best outcomes are achieved, personalized to every individual.

An emerging clinical use case for clinically integrated supply chain infrastructure has been demonstrated in surgical programs in the U.S. and the UK. Point of care scanning of product barcodes (or RFID) enables the capture of every product – every sponge, clip, implant and clamp used during a surgical case. Point of use capture of product use enables automated and highly visible product transparency to support the circulating nurse, to ensure every product used during the case is accounted for, and to ensure no foreign body is left in surgical sites. Just as a grocery

store clerk scans every item and the item appears on the monitor for both the cashier and the customer to see, so too are surgical products scanned and displayed for the clinical team to view the list of products opened and placed on surgical trays during the procedure. The visual representation of the scanned product list offers two opportunities: (a) the complete listing of items to account for, ensuring that no foreign body is left in the surgical cavity, and (b) an accounting of product use for each surgical patient to provide an accurate case costing. Joint implants, stents and all other products used for, or inserted into, a surgical wound would be fully accounted for, along with detailed product attributes such as presence of latex, metal and so on. This information can then be uploaded into patient health records to determine value outcomes for every individual patient.

Transparency for patients is further enabled when they are provided with an accurate list of products identified in their personal record in the event of a product recall or failure, or to inform future care decisions with provider teams. This fully visible and transparent system enables total accountability for products and processes used in all clinical settings.

03

Traceability of Product Performance, Product Notification and Recall

One of the most important features of a fully integrated supply chain infrastructure in healthcare is the opportunity it offers to manage and identifying possible risks for patients. As an example, the horsemeat scandal in the UK food supply was a challenge for the UK health system which was not able to track and identify individual patients who may have been exposed to the horsemeat contamination.³⁴

The highly developed supply chain infrastructure in grocery store chains enabled them to readily identify all horsemeat products on store shelves. This enabled tracking of the meat products right back to the farm, the plants that processed them and their distribution to the retail stores that sold them. UK health organizations, however, were unable to achieve the same tracking of contaminated products in healthcare settings.

Product manufacturers are estimated to send out approximately 3,500 notifications annually worldwide, reporting product failures or product warnings that require health organizations to locate and remove products, mitigating the risk of harm for patients. For every recall notification, health system stakeholders must identify the

patients who received the product and the outcomes patients may have experienced by manually reviewing patient records to locate use of recalled products. In an automated system, the identification of patients who received the product in question could be conducted in a matter of a few hours using the data infrastructure that cross references product attributes and recall information with patient care data that identifies which patients may be at risk due to exposure.

Standardized and automated traceability offers a further opportunity that is critically important for achieving a highly transparent health system. Automated traceability creates “extreme transparency” for healthcare systems by enabling safety information to be reported and made available to system stakeholders and the public for analysis and learning. When adverse events occur, disseminating what happened (e.g. the root cause) and, more importantly, how the event can be averted or prevented, is a key strategy that transparency achieves in healthcare systems. The sharing of information and resultant analysis between clinical units within hospitals, across hospital networks and community care providers, and healthcare stakeholders globally, creates a transparent platform for learning and sharing risk mitigation

strategies for all current or future patients. In both the UK and Australia, national registries exist for specific products such as orthopedic implants. These registries track patient outcomes for these products, alerting health systems of product outcomes and patient safety risks.³⁵ North American health systems rely heavily on these registries for identifying such risks³⁵ because there is no similar system in North America. Darrell Horn is a critical-incident lead investigator with years of experience at the Winnipeg Region Health Authority. He investigates adverse events across Canada. Based on his extensive experience, he has suggested that “releasing descriptions of incidents and lessons learned from them would be the most effective way to educate healthcare workers.”⁴⁴

Automated reporting of events and recalls, linked to patient outcomes, is a key feature of a highly transparent health system with a well-developed clinically integrated supply chain infrastructure. Such systems not only advise the public of progress towards safer healthcare, but also inform and enable clinicians, teams and organizations to quickly identify patterns and prevent adverse events. Additionally, they proactively protect patients from harm and effectively disseminate information across healthcare systems to further mitigate risk. An automated recall and tracking system not only provide system-wide analysis of adverse events; it also provides automated feedback for clinical teams, who can use the information to inform their practice and streamline processes to reduce the risk of error that causes harm to patients.

If the proposed clinically integrated supply chain infrastructure were adopted and scaled across health systems, automated tracking and traceability at the point of care could reduce adverse events substantially, and never events could be all but eliminated. In one large academic teaching center, integrated supply chain infrastructure resulted in reduction of medication-related adverse events by up to 40% (across 10 hospital sites), and never events involving medications decreased by 90% (Robin Walker, MD, personal communication, 2016). When the proposed features of high transparency healthcare systems are applied to the top 15 never events, all but one could potentially be prevented simply by implementing a clinically integrated supply chain infrastructure to achieve highly automated and transparent clinical environments. Table 1 identifies the strategy for eliminating never events using the supply chain strategies described above. These systems would also provide transparency to the industry, where healthcare safety data and know-how are required for the design of safer products.

Never Events	How Tracking and Tracing Could Eliminate Never Events
1. Surgery on the wrong body part or the wrong patient, or conducting wrong procedure	Tracking individual patients and correct surgical procedures that match chart and consent using barcodes to link procedure to patient armband.
2. Wrong tissue, biological implant or blood product given to a patient	Barcoded tissue or implant scanned to patient chart for automated tracking for recalls and evaluating outcomes.
3. Unintended foreign object left in a patient following a procedure	Every product is scanned in each operating room to reconcile product count and use during every surgery, using GTINs for product identification and GLINs to identify location of operating room where product was used.
4. Patient death or serious harm arising from the use of improperly sterilized instruments or equipment provided by the healthcare facility	Tracking of sterile/nonsterile product(s) to patient. Barcode identification to determine sterile/nonsterile product attribute based on accurate GTIN barcode.
5. Patient death or serious harm due to a failure to inquire whether a patient has a known allergy to medication, or due to administration of a medication where a patient's allergy had been identified	Barcode scan of medication to patient barcode to match allergy status of patient to medication content identified with the GTIN; scanning barcode alerts the provider to medication allergy status for all medications.
6. Patient death or serious harm due to the administration of the wrong inhalation or insufflation gas	Patient identification band barcode is scanned to inhalation gas barcode to alert anaesthetist to correct inhalation for correct patient procedure using system algorithms that alert surgical teams to all inhalation never events.
7. Patient death or serious harm as a result of one of five pharmaceutical events	Correct medication for correct patient can be achieved by scanning medication barcode and patient barcode to determine correct match (right drug, right dose, right route, right patient, right time) to patient record.
8. Patient death or serious harm as a result of failure to identify and treat metabolic disturbances	Barcoded lab results can be linked to patient ID barcode using algorithms that alert providers to contraindications for patients who receive medications matched to lab results, or other medications that, when given together, cause significant adverse events.
9. Any stage III or stage IV pressure ulcer acquired after admission to hospital	Tracking procedures completed by scanning patient barcode with nurse barcode to indicate every time a patient is turned and skin care is provided to prevent pressure ulcers.
10. Patient death or serious harm due to uncontrolled movement of a ferromagnetic object in an MRI area	Barcoded patient armband identifies presence of implanted device(s); barcode on the device identifies metal content of the device, alerting the provider team to those patients who CANNOT risk having an MRI due to the metal content of an implant—eg, hip, knee, defibrillator, pacemaker.
11. Patient under the highest level of observation leaves a secured facility or ward without the knowledge of staff	Barcoded armbands on all patients to track where they are in the healthcare facility using RFID technology, just as airline industry does for passengers.
12. Patient suicide, or attempted suicide that resulted in serious harm, in instances where suicide prevention protocols were to be applied to patients under the highest level of observation	Barcoded tracking of assessment procedures by nurse/provider to assess suicide risk 24/7.
13. Infant abducted, or discharged to the wrong person	Barcoded patient ID bands that link every infant to the mother's barcoded patient ID band.
14. Patient death or serious harm as a result of transport of a frail patient, or patient with dementia, where protocols were not followed to ensure the patient was left in a safe environment	Barcoded patient ID bands track location of patients during transport and during hospital admission to monitor location of patient at all times and prevent wandering—eg, tracking patients in ED so that staff can see patient movement and location (such as bathroom) to ensure safety.

Table 1: How System Transparency Could Eliminate Never Events

Environments with the ability to track and trace patients, products and processes create an alerting system to cue staff, enabling them to prevent an adverse event or an event that should *never* happen. The systematic reporting of all such events, using digital records of care transactions, helps leaders to identify patterns of adverse events and their root causes to inform strategies for prevention and improve organizational accountability.

04

Measurement Strategy that Captures Strategic Supply Chain Outcomes in Healthcare

Measurement in health systems has been well established for decades. However, measurement has focused primarily on patterns of illness or diagnoses, health system utilization, cost and performance (e.g. quality and safety). Unlike in so many other business sectors, we could find no health system measures that capture supply chain management outcomes, both for patients and for health systems.

A highly transparent healthcare system would enable a robust measurement framework to track progress towards strategic supply chain management. Key metrics that reflect supply chain transformation must include patient care outcomes, such as the prevalence and type of adverse events. For example, medication errors measured using automated reporting from digital infrastructure, product outcome measures such as frequency of shortages, product performance outcomes post-operatively including infection rates, product failures identified across clinical settings, and organizations using standardized measures. Health

system measures that reflect advanced supply chain management processes would include inventory cost savings, labor costs/case that contribute to the economic impact of adverse events, patient health and recovery time linked to product use and procedure quality and safety. Additionally, the ability to rate shortages and stock-outs, conduct accurate case costing, and health provider engagement in adverse event reporting and proactive prevention strategies can help reduce the rate and severity of adverse events in healthcare.

Measurement tools that leverage supply chain data assets could inform and support accountability for health services delivery as it enables leaders to use automated reporting systems, generated in near real-time, to understand root causes of adverse events and identify types of clinical settings where patterns of adverse events take place. This enables clinical teams to design and evaluate risk mitigation and prevention strategies to further strengthen the quality and safety of care delivery. A highly transparent system leads to best evidence strategies that achieve the greatest impact for patients, families and populations.



Summary

Health organizations need guidance and support to implement and scale clinically integrated supply chain infrastructure to advance quality and safety in health systems.

New maturity tools, and models, have been developed and tested to fill this gap. Models such as the HIMSS Analytics Clinically Integrated Supply Outcomes Models (CISOM) will serve as a roadmap and prescriptive framework for providers to follow and measure against to

support system improvement and personalized care. The model assists organizations in creating a high performing supply chain strategy to create transparency by embedding the necessary processes and tools into the infrastructure of health system environments.

Works Cited

1. Schneider, E. O. Sarnak, D. Squires, D. Shah, A. Doty, M. 2017. *Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care*. The Commonwealth Fund. Available from: <https://interactives.commonwealthfund.org/2017/july/mirror-mirror/>
2. Makary MA, Daniel M. Medical error—the third leading cause of death in the US. *BMJ*. 2016;353:i2139.
3. Leading causes of death, by sex (both sexes). <http://www.statcan.gc.ca/tables-tableaux/sums0m/l01/cst01/hlth36a-eng.htm>. Accessed August 17, 2016.
4. Leading causes of death. <http://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>. Accessed August 17, 2016.
5. Kohn LT, Corrigan JM, Donaldson MS. *To Err Is Human: Building a Safer Health System*. Committee on Quality of Health Care in America, ed. Washington (DC); 2000. doi:10.17226/9728.
6. *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS*. London: Department of Health; 2000.
7. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ*. 2001;322(7285):517-519.
8. Baker GR, Norton PG, Flintoft V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ*. 2004;170(11):1678-1686.
9. James JT. A new, evidence-based estimate of patient harms associated with hospital care. *J Patient Saf*. 2013;9(3):122-128. doi:10.1097/PTS.0b013e3182948a69.
10. Hogan H, Healey F, Neale G, Thomson R, Vincent C, Black N. Preventable deaths due to problems in care in English acute hospitals: a retrospective case record review study. *BMJ Qual Saf*. 2012;21(9):737-745. doi:10.1136/bmjqs-2011-001159.
11. Classen DC, Resar R, Griffin F, et al. “Global trigger tool” shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff (Millwood)*. 2011;30(4):581-589. doi:10.1377/hlthaff.2011.0190.
12. Levinson DR. *Adverse Events in Hospitals: National Incidence among Medicare Beneficiaries*. Washington, DC: Department of Health and Human Services; 2010.
13. Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med*. 2010;363(22):2124-2134. doi:10.1056/NEJMsa1004404.
14. Sari AB-A, Sheldon TA, Cracknell A, et al. Extent, nature and consequences of adverse events: results of a retrospective casenote review in a large NHS hospital. *Qual Saf Health Care*. 2007;16(6):434-439. doi:10.1136/qshc.2006.021154.
15. *Healthgrades Quality Study: Patient Safety in American Hospitals*. Denver, CO: HealthgradesInc; 2004. http://www.providersedge.com/ehdocs/ehr_articles/Patient_Safety_in_American_Hospitals-2004.pdf.
16. Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. *JAMA*. 2003;290(14):1868-1874. doi:10.1001/jama.290.14.1868.
17. Doran DM, Blais R, Harrison MB, et al. *Safety at Home: A Pan-Canadian Home Care Safety Study*. Edmonton, AB: Canadian Patient Safety Institute; 2013.
18. Weissman JS, Schneider EC, Weingart SN, et al. Comparing patient-reported hospital adverse: 8th Ann events with medical record review: do patients know something that hospitals do not? *Intern Med*. 2008;149(2):100-108.
19. Ellams et al. 2011. National Joint Registry for England and Wales, 8th annual report. The NJR Centre. Available from: <http://www.njrcentre.org.uk/NjrCentre/Portals/0/Documents/NJR%208th%20Annual%20Report%202011.pdf>

20. Agency for Healthcare Research and Quality. AHRQ: Patient safety organization (PSO) program. <https://psa.ahrq.gov/>. Accessed August 23, 2016.
21. US FDA: questions and answers on FDA's adverse event reporting system (FAERS). <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/>. Accessed August 23, 2016.
22. Classen DC, Resar R, Griffin F, et al. "Global trigger tool" shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff (Millwood)*. 2011;30(4):581-589. doi:10.1377/hlthaff.2011.0190.
23. Griffin, FA, Resar R. IHI Global Trigger Tool for Measuring Adverse Events. 2nd ed. Cambridge, MA: Institute for Healthcare Improvement; 2009. <http://www.ihl.org/resources/pages/tools/ihiglobaltriggertoolformeasuringaes.aspx>.
24. Medicare.gov: hospital compare. <https://www.medicare.gov/hospitalcompare/details.html?msrCd=prnt9grp1&ID=23003>. Accessed August 23, 2016.
25. Public Health England: public health profiles. <http://fingertips.phe.org.uk>. Accessed August 23, 2016.
26. Eckler J, Schneller ES. Physician Leaders' Roles in Supply Chain Management. *Physician Leadersh J*. 2015;2(6):22-25.
27. Schneller ES, Smeltzer LR. *Strategic Management of the Health Care Supply Chain*. San Francisco, CA: Jossey-Bass; 2006.
28. Never Events for Hospital Care in Canada: Safer Care for Patients. Edmonton, AB: Canadian Patient Safety Institute; 2015. <http://www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/Documents/Never%20Events%20for%20Hospital%20Care%20in%20Canada.pdf>.
29. US FDA device regulation. <http://www.fda.gov/medicaldevices/deviceregulationandguidance/UniqueDeviceIdentification>. Accessed August 18, 2016.
30. US FDA Drug Supply Chain Security Act. http://www.fda.gov/regulatoryinformation/guidances/ucm125505.htm#_Toc254967075. Accessed August 18, 2016.
31. GS1. GS1 Standards for Acute Trusts. <https://www.gs1uk.org/our-industries/healthcare/gs1-standards-for-nhs-acute-trusts>
32. Wilkinson L. GS1 UK healthcare conference 2016: scan4safety—our journey so far. 2016. <https://www.gs1uk.org/healthcare-conference/presentations>. Accessed August 18, 2016.
33. Smith P. The NHS GS1 programme—the inside story from Owen Inglis Humphrey. 2016. <http://spendmatters.com/uk/nhs-gs1-programme-inside-story-owen-inglis-humphrey/>. Accessed August 18, 2016.
34. Rising JP, Reynolds IS, Sedrakyan A. Delays and difficulties in assessing metal-on-metal hip implants. *N Engl J Med*. 2012;367(1):e1. doi:10.1056/NEJMp1206794.
35. Blackwell T. Inside Canada's secret world of medical error: "there's a lot of lying, there's a lot of cover-up." *National Post*. http://news.nationalpost.com/health/inside-canadas-secret-world-of-medical-errors-there-is-a-lot-of-lying-theres-a-lot-of-cover-up?__lsa=45ed-345b. January 16, 2015.
36. Proctor J. Tragic death leads to call for mandatory drug reaction reports. *CBC News*. <http://www.cbc.ca/news/canada/british-columbia/tragic-death-leads-to-call-for-mandatory-drugreaction-reports-1.3400832>. January 13, 2016.