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Visibility:

The New Value Proposition for Health Systems

Executive Summary

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Executive Summary

One of the greatest challenges facing global healthcare systems is patient safety: medical error has now become the third leading cause of death in North America, right behind heart disease and cancer. Not only are adverse events devastating for patients and their families; they are very costly to the organization and to the healthcare system. Unfortunately, healthcare systems have made very limited improvements in addressing patient safety issues despite decades of research and safety initiatives developed to address the problem, at both a country and the global level. While there is growing awareness worldwide of the challenge of patient safety, there has been little evidence of actual improvement in the increasing rates of deaths and serious injury related to error and adverse events.

In this paper, we propose a new direction to improve patient safety and performance that builds on existing research and best practice in this field. We believe the risk of error needs to be proactively identified to enable interventions *before* an error takes place, rather than retrospective approaches that focus on learning from errors that have already caused harm. Fundamentally, we suggest that adverse events and medical error are an outcome of a lack of well-developed supply chain infrastructure in clinical environments that would protect patients by making it nearly impossible for errors to happen, thereby substantially improving patient safety across healthcare systems.

This paper focuses on how clinical supply chain processes could transform the care delivery environment to ensure that adverse events are much less likely to take place. A successful example of transforming environments to improve safety is the automotive industry, which has created vehicle environments that alert the driver and occupants to proactively manage risk. Warning buzzers that encourage use of seat belts, and warning lights that alert drivers of potential collisions, have dramatically reduced the rate of accidents and severity of injuries. This and many other industry examples demonstrate the importance of the environment in supporting systemic factors to identify risk of error proactively and then intervene to prevent adverse events. The goal is to transform supply chain processes to create healthcare environments that are highly visible to stakeholders, proactively alert clinicians to risk, and protect patients from adverse events.

At present, there is little visibility with regard to the key conditions that contribute to adverse events in healthcare systems. In this paper, visibility is defined as *the ability to see or be seen* and *the quality or state of being known to the public, to providers, health system leaders and funders.* Essentially, the tools used to track and trace products, people and processes in almost every

other industry are simply missing in the health sector. Clinical environments lack the supply chain infrastructure to accurately identify products used during patient care processes, link these to patient outcomes, determine value and ensure that care processes are safe and protect patients from harm. This lack of infrastructure has resulted in a complete inability to link patients to procedures and products used during care, and accurately measure and report patient outcomes in all clinical settings.

Characteristics of Health Sector Environments

A number of key characteristics of health sector environments limit our ability to address the growing rates of patient safety outcomes, deaths and serious injury. These characteristics include the following:

- Patients do not have access to product information used during clinical care processes, impeding their ability to track outcomes linked to product use, report adverse events and respond to recalls.
- Providers do not have access to reports or searchable data to analyze patterns and root causes of adverse events in real time, or outcomes and trends across organizations and health systems that could prevent error or redesign processes to mitigate risk.
- Health organizations do not have the digital tools and infrastructure required to enable clinicians with automated “double-checks” and alerts to proactively manage risks and protect patients from harm.
- Health systems do not track product performance, or undertake post-market evaluation linked to patient outcomes, that can reveal problems early enough to prevent population-level impact and inform product design.
- Health system leaders do not have expertise in supply chain logistics and management, and this aspect of health management curricula is not well developed.
- Governments do not have policy frameworks in Canada that require traceability of products from the manufacturer to patient outcomes across health systems to ensure safety.

To help address these system gaps, three key elements need to be in place to support high-performing, high-visibility clinical environments:

1. **Adoption of GS1 barcoding standards as the global language of supply chain in healthcare systems to accurately identify patients, the products used in patient care and the location of care provided**

   The first and most critical step towards a highly visible healthcare system is creating a policy framework requiring every product and process in healthcare to use consistent global standards that uniquely identify patients, the processes they experience and the products used in care delivery, linked to providers who deliver that care.

2. **e-Commerce processes that automate supply chains in healthcare systems based on patient needs**

   Supply chain processes manage the movement of products from manufacturers and distributors to clinical settings so that health professionals can safely and effectively deliver care to patients using the right products available in clinical settings when and where they are needed. The adoption of a single product identification standard would allow any product to be identified accurately from the internal “back office” through to the patient receiving care in each clinical setting, saving time and resources among health professionals seeking to locate products. Supply chain processes also track and identify specific attributes (for example, product features such as “latex” or “single use”) that must be known or visible to clinician teams to ensure that the safest product is used for each patient to achieve the best outcome.

3. **Automated tracking, tracing and reporting of product performance, linked to patient outcomes across health systems**

   The automated tracking and tracing of patients, processes, procedures and products enables clinical teams to track and report patient outcomes and objectively assess value for patients and their families, determine outcomes of care processes, and prevent error (for example, reduce the risk of the wrong drug being given to the wrong patient) in protecting patients from harm—all of these factors directly lead to strengthening patient safety in healthcare settings. Automated barcode scanning alerts the provider to high-risk events, such as incorrect medication, thus enabling prevention of adverse events in clinical settings.

Creating a Highly Visible Supply Chain in Healthcare Systems

A fundamental assumption in this paper is that a fully visible, transparent health system will not only improve patient safety, but also holds the key to achieving value in healthcare through objective, accurate measures of the value that healthcare systems deliver for their patients and, more broadly, for the populations they serve. In this paper, "value" is defined from the perspective of health system stakeholders, namely, patients and families, clinicians, health organizations (hospitals, community care), industry (manufacturers of products or service providers) and policy makers. The key to achieving visibility in healthcare systems is to create the ability to "see" the value of healthcare delivery from the multiple, but different, perspectives of each stakeholder group. **In order to scale innovative supply chain transformation, healthcare systems must consider the value proposition for its stakeholder groups. The value propositions for these diverse and highly varied stakeholder groups set the stage for a scalable and transformational supply chain for global healthcare systems.** All of these stakeholders share a mandate to ensure that high-quality healthcare is delivered safely, efficiently and effectively. This mandate would contribute to the sustainability and performance of healthcare systems globally.

The Value Proposition of a Highly Visible Healthcare System

Healthcare systems are mandated, by their respective funders, to deliver value to the populations they serve. **This paper focuses on the value of "visibility" in healthcare systems, suggesting it is a core value for all health sector practitioners, funders and stakeholders and key to improving patient safety within the overarching healthcare system.**

Value proposition for patients and families

In a highly visible healthcare system, all care processes, products and care providers are tracked and linked to individual patients and their health outcomes. Records are easily available and accessible for patients and their families, so that they can report adverse outcomes and have accurate information to support their care decisions. Linking individual patients to products and care processes using global standards enables healthcare systems to analyze which individual patients experience the best outcomes and how care delivery (products, procedures, provider teams) contributes to the best outcomes. A highly visible system is

accessible to patients through patient portals that allow patients and families to monitor their care, identify products to which they have been exposed (in the event of a product recall or failure), provide information to support decision-making, and report outcomes such as return to work, emergency visits and readmissions to hospital.

If every process, procedure and product were scanned and tracked to each patient, patients and families would have the tools necessary to accurately and easily track their care processes and the outcomes they are able to achieve. Automated access to care transactions in a visible health system enables patients to oversee their care and better understand the treatments and procedures they are receiving.

Value proposition for clinicians and provider teams

Highly visible systems track product use objectively and automatically. This enables providers or their organizations to notify patients of possible risk directly, and facilitates assessment and monitoring for potential adverse events. Healthcare organizations with high visibility enable and support provider teams by allowing them access to detailed and accurate patient information. The patient's medical record becomes visible across the continuum of care, profiling the history of clients' unique needs, current treatment, history of allergic responses or sensitivities, health services they have accessed, healthcare professionals whom they have seen, what transpired, and what has worked or hasn't worked in terms of outcomes. Adverse events are flagged and automatically reported to ensure that incident disclosures and reporting outcomes are embedded into the clinical environment and are part of clinician workflows. The data is highly visible to provider teams, enabling standardized and comprehensive reporting to accurately track adverse events and their outcomes.

Value proposition for healthcare organizations

Value for the healthcare organization is achieved in terms of safety, efficiency, efficacy and sustainability. Digital tracking and tracing of devices, consumables and medications within a healthcare organization supports high-performing care delivery to patients that is safe and protects patients from harm, providing access to products, devices and medications when and where they are needed to restore and maintain patients' health, wellness and quality of life. A high-performing system relies on efficient procurement of products that meet patient care needs and demands, in the most cost-effective manner that offers the greatest value and makes better use of funds to ultimately improve organizational capacity to deliver timely and high-quality care to patients in a sustainable manner. Information regarding product performance and outcomes

adds tremendous value to clinical teams, enabling health professionals to understand which products offer patients the best value. Procurement teams receive value from data that informs purchasing decisions and helps to determine return on investment linked to product and patient outcomes.

Value proposition for industry

In a highly visible healthcare system, patient care processes are tracked, traced and reported, and product use such as use of drugs or devices is linked to patient care outcomes. These measures enable systematic assessment of value and provide *in vivo* evidence to demonstrate the value of product performance in the context of clinical care processes that meet patient care needs and demands. Tracking, tracing and reporting creates robust evidence to inform industry of how products are used, the procedures they are used for, the patient populations that are served and, most importantly, patient health outcomes linked to product use. Visibility at this level of detail across health systems offers much-needed insights to industry in planning current and future product design; it encourages innovation based on direct evidence of patient outcomes, and ultimately provides the evidence of product performance to support successful procurement.

Value proposition for health system leaders and policy makers

With regard to measuring costs and quality outcomes, visibility holds the potential to quantify value in healthcare systems. Accurate and objectively measured quality outcomes achieved across defined populations enable accurate costing of providing healthcare to populations. Visibility enables governments to have access to evidence of outcomes across the continuum of care regionally, provincially and nationally, to make the best investments to improve health system performance. Health system leaders are able to examine patient populations prospectively across healthcare organizations and jurisdictions, to identify processes or products that place patients at risk, and to inform the design and implementation of strategies to improve performance and care. This enables accurate measurement of value from the many and varied stakeholder perspectives in healthcare systems.

Solutions

Ultimately, the goal of this paper is to reframe the challenges of patient safety and care quality as a system infrastructure opportunity. A clinical environment could be created that supports health professionals to deliver the safest care possible. This would mean designing and integrating strategic supply chain processes to track and trace every healthcare product, process and patient to create a safe patient care environment. Such an environment has visibility, where frequency of adverse events is dramatically reduced and never events no longer occur. Supply chain transformation is the future for accountable healthcare systems because this type of system demonstrates a return on investment in delivering healthcare that is safe and highly effective in performance and quality. Such a system delivers value to patients and their families.

Creating a system of this nature requires the implementation of the following six recommendations.

1. **Create policy and regulatory frameworks to support a common language across global jurisdictions** to track and trace products, patients, care processes and outcomes for global surveillance of safety and value for populations. Canadian government ministries, accreditation bodies and federal regulatory agencies must create provincial policy and regulatory frameworks that align with global jurisdictions to incentivize and create the necessary catalysts to guide supply chain transformation. This can be achieved by requiring and mandating all organizations and provider teams to adopt global GS1 standards to enable the traceability of people, products and processes in all healthcare settings. Adopting global standards for traceability sets the stage for a fully visible healthcare system in which every clinician team, every health organization and every health system in the world is “speaking the same language,” whereby a product or a process is linked to an individual patient outcome. These standards provide the mechanism to ensure that every unique product is identifiable anywhere in the world. A global standards-based approach not only benefits healthcare systems; it also offers manufacturers and suppliers consistency in business processes for their customers to streamline costs and drive more efficient manufacturing and distribution of products needed in healthcare systems. This policy recommendation is a first and very critical step that makes it possible for health system organizations to begin to mobilize and achieve the value of strategic supply chain transformation.

2. **Invest in infrastructure,** transforming healthcare environments to integrate automated digital tracking tools and devices that are intuitively embedded in the clinical setting. In this way, every healthcare provider can easily and automatically scan (track) every patient, procedure and product used in health settings. Such infrastructure investment would create safer clinical environments with the following key features:

   - *Rapid and dynamic feedback of patient, product and procedure tracking.* This would enable clinical teams to identify situations at high risk for adverse events and ensure that steps are taken to intervene and protect patients from them. Supporting providers in this way would help them to deliver the safest care possible and ensure that care is delivered when and where it is needed, to restore or support patient health and wellness.

   - *Reduced clinician workload.* Reduced workload would overcome the limitations of voluntary reporting and recording of adverse events because scanning is highly automated: it tracks patients, care procedures and the products used that are linked to patient outcomes, thus achieving visibility; it documents every process, provider and product used for every patient systematically, using GS1 standardized definitions. These definitions are searchable to generate evidence of outcomes and value across organizations, clinical teams and healthcare systems serving unique patient populations.

   - *Automatic feedback to patients.* Patients are informed automatically about the use of products such as medications, joint implants, pacemakers, stents and vascular filters, so that they have a record of the exact product they received, the prescriber and the date it was administered. Such information can inform patients' care decisions with all provider teams in all clinical settings.

   - *An accurate and accountable system for measuring value in healthcare delivery.* Documenting every patient transaction—including products used and patient outcomes achieved—enables calculation and measurement of true value in healthcare delivery.

3. **Establish a national product registry** that holds accurate and up-to-date data on *all* healthcare products. A national registry would support tracking and reporting of patient safety, adverse events and health outcomes relative to use of health products in clinical settings. Ideally, it would build on the existing Health Canada product reporting registry to improve traceability of product use, patient outcomes and adverse events reporting. Using the GS1 standard barcodes as the index key, the registry would provide evidence of value and safety for each product used in health systems by combining product data with clinical data from the

electronic medical record (EMR) or product registries. A national registry offers value to health systems in terms of cost-effective and accurate e-commerce supply chain processes; it would ensure that products are available and distributed to clinical settings when and where they are needed, and that the healthcare delivered is timely and safe. A national registry achieves six key outcomes for healthcare systems:

- *Ensures that products are accurately identified* using global standards, including validated product attribute data that is highly visible to clinical teams. This helps to ensure safety and enables any clinical team to track patient outcomes.
- *Enables rapid, accurate and dynamic recall communication* with health organizations that is coordinated by a single national entity. This ensures that recall information is widely disseminated digitally to every clinical setting and every clinical team to prevent population-wide exposure to adverse events associated with product failure.
- *Enables direct product information, including notification of recall, communicated to patients and their families* to inform patients and providers of product performance and outcomes. Such product information, such as key attributes (for example, latex, metal, manufacturer) could also inform healthcare decisions, such as use of MRI diagnostic imaging for patients with implanted devices.
- *Enables value-based procurement that leverages traceable product costing, performance, usability and patient outcomes* to inform product purchases. A registry would also engage clinician teams in procurement to assess clinical value based on objective data of how products and procedures achieve optimal patient outcomes such as health, wellness and quality of life.
- *Establishes clear communication and transparency* between health system stakeholders (hospitals, clinicians, community organizations) and vendors to identify product use relative to patient population characteristics, patient outcomes and product performance. Improved communication and transparency would stimulate and accelerate the opportunity for product innovation.
- *Supports and disseminates results of post-market product evaluation and tracking to identify patient safety outcomes* at the population level. Early identification of safety outcomes would help avoid broad exposure to risk at the population level. For example, global collaboration across registries in Organisation for Economic Co-operation and Development (OECD) countries offers significant value for populations and for health systems.

4. **Build health system leadership capacity in the supply chain as a strategic asset** by leveraging the expertise and experience of strategic supply chain leadership demonstrated in other sectors, such as the grocery, retail pharmacy, travel and automotive industries. A council of strategic advisers could engage the expertise of leaders in other sectors in order to advance supply chain transformation in healthcare systems. Leadership capacity must be embedded in the care delivery system to achieve visibility in offering safe and high-quality care to patients and their families. Specific leadership capacity-building initiatives may include the following:

   - *Provincial government ministries* to develop a roadmap and business case for where and how health sector supply chain innovation investments should focus in the near, interim and long term, and how the value of such investments will manifest and be measured for all stakeholder groups.

   - *Business schools* to create the empirical evidence for the business case of supply chain transformation in healthcare, documenting what strategic investments create value, where investments need to be made, in what order and magnitude, and how those investments can be leveraged to achieve safety in clinical care. Business schools must also build capacity, expertise and research in supply chain and logistics for the health sector to develop the next generation of leaders who will guide and shepherd supply chain transformation across healthcare systems nationally and globally.

   - *Canada Health Infoway and the Canadian Institute for Health Information (CIHI)* to offer a national engagement opportunity in building collaboration across health systems. Linking safety and quality data with the national registry and measurement frameworks would document evidence of the impact of supply chain innovation investments.

5. **Design and implement supply chain visibility scorecards**. A "visibility scorecard" for ministries of health and accreditation organizations would measure progress towards achieving visibility for healthcare systems. As organizations and regional systems progress in achieving supply chain visibility, indicators in the framework would illustrate and inform leaders and stakeholders of the impact that visibility in the system is achieving for patients and families. Such a scorecard would include visibility indicators for safety and product recall that are accessible to patients and families, clinicians, industry and health system leaders.

   Visibility scorecard reports would be automatically generated and disseminated for stakeholders to include an analysis of adverse event tracking. This would enable the setting of targets to achieve improvement in adverse events. Visibility indicators and target goals for both

industry and health system stakeholders would focus on such indicators as inventory costs, targets for cost savings, product performance value indicators (cost of product/value achieved for patients) and inventory tracking. Specific examples of visibility indicators could include the following:

- *Number and type of clinical settings in a health system with GS1 standards* adopted and in use.
- *Number and type of clinical settings with digital tools* to scan, track and trace every product and process linked to patient outcome data.
- *Adverse event and "never event" tracking* automated and reported (daily/weekly) to inform clinical teams, organizations and systems of progress in safety outcomes.
- *Patient volumes and procedure tracking* to assist organizations in health system resource planning, and to inform manufacturers of product demand projections to reduce costly overstocking or product shortages that contribute to adverse events.
- *Inventory tracking* to inform product demand trending and replenishment processes for manufacturers, distributors and healthcare systems, including data management and quality control systems, to track every product, replenish supply based on use and identify product demand patterns for inventory management.
- *Clinical performance indicators* that include product and procedure tracking data to accurately and objectively capture the value of care services for patients (cost of procedures linked to health and wellness outcomes for patients) and to inform procurement processes and decisions.

6. **Align national and global supply chain policies** to streamline global supply chain processes and maintain Canada's viability as an international market and partner. Aligning policy frameworks—for example, by adopting GS1 standards for all products and standardizing regulatory approval processes—enables standardization of product, process and patient outcomes across global jurisdictions. For countries such as Canada, where populations are small and distributed across a vast geography, alignment with other jurisdictions makes it easier for companies to distribute their products to all clinical settings while reducing the risk of product shortages. For health organizations, streamlined policy and pathways would support and enable inventory cost savings and management, ensuring that clinician teams have the products available when and where they are needed for patient care.

Fundamentally, adverse events and error in healthcare are an outcome of an underdeveloped supply chain infrastructure. Supply chain innovation transforms healthcare environments, making it nearly impossible for error to occur. Visibility within and across healthcare systems enables all stakeholders to deliver safe and effective care that contributes to health, wellness and quality of life for Canadians. Requiring, enabling and scaling supply chain traceability based on GS1 global standards achieves better value and builds confidence in the healthcare system. Supply chain infrastructure in healthcare can and must be transformed.

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