PREMIER

Right Patient, Right Time, Right Device:

The Value of Creating A National Unique Device Identification System

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Right Patient, Right Time, Right Device:
The Value of Creating A National Unique Device Identification System

Executive Summary

A patient today faces a significant risk that a recalled medical device could be used in his or her treatment because there is no way for a provider to quickly and reliably identify a recalled device. Unique device identification (UDI), which is applying a uniform and transparent system to identify devices, will strengthen the ability of the Food and Drug Administration (FDA) and manufacturers to monitor adverse events related to medical devices. A national UDI that is coordinated with a global system would create a common vocabulary for reporting and enhance tracking abilities. Moreover, this system will reduce the cost of healthcare.

Although many device manufacturers bar code their products, an industry-wide device identification system with a common vocabulary does not exist, preventing hospitals from consistently tracking their overall device inventory. The lack of an industry-wide device identification system also burdens FDA resources – the agency must weed through large data bases of reported device problems from physicians and patients to identify trends that need follow up.

UDI will also greatly benefit the U.S. healthcare supply chain through increased efficiencies and improved order accuracy, which will result in substantial savings of an estimated **$16 billion annually**. The efficiencies gained and savings realized as a result of UDI will benefit all stakeholders in the supply chain, including healthcare providers, distributors and manufacturers. Patients will be the ultimate beneficiary of a more efficient supply chain system because providers will be able to track recalled products more accurately and improve the quality, safety and affordability of care they provide their patients.

To date, numerous studies and pilots in other industries have demonstrated the savings and efficiencies gained through supply chain data synchronization. In fact, unique identification and data synchronization have been embraced by 20 other industries because of the savings and improved efficiencies obtained. It is long past time for our health system to implement such proven methods of data synchronization.

- Wal-Mart decreased item maintenance **from 15-30 days to 1 day.**
- Procter & Gamble **saved $3 million in administrative costs** that had been devoted to manual information synchronization.
- Sara Lee reported a 59 percent reduction in cost mismatches after the initial 90 days of their price synchronization pilot.

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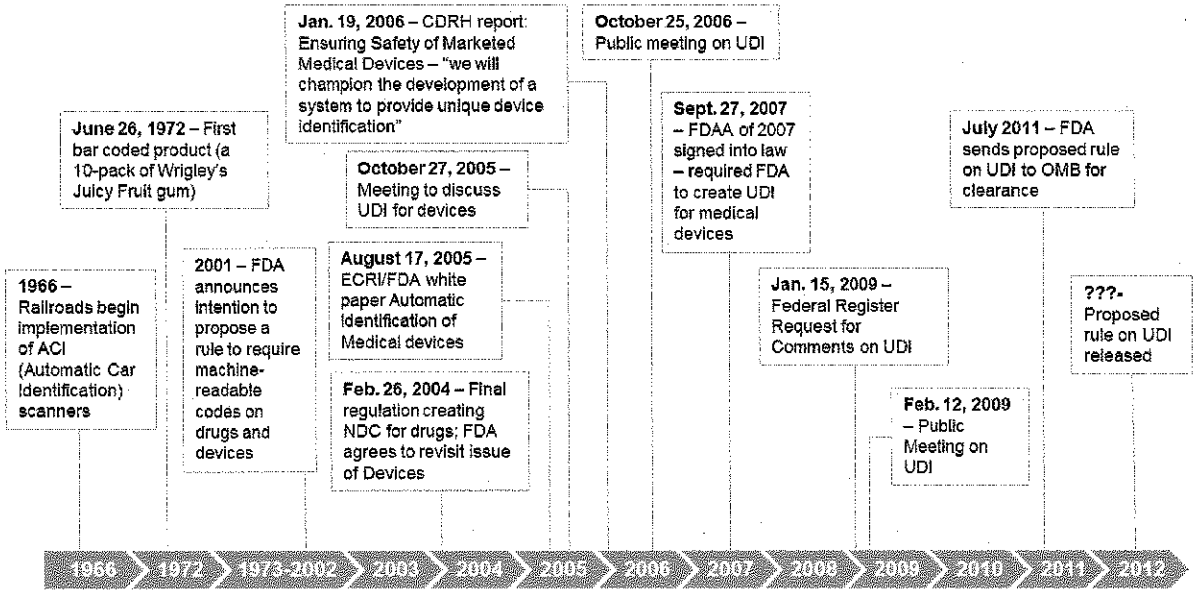
Introduction:

A patient today faces a significant risk that a recalled medical device could be used in his or her treatment because there is no way for a provider to quickly and reliably identify a recalled device. Moreover, without an appropriate identification and tracking system, a defective device could remain undiscovered for a longer time, which is a significant patient safety concern. Additionally, the ability to assess a device's effectiveness is compromised today because, unlike other products in America, no uniform, unique identification system exists for medical devices.

Unique device identification (UDI) will strengthen the ability of the Food and Drug Administration (FDA) and manufacturers to monitor adverse events related to medical devices. A national UDI system would create a common vocabulary for reporting and enhance tracking abilities. Currently, analysis of adverse event reports is limited by the fact that the specific devices involved in an incident are often not known with the required degree of specificity. Without a common vocabulary for medical devices, meaningful analysis based on data from existing voluntary systems is extremely problematic. According to the FDA, they received 66,000 adverse event reports, but 15 percent lacked a model or catalogue number, 50 percent lacked lot or other identifier and 10 percent lacked both.

The FDA has been working on this issue for more than eight years. In that time, the agency has held several public stakeholder meetings, solicited comments and commissioned several studies. Patients cannot afford to wait any longer.



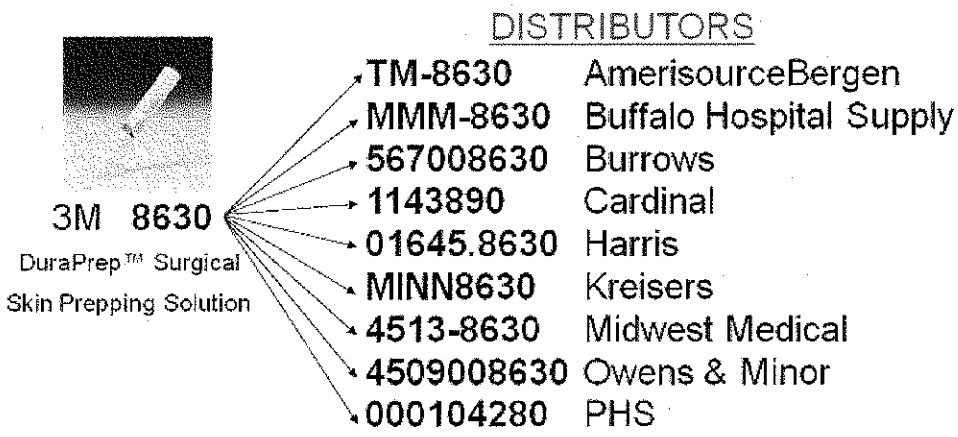
Patient safety case – it's a win-win:

Every year, more than 1,000 medical devices are recalled – many of which can potentially cause serious health problems or death. Manufacturers also issue countless device corrections each year that have serious health implications for patients, such as adding new instructions to devices to prevent device misuse and potential harm.

Even safe medical devices can pose dangerous health threats to patients if used together with other incompatible devices or machinery. For instance, certain pacemakers can negatively interact with the magnetic fields in magnetic resonance imaging (MRI) machines, causing life-threatening injuries – and even death – to thousands of patients undergoing routine imaging procedures. Without an industry-wide identification and tracking system for medical devices, however, healthcare providers cannot identify device incompatibilities in time to avoid these devastating patient safety errors.

Although many device manufacturers bar code their products, an industry-wide device identification system with a common vocabulary does not exist, preventing hospitals from consistently tracking their overall device inventory. As a result, most hospitals are left to manually enter data about devices and review countless records and patient charts when recalls occur – a labor-intensive process that poses a high risk for overlooking affected patients. The diagram below provides an example of how one product gets renumbered in the healthcare supply chain. This makes it very difficult to track and efficiently handle recalls.

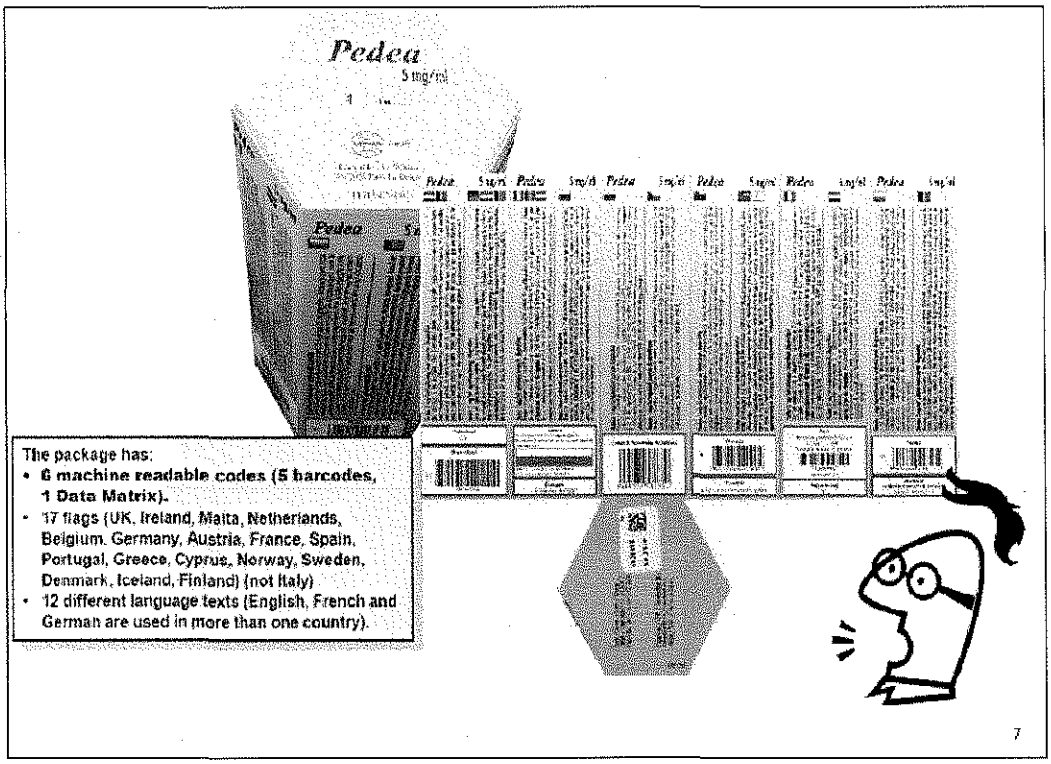
Same Product, Different Numbers:



... plus different numbers in each Hospital Group's MMIS

The lack of an industry-wide device identification system also burdens FDA resources – the agency must weed through large data bases of reported device problems from physicians and patients to identify trends that need follow up. FDA must then flag potential device defects for the public.

This is also a global problem and represents a significant burden to global manufacturers when trying to address country by country requirements for identification and marking. The example below demonstrates this problem.



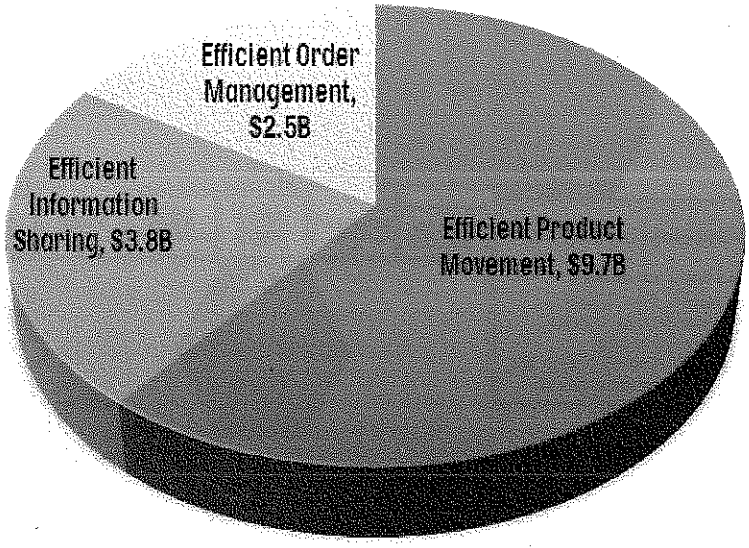
UDI and Supply Chain Savings:

UDI will also greatly benefit the healthcare supply chain through increased efficiencies and improved order accuracy, which will garner substantial savings of **$16 billion annually**. Specifically, UDI will result in accurate orders through improved catalog management and electronic order management, efficient product movement throughout the supply chain, improved inventory management and efficient information sharing.

Other industries have embraced this concept with the grocery industry leading the way on uniquely identifying products through the use of a Unique Product Code (UPC) and automatically identifying the products through bar codes over 30 years ago. On June 26, 1972 the first bar coded product identified with a UPC (a 10-pack of Wrigley's Juicy Fruit gum) was scanned at a check-out counter at a Marsh supermarket in Troy, OH. Since its inception, use of the UPC and bar code identification has grown well beyond the grocery industry so that today, there are over one million companies in more than 100 countries in over twenty different industry sectors enjoying the benefits of scanning bar coded products. It is time the healthcare sector followed suit.

In 1996, the Efficient Healthcare Consumer Response (EHCR) released a study entitled "*Improving the Efficiency of the Healthcare Supply Chain*" stating that $11 billion a year of supply chain costs are avoidable process costs, which could be saved through improved efficiencies. These savings were tied to the adoption of a healthcare identifier, universal product number, identification standards and electronic data interchange and bar coding. This study was recently updated by Arizona State researchers and now estimated supply chain savings total **$16 billion annually for a potential 10 year impact of over $150 billion in savings**.

The majority of the supply chain savings are gained through efficient information sharing, efficient order management and efficient product movement (see chart below). However, there are additional opportunities for savings through physical distribution, transportation, order management and inventory management.



Additionally all the stakeholders—healthcare providers, manufacturers and distributors—in the supply chain stand to share in the savings if the identification standards listed above are realized. However, the biggest beneficiary of a national UDI system will be patients. UDI will enable providers to more accurately and efficiently track medical device recalls, more accurately and improve the quality and safety of care they provide their patients. It will also allow electronic health records to be accurately populated so data to track adverse events and conduct comparative effectiveness research is reliable.

Where are the savings?	
Healthcare Providers	41%
Distributors	26%
Manufacturers	33%

Supply chain studies and pilots demonstrate savings:

As previously mentioned, numerous studies and pilots have been conducted regarding the savings gained through supply chain efficiencies and the creation of a national UDI system.

University of Arkansas: In a 2009 comprehensive survey entitled "*The State of Healthcare Logistics*" conducted by researchers at the University of Arkansas, it was determined that the healthcare supply chain is very inefficient. **In fact, the survey found that the average healthcare provider spends more than $72 million a year on supply-chain functions, which is nearly one-third of their annual operating budget.**

The lack of data standardization was the main obstacle to a mature or extended supply chain. Approximately 75 percent of survey respondents said the lack of data standards is a barrier to their ability to collaborate with other organizations in the healthcare supply chain. Data standards would increase compatibility, reduce redundancy and improve exchange and efficiency.

"Right now, all manufacturers, distributors and providers do not use the same system to identify items, whether they be surgical scissors, heart monitors or cafeteria trays," said Heather Nachtmann, associate professor of industrial engineering. "In short, the health care supply chain is starved for accurate and accessible data, which are the primary barriers to efficiency, collaboration and standardization. Perhaps, needless to say, this is an extremely expensive problem."

Department of Defense (DoD) Data Synchronization Pilot Program: Launched in December 2006, this pilot is the next step in DoD's ongoing, congressionally funded program to test a healthcare "product data utility" (PDU) to reduce healthcare costs, improve business processes and ultimately improve patient safety. In the first phase of the PDU program, the DOD synchronized product data from 23 medical manufacturers, two major distributors and 30 military hospitals, **and identified $10.1 million in savings for the hospitals to date**. The DoD standardized product identification and usage, and created a robust data bank containing more than one million medical/surgical items, including 165,000 synchronized records that represent 93 percent of DoD's most-used medical products.

By synchronizing data, the DOD had better visibility of product and associated contracts/pricing vehicles. EZSav, an application DOD developed to take advantage of the good data, showed customers alternatives for better pricing and also recommended ecommerce sources, eliminating manual contracting for those items. DOD has **saved $35 million purely on price reductions** by buying smarter for the 40 DOD hospitals currently participating. This doesn't take into account the savings accrued in time eliminated doing manual purchases when shifting to ecommerce (prime vendor or web based ordering).

If all participants in the supply chain use the same information, the process of managing the information can be automated. With the implementation of the global trade identification number (GTIN), DOD was able to readily reconcile supplier products to their system products. With this process, there was an estimated **50 percent time savings** in both contract price loads and new item profile data loads.

Premier Purchasing Partners: Premier Purchasing Partners is part of the Premier healthcare alliance, which serves more than 2,200 not-for-profit hospitals and health systems and over 63,000 non acute settings. Premier Purchasing Partners, which aggregates the healthcare provider purchasing power and contracts with suppliers for medical products, conducted a targeted impact study of the potential savings of UDI on

Premier Contracting/Sales Submission process. It was concluded savings would be obtained in several ways:

- Money can be saved on efficiencies if UDI was implemented in the Premier contracting process of over **$50,000 annually**. However, this only looks at efficiencies gained and doesn't remove steps from the process which would likely occur if UDI were implemented so savings could be significantly higher.
- Money can be saved on efficiencies if UDI was implemented in the Premier sales submission process of approximately **$250,000 annually**. However, this only looks at efficiencies gained and doesn't remove steps from the process which would likely occur if UDI were implemented so savings could potentially be significantly higher.

**It should be noted that this Premier savings analyses are based on looking at one process within Purchasing Partners and does not look at other Purchasing Partners activities such as data acquisition, market baskets, revenue reconciliation, contracting management processes, etc. Therefore, the total savings could be significantly higher.*

Global Benefits:

Other countries and companies with a global presence have looked at the issue of data synchronization and have demonstrated its benefits from a global economic aspect. Additionally, as medical device manufacturers distribute products world-wide, a single global unique device identification system would provide additional efficiencies for companies in terms of tracking shipments and reducing the instances of counterfeit products.

Strength In Unity: McKinsey and Co.: In a 2012 research study conducted with the participation of more than 80 healthcare industry leaders around the world, McKinsey estimated the potential value - in lives and dollars – of adopting a single global standard in healthcare. This study quantifies the investments each industry player would need to make to adopt global standards and the business benefits each player might reap. Some notable findings are as follows:

- Improved product recall process. (105,000 medical devices per year)
- Supplement electronic medical records and support management of personalized medicine and product effectiveness.
- Reduce redundant inventories and associated cost. ($60-$94 billion)
- Reduce Obsolescence. ($19-$27 billion)
- Improved supply chain efficiency.
- Every part of healthcare value chain can benefit.
-

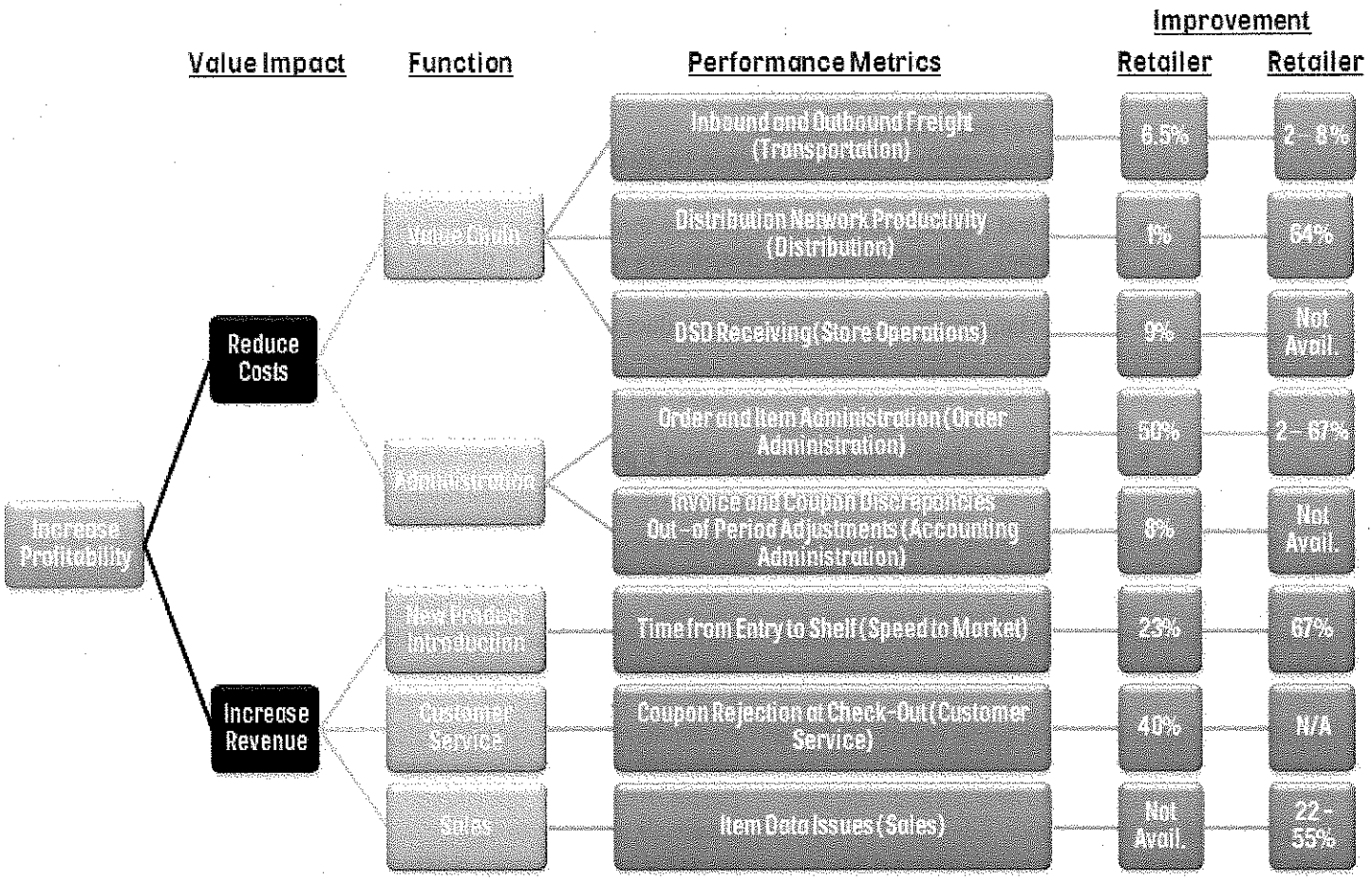
The study is entitled, *"Strength in Unity: The promise of global standards in healthcare."*

Cap Gemini Case Study: In a 2003 case study performed by CapGemini under the leadership of the Global Commerce Initiative (GCI) Steering Group, it was demonstrated that adopting and implementing a global data synchronization program would lead to a **1 percent to 3 percent savings in supply chain costs**. In 2005, GCI and CapGemini conducted a study entitled, *"Global Data Synchronization at Work in the Real World:*

Illustrating the Business Benefits." Researchers looked at several different industries and found all benefited from global synchronization. Some notable findings are as follows:

- Dutch retailer Albert Heijn improved productivity in their data management department by 30 percent.
- Wal-Mart decreased item maintenance from 15-30 days to 1 day.
- Gillette Venezuela improved order-processing productivity and eliminated master data discrepancies by aligning product information with their trading partners.
- Johnson and Johnson decreased out-of-stocks by 2.5 percent by virtually eliminating data integrity issues.
- Procter & Gamble increased purchase order accuracy by 3 percent by focusing on aligning obsolete products with La Fragua in Guatemala.
- Unilever Columbia significantly reduced data inconsistencies and improved new item speed to market by 2 to 3 weeks.
- U.S. retailer Wegmans Food Markets increased store sales by reducing speed to market on new items by two weeks.

Accenture Report: An August 2006 Accenture report entitled "*Synchronization—The Next Generation of Business Partnering*" clearly confirms that companies that take action are making progress and achieving real results with global data synchronization. Suppliers and retailers that have collaborated and taken an integrated approach to data synchronization have realized **even greater benefits** than originally expected.



Validation from other markets:

As mentioned previously in this paper, unique identification and data synchronization have been embraced by 20 other industries because of the savings and improved efficiencies obtained. Several highlights are described below:

- Item synchronization pilot between Procter & Gamble and their customer H.E. Butt.
  - ✓ 75 percent reduction in invoice deductions due to invoice pricing and product delivery discrepancies
  - ✓ 30 percent improvement in the number of accurate purchase orders received
  - ✓ 80 percent improvement in "speed to retail" for new items, price changes, and promotions (reduced the average time required to communicate and execute changes from 10 days to 2 days)
- Procter & Gamble also saved $3 million in administrative costs that had been devoted to manual information synchronization.
- In the food industry, Sara Lee reported:
  - ✓ 59 percent reduction in cost mismatches after the initial 90 days of their price synchronization pilot
  - ✓ Item mismatches were eliminated
  - ✓ Short pays down 86 percent
  - ✓ Over pays down 81 percent
  - ✓ Errors resolved in 2 days versus 10-30 days
- Electrical industry saved 1.75% of sales through error reduction and improved efficiency. Electrical industry distributors saved .75% of sales annually.
- CPG Manufacturers increased new product market share by 5-15 percent.
- CPG Retailers increased sales by 6 percent due to product visibility.
- Electrical industry manufacturers saved 1 percent of sales annually.

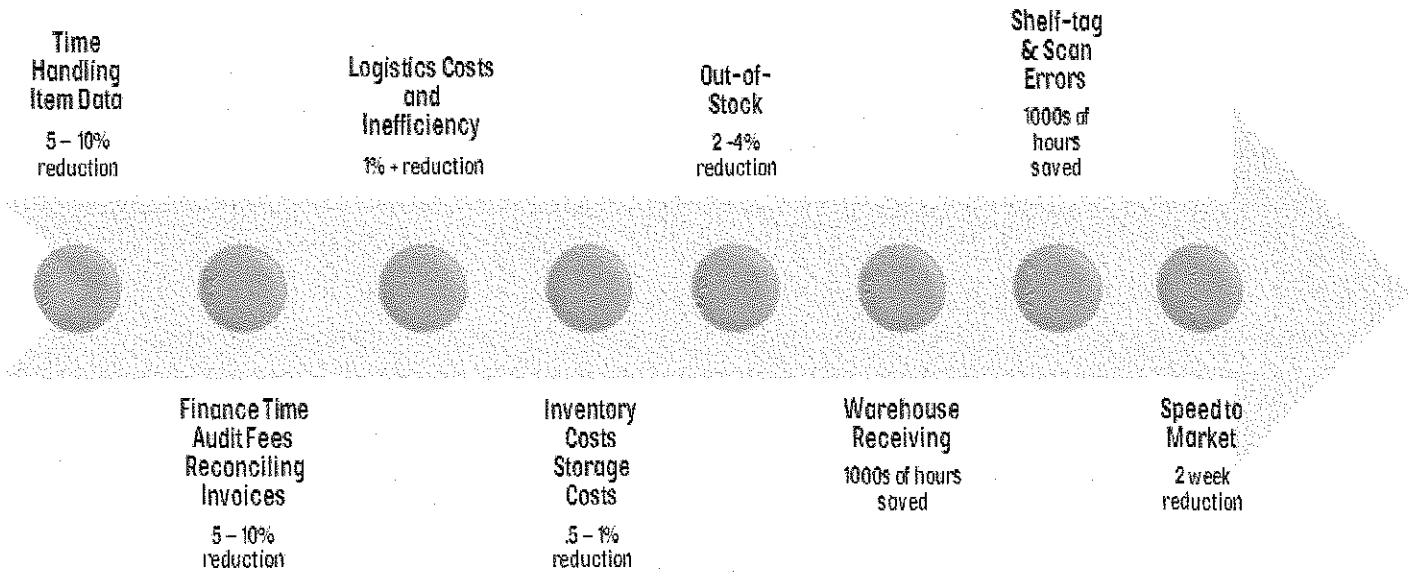
MANUFACTURER BENEFITS REALIZED:

- Three to 5 percent reduction in shelf out-of-stocks
- Two-week reduction in speed to market for new items – i.e., 14 extra days' sales of faster-moving items
- Seven to 13 percent reduction in sales force time communicating basic item information to customers, following up, resolving queries, etc.
- Reduction in call center and website queries regarding basic item information
- Five to 10 percent reduction in sales force and accounting time spent dealing with invoice disputes
- Reduction in invoice write-offs incurred as a result of data discrepancies
- Elimination of basic item data errors, currently found in up to 8 percent of total purchase orders
- 0.2 - 0.7 percent reduction in outbound logistics costs
- 0.5 percent reduction in inventory

RETAILER BENEFITS REALIZED:

- Three to 5 percent reduction in shelf out-of-stocks
- Two-week reduction in speed to market for new items – i.e., 14 extra days' sales of faster-moving items
- 10,000-30,000 hours saved in store labor costs resulting from shelf-tag and scan errors
- 5,000-10,000 hours saved in merchandising and data entry time dealing with new item introductions and updates
- 1,000-2,000 hours saved in finance time dealing with invoice disputes related to basic item information
- Reduction in invoice auditor fees
- One-half to 1 percent reduction in inbound freight costs
- 1,000-2,000 hours saved in warehouse and DSD time dealing with item discrepancies
- One percent reduction in inventory

A.T. Kearney: In 2002, the Grocery Manufacturers of America-Food Marketing Institute Trading Partner Alliance requested A.T. Kearney to conduct an independent review at six pioneering companies to establish a quantification of the costs and benefits of data synchronization. Three leading manufacturers and three leading retailers were selected to participate in the initial case studies – Ahold, USA, Kraft Foods, Nestlé Purina PetCare, Procter & Gamble, Shaw's Supermarkets and Wegmans Food Markets. All six have been pioneers in implementing data synchronization and represent a broad spectrum of size, from relatively small regional players to large diverse conglomerates. The following chart outlines the areas where improvements were achieved and the level of improvement.



Conclusion:

UDI is crucial for providers to ensure the right device gets to the right patient at the right time, which ultimately improves the quality of care for patients. UDI is also an important part of increasing the efficiency and accuracy of device recalls, improving adverse event monitoring and accurately populating electronic health records. Also, as described above, UDI is essential to realizing the estimated $16 billion in supply chain savings.

Given its impact on a broad range of factors—from improving patient safety to reducing costs—in the healthcare industry, it is critical the regulatory process move forward as expeditiously as possible.

APS Advancing Patient Safety Coalition

July 12, 2013

Sylvia Mathews Burwell
Director
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

Dear Director Burwell:

The Advancing Patient Safety Coalition is committed to improving patient safety through the establishment of the national unique device identification (UDI) system. As prominent hospital, physician, nursing, research, quality and patient advocacy organizations, we are writing to reiterate the critical importance of expedited implementation of the UDI rule, currently under review by the Office of Management and Budget.

The Food and Drug Administration Amendments Act of 2007 requires the Food and Drug Administration (FDA) to release a regulation implementing a UDI system. The UDI rule is critical to achieving patient safety improvement initiatives and medical error reduction.

Unlike virtually all other products on the market in America, there is no uniform identification system for medical devices, many of which are implanted in patients. Considering the number of medical device recalls each year, the risk and costs to patients continues to grow until we have a national UDI. In fact, in 2012 alone, the FDA recalled a total of 50 medical devices that were either defective or a risk to health. The resulting *ad hoc* approach results in increased clinical risks to patients and an estimated $16 billion in costs annually due to inefficiencies in the medical products supply chain.

It is critical now more than ever to expeditiously implement UDI. As we recommended in our previous comment letter, the implementation timetable in the proposed rule would mean that UDI labeling and related Global Unique Device Identification Database (GUDID) information submission requirements for class III, II and I devices would apply beginning one, three, and five years, respectively, following publication of the final rule. Further, for devices subject to direct marking requirements, compliance with these requirements would be required two years after the date specified for compliance with UDI label requirements for a device category. This would make for a seven-year implementation timeframe.

We believe that the proposed seven-year timeframe is simply too long and that patient safety would not be well served by such a leisurely implementation schedule.

We, therefore, urge the OMB to make clear the importance of an expeditious implementation of UDI and require a shortened timetable, where implementation of the UDI requirements relating to device labels and packaging would be completed within two years of the effective date of the final rule, and under which implementation of the UDI requirements related to direct marking of devices would be completed within three years of such effective date. And we strongly support the proposed one-year implementation timeframe for class III devices.

We also wish to emphasize that under our recommended timetable, labelers should be required to submit all relevant information to the GUDID at the same time that UDI requirements relating to labels and packaging take effect. The information to be incorporated into the GUDID is important to public safety, and public access to such information at the earliest opportunity will be of enormous benefit to all stakeholders.

We are anxious to see the UDI system up and running and contributing to patient safety efforts as soon as possible, and we appreciate your serious consideration of our recommendation regarding the critical importance of an expedited UDI implementation timeline.

Sincerely,

AARP
Association of American Medical Colleges (AAMC)
Alpha-1 Association
Alpha-1 Foundation
America's Essential Hospitals (formerly NAPH)
American Medical Association (AMA)
American Nurses Association (ANA)
Association for Professionals in Infection Control and Epidemiology (APIC)
Catholic Health Association of the United States (CHAUS)
COPD Foundation
Federation of American Hospitals (FAH)
National Association for Continence (NAFC)
Novation
PeaceHealth
Premier healthcare alliance
National Rural Health Association (NRHA)
The Society for Cardiovascular Angiography and Interventions (SCAI)
Truth in Medicine Inc.
University Health Systems Consortium (UHC)
VHA Inc.
West Virginia United Health System (WVUHS)

APS Advancing Patient Safety Coalition

November 6, 2012

Submitted electronically at: http://www.regulations.gov

Margaret A. Hamburg, MD
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
5630 Fishers Lane, room 1061
Rockville, MD 20852

Attention: FDA-2011-N-0090

Re: Unique Device Identification System

Dear Dr. Hamburg:

The Advancing Patient Safety Coalition is committed to improving patient safety through the establishment of a national unique device identification (UDI) system. As prominent hospital, physician, nursing, research, quality and patient advocacy organizations, we welcome the opportunity to submit comments regarding the proposed rule on the UDI system, which was published in the July 10, 2012 issue of the *Federal Register*.

The proposed rule would, among other things, require:

- The label and package of medical devices to bear a UDI unless alternative placement is permitted or an exception applies;
- Certain devices to be directly marked with a UDI; and
- Labelers of medical devices to submit information concerning each device to the Global Unique Device Identification Database (GUDID).

UDI basics

The proposed rule calls for the following UDI framework:

- A UDI would be a unique numeric or alphanumeric code that includes a mandatory device identifier, which is specific to a device model, and a production identifier, which includes the current production information for that specific device, such as the lot or

batch number, the serial number and/or expiration date, when those attributes are included on the label.

- The UDI would need to be displayed on the label and package of medical devices.
  - The FDA notes that a UDI would be required to appear on an individual device package, on a box of five packages, and on a carton of ten boxes of five device packages, because both the box and the carton would be considered device packages.
  - The UDI would need to be directly marked on the device itself for certain categories (an issue discussed in more detail later in these comments).
- A different UDI would be required for each version or model of a device.
- If a product is discontinued, its UDI would not be reassigned or reused for another product.
- Labelers would be prohibited from using more than one device identifier from any particular accredited system to identify a particular version or model of a device, but if they use systems operated by two or more issuing agencies, they would be permitted to identify a device with one identifier from each system.
- The UDI would need to be displayed in plain text format and also in a form using automatic identification and data capture (AIDC) technology, such as bar codes, radiofrequency identifiers, or other near-field communication.

We support the general UDI framework. **On patient safety grounds, we urge the FDA to ensure that UDI requirements apply down to the normal unit of use for a patient so that a device can be properly identified as it is being used by or furnished to the patient.**

Effective dates

The implementation timetable in the proposed rule would mean that UDI labeling and related GUDID information submission requirements for class III, II and I devices would apply beginning one, three, and five years, respectively, following publication of the final rule. Further, for devices subject to direct marking requirements, compliance with these requirements would be required two years after the date specified for compliance with UDI label requirements for a device category. This would make for a seven-year implementation timeframe. The FDA Safety and Innovation Act, P.L. 112-144, enacted following publication of the proposed rule, will, however, require implementation of final regulations with respect to the packaging and labels of devices that are implantable, life-saving, and life sustaining not later than two years after the regulations are finalized, and thus the proposed timetable would need to be revised accordingly.

In addition, we believe that the proposed seven-year implementation timeframe is simply too long and that patient safety would not be well served by such a leisurely implementation schedule. **We, therefore urge the FDA to finalize a shortened timetable, under which implementation of the UDI requirements relating to device labels and packaging would**

be completed within two years of the effective date of the final rule, and under which implementation of the UDI requirements related to direct marking of devices would be completed within three years of such effective date. And we strongly support the proposed one-year implementation timeframe for class III devices. We also wish to emphasize that under our recommended timetable, labelers should be required to submit all relevant information to the GUDID at the same time that UDI requirements relating to labels and packaging take effect. The information to be incorporated into the GUDID is of critical importance to public safety and public access to such information at the earliest opportunity will be of enormous benefit to all stakeholders.

Exceptions and alternatives

The proposed rule would provide a large number of exceptions to the UDI and related GUDID information submission requirements. For example, section 801.30(a)(1) proposes an exception for devices, other than prescription devices, that are sold at retail establishments, such as drug stores. This proposed exception would apply even when such devices are sold directly to a hospital or other healthcare facilities. The FDA gives as examples automatic external defibrillators, insulin syringes, glucometers, tampons, thermometers, toothbrushes, and bandages. The FDA further notes that labelers of such devices could choose to submit data to the GUDID on a voluntary basis. If they did, a device's UPC could serve as its UDI.

We are concerned about the proposed exception for devices sold at retail establishments and urge the FDA to reconsider. **For reasons of patient safety, we believe that these devices should be subject to UDI requirements, including GUDID information submission obligations, and that their UPC should be deemed to be the UDI for this purpose.** At minimum, devices, such as automatic external defibrillators and glucometers, for which a malfunction would pose a serious health threat to patients and consumers, should be subject to the UDI requirements.

Combination products and convenience kits

Under the proposed rule, a combination product whose primary mode of action is that of a device would be subject to UDI labeling requirements. On the other hand, if the FDA has determined that the primary mode of action of a combination product is not that of a device, it would not require a UDI on the label or package of the combination product. In addition, each device constituent part of a combination product would need to have its own UDI regardless of whether the combination product itself is subject to UDI labeling unless such constituent part is "physically, chemically, or otherwise combined with other constituents of the combination product in such a way that it is not possible for the device constituent part to be used except as part of the use of the combination product." The FDA also proposes to require a UDI on the label and device package of each convenience kit, as well as a distinct UDI for

each device in a convenience kit, unless an included device is intended for a single use (e.g., an adhesive bandage).

We generally support the above policies. For reasons of patient safety, we believe it would be important to ensure that any device constituent parts of a combination product that may be used independently or any device within a convenience kit that may be used more than once (whether or not intended for single use) is individually labeled with a UDI. In fact, we believe that labelers should err on the side of redundant labeling to ensure patient safety.

Direct marking of devices

Under the proposed rule, certain devices would need to be directly marked with a UDI, including implantable devices (but only if they are intended to remain implanted continuously for a period of 30 days or more, unless the FDA commissioner determines otherwise in order to protect human health). Further, the UDI conveyed by direct marking could be either the UDI that appears on the label of the device, or a different UDI used to distinguish the unpackaged device from the device while it remains in packaged form. As noted earlier, the FDA also proposes that the requirement for direct marking of a device would go into effect two years after the date specified for compliance with UDI label requirements for that device (for example, seven years after publication of the final rule in the case of class I devices).

On patient safety grounds, we are inclined to believe that allowing different UDIs for packaged and unpackaged devices for which direct marking is required could lead to some confusion. We are also inclined to believe that having the same UDI for both packaged and unpackaged products would be preferable in that it would appear to allow hospitals and others to more efficiently determine a device's UDI, record this information into medical and other appropriate records, and track devices in recall situations. **We, therefore, urge the FDA to assess these issues as it develops the final rule.**

We also recommend that all implantable devices be subject to direct marking requirements, not just those intended to remain implanted for 30 days or more. We believe this would be preferable from a patient safety perspective and simpler and easier to implement than the proposed approach of allowing the FDA commissioner to determine, on a case-by-case basis, whether devices implanted for periods of less than 30 days must be directly marked.

As noted earlier, **we also believe that the proposed timeline for requiring direct marking of certain devices should be considerably shortened to no more than three years after the effective date of the final rule. This would help ensure that important patient safety goals are achieved at the earliest possible opportunity.**

Global Unique Device Identification Database (GUDID)

Under the proposed rule, the FDA would establish the GUDID, which would contain critical information submitted by device labelers on the attributes of medical devices and which would be publicly accessible without charge. Labelers would be responsible for submitting data concerning a device to the GUDID, and for keeping the information up to date.

We urge the FDA to provide more information about how device recalls will be handled in the context of the GUDID, including the respective responsibilities of the FDA, device manufacturers and other stakeholders. On patient safety grounds, we believe that it would be extremely important for recall information to be easily accessible to those logging into the GUDID. For example, if a hospital accesses the GUDID, it should be readily and immediately apparent if a recall applies to a given device. We, therefore, urge the FDA to take the necessary steps to ensure this outcome.

We hope the preceding comments are helpful. We are anxious to see the UDI system up and running and contributing to patient safety efforts.

Sincerely,

AARP
Alliance for Advancing Nonprofit Health Care
Alpha-1 Foundation
American Congress of Obstetricians and Gynecologists
American Nurses Association
American Urological Association
Association for Professionals in Infection Control and Epidemiology
Association of American Medical Colleges
Catholic Health Association of the United States
COPD Foundation
Failed Implant Device Alliance
Federation of American Hospitals
MedicAlert Foundation
National Association for Continence
National Association of Public Hospitals and Health Systems
National Rural Health Association
Premier healthcare alliance
The Society for Cardiovascular Angiography and Interventions
Society for Healthcare Epidemiology of America
Truth in Medicine Incorporated
West Virginia United Health System

July 8, 2013

Sylvia Mathews Burwell
Director
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

RE: Release of the Unique Device Identifier Final Rule.

Dear Ms. Burwell:

We are writing to urge you to finalize U.S. Food and Drug Administration (FDA) regulations establishing a device identification system. This unique device identifier (UDI) system will serve as the cornerstone to improving medical device safety and quality. Section 614 of the Food and Drug Administration Safety and Innovation Act mandated that the administration finalize the UDI regulations by June 19. Further delay will impair the FDA's ability to conduct important safety surveillance of medical devices to improve patient safety and the quality of care.

The Pew Charitable Trusts is an independent, non-profit research and public policy organization. Pew seeks to enhance medical device safety and foster device innovation that benefits patients.

Premier is the nation's largest performance improvement alliance of more than 2,800 hospitals and 95,000 alternate sites using the power of collaboration and technology to lead the transformation to coordinated, high-quality, cost-effective care. Owned by healthcare providers, Premier is a world leader in measurably improving patient care through the nation's largest performance improvement collaboratives, including one in partnership with the Centers for Medicare & Medicaid Services.

Recent recalls and failures of medical devices—including metal-on-metal hips and cardiac defibrillator leads—clearly demonstrate the need to more quickly identify problematic products before they are used in hundreds of thousands of U.S. patients. Additionally, the Government Accountability Office found that more than half of medical device recalls conclude without the correction or removal from the market of all defective products.

Improved device identification will help address these deficiencies and realize significant benefits to patient care. Through the UDI system, medical device packaging—and, when applicable, the device itself—will bear a code corresponding to the product make and model as well as other relevant information, such as expiration date and lot number. The UDI system will ensure more accurate adverse event reporting, enable improved evaluations of marketed devices, reduce medical errors through improved device identification, decrease healthcare supply chain costs, and facilitate more comprehensive recall resolution.

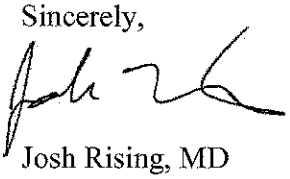
To achieve the benefits of the UDI system, the administration must first promptly finalize the UDI rule. The FDA has sought use of the UDI for well over a decade, and Congress instructed the FDA in 2007 to develop a medical device identification system to track products through their distribution and use. In 2012 Congress again mandated the development of the UDI system, this time requiring a final UDI rule within six months of closing the comments period on the proposed rule—that is, by June 19, 2013.

The FDA has identified UDI as a central component to the national medical device postmarket safety plan, which committed the agency to release the UDI regulations by the end of June. Furthermore, the final UDI rule is essential in order for the Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services to consider the capture of device identifiers into the next updates to electronic health record standards and meaningful use criteria. The agencies intend to commence rulemaking next year on these topics based on input from federal advisory committees, which are already compiling recommendations and have begun discussions on UDI.

Given the importance of this new device identification system to improve patient care and the missed statutory deadline, we strongly urge you to promptly complete review of the UDI final rule. This will clear the way for the FDA to begin implementing this new device identification system and achieving its significant benefits to physicians, health systems, manufacturers and—most importantly—patients.

Should you have any questions or if we can be of assistance to help realize the important benefits of the UDI system, please contact Josh Rising, director of medical devices at The Pew Charitable Trusts, at 202-540-6761 or jrising@pewtrusts.org or Blair Childs, senior vice president at the Premier healthcare alliance, at 202-879-8009 or blair_childs@premierinc.com.

Sincerely,



Josh Rising, MD
Director, Medical Devices
The Pew Charitable Trusts

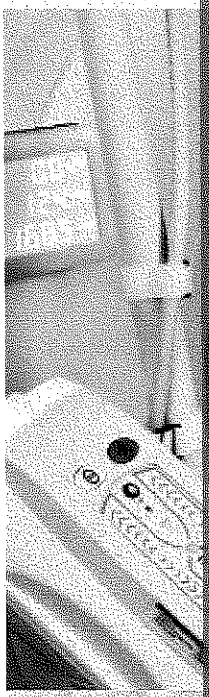
Blair Childs
Senior Vice President, Public Affairs
Premier healthcare alliance

McKinsey&Company

Strength in unity:

The promise of global standards in healthcare

October 2012



October 2012

Strength in unity:

The promise of global standards in healthcare

Thomas Ebel
Katy George
Erik Larsen
Everett Neal
Ketan Shah
David Shi

The authors wish to acknowledge Manuel Bäuml, Jackie Hu, and Sherry Kan for valuable contributions to the report

McKinsey would like to thank GS1 for its contribution to the analysis and fact base which provide the foundation of this report. McKinsey would also like to thank the interviewees for their expert insights.

Executive Summary

An opportunity for a new kind of healthcare innovation

Imagine a world where a patient's records capture the brand, dosage, and lot number of each drug and medical device she uses, along with the name of the physician who ordered the product and the nurse who administered it; where bedside scanning confirms that she gets the right product in the right dosage at the right time; where hospitals and pharmacies know the exact location of short-supply medical devices and drugs and when they can be delivered; where regulators can recall adulterated products with accuracy and speed from every point in the supply chain; and where manufacturers can monitor real-time demand changes and shift their production schedules accordingly.

In this world, patients would enjoy consistently safer and more effective healthcare, with fewer mistakes and shorter average hospital stays. Redundant activities and costs would be driven out of the system – reducing the cost of healthcare to society and enabling broader global patient access to cutting-edge medical technologies. Doctors and nurses could spend less time with paperwork and more with patients. Opportunities for innovation would open up – enabling new progress in personalized medicine, customized devices, and mobile health.

This world is technologically possible today. But it has yet to become a reality because the healthcare supply chain, from manufacturer to patient, remains fragmented, with limited visibility and interconnection. Certain channel partners are making progress by collaborating, and individual companies and even countries are documenting excellent results with cutting-edge practices. But only a few players are making these innovations and advances. More widespread adoption will permit significant, cost-effective improvements at scale. In fact, because these efforts are not consistent or global, they may actually raise the cost and complexity of the global healthcare supply chain by spawning incompatible requirements and systems.

To build a world of interconnected cost-effective healthcare, the healthcare industry could align around a single set of global standards that support the processes and capabilities required to achieve the kinds of benefits we describe. The consumer and retail industries have demonstrated the value of this kind of standards alignment with their adoption of GS1® standard barcoding, which has reshaped these industries and created billions of dollars in value. While new processes, tools and systems were required to deliver this value, usage of one single global standard was a critical prerequisite.

New research by McKinsey & Company, conducted with the participation of more than 80 healthcare industry leaders around the world, has estimated the potential value – in lives and dollars – of adopting a single global standard in healthcare.

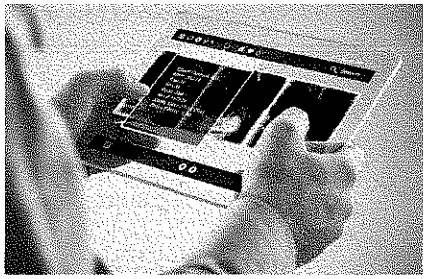
This report presents those findings and also quantifies the investments each industry player would need to make to adopt global standards and the business benefits each player might reap, assuming global adoption of a common standard and supporting processes. We point to some of the new insights, products and services that might arise from global standards, as they have in the retail industry. We also look to the precedent set by the consumer and retail industries to understand how leaders in the healthcare space could begin aligning around a single global standard.

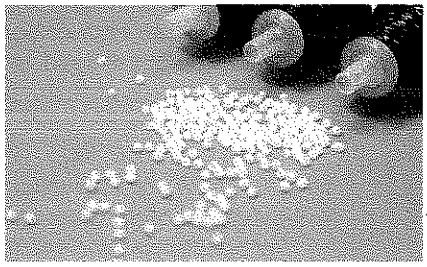
The value at stake is significant in patient safety and supply chain efficiencies

Global standards that link geographies and stakeholders, from manufacturer to patient, could help the industry improve patient safety and the efficiency and effectiveness of healthcare systems. Using global product identification to match patients with drugs, for example, could help hospitals reduce the number and severity of adverse drug events, which, according to our research, now stand at more than 25 million with over 100,000 deaths annually. Product recalls, now occurring about 15 times per week in medical devices and 20 times per week in pharmaceuticals in the U.S. alone, could be managed more efficiently and more comprehensively. Global product identification could help reduce the growth of counterfeit drugs and allow faster responses upon detection in the supply chain. Global standards could supplement electronic medical records and support the management of the complexity associated with personalized medicine and customized medical devices.

Furthermore, global standards could reduce the need for redundant inventories across the healthcare value chain. Today, the healthcare industry has half a trillion dollars tied up in inventory, but better collaboration enabled through global standards could reduce obsolescence and inventory redundancy. Global standards could enable inventory reduction of $60-94 billion and reduce the costs of managing and storing inventory by $10-14 billion. Furthermore, it could help reduce obsolescence by $19-27 billion.[1]

However, the potential impact enabled by global standards goes well beyond the use cases that we can identify and quantify today. For example, with global standards in place, payors, regulators and epidemiologists could learn more about the effectiveness of drugs, medical devices and treatments, improving health and yielding savings at the institutional and even national level. End-to-end supply chain visibility could create new opportunities in mobile health, helping patients to maintain their regimens, avoid drug interactions, and learn more about products and how to order refills electronically for delivery at home.





[1] All financial figures in this report are in U.S. dollars unless otherwise noted.

Every part of the healthcare value chain can benefit

In order to align around a single set of global standards, companies would have to come together across geographies and parts of the value chain. The healthcare executives we spoke with acknowledge that achieving this won't be easy. They recognize that major players would need to agree on global standards that might differ from what they use today—and then adopt new processes and systems to make the best use of those standards.

Some healthcare pioneers have already begun the journey. Certain pharmaceutical and medical device manufacturers and hospitals are now using global standards such as GS1® Global Trade Item Numbers (GTIN®), GS1 Global Location Numbers (GLNs), and data exchanges such as the GS1 Global Data Synchronization Network (GDSN®). Their approaches leverage standards as a foundation for collaboration across the value chain – enabling new processes and capabilities that create both patient and business value:

- **Bedside scanning to match each patient**, healthcare professional, and drug or medical device, reducing errors in the hospital;
- **Efficient and effective recall administration** using automatic identification and data capture along the supply chain and at medication dispensing points and operating rooms;
- **Medication authentication** to help pharmacies, hospitals and physicians identify counterfeit drugs and reimbursement fraud;
- **Inventory management collaboration** between dispensing and usage points and manufacturers, and product availability data from manufacturers to pharmacies and hospitals; and
- **Automated transaction and data-sharing** that eliminate manual data entry, validation and correction, reducing errors and costs.

We have reviewed more than 25 case examples of these kinds of collaborations. Our evaluation of these examples of early standards adoption suggests that even in these one-off applications, each participant in the healthcare system "microcosm" generated significant benefits. Furthermore, our analysis of expected investments and potential benefits that could accrue to each player in the healthcare value chain indicates that all parts of the system could achieve a positive return on investment from adopting global standards and enabling business processes – if a "critical mass" of channel partners adopt the same standards. In other words, global standards adoption is not a "zero-sum" game in healthcare: benefits could be shared across the value chain, given sufficient adoption and standardization. We also estimated the cost impact for players to work with multiple standards and found that, even if players needed to support two standards rather than one, the additional one-time investment and ongoing operating cost impact could be significant.

Collaboration: A vision of progress for patient benefit

While our research indicates that all healthcare players could benefit from global standards, aligning around a single standard presents inherent challenges. In the consumer packaged goods industry, large global players collaborated and negotiated to set standards for the rest of the industry. The healthcare industry, however, is much more regional and fragmented. While a few major retailers could set expectations and requirements for consumer packaged goods suppliers, manufacturers represent the largest and most global segment in healthcare. Healthcare is also more heavily regulated. Indeed, some regulators are already defining standards to meet national rather than global goals, creating a range of sometimes conflicting requirements, although there are also efforts at harmonization, such as the International Medical Device Regulators Forum for global harmonization of medical device regulation, and the European Commission for harmonization of serialization of pharmaceuticals across the EU.

Many of the leaders we interviewed are keen to help the industry move up the adoption curve in healthcare. They are united by a collective commitment to improving patient safety. They understand that achieving this improvement will require a concerted effort by industry leaders who work across competitive and customer-supplier relationship boundaries to agree on a common vision and approach. They expressed a need for a deeper understanding of the requirements and the benefits and costs of global standards. Some are already considering how to leverage global standards to do more than comply with regulations: they aspire to create distinctive value in customer and patient service and relationships. As a group, they are very interested in working together to define a collective strategy and approach for standards alignment, adoption and benefits capture and a growing understanding that this must include the selection of a single global system of standards.

In this paper, we present an objective assessment of factors that industry leaders might consider in this effort.

"Supply chain data standards will greatly improve healthcare safety and efficiency, but safety is our primary value. The needs of the patient come first."

–Medical device executive

1. Introduction and context:
Today's Healthcare Supply Chain

Supply chain opportunities look bigger than ever

Healthcare organizations have sometimes been slow to recognize the importance of supply chain improvements. Some manufacturers have worried more about keeping their pipelines full than about excess inventory or inaccurate demand forecasts, for example. Hospitals, many facing significant constraints in financial and human resources, necessarily have often focused more on patient care than on tracking drugs and medical devices from pharmacy to bedside.

Healthcare leaders are now beginning to understand how basic supply chain improvements can significantly improve patient care and free up human and financial resources for advances in other areas, including forecasting and R&D.

Nevertheless, the industry has just begun its journey to supply chain excellence. In some ways, in fact, it may be 30 years behind the grocery business in terms of sophistication. Consider a few performance indicators:

- The average pharmaceutical manufacturer carries 7 months of inventory, and the whole value chain, down to the patient, holds about 9-10 months of inventory—triple or quadruple the inventories of many consumer goods segments.

- Obsolescence costs the typical pharmaceutical manufacturer 3-4% of the cost of goods, although some see rates of up to 6-8%. Assuming additional obsolescence of 1-2% downstream, pharmaceuticals carry 4-6% of product cost in obsolescence, roughly the same as fresh products like dairy. But the shelf life of milk is only about 2 weeks; most drugs have shelf lives of 2 years or more

- Pharmaceutical companies are not immune to service challenges. Customer service levels sometimes fall as low as 93%—far below what would be acceptable at many retail companies.

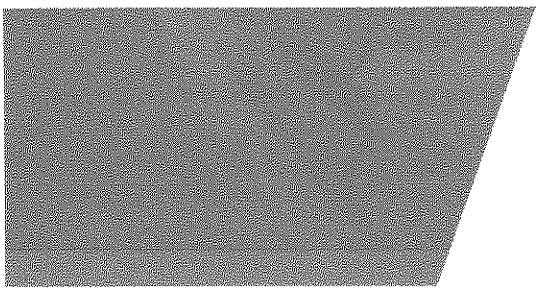
"We're seeing growth opportunities in some emerging markets. But to generate significant profits there, we'll need a more streamlined supply chain."

—Senior executive at a medical device manufacturer

The situation appears to be changing. In our work with clients and in industry forums, we are engaging leading supply chain executives and senior management on supply chain issues. Nearly all agree that supply chain improvements are now among the top priorities, at least in the operations function, if not the entire organization. Most agree that the supply chain will become even more important, and aspire to go beyond incremental changes to make step-change improvements.

An increasing number of executives see supply chains as a critical cross-functional topic and enabler of commercial functions and customer relationships that can drive substantial top- and bottom-line impact. They recognize that making these changes will not be easy, particularly in the currently challenging economic times. The supply chain executives and CEOs we have spoken with this year have three top concerns:

- Increasing complexity due to product proliferation and geographical expansion;
- Increasing regulatory scrutiny and quality issues; and
- IT challenges, including the lack of systems integration, interoperability, and the efforts associated with major IT projects.



An increasingly global marketplace means more complexity

Opportunities abound in emerging markets, but serving them presents formidable challenges. Forecasts suggest that the pharmaceutical markets in India and China will grow at about 17% in each of the next 5 years, while the medical device markets grow at 11% and 22% in each country respectively,[2] far outstripping growth in overall regional trade balances. Over the past 10 years, medical device and pharmaceutical trade flows have grown at least twice as fast as manufacturing trade balances on average.[3]

Global manufacturers are positioning themselves to benefit from this growth, but many will need to lower their price points significantly.

An efficient supply chain is a key to profitably serving emerging markets, especially as products and packaging become more complex. McKinsey benchmarks show that for pharmaceutical manufacturers, the number of SKUs (stock keeping units) per packaging line has increased by more than 50% in the last 3-5 years.[4] We do not have similar benchmarks for medical devices, but innovations, such as in stents and other drug-device combinations, continue to add complexity.

[2] Global Insight's World Overview; BMI.
[3] World Trade Organization.
[4] Based on 10 solids plants with recurring participation in McKinsey benchmarking

Quality and safety are more important than ever

Across the industry and around the world, quality is a rising concern. In the medical device sector, the number of patients reported injured in serious adverse events in the US increased by 17% per year from 2001-2009, topping 28,000 in 2009. The number of medical device recalls in the US grew 6% per year from 2003-2009, surpassing 700 in 2009.[5]

Pharmaceutical recalls have grown even faster: by 26% per year from 2005-2011, to more than 1,000 per year now.[6] Not surprisingly, regulatory scrutiny has increased along with safety issues: the US FDA issued 18 Good Manufacturing Practice (GMP) warning letters to pharmaceutical manufacturers in 2005, and 53 in 2011—a nearly 200% increase. Regulators' response times also increased: the share of FDA warning letters issued within 4 months of inspection rose from 14% to 26%.

Few healthcare organizations have responded to the rise in recalls by improving the efficiency or effectiveness of their recall processes. Many recalls still require hundreds of hours of manual labor and still fail to remove all affected products from inventories or locate every exposed patient.

The pressure to improve will increase as payors move to different reimbursement models. This primarily impacts provider organizations, which see their revenue stream changing from fee-for-service to capitated models or other forms of risk-sharing agreements. Providers who can optimize safety and the quality of care without raising costs may thrive under such models—if they can show how their pharmaceutical, medical device and supply choices affect patient outcomes. Standardized identification and automated tracking of healthcare products, from factory to bedside, could help make this possible.

"We're seeing dramatic increases in recalls and in harm to patients. What we're not seeing is any major improvement in recall processes."

—National regulator

[5] MAUDE database, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
[6] FDA Gold Sheet.

The healthcare industry faces a potentially costly patchwork of requirements

Regulators around the world are defining new supply chain requirements to protect patients from substandard and defective products and ever more sophisticated counterfeits, especially pharmaceuticals, although medical devices are also raising concerns. Pharmaceutical manufacturers are being required to serialize products with unique identifiers at the unit of sale level, which often requires new capabilities and large investments in hardware and software.

Some markets, including China, India (export only) and Turkey, have such requirements today, and many other major markets are expected to follow suit in the next few years. California may adopt E-Pedigree, for example, and the EU member states may ratify yet to be defined medication authentication systems following the EU's Falsified Medicines Directive. Recent research for a global pharmaceutical manufacturer indicated that over 70% of its sales would be subject to these new regulations by 2017.

Many of these developing requirements vary by country. Some authorities are looking to GS1 standardized barcodes and product identifiers, such as GTIN, while others have developed or are developing different systems to protect the supply chain. The EU may be considering serialization and authentication of medications only during dispensing at retail pharmacies.

While these rules may be based on a single global standard, they vary widely around the world, posing complex new challenges for global manufacturers and raising costs at every step of the value chain. Over the long term, the patchwork could become unworkable. Our analysis suggests that adopting a single set of global standards will cost significantly less than two and far less than three or more.

"It is a fantastic amount of work to scrub and clean data so we can connect the dots; in every planning period, people spend weeks trying to reconcile data and geographies...it is diabolical."

—Pharmaceutical supply chain executive

II. Standards as a foundation for change

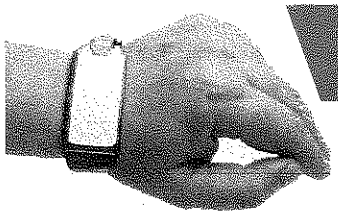
Global standards could help save thousands of lives and billions of dollars each year

Global standards could be a critical enabler to improving the safety and quality of patient care in a cost-effective way. Our analysis suggests that these standards have greater potential to improve care and save resources if they are truly global and adopted by all stakeholders, including manufacturers, distributors, wholesalers, pharmacies, and providers.

Universally accepted methods for identifying products and locations and exchanging data could enable organizations to share vital information along the entire value chain, eliminating today's broad array of custom data configurations, while improving compatibility and interoperability, reducing redundancy, preventing medication errors, enhancing visibility, and enabling seamless, automated information exchange among supply chain partners.

The "Five Rights" are the cornerstone of safe medication practices. A complete and uniform definition for the "Five Rights" does not exist, but healthcare practitioners generally understand the essential meaning in the following way:

"Five Rights"



1 Right patient

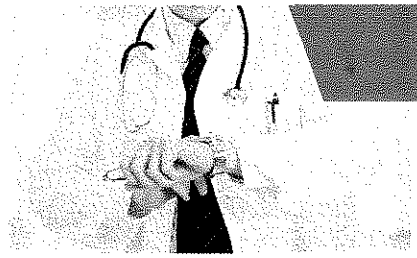
The patient's identity must be verified against the prescription to ensure the right patient is receiving treatment;

2 Right medication

The provider must verify that the right medication is used;

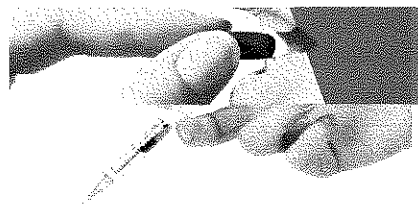
3 Right dose

The right dose should be confirmed against the prescription;



4 Right time

Medications should be given at the right time; and



5 Right route

Medications that can be given in different ways, such as intramuscularly or intravenously, must be given via the right route;

The Five Rights contain no procedural guidance, relying more on "strong policies and procedures – a system organized around modern principles of patient safety, and a robust safety culture" than on individual performance.[7] Similar Five Rights can be construed for the use of medical devices.

[7] AHRQ PSNET (Agency for Healthcare Research and Quality, Patient Safety Network), http://www.psnet.ahrq.gov/

Global standards could enable industry-wide applications and processes that support the Five Rights, improving patient safety and supply chain efficiency:

- Bedside scanning: Before administering medications, caregivers could scan barcodes on medications, patient wristbands, and their staff ID badges to conduct an automated Five Rights check. This simple process could eliminate thousands of errors and help prevent the use of expired and recalled medication and medical devices.

- Targeted full recall administration: An automated data capture process at medication dispensing points and operating rooms could use unique identifiers. Pharmacists, operating room staff, and caregivers could record the production identifiers associated with medications and medical devices administered to each patient. In the event of a recall, providers could promptly identify and contact each patient who received the product and remove every recalled product from inventory.

- Traceability of medical devices: Supply chain partners could use barcodes to track medical devices through the supply chain according to their risk category, and for the appropriate class of products, full traceability of medical devices could further enhance the processing of recalls and facilitate inventory management.

- Medication receipt authentication: Distributors, pharmacies, and hospitals could use barcodes to track and validate all medications against data from manufacturers and potentially other supply chain points, making it significantly more difficult for counterfeit and compromised products to reach patients.

- Inventory management collaboration: Dispensing points, distributors, and manufacturers could seamlessly exchange medical device or medication usage, location and product availability information. Inventory planning and forecasting programs could analyze the data to optimize inventory levels, improve medication and medical device availability across the supply chain, and ensure that medical products are available at critical moments of treatment.

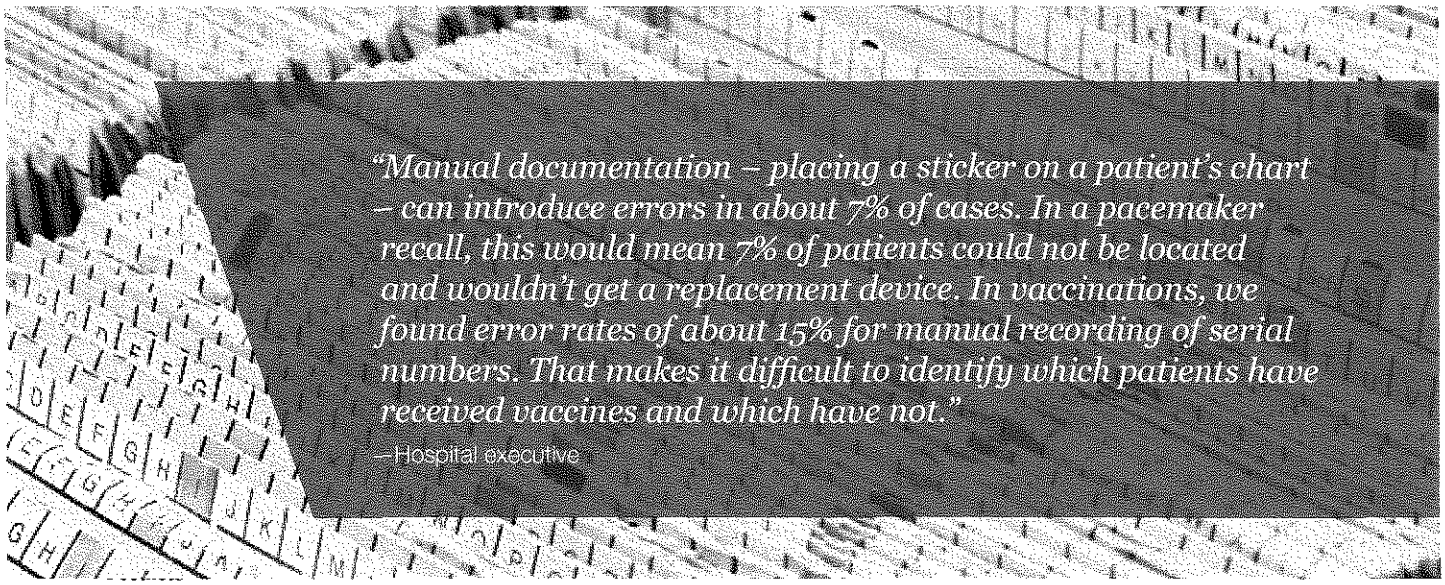
- Transaction automation: Processes and systems can be automated, eliminating most of today's manual data entry, validation and correction. Medication and medical device administration could be captured through barcode scanning and automatically fed into logistics, billing, and procurement systems that connect all stakeholders, including payors and registries.

In the following sections we will describe the impact global standards can have at the global level and for individual stakeholders.

Global standards can support multiple stakeholder needs

Global standards can be configured to meet a wide range of different stakeholder needs. Their implementation can be phased as appropriate for each participating organization.

Identifying every product that may be sold, delivered or invoiced – and capturing data about that product at every point in the supply chain – are fundamental elements of global standards that are designed to enable participating stakeholders to identify and monitor each product from factory to patient. We consider three basic categories in global standardization of supply chain data in this report: product identification, location identification, and master data exchange.



"Manual documentation – placing a sticker on a patient's chart – can introduce errors in about 7% of cases. In a pacemaker recall, this would mean 7% of patients could not be located and wouldn't get a replacement device. In vaccinations, we found error rates of about 15% for manual recording of serial numbers. That makes it difficult to identify which patients have received vaccines and which have not."

—Hospital executive

Product identification

Unambiguous product identification is a foundation of global standards. In the GS1 system, it is achieved via the Global Trade Identification Number (GTIN), and the Labeler Catalog Number in the HIBCC standard (medical devices only, except in the Netherlands, where it is used for pharmaceuticals as well). Trading partners who use standardized product identifiers can avoid errors in order processing and financial transactions and reduce non-value-added work such as relabeling or overlabeling of barcodes with their own inventory numbers. Organizations that use globally standardized product identifiers greatly facilitate internal accounting and processes supporting external reporting.

Moreover, when products are barcoded, the standardized product identification can be captured automatically as the product moves through the supply chain, down to the point of use, which has many additional benefits. The barcode can be applied to secondary or primary product packaging, as well as higher packaging levels (e.g. cartons or pallets), and certain barcodes allow multiple data elements to be captured, such as GS1 DataMatrix, which can then support other benefits (Exhibit 1).

- Globally standardized product identification with a barcode on secondary packaging can help streamline inventory management and other logistical processes, as products are scanned when they enter and leave stock rooms and warehouses.

  Coding lot numbers and expiry dates in barcodes can also offer important benefits, especially in recalls, which typically occur at a lot level. Capturing expiry dates can help distributors, pharmacies, and hospitals manage inventories to avoid product obsolescence and prevent dispensing expired products.

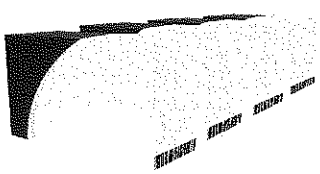
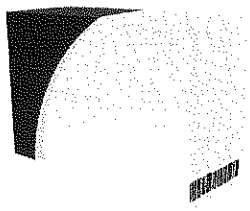
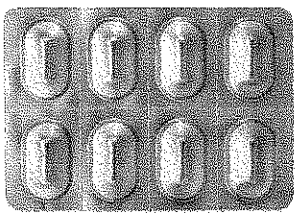
- Serialization at the secondary package level can help providers identify specific packages of a particular product. Some pharmaceutical products already carry this serialization to help providers authenticate the product against a secure database, preventing the dispensing of counterfeits and keeping them out of the hands of patients. A few health authorities already require this, and some others are developing systems to enable it. Some manufacturers have implemented serialization systems voluntarily, aiming to reduce the counterfeiting of specific products in their portfolio, as a preparation for systems that would authenticate their products at the dispensing points.

  For medical devices, there is no general trend or regulatory requirement towards serialization; instead, a risk-based approach may be more likely. High-risk medical devices such as implants may be the most viable candidates for serialization as this would help facilitate recalls, for example, while lower-risk classes of products, such as gloves or syringes, may never be serialized if the cost to do so would outweigh the benefits.

- Globally standardized product identification with a barcode on primary packaging may help prevent medication errors in hospitals and improve supply chain efficiency by increasing the visibility of true product usage. Each level of packaging could be identified by a barcode – something that only a few manufacturers are doing today. Barcode scanning when medications or medical devices are used can offer detailed, real-time insights into usage and demand that are valuable to manufacturers, providers and regulators. Although it is conceivable to add production identifiers like serial numbers to barcodes at the primary packaging level, thereby identifying each package individually, we are not aware of any manufacturer pursuing this approach.

Exhibit 1

Barcoding offers benefits at each packaging level

	Barcode on secondary packaging		Barcode on primary packaging
	Without Serialization	*With Serialization*	
Information on barcode	• Product identification • Lot Number • Expiry	• Product identification • Lot Number • Expiry • Serial number	• Product identification
Selected benefits	• Inventory management • Recall effectiveness for pharmaceuticals	• Medication authentication • Recall effectiveness for implanted devices	• Prevention of medication errors
Examples	• Identifies product	• Identifies one pack of a product	• Identifies single unit packaging of product
			

Location identification

Location identification links to an organization's name, address, and type. It can identify a functional entity such as a hospital purchasing department or pharmacy, a physical entity, such as a nursing station or loading dock, or a legal entity such as a hospital or manufacturer. A standardized and globally unique location identifier will precisely identify a location anywhere in the world.

In the GS1 system, it is achieved via the Global Location Number (GLN), and the Healthcare Identification Number (HIN) in the HIBCC standard, although the latter only identifies human and animal health facilities, and healthcare practitioners. Location identification numbers provide links to the information pertaining to it in central databases, reducing effort to maintain and communicate this information between trading parties. This increases the efficiency, accuracy and precision of sharing location information, crucial to logistical operations. Location identification numbers are critical enablers to achieve traceability in healthcare and improve supply chain efficiency and visibility.

Data exchange network

A single source of product master data and a global registry could allow fast, accurate transmission of data from manufacturers to customers. The network could provide continuous, automated access for authorized parties and ensure that accurate, consistent product information is available among supply chain partners. This capability can streamline and accelerate business processes, improve accuracy in processing orders, and ultimately reduce cost. By incorporating clinical information into the master data, patient safety is also improved.

The HIBCC system uses the UPN Repository, a form-based asynchronous database where users can upload and download product master data, hosted on the Internet. The GS1 system incorporates the Global Data Synchronization Network (GDSN), comprising a product registry, and interconnected third-party data pools across the world that synchronize data among authorized parties, and is accessed using GTIN and GLN identifiers.

Our research indicates that in a global supply chain standards system, product identification, location identification, and data exchange may provide the strongest synergies and maximum benefits when adopted together, throughout the supply chain.

Learning from the retail industry: Standards laid the foundation for transformation and value creation

Global standards have yielded enormous benefits in other industries. In grocery, for example, the GS1 barcodes and global standards created billions of dollars of value each year beyond original expectations. The original investment was made based on a business case that anticipated only the improvements in productivity at check-out, but the unanticipated benefits have proven far greater. These benefits include support of larger product assortments, improved forecasting and in-store marketing and promotion, more efficient end-to-end supply chain operations, and customer analysis through loyalty programs. The story of how the grocery and retail industries overcame barriers to global standards provides useful lessons for healthcare.

In the 1970s, grocery pioneers piloted product barcodes and checkout scanners, delivering in-store productivity gains of 4-5%. As adoption accelerated, retailers were surprised by what they discovered about price and product movement. An efficient data exchange in supply chain operations spurred more innovation, and in the 1990s, many major players made heavy investments in global standards. Global standards entered a new era in 2000. The New Ways of Working Together framework allowed trading partners to collaborate better to grow their businesses.[8] Many large retailers began sharing data free of charge and standardizing a roadmap for collaboration between trading partners.

Research shows that the U.S. retail industry has used these approaches to create $17 billion in supply chain savings and operational efficiency improvements.[9] Before adopting global standards, the industry overcame several barriers:

- Unclear economic benefit: New barcode scanner systems were expensive and didn't always work perfectly, and the economy was unstable in the 1970s which made predicting the economic return from the new investment difficult.
- Limited trust and adversarial relationships: The competitive nature of the grocery industry made it difficult to build trust among players, and differences among different players caused inconsistency and complexity.
- "Critical-mass" problem: In the beginning, manufacturers, retailers, and hardware vendors were not willing to make the first investments.
- Resistance from other stakeholders: Some unions worried about job losses, and consumers and regulators had concerns about giving retailers more pricing power.

[8] "New Ways of Working Together: Preparing our People for the New World," Corporate Executive Board, 2009.
[9] "17 Billion Reasons to Say Thanks: The 25th Anniversary of the U.P.C. and Its Impact on the Grocery Industry," PriceWaterhouseCoopers.

The industry relied on four tactics to spur adoption:

- A strong business case based on realistic but conservative savings estimates as technology became cheaper and more reliable;
- The U.S. Supermarket Ad-Hoc Committee, established by the US National Association of Food Chains, enlisted knowledgeable, well-respected executives to represent all interests and guide the standards development and adoption process;
- Relentless marketing, including country tours to pitch for the standard, and open and sustained communication to build momentum; and
- Real benefits perceived by workers and consumers, together with new legislations and a strengthening economy.

The healthcare industry will likely face many of the same challenges that the retail industry faced in the 1970s. But the benefits of a transformation in healthcare could dwarf any success in retailing, due to several factors:

- The size of the industry: Healthcare spending represents about 10% of GDP in OECD countries. At historical growth rates, the OECD average will be 13-14% in 2040.[10] Other countries will spend much more. The U.S., for example, spends about 16% of GDP on healthcare today, and if historical trends continue, this could be nearly a quarter of GDP in 2040;
- Better technology: Barcode and scanner technology is much more advanced today, as are data-sharing and data-mining capabilities;
- Payor and regulatory trends: Market access and reimbursement organizations are asking for more granular data, while Unique Device Identification (UDI), serialization and medication verification regulations are forcing many healthcare players to invest in technology that supports the use of global standards; and
- Public awareness: People all over the world are clamoring for lower healthcare costs and innovation; patients are more involved and demanding more information and better quality care from healthcare providers.

[10] OECD; McKinsey analysis

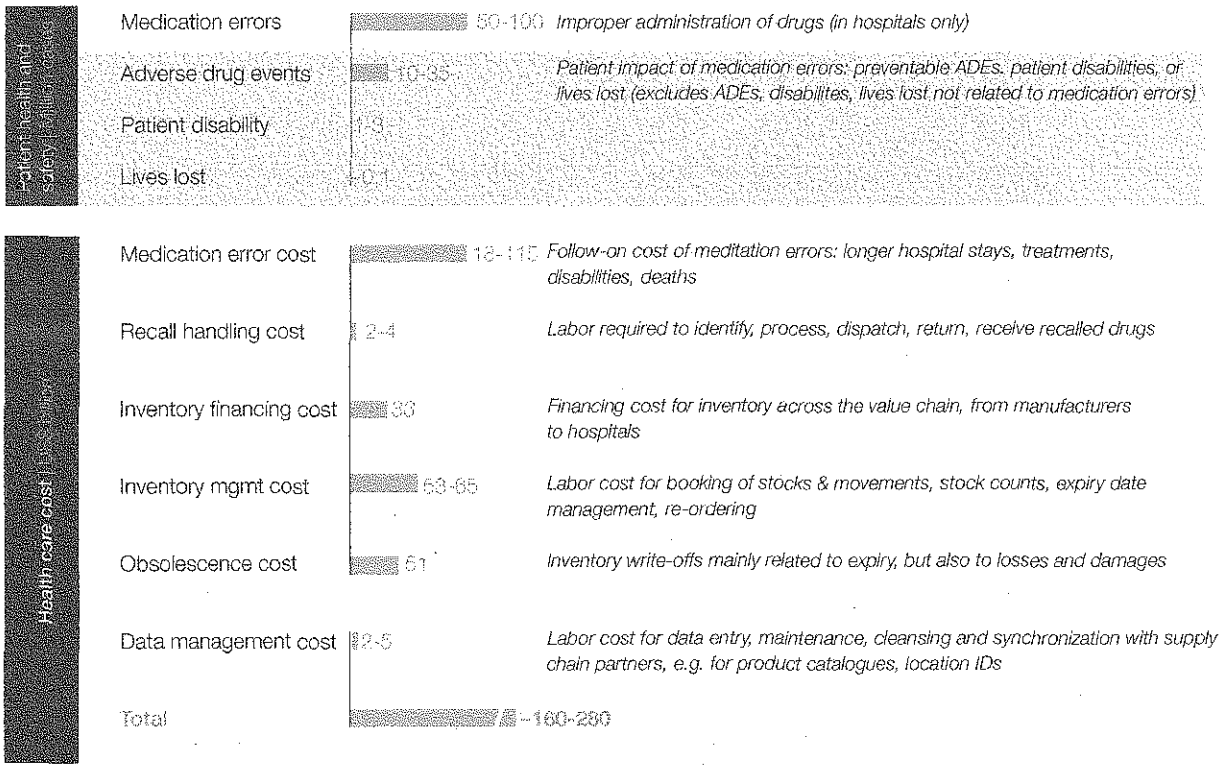
III. Global standards: The system-wide benefits to patient safety and healthcare efficiency

Global standards: The system-wide benefits

Healthcare supply chain performance has significant room for improvement. Across the value chain, major pain points range from patient outcomes to supply chain efficiency, including the prevalence of medication errors, inefficient, ineffective product recalls, and bloated inventories. Global standards could help address patient health and safety, as well as reduce key components of healthcare cost (see Exhibit 2 below). In this chapter, we review each of the pain points, understand its scale and source of inefficiency, and explain how global standards could help address these. In order to quantify the potential impact of global standards-enabled improvement, we have leveraged over 80 interviews with healthcare executives, the examination of 25+ case examples of standards-enabled improvement, and McKinsey's internal benchmarking.

Exhibit 2

Millions of patients are at risk for adverse drug events, and $160-280 billion are lost due to inefficiencies and errors



Reducing medication errors

Medication and device errors occur when a drug or medical device is not administered or used according to the "Five Rights" of medication safety: right patient, right route, right dose, right time, and right medication (see chapter 2). The risks to patients include longer hospital stays, disability, and even death.

Medication errors can occur at any point in the medication process, from prescription ordering (39%), to transcription (14%), dispensing (21%), and administration (26%). Many providers still conduct these processes manually, creating opportunities for human error. Many drugs have similar names, packages and abbreviations, and different dosage units and strengths. Manual record-keeping makes it harder for caregivers to anticipate potential allergic reactions and drug interaction issues. Given the many sources of potential error, the exacting nature of administering medications, and the workloads of caregivers, even the most diligent professionals can make mistakes.

In developed markets like U.S. and U.K., medication errors occur during 10-20% of all inpatient admissions.[11] The rate may be even higher in developing nations. Research found rates as high as 33% for two Brazilian[12] hospitals and 52% for an Indian[13] hospital. Unfortunately, error rates are likely to get worse, given seemingly ever-increasing cost pressure on healthcare systems.

Medication errors sometimes lead to adverse drug events (ADEs) – injuries resulting from and related to the use of a drug. Injuries include any physical harm, mental harm, or loss of function associated with medication use.[14] Reported incidence rates of preventable ADEs vary from 2-7% of hospital admissions in developed countries[15] to as high as 18% in developing nations.[16] These have led to thousands of patient deaths and millions of short- and long-term disabilities every year.[17] These injuries are also financially costly. The average cost per ADE in U.S. is $4,700-8,750,[18] while in the U.K., the National Health Service (NHS) has reported £2 billion per year in avoidable hospital stays.[19]

"In the developed world, standards create efficiencies and safety advantages, but in the developing world they can actually enable things that are otherwise difficult or impossible. So they're eager to use these developments, including standards, to make quick progress."

– Senior pharmaceutical executive

[11] E. G. Poon et al. "Effect of Bar-Code Technology on the Safety of Medication Administration," New England Journal of Medicine 362 (2010): 18; U.K. Ministry of Health 2007, "Coding for Success: Simple Technology for Safer Patient Care."
[12] L. A. Costa et al., "Medication errors in two Brazilian hospitals" (2006).
[13] S. Pote et al., 2006
[14] D. W. Bates, D. L. Boyle, M. B. Vander Vliet, J. Schneider and L. Leape, "Relationship between medication errors and adverse drug events," Journal of General Internal Medicine 10 (1995): 199-205.
[15] Bates et al., ibid.; Bates et al. JAMA 1994; Jha, et al., Journal of the American Medical Information Association 1998; Classen, et al. JAMA 1997
[16] R. M. Wilson et al., "Patient safety in developing countries," BMJ 2012
[17] Institute of Medicine 1999, "To Err is Human"
[18] U.S. Agency for Healthcare Research and Quality
[19] "Coding for Success: Simple Technologies for Safer Patient Care," U.K. Department of Health, 2007.

Canadian hospital initiatives: GS1 standards to reduce medication errors

Canada requires that pharmaceutical manufacturers add an eight-digit drug identification number to each product before it is sold. This number is of limited value to healthcare providers, however, since it is unique to Canada and often corresponds to a proprietary barcode or none at all. And while nearly all medications are marked with a GS1 GTIN at the bulk level, the hundred doses in a typical package may not be.

In 2005, Doris Nessim, then the Director of Pharmacy Services with North York General Hospital, a 434-bed hospital in Toronto, sought to reduce the risk of medication errors, streamline pharmacy operations and rationalize drug costs. As NYGH moved to implement electronic medical records, Nessim sought to incorporate closed-loop medication barcoding to enhance patient safety and optimize processes by integrating accurate electronic medication identification and documentation. Toward this goal, she began researching sustainable dose-level barcode strategies for the roughly 2,200 medications in the formulary. Ms. Nessim now works for GS1 Canada.

As she explains, "No healthcare provider comes to work wanting to make a mistake. And while some errors simply cannot be prevented with barcoding, the majority will be. Our goal is to make it easier for clinicians to do the right thing and harder to make a mistake. The right medication barcoding standard, content, symbology and strategy are critical to achieving this goal."

Other industry experts agree. A director of process excellence at a medical device manufacturer points out that medication errors are likely to increase along with demands on staff productivity. Other pharmaceutical executives say that global standards are an essential part of reducing dispensing errors.

Research by a VP of supply chain at another hospital estimated that manual data entry introduces errors in 15% of vaccine serial number records and about 7% of implant records, putting some patients at risk in recalls.
In conducting its research, NYGH identified about 35 medication touch-points from procurement to bedside. It compared barcode types and considered how a barcode could be attached to each dose, how the pharmacy provided nurses with drugs, and how nurses administered the drugs to patients.

Working closely with vendors and other internal and external stakeholders, the hospital concluded that each barcode would have to be unique, specific, and static, enabling Pharmacy Services to identify the product at each step in the process, from the point of inventory management to medication compounding and dispensing, and ultimately to administration.

"The only solution that met these criteria," reports Ms. Nessim, "was the GS1 GTIN."

The hospital adopted a process to barcode each dose of every medication. It began with an automated system to repackage medications into units of use, a barcode generator system and a hand-held scanner to ensure that each barcode will be readable and accurate at the point of dispensing and administration. These devices required capital investments of approximately $338,000, but the hospital reports that they were able to save 7-8% in medication inventory and associated drug costs.

In the absence of a national mandate for medication barcoding in Canada, hospitals are working with group purchasing organizations and patient safety advocacy organizations to adopt GS1 Standards and Services, including medication barcoding, to advance patient safety, improve operational efficiencies, and control drug costs across the country.

[Sources: McKinsey interviews and "Automating the medication use process: North York General Hospital Pharmacy Services," by Doris Nessim in the GS1 Healthcare Reference Book 2010/2011.]

At the global level, we estimate an annual incidence of 50-100 million medication errors, resulting in 10-35 million preventable ADEs, and $18-115 billion in associated potential healthcare costs.[20]

A global data standard can help substantially reduce medication errors:

- Clinical decision-making applications can suggest better dosing based on patient and product data, and avoid interactions;
- Computerized physician order entry (CPOE) can replace hand-written prescriptions with electronic orders to reduce transcription errors;
- Product ID scanning can eliminate confusion caused by similar-sounding names of different medications or devices, and unit conversions, reducing dispensing errors;
- Bedside barcode scanning can match the patient to the medication or device, preventing administration errors; and
- Electronic prescription records, along with allergy checks and drug interaction programs, can reduce ordering and administration errors.

The opportunities are huge. Barcode-based scanning procedures cut potential ADEs by 51-63% at Brigham and Women's Hospital[21] and by 75% at Gelre Hospital in the Netherlands.[22] Assuming 50% reduction rate, implementing global global standards across the entire healthcare supply chain could save 22-43 ,000 lives, avert 700,000 to 1.4 million patient disabilities, and save $9-58 billion in healthcare costs on an annual basis. We have not estimated the potential impact of global standards on medical device error reduction, but similar logic would apply.

Improving recall efficiency and effectiveness

Thousands of pharmaceuticals and medical devices are recalled every year due to safety concerns, including contamination, wrong dosage or release mechanism, and process controls. The number of recalls has more than doubled in the last 5 years. On average, about 200,000 units are affected per drug recall and 105,000 units per medical device recall.

Since the industry cannot generally track affected products across the value chain, today's recall process remains largely manual and therefore inefficient, ineffective, and costly, causing waste and threatening patients.

Without specific batch information, stakeholders throughout the supply chain must sometimes return all of the products, including unaffected ones, to manufacturers. The typical recall of a medical device can take up to about 2 man-days of effort in the hospital (involving various departments: procurement, logistics, medical physics), and in some cases more time, especially for implanted devices, where substantial effort is required to contact affected patients. Pharmaceutical recalls are less time consuming, taking at least 1-2

[20]The resulting wide range of estimate due to compounding effect of reference data variance
[21]Brigham and Women's Hospital presentation 2010
[22]Gelre Hospital presentation 2007

"In 2010, we received almost 900 recalls. In 2011, we got over 1200. Our process is manual. I can't guarantee that we haven't missed anything along the way. We need an integrated process in place across the supply chain for seamless, effective and efficient recalls. No individual segment can solve the issue."

—Senior pharmaceutical executive

man-hours at hospitals, although in some cases it could take significantly longer. Retail pharmacies, while spending less time are also actively involved in recall processing.

Manufacturers may spend up to a few man-months in executing a recall, and face losses due to product write-offs and in some cases compensation to their trading partners. In some extreme cases, such as in recent implant device recalls, a single event could cost millions of dollars in handling costs, product write-offs, and litigation expenses and damages.

Moreover, despite extensive manual searches, not all recalled products are removed from the supply chain. Some overlooked products could remain in "private stock" of caregivers or in the hands of patients. Hospital experts we interviewed reported that 5-10% of affected products could remain missing after an exhaustive recall search, resulting in ineffective treatment or even life-threatening outcomes.

Extrapolating this by number of healthcare institutes and organizations around the world, we estimate the global healthcare supply chain spends 130-270 million man-hours on recalls every year and misses 40-80 million device units and 90-180 million drug units.

Implementing global standards could improve recall processing in three ways:

- Labor savings: Clinical staff can spend less time on recalls and more on patients, improving care. During mock recall exercises, both St. James's Hospital and Michigan Congenital Heart Center reduced recall processing time from several hours to less than 30 minutes.

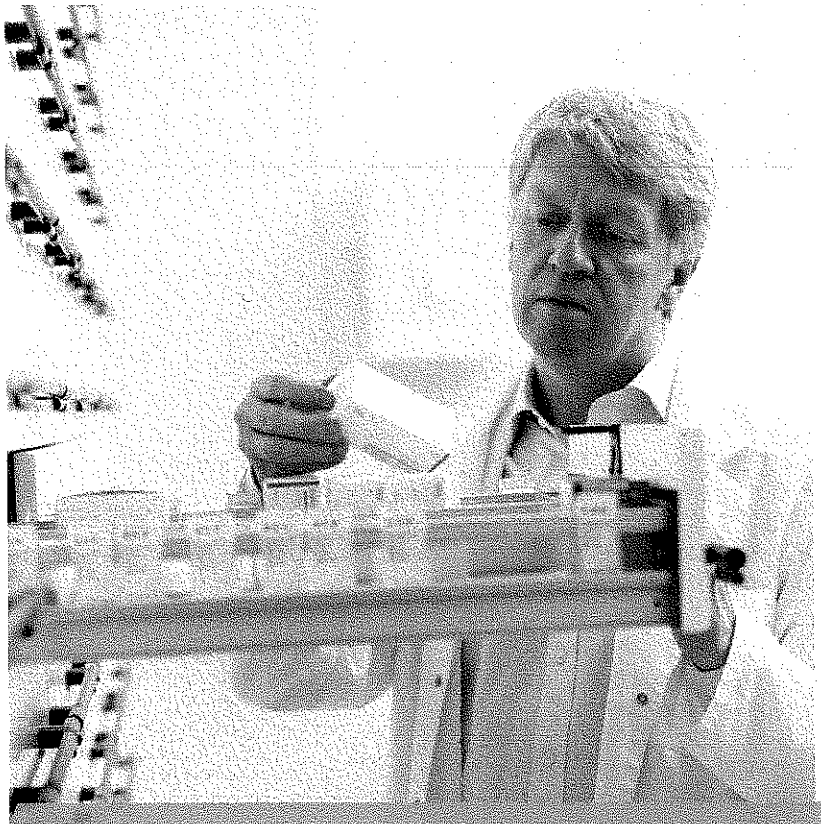
- Minimizing product waste: With better data and tracking, manufacturers will be able to target affected product batches at specific pharmacies, distributors and hospitals. One manufacturer reportedly spent $55 million recalling every unit of a non-identified product, a massive effort that would be avoidable if global global standards were in place.

- Improving patient safety: With standard product identification and electronic medical records, hospitals and retail pharmacies might be able to pinpoint affected products and patients more quickly. Even if some affected products are missed during the recall process, bedside scanning synched to centralized product information could alert caregivers of recall status and prevent those products from reaching the patient.

"We had a hip replacement recall a few years ago. The supplier told us the lot number that was affected, but it took us a month to figure out which patients got the medical devices. The difficulty is that data is everywhere—it's just difficult to pull out."

—Director of materials management at a major hospital

[23] Alien Technology Whitepaper: "Pharmaceutical Shifts Towards UHF RFID for Savings"



"For critical recalls, we send people to check every closet of every single unit. It takes 24 hours, and the cost is high, but we get 90–95% of the recalled product off the shelves. For less critical cases, without major medical risk, we ask nurses to check. They get about half of the recalled product."

—Hospital administrator

"We found that 25% of clinical staff's time is spent looking for things, and 10–15% of their time in the OR is spent looking for instruments."

—Hospital administrator

Hospital speeds recalls, cuts waste and improves patient satisfaction

Dublin's National Centre for Hereditary Coagulation Disorders at St. James's Hospital manages patients with bleeding disorders, including about 200 with severe hemophilia.

In the 1980's, contaminated plasma infected some patients with HIV and hepatitis. To make matters worse, some of the contaminated plasma remained in inventories even after the recall, leading to more infections. In responding, the hospital focused on the supply chain, incorporating serialized global trade identification numbers (GTINs) for all hemophilia medications. The new cold chain connects the manufacturers, distributor, hospital and patient, allowing caregivers to monitor consumption precisely and manage the inventory in each patient's refrigerator.

Since the manufacturers of those medications did not use standardized barcodes, the codes had to be applied by TCP Ltd., the cold-chain distributor who delivers them to hospitals and patients' homes. The initiative assigned a unique GS1 code to each patient, drug product and location, automatically linking and capturing data during the supply process, tracking each step of cold chain storage and delivery in real time, ensuring that the correct drug is prescribed to the right patient and automatically updating the inventory system to track patient consumption trends.

St. James's made barcoding and serialization part of their tender process, so the supplier applies them to each package. The hospital now knows exactly where to find each unit of hemophilia medication at any point in the supply chain—and can locate any batch of recalled product within 10 minutes—without relabeling. Patients are happy with a more reliable delivery service. Product wastage due to failure of cold chain conditions or documentation has been eliminated. About €5 million worth of medication has been removed from the supply chain, probably because patients no longer "over-order" and because inventory management is more efficient.

St. James's is not alone in seeing the need to improve recall effectiveness. A major US hospital system received 894 recalls in 2010 and 1,205 in 2011—and conducted them all manually. "We need an integrated process across the supply chain for seamless, effective and efficient recalls," says their VP of Procurement & Supply Chain. "No single segment of the industry can solve the issue."

[Sources: McKinsey interviews and "Bar coding on pharmaceutical packaging cuts costs and improves patient safety" by Feargal McGroarty in the GS1 Healthcare Reference Book 2011/2012]

Protecting patients from counterfeit products

Counterfeit drugs represent a major and growing problem for public health and the industry. The WHO defines counterfeit drugs as follows:

"A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."

Counterfeit drugs may lead to low treatment efficacy, increased medication resistance, adverse side effects, and even death. Counterfeit drugs also cut into manufacturers' sales and government tax revenues. Drugs known to have been counterfeited include the cholesterol-lowering drug Lipitor, Avastin for cancer treatment, Viagra and Cialis for erectile dysfunction, Serostim for low testosterone, biologics, birth control pills, and many, many others.

Although it is difficult to pinpoint the counterfeit drug rate, estimates range from 2-4% to 5-10% globally,[24] with significant variations across countries. Many experts estimate the rates at 1% or less in developed countries and anywhere from 10 to 30% in developing countries. These estimates, based on isolated studies and extrapolations, must be treated with caution, but the penetration of counterfeit drugs has continued to rise and will likely continue doing so, driven by the growth in developing markets. In parts of Africa, Asia, and Latin America, more than 30% of medicines could be counterfeits. For example, according to reports in August 2012, China seized $182 million in counterfeit medicines, including diabetes, hypertension, and cancer drugs.[25]

Implementing global standards could help fight counterfeit medications, as serialization, traceability, and authentication would catch duplicative and unauthorized serial numbers and allow stakeholders to verify supply chain history for each product.

Individual pharmaceutical firms have had some success in turning back counterfeiters. In 2005, for example, Pfizer began serializing individual bottles and cases of Viagra sold in the U.S. market. Since then, the company has not seen a breach in the legitimate U.S. supply chain for Viagra.. Similarly, although Purdue Pharma's painkiller, OxyContin, is a prime target for counterfeit activity, the company has not experienced a significant counterfeiting problem since its adoption of a standards-based security initiative.[26]

[24]WHO Fact Sheet No. 275: "Counterfeit medicine," February 2006; The Wall Street Journal: "Counterfeit Drug Count Is Tough to Swallow," September 2010
[25]NYTimes August 2012: "2,000 arrested in China in counterfeit drug crackdown"
[26]Cindy Dubin: "Government and Industry Come Together to Stop a $75-Billion Drug Counterfeit Ring"

The battle against counterfeits goes on

In 2002, J&J executives were "horrified" to learn that sophisticated counterfeiters had targeted their anemia drug, Procrit, the company's biggest-selling prescription medicine and a life-saver for some cancer patients. The crooks had relabeled genuine vials of low-dosage Procrit, worth about $22 each, as the stronger and most commonly prescribed doses that were $450 each.

Within a week of the recall, the company had sent 200,000 letters alerting healthcare professionals to the mislabeling. The company then launched a crash program to change the packaging, which required new equipment, new processes and FDA approval. A new seal on the package helped—but counterfeiters came up with fake versions of the seal within months. J&J continued devising new measures to stay one step ahead of the Procrit counterfeiters.

Despite these efforts, even the largest manufacturers cannot defeat counterfeiters alone. But working together, they can succeed.

"If there is a gap in supply chain security, someone will exploit it," concedes a VP for one of the major pharmaceutical manufacturers. "That's why every segment needs to be engaged. We need global interoperability if we're going to protect the entire value chain."

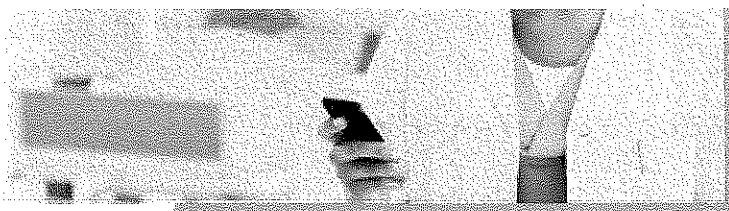
[Sources: McKinsey interviews; "Protecting Procrit," Sunday Star-Ledger (New Jersey), September 21, 2003.

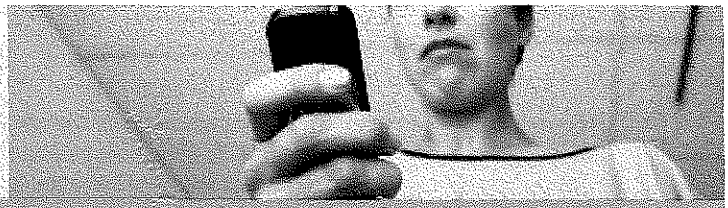
Countries have had similar successes. A track and trace system, along with "consumption notification" to decommission used serial numbers, has halted reimbursement fraud and counterfeit activity in Turkey, resulting in a significant economic benefit to the government.[27]

A combination of serialization technology and SMS authorization services has been used by a few manufacturers in India. This proprietary method has reduced the prevalence of counterfeits on some of their vulnerable products – although this is not a standards-based approach, and it is not mandated by the government (serialization is required for export market only), it indicated the effectiveness of serial-number based authentication by the end-user in countries with high levels of counterfeiting. Scaling up serialization efforts following a standards-based approach might therefore have significant impact on counterfeiting.

Rolling out such standards-based systems globally could prevent tens of billions of dollars' worth of counterfeit drugs from entering the legitimate supply chain, resulting in significant improvement in health outcome and supply chain savings.

[27] Interviews with Turkey solution provider





"Some manufacturers in India now provide patients with authentication. The patient sends an SMS with a unique code to a service database and receives a verification note by SMS."

—Indian pharmaceutical executive

Reducing inventory assets and associated costs

Without a clear picture of stock levels down the supply chain, manufacturers find it difficult to build lean and responsive supply chains with minimum stock, despite mostly low volatility of patient consumption in many disease areas. Without real-time usage data on their customers or patients, many distributors and providers must carry excess inventory to avoid product shortages. And in interviews, hospital executives report that medical staff, anticipating drug or supply shortages, often keep a "private" supply outside of official stock locations, further complicating inventory management and recall efforts.

Excess inventory imposes needless expenses at every step in the value chain. The potential savings opportunities may be huge, given that global inventory is worth about $516 billion,[28] most of it at manufacturers ($181 billion) and hospitals ($165 billion). Carrying half a trillion dollars in inventory comes at a price: we estimate inventory financing costs at about $33 billion globally,[29] and inventory management costs at $53-65 billion.[30]

Global standards may reduce those costs by enabling collaboration and data-sharing from factory floor to bedside: reducing inventory would free capital and physical space and taking the guesswork out of inventory planning could reduce inventory inflation without raising stock-outs.

"Global standards are an essential part of our patient safety strategy. Since we have moved forward with serialization to secure our supply chain, we have not seen any more counterfeiting incidents in the legitimate supply chain."

—Pharmaceutical supply chain executive

[28]McKinsey analysis based on annual corporate reports
[29]Cost of capital used: 6.5% for pharmaceutical manufacturers, 7.6% for medical device and supplies manufacturers, 5.1% for distributors and wholesalers, 7.6% for retail pharmacies, 6.0% for hospitals
[30]McKinsey benchmarks for estimated inventory management cost as percent of sales: 0.7% for manufacturers, 0.25% for wholesalers and distributors, 0.9% for retail pharmacies, and 0.9% for hospitals

Pioneers are showing the way: Comanche County Memorial and Shore Memorial hospitals found that barcode-based automation of stock management helped reduce medication stockouts by 75-80%; after implementing barcode based product identification standards.[31]

Case studies and interviews suggest significant improvement opportunities through the implementation of global standards. We estimate that inventory levels could be cut by $60-94 billion, or 12-18%, without reducing product availability. This could result in a proportional decrease in financing costs (estimated to be $4-6 billion globally per annum). Multiple US hospitals showed a 15-30% reduction in inventory management costs[32] for medications, and experts say they can make improvements of around 15% across the value chain through reduced manual effort in booking of movements, searching and counting, simplified expiry date management, and automated re-ordering. This could potentially save $6-8 billion annually. The actual savings impact could vary significantly by sub-sector. For consigned medical device products such as orthopedic implants and stents, the inventory level is typically challenging and global global standards could lead to substantial improvements. Moreover, additional savings could be achieved where real-time demand signals are enabled across the supply chain.

Inventory management in the healthcare industry is likely to become more challenging as product complexity rises and supply chains become more global. More products with a smaller quantity of each would raise demand variability and force players to increase inventory levels. The adoption of global standards and better collaboration along the supply chain could offer a viable way to manage these challenges.

[31] Silvester et al., McKesson: The Business Case for BarCode Readiness
[32] Silvester et al., McKesson: The Business Case for BarCode Readiness

Leeds – driving inventory savings and management

Leeds Teaching Hospitals, the largest healthcare trust in the UK, employs more than 14,000 people in six facilities and must track a vast trove of medical products from a huge array of vendors across hundreds of exam rooms. According to a 2010 report, "some of the most common, costly and time-consuming challenges facing the healthcare supply chain are created by inaccurate product data and synchronization between buyers and sellers."

The challenges are daunting. The medical device industry, for example, "speaks ten languages," according to senior executives at a global medical device manufacturer. Transactions are faster than ever, thanks to e-commerce, but this can simply speed the transmission of bad product data, along with "purchase order errors, delayed fulfillment, hours of staff time spent researching these issues, and associated lost opportunity costs for both customers and suppliers." The Trust had already gotten stock levels under control in Cardiology and hoped to achieve similar results in the Chapel Allerton Orthopedic Centre, reducing incidences of misplaced equipment, improper stock ordering, and billing mismanagement.

They began by adding radio-frequency identification (RFID) to augment the established e-procurement system and common item catalog. Barcodes on 3000 items, which can be scanned at 270 stocking points throughout the Trust, help keep patients safe and help staff organize and track complex medical procedures.

Each joint replacement, for example, is unique, since "one size most definitely does not fit all." A custom joint replacement kit can contain between 20 and 200 components worth about $60,000 in all. There is no room for error in ordering these kits: they must contain all of the correct parts before the procedure can begin. Each order needs to be tracked from placement of the order to delivery and payment. Manual checks were costly, time-consuming and prone to errors.

In a pilot, each item was tagged with RFID and integrated with the Trust's stock control, purchasing and corporate ERP system to allow the manufacturer and hospital staff to track all of the elements in each kit. Staff could also "shop" using simple drag-and-drop requisitioning. Requisitions were then matched with the purchasing system where orders were produced and transmitted electronically to suppliers.

Clinical staff can now check the contents of each kit instantly. Turnaround time has been cut from two months to ten days. Thanks to these and other improvements, the Trust has reduced stock levels by $884,000 in the last three years while improving service levels to 98%.

[Sources: McKinsey interviews and "The Chapel Allerton RFID Solution," by Leeds Teaching Hospitals NHS Trust, published in the Computerworld Honors Program.]

Reducing product waste due to obsolescence

Pharmaceuticals and medical devices that reach their expiration dates are considered unsuitable for use. We estimate that obsolescence costs the world more than $51 billion[33] each year, mostly at providers. Experience at leading organizations has shown much of this expense might be avoided along with optimized inventory levels and better inventory control enabled by global standards.

A better view of downstream inventory levels would allow manufacturers to produce more in sync with consumption and reduce inventories. Visibility of lot numbers and expiry dates would help hospitals and pharmacies more easily manage the shelf lives of products in their inventories. Standardized product identification and a master data exchange via information-sharing networks with manufacturers would allow providers to minimize waste. Similar procedures in place in chemicals track unstable chemicals with short shelf lives, saving millions each year.[34]

By implementing global standards and collaborating across the industry, the healthcare supply chain can reduce product obsolescence by tens of billions of dollars. Studies have found that 20% of inventory assets at hospitals are discarded due to product expiry,[35] translating to $33 billion worth of obsolescence at providers alone.

Given that the highest levels of expiry and waste occur at hospitals, it's not surprising that within these organizations we estimate the greatest potential for standardization. After establishing product identification standards and automation, US hospitals saw a 54-75% reduction in expired medication costs.[36] That level of impact on a global scale would mean reducing the waste of expired products by $18-25 billion. Experts estimate a reduction potential of 5-15% for manufacturers, distributors, and pharmacies, so we estimate an overall potential obsolescence reduction of $19-27 billion across the entire supply chain.

Reducing data management cost

For all players along the healthcare supply chain, the product catalog is a key to many daily operations, including procurement and invoicing, but it is also an important source of clinical information. However, many healthcare product databases today feature unique, incompatible numbering systems and data that must be input manually. Inaccuracy and inconsistency create issues for users and vendors. For example, the US Department of Defense discovered that hospital product catalogues had problems matching the correct manufacturer identifier for 30% of the medical devices they listed in their catalogue; at a leading US GPO, a single part number in the product catalogue linked to 9 identifiers and different products from different distributors.[37]

Without an automated information-sharing system, all players must invest a tremendous amount of time and labor to keep their product catalogues up to date with new product and pricing information. Despite these efforts, inaccuracies are prevalent, leading to erroneous transactions and the need for costly reverse logistics and canceled procedures because the right products are not available.

[33] McKinsey analysis, corporate annual reports
[34] Alien Technology Whitepaper: "Pharmaceuticals Shifts Towards UHF RFID for Savings"
[35] GS1 Healthcare Reference books
[36] McKesson "The Business Case for Bar-Code Readiness"
[37] GS1 Healthcare White Paper on UDI Implementation

The Netherlands move ahead on traceability standards

The Dutch government, looking to overcome the familiar challenges of serving an aging population with better medical care at a reasonable cost, has turned to GS1 Global Traceability Standards.

GS1 Netherlands, a not-for-profit organization, is promulgating these standards to automate recall procedures, reduce obsolescence, stock-outs and associated delays in care, and shrink inventories while speeding ordering, delivery and billing and tracking costs and results more accurately.

The organization also aims to protect patient health—estimating that almost 40% of cases of avoidable unintentional harm to a patient might be prevented. The groups points out that "missing, unclear, or a surfeit of information during treatment may cause unintended incidents and harm to patients."

The group seeks supplier-created barcodes that capture the GTIN, expiry date and batch or serial number. All of this information will link to software that supports business processes from supplier to each patient with a barcode on a wristband, and to each employee with a barcode on his or her ID badge. With these measures, the group explains, "it will always be clear which product has been used to treat which patient, and who is responsible."

The group's objective is that by the end of 2012, all primary and secondary packaging will carry GS1 codes (GTIN, batch and/or serial number and expiry date, as appropriate), preferably in a GS1 DataMatrix.

Many industry leaders have taken action. Medical device suppliers now using GS1 Standards for product identification in the Dutch market include 3M, Abbott BV, Alcon, Baxter, Biomet, Synthes, Becton Dickinson BV, B. Braun, Boehringer Ingelheim BV, Coloplast, Covidien, EV3, J&J BV, Kimberley Clark, Koninklijke Utermohlen NV, Medeco, Medtronic, Nutricia, Spruyt hillen and Van Straaten Medical.

While the Dutch group concedes that hospitals and their suppliers will need to make investments in hardware, software and personnel, it expects improvements in patient safety and annual savings of $138-219 million at hospitals alone, with a payback time of less than a year in in the conservative scenario. These savings correspond to cutting hospitals' inventory by 20%, new inventory handling expenses by 25% and obsolescence by 80%.

[Sources: "Patient Safety and Efficiency in the Operating Theatre," GS1 Traceability Business Case, GS1 Nederland]

"Without location ID or product ID, there's a massive need for cross-reference tables that need to be constantly updated. It's very time-consuming, labor-intensive work—from dozens to hundreds of people on the manufacturers' side, but hundreds on the distributor level. Some hospital systems employ 8-10 people to create master data as well."

– Senior executive at a medical device company

A large health system in Asia replaced their procurement process with a solution that included a centralized product catalog with automatically synchronized data. In the first year, the new system saved $1 million by streamlining the data processing group's work.[38] After switching to an e-commerce based platform with GS1 standards, a large wholesaler in Australia improved their pricing and data accuracy to near 100% within just two months of implementation, leading to significant reduction in costs associated with reverse logistics.[39]

The healthcare supply chain spends 24-30% of administration time cleansing data and resolving order processing errors.[40] Using our industry benchmarks and corporate reports, we estimate that this translates to $2-5 billion annually in data cleansing and error resolution costs across the healthcare industry.

Global standards together with a harmonized system of exchanging information between supplier and customers could greatly simplify data processing, reduce duplication of efforts, and improve operational accuracy. With unique product identifiers, numbering systems would no longer overlap and require cross-referencing tables. Automated data-sharing would remove the need to manually update disparate databases across the healthcare system whenever a supplier changes product information. And by using an authoritative source for product ordering, hospitals and pharmacies would see fewer erroneous transactions. Better data would help healthcare providers enhance patient safety. More accurate product catalogs would mean fewer procedure delays due to erroneous orders. It would also enable hospitals to provide more robust product information in reporting adverse events. With more complete information, health authorities could more efficiently conduct post market surveillance and monitor the safety and efficacy of drugs and medical devices.

We estimate that the healthcare supply chain could cut data processing costs by 50-70% using global standardization and synchronization, which would save $1-2 billion per year.

[38] NSW Health interview, 2012
[39] Interview with Australian wholesaler, 2012
[40] Healthcare Financial Management Association. "The time is right for Data Synchronization" 2007

A decade of collaboration from factory floor to bedside yields major benefits

Mercy, a major healthcare system in the US, worked hand-in-hand with its supply chain company, ROi, and Becton Dickinson (BD) to adopt GS1 Standards from the factory floor to the bedside. In the decade since implementing these changes, patient safety has improved and the supply chain is considerably more streamlined.

The companies use Global Location Numbers (GLNs) and Global Trade Item Numbers (GTINs) to automate transactions. BD assigns GTINs to all products and relevant packaging levels (each shelf pack and case) and stores the data in a central master file. ROi relies on GTINs for BD products rather than creating custom labels. The distributor is also working with vendor partners to replace custom account numbers with GLNs, reducing errors throughout the supply chain.

In each of Mercy's 30 hospitals, nurses scan each product and each patient's wristband at bedside to make sure the patient receives the right product and the right dose at the right time. This scanning and associated software help staff manage inventory by recording lot numbers and expiration dates, and link each product to each patient's electronic health record, improving tracking during recalls and the accuracy of billing.

The changes have yielded a wide range of additional benefits:

- The data collected in EHRs can improve comparative effectiveness research;
- Days payable outstanding have fallen by 30%, along with the need for manual intervention;
- Discrepancies have fallen by 73%, thanks in part to replacing vendor part numbers and units of measure with GTINs on purchase orders;
- Sourcing with a single scan allows the hospital to determine the right product and unit of measure for each reorder;
- Customer service receives fewer calls during the sourcing process;
- Stock-outs have fallen; and
- Charge compliance has improved.

[Source: "Perfect Order and Beyond: BD and Mercy/ROi Achieve Far-Reaching GS1 Standards integration']

Improving transaction accuracy

The healthcare industry is challeneged by complex transactions—including patient billing, chargebacks, and returns—that demand costly resources and can lead to financial losses. Limited supply chain visibility can make these processes very inefficient and / or difficult to execute correctly.

A global product identification system could help all parties significantly reduce transactional labor and costs. A platform that accurately identifies usage by automatic identification and data capture (AIDC) using primary package barcoding (or direct-part marking for medical devices) can help ensure that items are correctly billed to patients. Executives across the industry indicate that errors in financial transactions occur due to manual and non-standardized processes, and resolving such errors may take up to 20% of staff time in hospitals.

Although the losses due to these inaccuracies and inefficiencies are not known, the illustrations above show a considerable cost in time and effort across the supply chain. Our client service experience and interviews conducted as part of this research have indicated a strong interest in the industry to leverage global standards and serialization to streamline and improve the processes.

A hospital drives standards up the supply chain

The Herz-Zentrum, a 256-bed German hospital specializing in cardiovascular diseases, found that meeting Diagnosis-Related Group (DRG) guidelines in cost unit billing was costly and error-prone. By introducing standard barcodes in 2007, the hospital could finally make accurate DRG calculations—while documenting consumer materials 78% faster.

Incorporating the new process took more than two years, since suppliers had to make the move to GS1 Standards on their products. Once the standards were in place, however, the hospital's initial investment paid for itself in the first year.

Today, materials are scanned and allocated directly to patients through the IT system. This data is now available instantly in electronic form. After implementing the automated process in functional departments, the accounting department no longer needs to enter data to control or allocate special products to patients. Both tasks were eliminated.

With up-do-date inventory data, the ordering process is now automated: when stock falls below a predefined amount, the system places a refill order. This does away with stock planning, saving time and labor. The purchasing department can also monitor inventory in real time.

"Since parallel processes lead to unnecessary expenditure of time—and the benefits speak for themselves—the hospital's message to its suppliers is unmistakable: products need to be identified with GS1 barcodes across all packaging sizes, enabling universal use from production to patient," says Holger Klein, Head of Inventory Management and Logistics at Herz-Zentrum.

[Source: "Return on Investment of Standardized Bar Coding at Herz-Zentrum Bad Krozingen," GS1 Healthcare Reference Book 2009/2010]

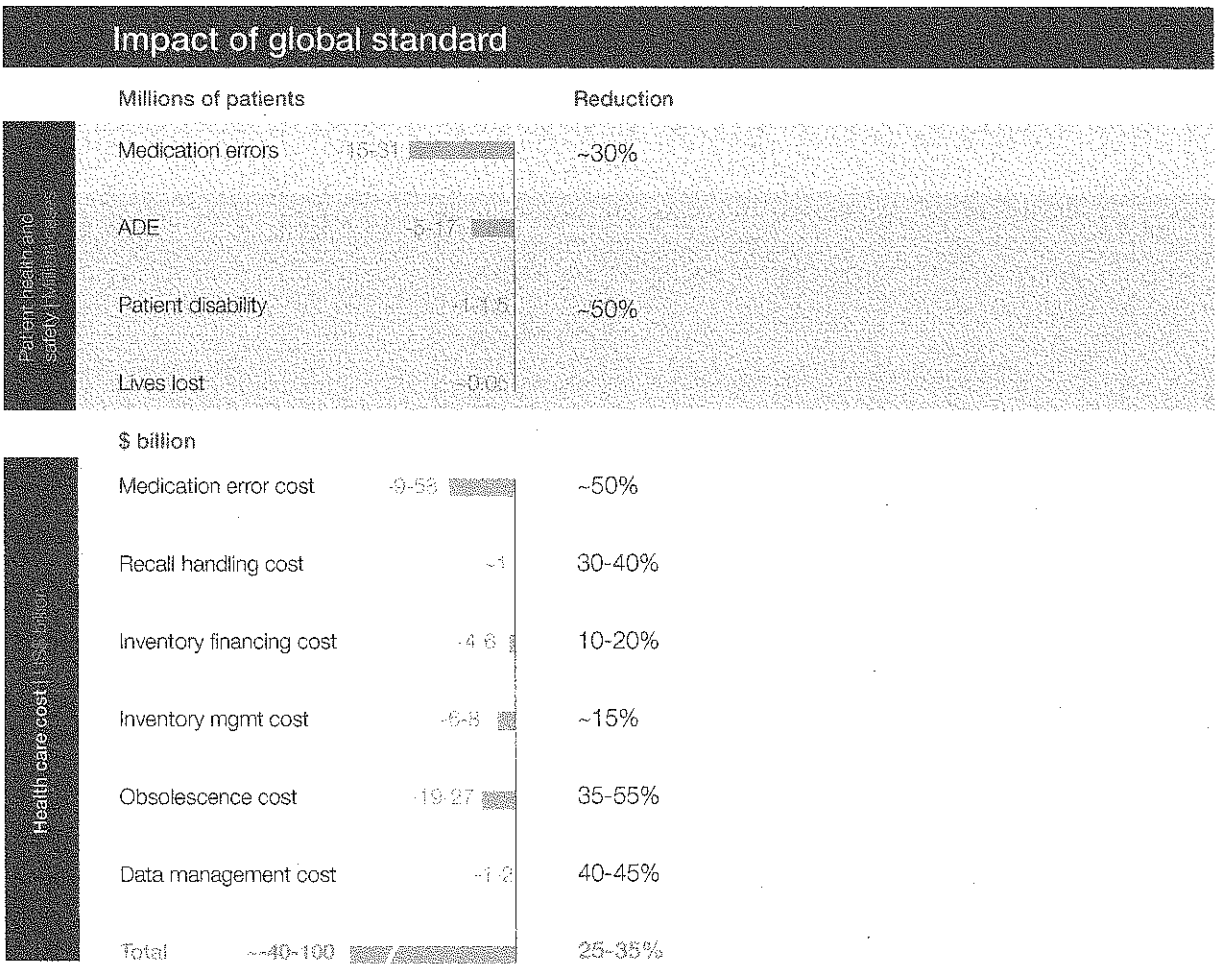
Summary of benefits

We have seen in this chapter that global standards have the potential to enable substantial patient health benefits, and help reduce healthcare costs. Taking a conservative approach, we estimate that healthcare cost could be reduced by $40-100 billion globally, mainly from reduced follow-on cost of medication errors ($9-58 billion), cost from improved inventory management (financing, processing, obsolescence cost reduction of $30-42 billion), and reduced data management cost ($1-2 billion). (Exhibit 3)

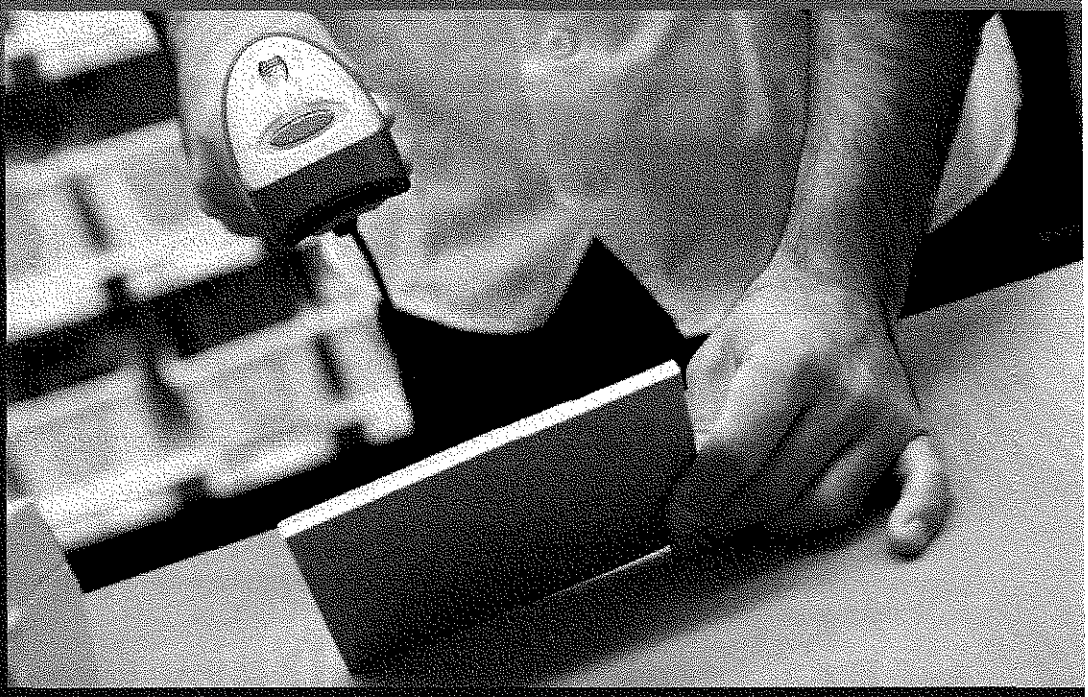
This figure may be substantially higher, since global standards may deliver a variety of smaller benefits that are not included here, as they are more uncertain or difficult to quantify.

Exhibit 3

Global standards could enable substantial patient safety benefits and enable total healthcare cost reduction of $40-100 billion



IV. Global standards: The benefits for individual organizations



Global standards: The benefits for individual organizations

As we have outlined, global standards hold the promise of significantly improving patient safety and supply chain efficiency. But what does this mean for individual healthcare organizations? How does a typical hospital, for example, handle general patient safety risks? How much waste can a typical manufacturer eliminate? In this section, we attempt to quantify the benefits of global standards for four main categories of stakeholders: manufacturers, wholesalers and distributors, retail pharmacies, and hospitals.

These analyses are not intended as investment cases for individual organizations; investment decisions depend heavily on each organization's unique capabilities, technology, product portfolio, region and strategic priorities. Rather, these analyses are illustrative examples of what may be achievable through the adoption of global standards. In conjunction with technology investments, our analysis predicts this could yield significant benefits under most circumstances. Organizations can consider using these analyses as a starting point to build their own business cases tailored to their unique circumstances.

Here we assume that global standards—product identification, location identification, and data exchange networks—are in place throughout the healthcare supply chain. We also assume that organizations have adjusted their technology and business processes to enable system interoperability. Benefits, investments, and operating costs have been sourced from case studies, articles, expert interviews and McKinsey client service experience.

Global standards bodies may charge annual fees and one-time fees for allocating identification number ranges; external data-sharing providers which host the data pools will also charge fees. We did not factor in these costs, as they are relatively modest compared to internal technology and implementation program costs.

For each business case, we first provide the profile and operations context of a hypothetical organization. We then discuss both quantitative and qualitative benefits resulting from global standards, and describe associated investment requirements, including both one-time and ongoing costs. For manufacturers, we describe benefits separately for pharmaceutical and medical device manufacturers. Finally, we present estimates of the impact to industry players of supporting multiple standards rather than one.

Pharmaceutical and medical device manufacturers

First we set out the benefits and required investment for a representative global pharmaceutical manufacturer— one with 25 packaging lines, annual revenue of $4 billion, and earnings before taxes of $720 million, or 18% of sales, in line with McKinsey industry benchmarks. We assume 70% of revenue is earned in developed markets and 30% in developing markets (used to estimate exposure to high-counterfeit markets).

Next we set out the benefits and required investment for a representative global medical device manufacturer—one with annual revenue of $4 billion, and earnings before taxes of $470 million (12% of sales). Given the wide variety of medical devices with different supply chains and potential patient risks, individual organizations may see a different profile of benefits and costs than our "typical" industry estimate.

Benefits for pharmaceutical manufacturers:

By adopting global standards in partnership with its trading partners, our representative pharmaceutical manufacturer might expect a range of benefits worth about $43-62 million annually, which represents about 1-1.6% of base revenue and about 6-9% in earnings before taxes. In addition, a one-time cash flow benefit of about $90 million would accrue due to reduction in inventory assets.

The potential benefits to pharmacuetical manufacturers

Source of value	Primary value drivers	Key assumptions	Impact estimate and potential for case-by-case variation
Reduce inventory assets	• Improve demand forecasting and inventory planning	• Inventory: 180 days • $600 million inventory assets (15% of revenue) • 15% inventory reduction potential	• **$90 million one-time cash flow** • Base inventory holdings - does not vary drastically between companies
Reduce inventory financing and holding cost	• Reduce financing of working capital due to lower inventory assets • Reduce inventory management cost with more efficient and accurate processes	• $43 million inventory assets financing cost (cost of capital 7.1%) • $29 million inventory management cost (0.72% of revenue) • 15% financing cost and inventory management cost reduction	• **$11 million annual savings** • Base inventory holdings - does not vary drastically between companies
Reduce produce waste due to obsolescence	• Improve inventory management to shrink inventory levels and unused product	• $44 million obsolescence cost: 7.5% of inventory • 10% obsolescence reduction	• **$4 million annual** • Product portfolio - can vary supstantially for individual organizations
Reduce cost of recalls	• More efficient execution (increased supply chain visibility) • Reduce scope of recalls (better targeting)	• $1-2 million cost per recall [41], not including product write-offs • 6-12 recalls per year[42] • 50% reduction in number of customers notified	• **$3-12 million annual** • Number and scope of recalls cost and savings could be signifigantly higher or a little lower
Reduction in counterfits and recovery lost profit	• Reduction in counterfit supply raises sales volume	• 6% of manufacturer's supply lost to counterfeiting • Ex-manufacturer price per pill of about $1.50 in developed countries, $0.20 in developing countries • 25-35% average reduction in lost sales • 70% gross margin	• **$25-35 million annual** • Highly dependent on extent of sales in high counterfeit markets and type of products sold, P&L impact estimate can vary substantially

[41] Typical "small" recalls – exceptional and large recalls can cost hundreds of millions of dollars or more
[42] Typical range of recalls by pharmaceutical manufacturer, from FDA Gold Sheet 2011

Benefits for medical device manufacturers

By adopting global standards in partnership with its trading partners, our representative medical device manufacturer can expect benefits worth about $16-19 million annually, which represents about 0.5% of base revenue and about 4% in earnings before taxes.

The potential benefits for medical device manufacturers

Source of value	Primary value drivers	Key assumptions	Impact estimate and potential for case-by-case variation
Reduce inventory assets	• Improve demand forecasting and inventory planning	• Inventory: 133 days • $600 million inventory assets (15% of revenue) • 15% inventory reduction	• **$90 million one-time cash flow** • Base inventory holdings - does not vary drastically between companies
Reduce inventory financing and holding cost	• Reduce working capital requirements by lowering inventory assets • Reduce inventory management cost with more efficient and accurate processes	• $46 million inventory assets financing cost (cost of capital 7.6%) • $29 million inventory management cost (0.72% of revenue) • 15% financing cost and inventory management cost reduction	• **$11 million annual** • Base inventory holdings - does not vary drastically between companies
Reduce product waste due to obsolescence	• Improve inventory management to shrink inventories and unused product	• $33 million obsolescence cost (5.5% of inventory) • 10% reduction in obsolescence	• **$3 million annual** • Product portfolio – can vary substantially for individual organizations
Reduce cost of recalls	• More efficient execution (especially with serialization for implants) • Reduced scope of recalls (better targeting)	• $5-10 million cost per recall, not including product write-offs • 1 recall per year • 50% reduction in number of customers notified	• **$2.5-5 million annual** • Number and scope of recalls, cost and savings could be significantly higher or a little lower

Non-quantified benefits for manufacturers

Other non-quantified benefits include helping to prevent medication errors in the case of pharmaceutical manufacturers by applying barcodes with product identification at the primary packaging level, and providing accurate and up-to-date medication information to hospitals and pharmacies via a data exchange network. Manufacturers need to apply barcodes with product identification at the primary packaging level. They could consider subscribing to a data exchange network and maintaining master product information on a regular basis, so hospitals can receive automatic, near real-time updates when this information changes.

For medical device manufacturers, such benefits of applying barcoding to the primary packaging or directly on the device may be similar. According to the Global Harmonization Task Force's (GHTF) final document on UDI Systems for Medical Devices, standardized barcoding and product identification will identify medical devices in cases of adverse events, reduce medical errors, and assist with documentation and longitudinal capture of data on medical devices to better understand their effectiveness and safety profiles, in addition to benefits in the recall process that we already identified earlier.

Although we do not quantify the benefit for manufacturers in this case, it may be worth considering for the sake of patient safety and differentiation. As more hospitals adopt technology to avoid medication and medical errors, manufacturers that provide primary package or direct-part barcoding may enable more cost-effective and accurate approaches to patient safety improvement.

Efficiencies in data and order processing

The healthcare industry spends a great deal on manual data updates, data cleansing and processing. A major driver of this cost is product catalog updates from suppliers, which need to be incorporated manually into customers' systems, sometimes by dedicated vendors. As described in the prior section, automatic data synchronization can create enormous efficiencies in this process and greatly improve accuracy.

Manufacturers may see major benefits as well. Automatic data synchronization would greatly reduce ad hoc customer requests for product information, decreasing the burden on manufacturer staff to respond to these requests and allowing them to spend more time on value-added customer service.

Generating reports could also become more efficient. Global manufacturers face significant challenges in rolling up data across divisions and regions. One executive told us that his finance, local and hub planning locations and various other functional units could create as many as 5 identification numbers for a single product within the same company.

Leading organizations could potentially generate valuable insights from data faster than their competitors and gain competitive advantages. Laggards may continue to struggle with basic analysis in an increasingly data-driven world. Also, as public and private payors scrutinize costs more carefully, pressure increases for organizations to cut simple transactional costs.

"Brazilian companies want to take market share from multinationals, so they agreed to barcode each vial to gain a competitive edge in safety."
—Senior hospital pharmacist in Brazil

[49]GHTF Final Document, UDI System for Medical Devices, Sep 2011

"Overcoming organizational inertia could be difficult. It may require an attitude shift for historically cost-centric organizations. But showing everyone the end-game 'pot of gold' could do wonders to motivate the 'selfish' individual players."

—Shipping executive

Investments, operating expense and business case

Manufacturers could stand to reap significant returns on their investments in adoption of global standards and in their capabilities to print barcodes on packages; the size of the investment and the recurring operating cost depends on what level of packaging the barcode is applied, and whether or not serialization is implemented. We estimate investments for both pharmaceutical and medical device manufacturers – actual cost for either type of company will depend on the specific situation.

We estimate representative costs to upgrade enterprise IT, packaging line equipment and software, and project costs for our example manufacturers with $4 billion in revenue and 25 packaging lines. These cost estimates are illustrative and not intended as an investment case. Actual costs will vary for each organization depending on existing capabilities.

Overview of implementation cost for manufacturers

Type of barcoding	Key assumptions	Major potential source of variability in actual cost
Product identification, lot number, and expiry date on secondary packaging	• $150-225,000 capital per each of 25 packaging lines • $1-2 million in licenses and integration cost for enterprise software • Annual expense 10-15% of invested capital (depreciation, maintenance, operating expense)	• Number of packaging lines • Existing packaging line equipment • State of enterprise software applications and interfaces
Product identification, lot number, expiry date, and serial number on secondary packaging	• $500,000 for equipment, line-level software, and project cost per packaging line[44] • $3-5 million in licenses and integration cost for enterprise software • Operating cost based on EFPIA estimate, scaled proportionally to revenue (EFPIA Individual Response to European Commission Concept Paper on the Delegated Acts for Coding & Serialisation, April 2012)	• Number of packaging lines • Extent of standardization across packaging lines and facilities • Equipment and software procurement effectiveness • Nature of existing enterprise software system serialization licenses already in-house
Product identificationon primary packaging	• $300-500,000 capital per each of 25 packaging lines • $1-2 million in licenses and integration cost for enterprise software • Annual expense 10-15% of invested capital (depreciation, maintenance, operating expense)	• Number of packaging lines • Existing packaging line equipment • State of enterprise software applications and interfaces

[44]The investment cost would roughly double if aggregation is also required (expert interviews)

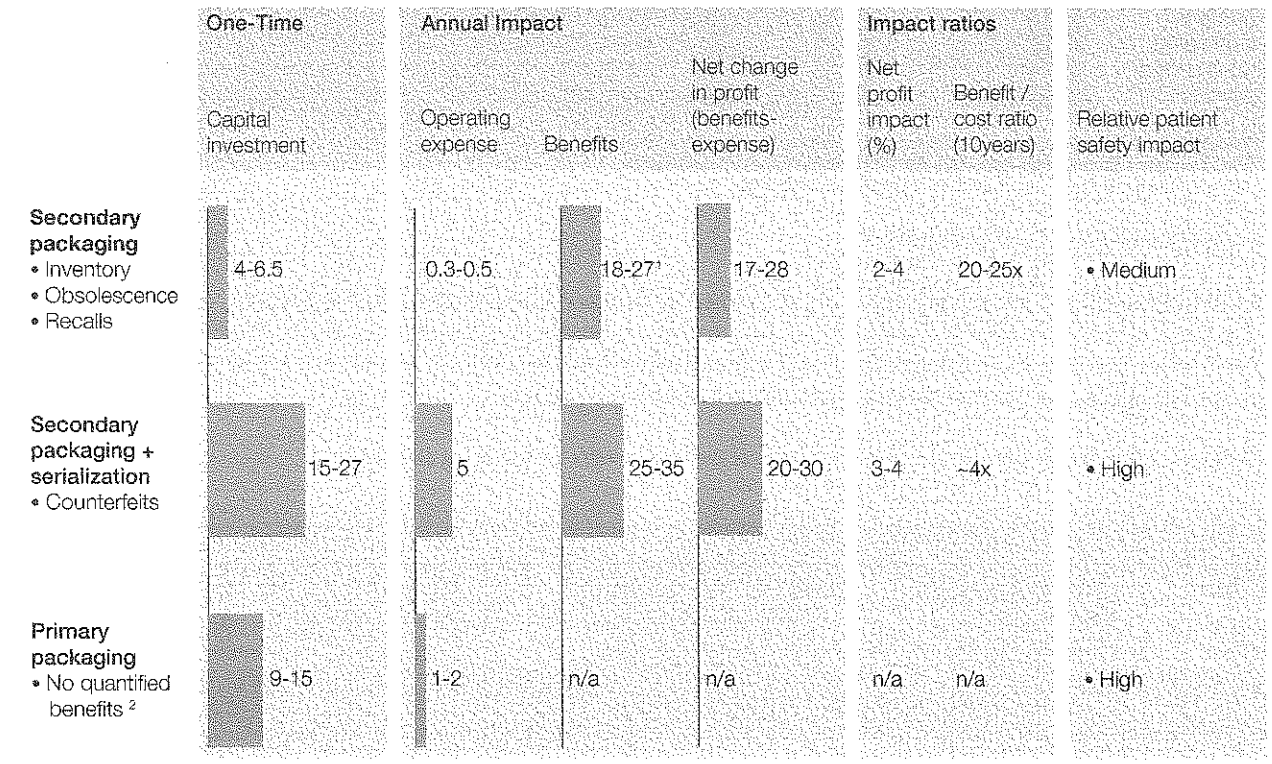
Net benefit to manufacturers

As our preceding analysis shows, there could be significantly positive returns to both pharmaceutical and medical device manufacturers from investments in adoption of global standards. Exhibit 4 shows investments, annual cost and benefits, and impact to patient safety for the three different types of barcoding for the pharmaceutical manufacturer. Each type of barcoding lists the benefits that can be obtained. Accumulating the benefits and both one-time and annual costs over 10 years, we expect barcoding at the secondary packaging level to deliver about 20-25x times more benefits vs. costs, while serialization would have a 4x benefit/cost ratio. Since we have not quantified the benefits of barcoding at the primary packaging level, we do not have a 10-year benefit/cost ratio for this capability.

For medical devices, the situation is more complicated – the variety of products precludes a simple assumption on how barcoding with serialization might be used, or barcoding on primary packaging. Exhibit 5 shows the same breakdown, now for the medical device manufacturer – but the investments and resulting benefits for serialization and primary package barcoding are highly dependent on the nature of the product. Secondary package barcoding by itself does have a clear business case, with about a 15-20x benefit/cost ratio over 10 years.

Exhibit 4

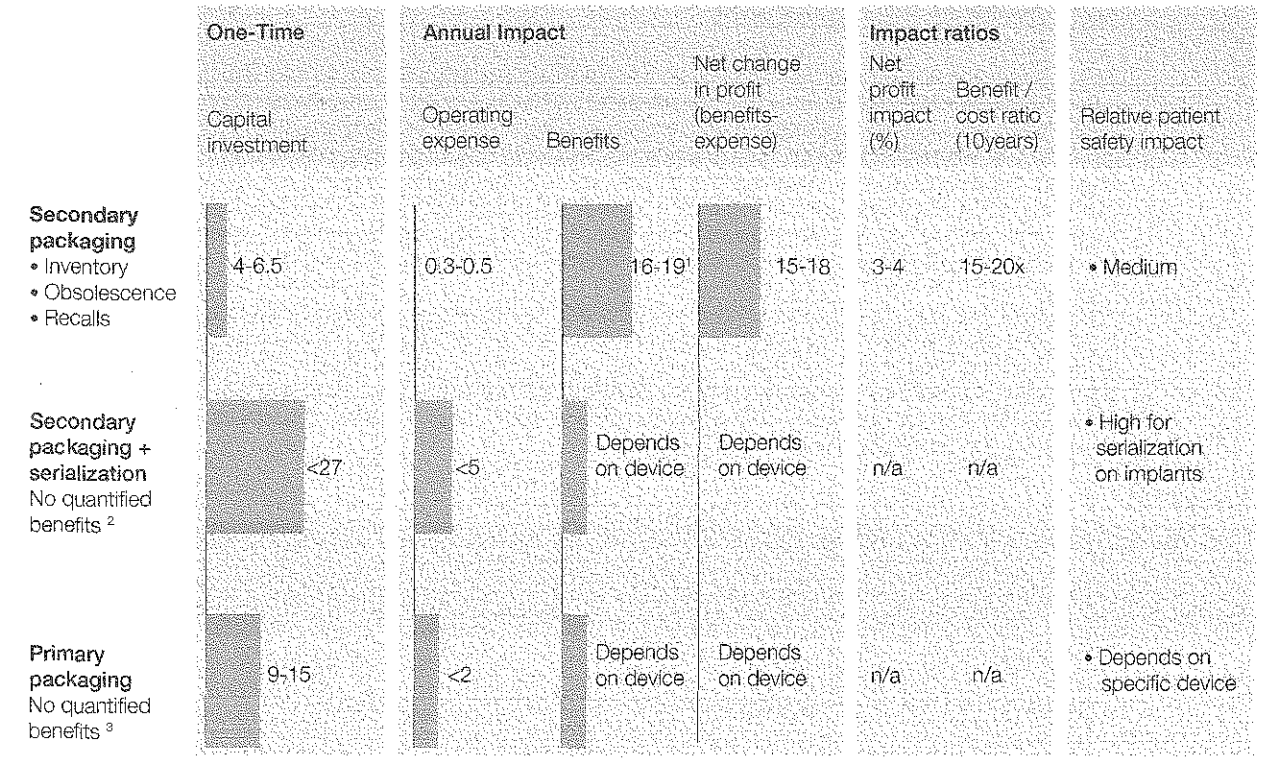
Illustrative business case for pharmaceutical manufacturer
$ millions



[1]Does not include a $90 million one-time cash benefit from inventory reduction
[2]See main text - increasingly important for hospital customers

Exhibit 5

Illustrative business case for medical device manufacturer
$ millions



[1]Does not include a $90 million one-time cash benefit from inventory reduction
[2]See main text - increasingly important for recall efectiveness with implants
[3]See main text - increasingly important for hospital customers

Distributors and wholesalers

Most distributors and wholesalers have not yet adopted global standards and associated IT systems. Although many pharmaceutical distributors now use barcode scanners and related IT systems to meet national standards, such as the National Drug Code regulations from the US FDA, few have adopted global standards. For medical devices, the situation is even less favorable.

We built our business case based on a hypothetical distributor with the following parameters:

We estimate the distributor could achieve annual savings of $1.2–1.9 million, 3-5% of base profit, after implementing global standards.

Other non-quantified benefits include:

- Recall effectiveness: Depending on the geography in which it operates, the distributor may need to meet future regulations, e.g. on Good Distribution Practices (GDP) in EU, or E-Pedigree in California, which will require (among other things) that distributors capture shipment lot numbers for potential recall processing. In the absence of any regulatory requirement, global standards can make the recall process more efficient for distributors, and they can often pass on a portion of the cost of executing a recall to the manufacturer, so that there is not a direct financial benefit for increased efficiency.

- Counterfeits: The distributor would comply with potential country or regional-level track-and-trace regulations, and mitigate the risk of inadvertently accepting counterfeit or diverted products into its supply chain. Currently, only Turkey, China a few other countries require this. The distributor would have to comply with any other future requirements; and

- Transaction challenges: As outlined in Section 3, serialization could create efficiencies in the chargeback process for distributors subject to this practice, and make returns processing more effective and accurate.

The potential benefits for distributors and wholesalers

Source of value	Primary value drivers	Key assumptions	Impact estimate and potential for case-by-case variation
Reduce inventory assets	• Improve demand forecasting and inventory planning	• Inventory days: 25-35 • $125 million inventory assets (6% of revenue) • 10-15% inventory reduction	• $13-19 million, one-time cash flow
Reduce inventory financing and holding cost	• Reduce working capital requirements by lowering inventory assets • Reduce inventory management cost with more efficient and accurate processes	• $6 million financing cost (5.1% cost of capital • $6.5 million inventory management cost (0.25% of revenue) • 10-15% holding cost reduction	• $1.2-1.9 million, annual

The distributor would need to invest $0.6-1.1 million at minimum up front and $20-50,000 in ongoing operation spending to establish barcode reading and IT processing capability. This would include barcode scanners and software for reading, storing and processing relevant information and linking to inventory management applications. This also covers project and training resources required for process changes, system upgrades, and coordination with supply chain partners.

In some cases, instead of simply passing on products with serialization information to its customers, the distributor may also need to invest to process serialization information. This will certainly be the case if it operates in a market where intermediaries would be required to authenticate received products, e.g. as part of a track and trace requirement. We estimate an investment of $2.2 million up front and $1.2 million in annual spending for such a capability, in the case of our hypothetical distributor. The operating expense is high because the distributor will need to re-aggregate the outgoing shipments, i.e. establish parent-child relationships between serial numbers at the various packaging levels, such as secondary packaging, case and pallet. This is typically done with 2 operators, and might have to occur at all distribution centers and warehouses.

Overview of implementation cost for wholesalers and distributors

Type of barcoding	Key assumptions	Major potential source of variability in actual cost
Product identification, lot number, and expiry date on secondary packaging	• $300 per scanner, 90 scanners needed (40 for distribution center, 10 for each warehouse) • $0.5-1.0 million for software systems and implementation • Annual expense 10-15% of invested capital (depreciation, maintenance, operating	• Existing enterprise software system capabilities • Number of major distribution centers • Number of warehouses • State of Enterprise software applications and integration may swing costs up or down
Product identification, lot number, expiry date, and serial number on secondary packaging	• Capital for equipment and enterprise software including serialization capability – $0.9 million for the Distribution Center – $0.25 million for each warehouse • Annual expense (operators, maintenance, depreciation) $0.4 million for Distribution Center, $0.2 million for each warehouse	• Extent to which aggregation is needed through the distribution network • Existing enterprise software system capabilities • Number of major distribution centers • Number of warehouses • Number of operators used for aggregation
Product identification on primary packaging	• Not applicable for distributors – primary packaging is not handled	

In sum, the distributor could see a 10-15x benefit/cost ratio over 10 years by implementing global standards and processing barcodes and information at the secondary packaging level. This includes only inventory reductions and associated reduced financing needs, and more efficient inventory management. Serialization and aggregation are far more costly capabilities for distributors—they would not see a benefit in recovery of lost sales due to counterfeits such as manufacturers may. However, serialization could be beneficial to financial transaction efficiency.

The improved data accuracy, faster response times, and simplified operation would also confer critical competitive advantages. In any case, the distributor will likely have to move along with its suppliers and customers as they adopt global standards in pursuit of patient safety and supply chain operation benefits (Exhibit 6).

Exhibit 6

Illustrative business case for wholesalers and distributor

$ millions

	One-Time	Annual Impact			Impact ratios		
	Capital investment	Operating expense	Benefits	Net change in profit (benefits-expense)	Net profit impact (%)	Benefit / cost ratio (10years)	Relative patient safety impact
Secondary packaging • Inventory	0.6-1.1	0.02-0.05	1.2-1.9[1]	1.1-1.8	3-5	10-15x	• Low
Secondary packaging + serialization • Regulatory compliance transaction efficiency	2.2	1.2	Not quantified	n/a	n/a	n/a	• Medium
Primary packaging *Not applicable to distributor*	n/a	n/a	n/a	n/a	n/a	n/a	• n/a

[1]Does not include a $13-19 million one-time cash benefit from inventory reduction

Retail pharmacies

Many retail pharmacies, especially in more developed countries, have already installed scanning technology, linking product receipt, inventory management, and patient dispensing. Those systems typically follow multiple manufacturer-driven coding algorithms, however, and can miss critical information, such as lot numbers.

We built our business case based on a hypothetical independent retail pharmacy, with the following parameters (Exhibit 7):

We estimate this pharmacy could achieve annual operation savings of $30-40,000, or 0.6-0.8% of revenue, after implementing global standards and updating its key processes.

The potential benefits for retail pharmacies

Source of value	Primary value drivers	Key assumptions	Impact estimate and potential for case-by-case variation
Reduce recall processing cost	• Minimize manual recall processing such as visually inspecting products and contacting all patients potentially impacted	• 1,000 annual recalls • 1 hour to process recall • $60,000 in labor costs: (8 hours per day, 5x48 days per year) • 20-30% labor cost reduction	• **$10,000, annual** • Labor rate will vary by country • Number of recalls may vary
Reduce data cleansing cost	• Reduce staff to cleanse supply chain data, such as matching product data with master catalogue, validating accounts receivable and payable data	• 1 FTE dedicated to data cleansing • $60,000 in staff labor cost • 30-50% cost reduction	• **$20-30,000, annual** • Labor rate will vary by country • Number of recalls may vary

Other non-quantified benefits include a reduction in counterfeit risk. The pharmacy would validate product authenticity upon receipt by the barcode on the secondary packaging, which contains product identification and a serial number with central data exchange network, catching counterfeits before they are dispensed to patients. In this respect, pharmacies will play an important role in ensuring patient safety, especially in areas with high prevalence of counterfeit products. In developed countries, the legitimate supply chain is widely believed to be virtually free of counterfeit products, which mostly end up with consumers via illegitimate internet pharmacies.

Obsolescence reduction is another potential area where pharmacies could see benefit. The standard process is highly manual, where pharmacy technicians need to check all shelves for products to avoid dispensing expired product. A national retail pharmacy association in Europe estimates that pharmacies can save about $30,000 in labor costs annually and reduce obsolescence by about $20,000 annually, through standardized barcodes which contain expiry dates. Because there are no other studies for obsolescence reduction in retail pharmacies, we have not included this in our benefit calculation, as the estimate would rely too much on this single data point.

Our hypothetical pharmacy needs to invest $10-20,000 upfront and less than $10,000 in ongoing operation costs to upgrade existing barcoding capability to include serialization information processing capability. This includes barcode scanners and serialization software, project and training resources required for process changes, system upgrades, and coordination with suppliers.

Overview of implementation cost for retail pharmacies

Type of barcoding	Key assumptions	Major potential source of variability in actual cost
Product identification, lot number, and expiry date on secondary packaging	• Minimal additional investment and annual expenses needed for processing barcodes on secondary packaging	• Scanners already available at the pharmacy and their capability
Product identification, lot number, expiry date, and serial number on secondary packaging	• 5x scanners $300 each • $15,000 for system upgrades and training • Operating labor expense $10,000 • 10-15% of initial software investment for annual software and usage licenses	• Software / systems / database cost • Number of shipments received and scanned • Labor rate
Product identification on primary packaging	• *Not applicable for retail pharmacies – primary packaging is not handled*	

In sum, our pharmacy could improve patient safety, generate annual P&L impact and recover the cost 3x over 10 years by implementing global standards. More effective recall management and counterfeit prevention, and the growing regulatory focus on track-and-trace capability, will soon make global standards more widespread in retail pharmacy operations.

Exhibit 7

Illustrative business case for retail pharmacy

$ millions

	One-Time	Annual Impact			Impact ratios		
	Capital investment	Operating expense	Benefits	Net change in profit (benefits-expense)	Net profit impact (%)	Benefit / cost ratio (10years)	Relative patient safety impact
Secondary packaging • Recalls • Data processing	<0.01	<0.01	0.03-0.04	0.03-0.04	~5	~3x	• High
Secondary packaging + serialization Regulatory compliance / transaction efficiencey	0.01-0.02	0.01	Not quantified	Not quantified	n/a	n/a	• High
Primary packaging Not applicable to retail pharmacy	n/a	n/a	n/a	n/a	n/a	n/a	• n/a

Hospitals

A few hospitals have begun adopting global standards. Some teaching and university hospitals have implemented barcode procedures, for example, and trained nursing staff on related procedures. Overall adoption is still low, however, as others hesitate to make the investments to upgrade internal capabilities and legacy systems to adopt global standards.

We built our analysis based on a hypothetical hospital with following parameters:

We estimate this hospital could achieve annual savings of $2.7-4.3 million, 0.9-1.4% of revenue, after implementing global standards and implementing the necessary additional system and process changes.

The potential benefits for hospitals

Source of value	Primary value drivers	Key assumptions	Impact estimate and potential for case-by-case variation
Reduce adverse drug events	• Reduce preventable medication errors and ADEs through bedside scanning	• 10% medication error rate on inpatient admissions (2,000 per year • 40% ADE rate on medication errors (800 per year) • Cost per ADE: $4,700-8,700 (US benchmark) • 30-50% reduction in ADEs	• **$1.1-1.9 million, annual** • ADE rate may vary based on systems/ procedures already in place • Cost per ADE will correlate with local healthcare cost
Reduce inventory levels	• Improve demand forecasting and inventory control	• $11.1 million inventory assets (3.7% of revenue) • 15-30% inventory reduction	• **$1.7-3.3 million one-time cash flow** • Inventory level and reduction potential fairly stable
Reduce cost of inventory (financing and management)	• Automate processing for inbound receiving, SKU management, stock audits, product returns	• $0.89 million financing cost (8% cost of capital) • 15-30% inventory reduction • $0.75 million inventory management cost (0.25% of revenue) • 20-25% labor cost reduction	• **$0.18-0.25 million annual** • Inventory management cost and reduction potential fairly stable
Reduce obsolescence	• Improve inventory control and visibility on product expiry)	• $2.2 million obsolescence (20% of inventory assets) • 50-75% reduction in obsolescence	• **$1.1 million-1.7 million, annual** • Obsolescence level and reduction potential fairly stable
Reduce recall processing costs	• Minimize time spent searching for information	• 1,000 annual recalls • Hospital staff labor cost: $98,000 • 60-80% labor cost reduction • 4-20 hours required to check stock for typical recall	• **$0.11-0.16 million, annual** • Depends strongly on nurse labor rate • Recall processing effort depends on systems in place and can be substantially higher for complex cases
Reduce data cleansing cost	• Automate data management, order processing, financial transactions	• 10 FTEs dedicated to data cleansing • Hospital staff labor cost: $98,000 • 20-30% labor cost reduction	• **$0.2-0.3 million, annual** • Number of FTEs dedicated to data cleansing may vary significantly • Labor rate can vary significantly

The hospital would face an investment of at least $0.6-0.8 million up front and $3-4,000 in annual spending to establish barcoding processing capability on secondary packaging. This could include barcode scanners and software for reading and processing barcode information and optimizing inventory management in central storage, operating rooms, and other supply points. Our budget also covers project and training resources required for process changes, system upgrades, and coordination with supply chain partners.

Overview of implementation cost for hospitals

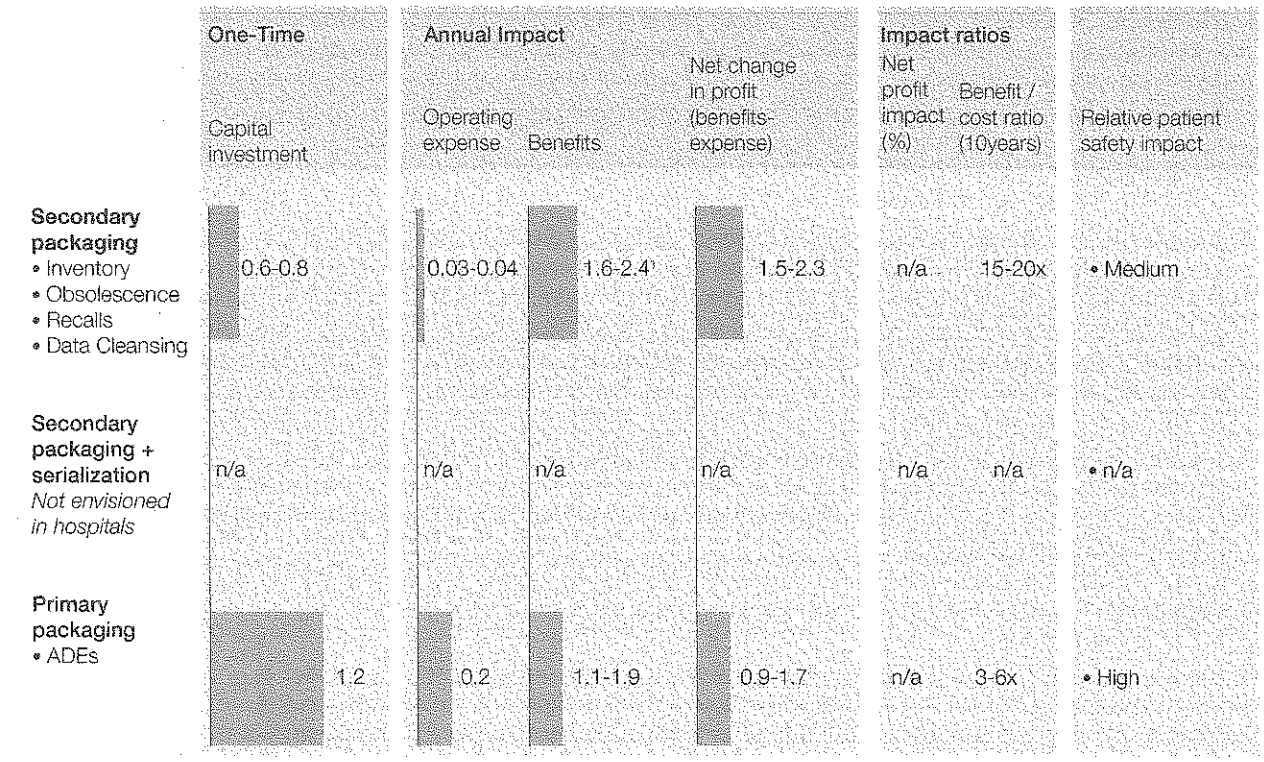
Type of barcoding	Key assumptions	Major potential source of variability in actual cost
Product identification, lot number, and expiry date on secondary packaging	• 4 basic scanners at $300 each • 10 rugged scanners at $2,450 each • $0.3-0.5 million for software capital, implementation, and maintenance cost • ~10-15% of capital investment for annual operating cost/ license fee	• State of Enterprise software applications and integration may swing cost up or down
Product identification, lot number, expiry date, and serial number on secondary packaging	• *Not foreseen in hospital*	
Product identification on primary packaging	• 150 basic scanners at $300 each for bedside scanning • ~$0.7-0.8 million for software capital, implementation, and maintenance cost • ~10-15% of capital investment for annual operating cost/ license fee	• State of Enterprise software applications and integration may swing cost up or down • Hospital investment into barcode labeler and repackaging machine may be needed if manufacturer does not provide primary package barcoding (cost for both ~$0.3-0.4 million together)

To enable bedside scanning throughout the hospital, it needs to invest in scanners to read barcoding on primary packaging, amounting to 150 additional scanners. Although some hospitals print their own barcodes, in the absence of manufacturers providing barcodes on the required level, we have assumed global standards adoption throughout the value chain, so that the hospital need not invest in these capabilities.

In sum, hospitals could realize significant benefits from adopting global standards, since it will help them reduce medication errors and thereby improve the safety and quality of care. The financial case is also sound, since the 10-year benefit/ cost ratio is 15-20x for barcoding at the secondary packaging level and 3-6x for barcoding at the primary packaging level. Eliminating manual processing could also relieve hospital staff from non-value-added chores, allowing them to focus more on patient care and have a better work environment.

Exhibit 8

Illustrative business case for hospital
$ millions



[1]Does not include a $1.7 - 3.3 million one-time cash benefit from inventory reduction

Impact of multiple standards

The estimates above assume that each player has adopted one single global standard. But what if the healthcare landscape continues to evolve with multiple standards options, and with different requirements by customer or country? To answer this question, we estimated the nature of the impact from moving from one global standard to two. We found that both the one-time and ongoing costs of global standards implementation would be significantly higher for every player in the value chain who must manage more than one standard. Given that players are increasingly working across multiple product segments—and given that technology evolution is blurring the boundary between product segments—the extra costs of multiple standards would affect an ever-growing portion of the total healthcare industry.

Manufacturers

Manufacturers would need to manage more complexity, through a greater number of SKUs and shorter production runs per SKU. We estimate that the one - time costs of implementation could increase by an estimated 15-25% compared to the investment needed for one standard on account of additional system costs, additional equipment costs (e.g., more expensive printers or dual printers on packaging lines) and additional implementation costs. Costs could be higher if additional complexity requires additional capacity to be added to offset loss of productivity. Ongoing costs (conversion costs) were estimated to increase by up to 5% due to lower productivity on account of shorter production runs, more or longer changeovers and potentially increased costs of supplies. The impact could also extend to the need for higher inventories as well as higher likelihood of increased errors in fulfilling orders to its supply chain partners. Regulatory compliance costs could also increase based on the need to maintain compliance to multiple standards rather than just one.

Distributors

Distributors, especially those that work across customers in different countries, would also need to manage more complexity with two standards versus one. We estimated that the one-time costs of implementation could increase by 10-20% compared to the investment needed for one standard, due to additional system costs, additional equipment costs (e.g., more expensive scanners) and additional implementation costs. A multi-standard environment might also result in additional space requirements and cost to accommodate additional slots in the warehouse. Distributors might need to provide over-labeling services to their customers to help them manage multiple standards. The impact on ongoing operations costs could be as high as 10% due to reduced productivity as a result of longer pick/putaway paths in the warehouse, additional inventory management costs (e.g., for cycle counts) and potentially additional logistics costs from less efficient inbound and outbound cube utilization.

Providers

Providers would also be impacted by an increase in complexity from moving from one standard to multiple, if they are not able to require one standard only from their suppliers. This impact could potentially result in additional one-time implementation costs of up to 10-20%, given the need for additional system costs, additional equipment costs and additional implementation costs. Alternatively, providers might bear the costs of "over-labeling" to ensure one standard only in their facilities. The patient safety benefits we estimated may also be put at risk, if supply chain information is not fully shareable and common across all partners in the supply chain.

V. A possible roadmap to adoption

A possible roadmap to adoption

Adopting global standards has the potential to positively impact all participants in the healthcare industry through applications that are already well understood. Furthermore, similar to the consumer packaged goods and retail industries, end-to-end supply chain connectivity could unleash new insights and innovations that would spur the creation of yet-to-be-envisioned products and services. The technology needed to bring these benefits to life already exists. Industry alignment could make the full potential of global standards a reality.

In the 1970s, the grocery industry formed a committee of well-respected leaders of major manufacturers and retailers. In consumer packaged goods, a few global players worked together tirelessly to align on GS1's single global standard for the industry. More recently, the Consumer Goods Forum organized senior executives to define requirements for global data synchronization. These leaders worked together across the value chain, and their decisions drove adoption throughout the sector.

Healthcare is a more fragmented and regional industry. Unlike consumer packaged goods, healthcare has no major players who could set new requirements for suppliers. In healthcare, manufacturers, not customers, are the largest and most global players, and regulators have more influence.

Industry leaders who are convinced of the benefits of global standards are in a position to work across competitive and customer-supplier relationship boundaries to agree on a common vision and approach. Customers, vendors, competitors and regulators will have to act and collaborate in new ways. Their aim will be to create interoperable systems; these are the enablers for change.

"Pursuing global standards, we've learned a few things: start early, learn by doing, and don't wait until the eleventh hour. Trading partners also appreciate this and overall, early adopters usually reap the largest benefits."

—Senior pharmaceutical executive

A role for each participant in the value chain

Given the structure of the global healthcare industry, each channel segment could play a unique and critical role in shaping standard-setting and adoption.

1) Manufacturers have much to gain—and to lose

Pharmaceutical and medical device manufacturers are the largest and most global players, and can therefore play a unique role in driving global standards adoption. As we demonstrated above, they will bear significant costs if requirements proliferate across customers and in each country. The cost of managing the resulting complexity in packaging operations and distribution centers is significant – particularly considering the indirect costs of maintaining quality and compliance requirements.

Manufacturers could realize significant benefits if they work together to shape processes, industry norms, channel partner agreements and data management responsibilities to create greater visibility to their products' end-to-end supply chain and demand patterns. In retail, manufacturers benefitted from access to point-of-sale data about shelf space, stock, and retail forecasts, which enabled a second wave of supply chain optimization, including optimized assortments and delivery frequencies, collaborative forecasting and replenishment, and improved on-shelf availability. Healthcare manufacturers could also benefit greatly if they improve control over their products' shipment and usage conditions, protect brand reputation and improve patient safety and effectiveness outcomes.

2) Large hospitals and retail pharmacies are positioned to integrate across product segments and to drive compliance

As in retail, the final stage of the supply chain could realize great gains from global standards adoption, at less cost, relative to manufacturers. Large hospitals and retail pharmacies, as well as industry associations and GPOs, might consider defining requirements and driving adherence up into the supply chain through their interactions with suppliers and distributors. Since hospitals and pharmacies can also integrate pharmaceutical and medical device technology segments, they have the most to gain from global standards.

Leaders in these institutions will be best positioned to make the right decisions if they develop a rigorous understanding of how a manufacturer's or distributor's use of global standards improves their total cost of ownership and their own safety metrics, once they have invested in systems and processes to take advantage of global standardization within their own organizations.

Building on this information, they could consider the requirement for global standards and coding as a prerequisite for delivery – or exact the cost of non-compliance through pricing. Key retailers pioneered supplier requirements, including global standards, coding, and information flow for the retail industry. Internally, hospitals and pharmacies might consider the development of a multi-phase strategy to benefit from standards with increasingly sophisticated applications for patient management and outcome monitoring.

3) Distributors, third-party logistics and solutions providers could create unique services around value chain connectivity

Distributors and 3PLs could add unique value by creating products and services that enable total supply chain connectivity based on global standards. Solution providers also could create new ways to enable the integration and adoption of global standards. These players could extract even greater value if they can also maintain proprietary access to the data generated – giving them further opportunities to generate service offerings to manufacturers and to hospitals and pharmacies. Distributors and 3PLs in the fast-moving consumer goods industries have generated value by acting as "connectors." In the retail sector, these players have captured value by improving materials-handling, booking, planning and resource allocation and balancing. Data connectivity has also enabled attractive new business models: such as providing customer order management and invoicing or co-packing services for manufacturers.

4) Regulators are uniquely positioned to improve global harmonization and alignment

Regulators are likely to play a major role in driving global adoption, no matter how it unfolds. Parties in both the public and private sectors are considering how they can begin working together now to develop a clear vision of global standards and how they will enhance patient safety and outcomes. This vision could guide health authorities and regulators around the world as they develop their requirements, avoiding (or minimizing) the fragmentation now underway.

One approach for driving adoption

Despite the clear incentives and opportunities for each segment, adoption may depend on the ability of a group of leaders across geographies and value chain roles to align on and commit to a single set of global standards. Our conversations with many of these leaders uncovered nearly universal goals of identifying and aligning around a set of global standards, accelerating implementation within their own organizations, and working with channel partners, peers and regulators to adopt it as well.

While Belgium, China, Germany, Italy, and Portugal have traditionally worked with their own national standards, most regulatory environments are evolving to align with global standards. These environments are most often aligned with the GS1 standard (Turkey is one notable example which has allowed both GS1 and HIBCC standards for medical devices). In the "standards comparison grid" (Exhibit 10), we compare national standards, GS1 and HIBCC according to the criteria that industry leaders might use to align around a single solution, including technological capabilities and flexibility, the nature and global scope of infrastructure support, and the momentum in adoption to date.

Many of the executives we spoke with said that they are actively working to unify the end-to-end healthcare industry around a single standard, as uncertainty about the universal industry adoption of a single standard is preventing their companies from moving forward with the investments needed for achieving the potential benefits of global standards. Industry leaders, such as the members of the GS1 Healthcare Leadership Team, are eager to collaborate across the industry to make a clear and collective decision on the best global standards and to shape an adoption path that will benefit all industry players – and the patients they serve.

The approach that leaders in the retail and consumer industries took may suggest a path forward for healthcare executives as well. In order to create a similar experience in healthcare, representatives from leading companies across the global healthcare value chain would need to convene to articulate a concrete vision for adopting global standards. These leaders would need to set clear time frames, with milestones and objectives along the path to full realization of benefits.

As their predecessors in the consumer industry did, healthcare leaders would need to prepare for the debate. They would need to be fully informed on their organizations' economics and the strategic opportunity that global standards present. Specifically, preparation could include:

- Identifying the investments needed to meet minimum regulatory requirements, but also those enabling other sources of value from standards adoption. Participants could also find it helpful to have an understanding of the value to their organization at different levels of trading partner adoption to understand the "breakpoints."

"Stricter standards are coming. Whether they'll be a burden or a benefit depends on whether trading partners can let go of some of their competitive habits and learn to collaborate more and in new ways."

—Senior supply chain executive

- Clarifying the strategic goals from end-to-end supply chain connectivity and visibility. What value will this connectivity and visibility create for your organization? For your customers? A holistic vision should define the investments that will be required, and the organization's priorities as the industry's processes and incentives evolve.

Exhibit 9

Standards comparison grid

	GS1 Standards	HIBCC Standards	National codes
Availability of high information density data carriers	Yes (GS1 DataMatrix and RFID)	Yes (3 ISO 2D Matrix and RFID)	Generally not (linear barcodes)
Comprehensiveness of the standard in terms of identification definitions	10 identification keys (incl. GTIN, GLN)	Product (UPN), location (HIN)	Product code only
Master data synchronization	GDSN (Global network)	UPN repository	No
Includes traceability standard	Global Traceability Standard for healthcare	No	No
Interoperability with national ID numbers	National numbers compatible with use of GS1 standards	Not applicable - no national codes for medical devices	Not intended to be used outside country
Used in all global geographies	Yes	Yes, except Japan	Only in country
Span across product types	Pharmaceuticals and medical devices	Medical devices (pharmaceuticals in The Netherlands)	Pharmaceuticals only
Global organization infrastructure andsupport	Global infastructure and support (global office and 111 member orgs)	US; support staff in Australia and Europe	Within relevant country
Additional industry coverage	Core sectors in Retail, Healthcare, Transport and Logistics; 20 others	Healthcare only	Pharmaceuticals only
Regulatory agencies / jurisdictions accepting use of standard	65	Turkey only	China, Germany, Italy, Belgium, Portugal

With this information in hand, senior decision-makers from across the global healthcare value chain might consider the following questions:

- What are the collective industry-level goals to be achieved through standards adoption?
- What specific use cases will be prioritized?
- What global standards will be required?
- What specific global standards are best?
- What is the right timeline for adoption?
- How will the group measure their success in driving adoption and in realizing benefits? What milestones and metrics will we track and publish?
- What steps will the group take to influence regulators and other key stakeholders to support the group's strategy?
- How will the group "market" its efforts and ensure that the benefits are recognized and celebrated by their organizations and other key stakeholders?

Lessons from the CPG/retail industry point toward a collection of principles that would likely make these meetings most effective:

- Encourage broad and global participation. Representatives from major manufacturers, national and private hospitals, distributors, pharmacies, solution providers, standards organizations, and regulatory agencies should be included.
- Create a structured and facilitated approach for the group to receive input, drive the dialogue, make decisions, and document agreements.
- Agree up front on the principles for decision-making, including criteria for decision-making, majority or consensus required by the type of decision, and voting procedures.
- Ensure there are advocates for opposing points of view in the room, and structure the discussion such that all points of view are heard.
- Create a "neutral" forum—not sponsored by any particular industry group or standards organization.
- Prioritize "win-win" opportunities where all trading partners will benefit.

- Go beyond regulatory compliance: the group should identify benefits to their patients and their organizations that go beyond regulatory requirements
- Celebrate the success that has already been achieved and find ways to celebrate successes at each step in the journey.

Healthcare at a crossroads - Strength in unity

Our research suggests that the healthcare industry can create significant value from the adoption of a single global standard—both in terms of business value and in terms of meaningful improvements in patient safety and quality of care. Our research also suggests that these benefits would be put at risk if the industry continues to try to manage the complexity of multiple standards rather than aligning around one. Global healthcare leaders have a window of opportunity now to work together to align around a single set of global standards and to collaborate to drive adoption of the practices enabled by these standards.

The patient would be the ultimate beneficiary

The healthcare industry is at a crossroads, and our research suggests that the case for alignment on a single global standard is compelling at both the total industry level, and for representative players in the industry. More importantly, the case for alignment on a single global standard is compelling in terms of the number of lives saved and medication/device errors averted. The industry has an opportunity to create a true win-win opportunity: a "win" for industry, and a "win" for the patient.

"Global standards are the right thing to do. They will benefit patients and consumers around the globe."

– Pharmaceutical executive

V. Glossary

AIDC: Automatic Identification and Data Capture – refers to the method for automatically identifying objects, collecting data about them, and entering data directly into computer systems

Five Rights: Method for safe medication practice: administering the right medication, in the right dose, at the right time, by the right route, to the right patient

GDSN: Global Data Synchronization Network, part of the GS1 Standards. Allows real-time data master sharing between trading partners

GLN: Global Location Number, part of the GS1 Standards. An identification key that uniquely identifies locations or legal entities

GS1: Global supply chain standards organization, with core sectors in retail, healthcare, transport & logistics, and 20 others

GTIN: Global Trade Item Number, part of the GS1 Standards. An identification key that uniquely identifies products.

HIBCC: Health Industry Business Communications Council; global supply chain standards organization for the medical device sector

HIN: Health Industry Number, part of the HIBCC standards. A unique identification for trading partners

Primary packaging: The first level of packaging for the product. For non-sterile packaging, the first level of packaging can be in direct contact with the product. For sterile packaging, the first level can be any combination of the sterile packaging system. It may consist of a single item or group of items for a single therapy, such as a kit.

RFID: Radio Frequency Identification

Secondary packaging: A level of packaging that may contain one or more primary packages or a group of primary packages containing a single item. This is what is normally seen in the retail point of sale.

Serialization: The process of assigning a unique number to each product package such that different packages of the same product are distinguishable.

Track and trace: The process of being able to follow a products' movement through the supply chain, in both the forward (Track) and backward / reverse (Trace) direction

UDI: Unique Device Identification.

UPN Repository: An online database with product master data, part of the HIBCC standards.

October 2012
Designed by the US Design Center

www.mckinsey.com