



## **The Case for Global Standards in the Healthcare Supply Chain**

prepared for      The GS1 Global Healthcare Users Group

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**This is an extract of**

**“The Case for Global Standards in the Healthcare Supply Chain”**

The full report is available at [www.gs1.org/healthcare](http://www.gs1.org/healthcare)

## Introduction

This report summarizes the benefits and advantages of global standards for automatic identification for all stakeholders in the worldwide healthcare supply chain.

This document provides a brief overview of the complexities of the current situation, and makes recommendations regarding how global standards can play a role in ensuring that the healthcare supply chain is safe and efficient.

Efforts were focused around three main research areas: health risks (patient safety), supply chain, and automatic identification.

## Issues of the Legitimate Healthcare Supply Chain

The complexities of the increasingly global system are vast. Supply chains that deliver healthcare products cross in and out of geographic and political borders, with products changing ownership a number of times. Significant inconsistencies in the amount of legislation, regulation and resources exist from country to country, and these inconsistencies further complicate an already complex distribution system.

Healthcare products are supplied through complex, multi-echelon global supply chains that currently lack transparency. Products are not shipped directly from the manufacturer to the customer, but are instead sold through primary and secondary distributors. There can be as many as 17 levels of intermediation between a manufacturer and a consumer. (Lara 2005).

## Illicit Activities and the Need for Standardization

Many reasons conspire to encourage illegal activities in the healthcare supply chain. These include:

- Lax penalties,
- The use of “lifestyle” medicines
- The rise of the internet pharmacy
- Complexities in the medical industry supply chain
- The globalization of the drug industry and free trade, making distribution of products easier (Anonymous 2006)

The WHO estimates that counterfeit drugs account for as much as 10% of global pharmaceutical trade and are worth between \$35 billion and 44 billion annually.

Developing countries are an easy target for counterfeiters because of the serious need for anti-malarias and other drugs and no hope of controlling the pharmaceutical supply chain due to under-funded governments.

“Counterfeit drugs also pose a danger to public health and safety in developed countries though the issues are somewhat different. There, many of the counterfeit drugs are not taken for life-threatening illnesses, but as lifestyle medicines. Drugs taken for erectile dysfunction, to control cholesterol levels and to enhance athletic performance make up the bulk of the illicit trade.” (O’Mathuna and McAuley 2005)

## The Hospital Supply Chain and the Need for Standardization

Complications of managing hospital inventories include the fact that items to be tracked are varied. Healthcare products used in medical settings are large and small, durable and expendable, disposable and reprocessed, numerous and few, as well as critical and non-critical to care. As such, the information that is relevant varies from item to item.

As a result, the optimal supply system for one hospital may not be ideal for

another hospital or even for other wards within the same one. However, the need for information regarding the products that are used throughout the hospital is undisputedly important because it is critical in the prevention of medication errors as well as the optimization of supply chain efficiencies.

### Medication errors

In 1999, the Institute of Medicine published "To err is Human," reporting that in 1997, between 44,000- 98,000 people in America, alone, die each year as the result of medication errors. "Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8<sup>th</sup> leading cause of death. More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516)." (Institute of Medicine of the National Academies 2006)

Estimates of cost for the US figures include the expense of additional care that is necessitated by the errors, as well as lost income and household productivity from resultant disability. These have been estimated at \$17-29 billion annually. Estimates for the cost of an adverse drug event (ADE) for each patient range from \$2,000-\$5,000 USD. (Healthcare Distribution Management Association 2004)

Estimates from the UK indicate that "about 10% of inpatient episodes result in errors of some kind, about half [of which] are preventable." (Department of Health 2007)<sup>1</sup> A study published by Vincent and Neale et al. (2001) suggested that of the approximately 8 million hospital admissions that occur in England each year, about 850,000 result in a patient safety incident, costing the National Health Service (NHS) approximately £2 billion in extra

hospital days. (Department of Health 2007)

This has led the Department of Health to call for the use of standardized information, delivered through the use of automatic identification and data capture technologies. (Department of Health 2007)

"The case for coding is compelling, but all stakeholders need to work to commonly agreed standards if the benefits are to be realized fully. The Department of Health is recommending that the GS1 System should be adopted throughout the healthcare system in England, both for manufactured products and for coding systems used within healthcare settings, such as patient identification codes on wristbands." (Department of Health 2007)

Statistics reported from New Zealand regarding medication error are comparable to those reported in the US and the UK. The New Zealand Quality of Healthcare Study (Davis, Lay-Yee et al. 2001) indicates that in-hospital adverse drug events occur at a rate of 10%. (Anderson 2007) Of the 10%, approximately 7.5% are classified as preventable. Researchers further indicate that 0.78 percent of hospital admissions in New Zealand result in a preventable adverse drug event, a medication error.

An extrapolation of the study suggests,

"that in New Zealand, each year, about 5,000 patients are subject to medication errors. As a result of these errors about 150 patients die, over 400 are permanently disabled and nearly 3,500 are disabled for less than one year." (Anderson 2007)

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<sup>1</sup> Note the inconsistency in terminology- preventable vs unpreventable and error.

As is the case with the UK data, this has led government officials in New Zealand to investigate the cost effectiveness of implementing Automatic Identification.

### **Automatic Identification in the Healthcare Industry**

There has been significant interest in developing standardized information that leverages automatic identification (Auto-ID) technologies to convey the information up and down the chain. Such a system not only has the potential to decrease medication error, but also to enhance the efficiency and profitability of the supply chain.

Work done by Nathan and Trinkaus (1996) suggests that implementation of more effective information systems would not only impact on the well-being of the public, but also on hospital budgets. This group indicates that inventory management accounts for between 17% and 35% of a hospital's total revenue. "For example, a hospital running at 5% profitability, with 30% inventory management costs could improve profitability by 60% with a 10% reduction in its inventory costs. Hospitals can then reinvest these savings into equipment and personnel that further enhance patient care." (DeScioli 2005)

Automatic Identification (Auto-ID) processes are changing the way supply chains operate throughout the world. Auto ID enabled processes are faster, more efficient and lower cost than human identification alone.

These technologies ... can provide system benefits that are maximized when standardized and interoperable.

In order to garner system-wide benefits, Auto ID depends on the participation of the entire supply chain. (AIM 2007) To maximize the benefits of the technology, the system requires procedures that insure all trading partners gain value.

### **Studies of the Costs and Benefits of Auto ID in the Healthcare Supply Chain**

The need for a global standard for identification is clear. A common language is needed, regardless of the characteristics of the systems that use it.

Furthermore, a standard identification system is critical for modern supply chain management, which is based on principles of synchronization and data sharing. By sharing standardized supply and demand data, industries are better able to streamline processes and minimize the cost of inventory.

Healthcare has been slower to adopt automatic identification than the grocery industry because it is so much more complex. Unlike the more consolidated grocery industry, in which the retailers mobilized to relatively quickly organize around the UPC bar code standard, the healthcare industry has adopted automatic identification on a piecemeal basis.

But there is plenty of evidence that automatic identification can add efficiency and accuracy to healthcare supply chains. Some of the ways in which Auto ID can benefit healthcare include:

- Effective order processing and transmittal for manufacturers, distributors and providers
- Inventory control for manufacturers, distributors and providers
- Bills of lading and ownership documentation (electronic pedigree)
- Information for regulators and customs agents
- Integration with Computerized Physician Order Entry (CPOE) Systems

- More effective utilization of devices and other supplies (accurate tracking of reprocessed equipment, for instance)
- Improved patient use validation
  - ensuring the five rights in the case of medication
  - ensuring the eight rights associated with medical devices
- Effective recall activation, tracking and control of the reverse chain
- Efficient billing and reimbursement
- More effective public health emergency response- locate and divert product to where it is needed, even under chaotic circumstances
- Improved level of evidence when prosecuting those suspected of illicit activities

Studies that have investigated impact of Auto ID technologies on healthcare supply chains have generally returned favorable results, both human and financial.

### **Pharmacy, Hospital and Patient Studies**

Most pharmacies already use UPC codes on over-the-counter drugs to automate transactions with consumers, similar to the manner in which grocery stores use them. Some also scan bar codes on prescription drugs for inventory control, ordering and prescription verification.

A study conducted by the American Hospital Association (AHA) indicates that bar coding, or some other form of product identification management, is being implemented by a majority of hospitals. The survey noted,

“more than half of all hospitals [surveyed] have adopted bar-coding technologies for at least

one purpose... twenty-six percent of those surveyed had fully implemented or partially implemented bar-coding for pharmaceutical administration in 2006.” (American Hospital Association 2007)

One VA medical center in Topeka, KS (U.S.) reported "bar coding reduced its medication error rate by 86 percent over a nine-year period." (Meadows 2003) Largely as a result of the success demonstrated in the VA hospitals, the US FDA initiated a rule requiring linear bar codes on human drugs and biologics.

It was also estimated that the rule will help prevent nearly 500,000 ADEs and transfusion errors over the next 20 years, saving approximately \$93 billion in healthcare costs.

On May 5, 2007 WHO announced a new core program of the WHO World Alliance for Patient Safety, Patient Safety Solutions. The purpose of the program is to help reduce the death toll of healthcare-related harm affecting millions of patients world-wide. It lists nine solutions for patient safety. One solution addresses the problem of look-alike, sound-alike medication names. Another is patient identification. Two others address communication issues when the patient progresses through stages of the healthcare system. (Anonymous 2007) Auto ID technologies are not required to implement the solutions, but where they are available, existing auto ID technologies can act as carriers of the information used. All nine of the solutions can be implemented in systems utilizing Auto ID, and all of them enhance patient safety.

On a global scale, both bar coding and RFID are used, though the predominant technology is still bar codes. Here, there are a variety of data standards in existence.

The plethora of symbologies is, potentially, a driver for the move to standardize Auto ID on a global scale.

Additionally, the process will have to consider the many regulatory and legislative activities that are occurring throughout the world that have the potential to impact harmonization (or lack thereof).

### **Standardization**

Standards must be prepared in an atmosphere of openness, impartiality and consensus, and they must be effective and relevant to the activity or item for which they are written. (ASTM International)

Global standards, harmonization, interoperability and automatic identification are bound together to form a system that enables supply chain members to share information and consequent data processing, without human intervention. This removes from the system a major error source – human error.

### **Conclusions**

The complex multi-echelon global healthcare supply chains that exist today favor the adoption of data standards for their economic benefits in automatic identification applications. When the identification data are standardized, as with any language, they provide rapid, clearly understood communication from any sector of the supply chain to all others. Automatic identification enables a higher degree of inventory visibility and order management efficiency. In an increasingly global supply chain, global standards are required.

Legitimate actors in the healthcare supply chain, from the beginning to end, throughout the entire world, are calling for information about products. They want information to be readily and

quickly available in standard format that can be accurately read.

The literature reviewed for this report suggests that standard automatic identification can be affordable, and potentially provides a satisfactory return on investment.

The use of automatic identification systems offers great benefits, both human and financial, to the global supply network. However, such a system is doomed to failure if the complex, multi-echelon supply chain is not operating globally with efficiency and interoperability. Since the global supply chain is not able to offer “equivalence” in the way of information flow, the chain cannot operate efficiently throughout the world.

Healthcare and the information technologies that serve it must become a closely connected network that provides global flow of accurate, uniform information about every element of the healthcare system. And the information must be readily available to every operating element of the system.

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This report was prepared for the GS1 global Healthcare User Group.



GS1 Healthcare is a voluntary, global user group bringing together all related healthcare stakeholders: pharmaceutical and medical devices manufacturers, wholesalers and distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, governmental and regulatory bodies, and associations.

The mission of GS1 Healthcare is to lead the healthcare sector to the successful development and implementation of global standards by bringing together experts in healthcare to enhance patient safety and supply chain efficiencies.

The goal of the global Healthcare User Group is to be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders who are seeking input and direction for global standards in healthcare for patient safety, supply chain security & efficiency, traceability and accurate data synchronisation.

The user group has issued a Position Statement advocating a global approach for Automatic Identification Standards in Healthcare. The GS1 System of Standards is extremely well suited to fit the specific needs of Healthcare. Therefore, the user group strongly recommends governments worldwide to endorse the use of the GS1 system. Global standards for automatic identification provide the opportunity to make the Healthcare supply chain more efficient and accurate, and thus safer. However, to realise all the benefits, these standards need to be global.

For more information, please visit [www.gs1.org/healthcare](http://www.gs1.org/healthcare)