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ERG Final Report

UNIQUE IDENTIFICATION FOR MEDICAL DEVICES

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SECTION ONE

INTRODUCTION

In 2004, the United States Food and Drug Administration (U.S. FDA) promulgated a regulation to require bar code identification on pharmaceutical labeling (FDA, 2004). While developing that regulation, FDA asked for public comment on whether such a regulation should be extended to medical devices. In the course of its deliberations, FDA chose not to include medical devices in the bar code rule, noting that such devices lack a standard and unique identifying system comparable to the National Drug Code system for pharmaceuticals.

FDA is reconsidering whether some form of unique device identification (UDI) is warranted for medical devices, given the potential of UDI to help reduce medical errors, facilitate recalls, identify incompatibility with devices or potential allergic reactions, improve inventory control, improve reimbursement, and reduce product counterfeiting.

In this document, we examine the outlook for implementing some type of UDI system for medical devices. We begin with a discussion of where we are now (Section One). Subsequent sections of the document address:

- Section Two: Potential Benefits and Interests of Stakeholders
- Section Three: Medical Device Management Scenarios
- Section Four: UDI Implementation: Possible Steps and Challenges
- Section Five: Conclusions about the Potential Government Role in UDI

1.1 OVERVIEW OF THE MEDICAL DEVICE INDUSTRY

The United States is the largest producer of medical devices and technology in the world (AdvaMed, 2004c). FDA currently lists 80,000 brands and models of medical devices used in homes, physician's and dental offices, and hospitals (FDA, 2002). In this listing, multiple sizes of product (e.g., a 100-glove box and a 500-glove box) appear as one item, so the number of medical device shelf-keeping units (SKUs) is actually much larger than 80,000.

The 2002 Census lists 5,394 companies, comprising 6,007 establishments, as active in medical device manufacturing, with a total value of shipments of $85 billion (see Table 1-1). The vast majority of these establishments are small, with fewer than 20 employees (U.S. Department of Commerce, 2004). Many devices have small niche markets. Thus, many medical device companies are specialized as well as small. The U.S. medical device industry is extremely diverse. Medical devices vary dramatically in size, complexity, packaging, and use. They include disease screening technologies, therapies, equipment, and supplies—everything from expensive, complex capital equipment (such as x-ray machines) to simple items (such as bandages and tongue depressors). Some are packaged individually and others are packaged in boxes of hundreds or thousands. They may be used once and thrown away, used and reprocessed, or used for their lifetimes. Some devices are implanted; these carry a particular set of risks to the patient.

Table 1-1
Size of the Medical Device Industry

NAICS 325413, Diagnostic reagents	196	236	$7,296,122
NAICS 334510, Electromedical and electrotherapeutic apparatus manufacturing	480	546	$15,587,402
NAICS 334517, Irradiation Apparatus Manufacturing	153	169	$4,395,270
NAICS 339111, Laboratory apparatus and furniture manufacturing	402	425	$4,480,552
NAICS 339112, Surgical and medical instrument manufacturing	1,216	1,352	$21,819,423
NAICS 339113, Surgical appliance and supplies manufacturing	1,607	1,845	$24,525,091
NAICS 339114, Dental equipment and supplies manufacturing	852	875	$3,087,183
NAICS 339115, Ophthalmic goods manufacturing	488	559	$4,250,579
TOTAL	**5,394**	**6,007**	**$85,441,622**

Source: U.S. Department of Commerce, 2004.

The medical device industry is also characterized by innovation, resulting in short life cycles for many products. Many medical devices undergo constant development based on feedback from medical practitioners and advances in other sciences relevant to medical device technology (AdvaMed, 2004b). Given this level of innovation, competition among companies is keen (Field and Tilson, 2005). Small firms are thought to play a greater role in research and development of new medical devices, with large firms providing organizational and capital assets that help ensure new products' commercial success (Field and Tilson, 2005). With this constant innovation, the medical device industry spends heavily on research and development. The industry spends a large percent of revenues on R&D, with that percentage being substantially higher for small firms. In 2002, overall the industry spent 11.4 percent of revenues on R&D (AdvaMed, 2004a).

The government also plays a role in the innovation process, supporting research and development, regulating market approval, and paying for clinical intervention through various benefit programs such as Medicare and Medicaid. The agency primarily responsible for medical device regulation is FDA, with seven offices within FDA's Center for Devices and Radiological Health (CDRH) each addressing a set of responsibilities associated with the regulation of medical devices. FDA's Center for Biologics Evaluation and Research (CBER) is also responsible for regulating biological medical devices, such as those that include blood or cellular products.

In light of the diverse and evolving nature of the medical device industry, FDA has considered how different classifications of medical devices might influence selection of a UDI system. During a recent meeting (FDA, 2005), FDA noted that medical devices can be classified by:

- Implant type (permanent, temporary, active, non-active)
- Device material
- Capital equipment
- In vitro diagnostics
- Risk to patient
- Infectious risk/sterility
- Supplies (disposable or non-disposable)
- Single-use only
- Reprocessed devices
- Reusable devices
- Interoperability (mechanical, electrical, software)
- Care setting (e.g., home, clinic)
- User of device
- Kits vs. components
- Systems vs. components
- Devices requiring expiration dates
- Devices relevant to bioterrorism

These classification criteria focus on many different aspects of medical devices and have varying levels of relevance for patient safety, product tracking, inventory control, etc. Some of the criteria are overlapping, so multiple criteria may apply to a single device. How to prioritize and consider these issues will affect the design of a UDI system.

1.2 CURRENT REGULATIONS GOVERNING MEDICAL DEVICES

Medical devices must undergo an approval process before being introduced to the market. Once approved, ongoing regulatory requirements fall largely into two categories: labeling and tracking.

Currently, medical device labeling must include the name of the product, the name of the manufacturer, and the place of manufacture. Manufacturers must also provide adequate directions for use, although some products are exempted from this requirement if they meet certain conditions (e.g., directions are commonly known). For over-the-counter devices, labeling must include a statement of identity and net quantity of contents. This information does not need to be machine-readable and does not uniquely identify the product. Therefore, current requirements do not ensure that devices can be tracked on a lot number basis.

Under the 1990 Safe Medical Devices Act (SMDA), manufacturers must implement a tracking system for certain devices whose failure is likely to have serious health consequences for users. FDA issues letters to manufacturers who make and/or distribute devices subject to this requirement. After receiving notification, a manufacturer must write a standard operating procedure detailing how its product can be tracked through distribution, including audit procedures, in the event that the device must be removed from distribution and/or use. Final distributors must also furnish the manufacturer with patient identification data and device information (lot number, batch number, and/or serial number) to ensure effective tracking of the device if necessary. While effective practices are in place to fulfill these requirements, it is possible that these tracking systems could benefit from UDI as well.

1.3 CURRENT USE OF MEDICAL DEVICE IDENTIFICATION

Currently, use of medical device identification encompasses four main elements:

- Use of the universal product number (UPN), devised by the Department of Defense (DOD) to streamline purchasing operations.
- Use of a product data utility (PDU) to maintain accurate product data for electronic data interchange.
- Use of auto-identification technologies, such as bar coding, that allow distributors and purchasers to electronically read UPNs or other identification information.
- Use of identification systems in hospitals that can read UPNs and capture data or link UPNs to a PDU database.

These types of medical device identification are quite disparate and have penetrated the market to widely varying degrees. UPN use is growing but is not yet industry-wide, although many efforts are ongoing to make it so, driven by a need for improved supply chain management. Product data utilities are used in some industries, but are new to the medical device industry. The auto-identification technology most in use on medical devices is bar coding and is more common among large companies. Only a few hospitals are making use of identification systems in their operations.

1.3.1 Use of UPNs

The UPN is a unique product identifier that can be represented on medical devices in both human readable and bar code or other automatic identification formats. UPNs are used primarily in supply chain management of durable equipment and supplies, although firms also use UPNs for traceability, purchasing, and materials management. Each UPN is a string of 14 or 20 characters. The UPN can be assigned by the Health Industry Business Communications Council (HIBCC) or the GS1 organization (formerly the Uniform Code Council (UCC)). Firms choose between HIBCC and GS1 based on what numbers they already use and where they plan to sell their products. After choosing the format, the firm must purchase a labeler identification code (HIBCC) or manufacturer's identification number (GS1). In addition to the labeler identification code or manufacturer's identification number, the UPN includes a manufacturer-assigned product number, a package-level code, and a check digit. Thus, each product is assigned a unique number at every packaging level, from bulk boxes to unit-of-use.

In 1995, the DOD created the UPN system to streamline its purchasing operations and reduce costs. Currently, the DOD requires use of a UPN on shipping containers of all purchased products. Other industry groups have also joined the initiative and are supporting or requiring UPN adoption by medical device suppliers. In May of 2004, the Global Healthcare Exchange (GHX), which consists of healthcare providers, suppliers, and GPOs, launched an initiative to increase the use of UPNs as standard product identifiers. More than 30 suppliers, distributors, and delivery systems agreed to adopt UPNs to facilitate electronic supply management.

As a result of these initiatives, UPNs are employed on the majority of medical devices supplied to the DOD as well as on a large number of medical devices in general commerce. In 1999, UPNs were found on approximately 70 percent of medical and surgical supplies (HHS, 1999). Navas reports that all sutures are marked at the box and unit-of-use levels and that many implants are marked at all packaging levels. General supplies are also fairly well marked, with at least one manufacturer marking a product line (Navas, 2000). A UPN repository maintained by the HIBCC currently includes more than 250,000

records (HIBCC, 2005). Overall, however, the additional expense of implementation and the voluntary nature of the effort have resulted in slow adoption of the UPN by manufacturers (Navas, 2001).

Product Data Utility (PDU)

A unique identifier such as the UPN helps standardize communications in the industry and reduce errors in product identification and transactions. However, in other industries it has been found that product data inaccuracies and errors still occur. Some of these errors stem from human error, such as omissions and miskeying of data. Correcting these errors involves inefficiencies and costs. A product data utility (PDU) is a centralized content repository of product data. The purpose of a PDU is to enable standardization, synchronization, and maintenance of accurate product information from the manufacturer through the supply chain to the end user in near real time (Jester and Hagemeier, 2003). A PDU is believed to alleviate product data problems and allow for more effective communication among supply chain partners (Hagemeier, 2003). In other industries, PDUs have been used successfully to maintain accurate product data for electronic data interchange (EDI). The creation of a PDU involves:

1. Agreement on core product data attributes (e.g., manufacturer, packaging level).
2. Initial clean up, loading, and validation of data with new core attributes.
3. Synchronization of product data.
4. Maintenance of a central repository of accurate product data that can be distributed.

The DOD recently conducted a congressionally funded pilot test of a PDU to demonstrate that accurate, synchronized medical device data can flow through the supply chain, resulting in efficiencies and cost savings. The pilot involved data from a limited number of manufacturers and distributors. During the process of standardizing the data and synchronizing a set of core data attributes, DOD found a large number of data discrepancies, illustrating the need for such an initiative. Some of the discrepancies encountered include inclusion of obsolete products, bad product descriptions, and pricing problems (Garvin, 2005). According to Garvin (2005), while these data synchronization efforts were undertaken to increase DOD wartime readiness, improve supply chain interactions, and reduce costs, the entire industry can benefit from the existence of a PDU. Having correct data (via a PDU) will help ensure that medical devices can be properly identified and tracked.

The general absence of a comprehensive PDU for the medical device industry is a major stumbling block to advancement of automatic identification systems in healthcare. While a majority of medical devices have UPNs, at the present time the UPNs cannot be linked to any reliable, reasonably comprehensive database of product information (i.e., a PDU).

1.3.2 Use of Auto-Identification Technologies

Auto-identification is the broad name given to a host of technologies that are used to help machines identify objects. Auto-identification is often coupled with automatic data capture. That is, companies want to identify items, capture information about them, and get the data into a computer without having employees type it in. The aim of most auto-identification systems is to increase efficiency, reduce data entry errors, and free staff to perform more value-added functions, such as providing customer service. The three main types of auto-identification technologies are:

- Bar coding, in which a machine-readable graphic representation (with bars and spaces of varying width) is placed on the product.

- Radio-frequency identification (RFID), in which products (or patients) are tagged with identifying information that can be read by a radio-frequency (RF) reader.
- Optical character recognition (OCR), in which images of printed characters are converted into ASCII code that a scanner can read (see http://www.rfidjournal.com).

Currently bar coding is the primary auto-identification technology used by the medical products industry. The use of RFID is less common, but may increase in the future. OCR could be used to identify medical devices, however, its use is extremely limited at this time. Other types of auto-identification technology, such as smart cards, voice recognition, and some biometric technologies (retinal scans, for instance), are beyond the scope of this document. For more information about bar coding, RFID, and OCR, see the appendix at the end of this document. Below, we discuss the current use of bar code technologies by the medical device industry.

Bar Code Scanning

Several organizations have conducted surveys on the use of bar coding (and other auto-identification technologies) in the medical device industry. Spurred by interest in medical error reduction, Advamed, the larger of the two industry trade associations, conducted the most recent survey in 2004.

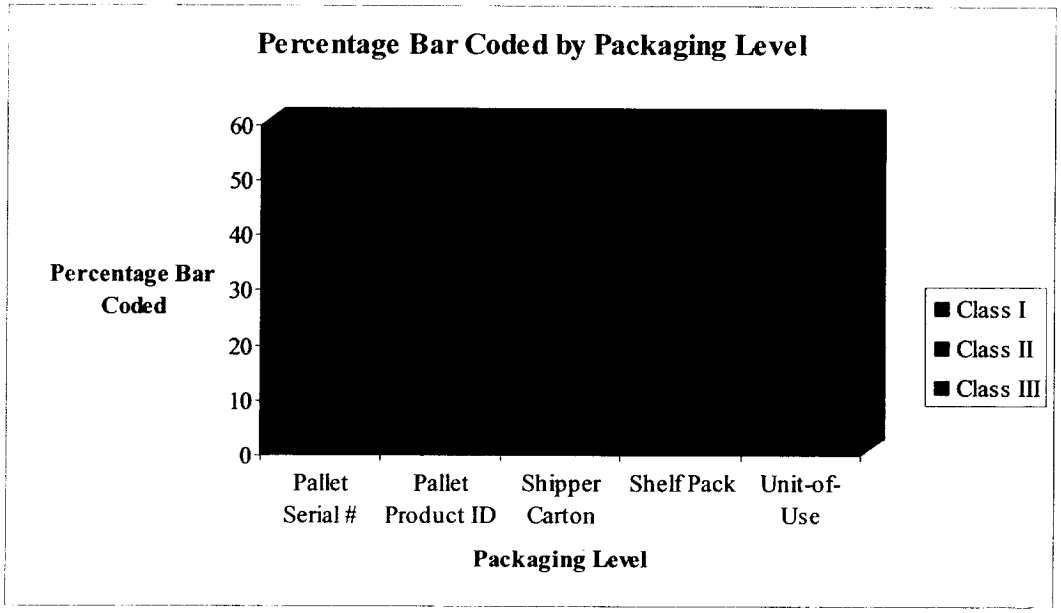
The AdvaMed survey was designed to determine the current and possible future use of bar coding and other auto-identification systems (AdvaMed, 2004a). The survey was conducted on the Internet, and participation was voluntary. Because only 37 medical device companies completed the survey form, these results are not representative of the industry. The results might be biased due to higher participation rates among firms using bar coding. Firms not using bar coding might be more likely to ignore such a survey.

In reporting its survey results, AdvaMed indicated that a large majority of medical device companies are applying bar codes to their products in some fashion, but that the practice varies by company size. Larger companies are substantially more likely to be using bar codes than small ones. Among companies with less than $30 million in revenues, only a minority is applying bar codes.

Figure 1-1 shows the percentage of products with bar coding, by level of packaging. More products are bar coded on the shipper carton and shelf pack than on the unit of use. According to survey results, about 25 percent of FDA Class I, 44 percent of FDA Class II, and 50 percent of FDA Class III unit-of-use products are bar coded; collectively, across all device classes, fewer than 45 percent of medical devices are bar coded at the unit-of-use level. Other observers have judged that bar coding is not very common at the unit-of-use level (e.g., Hagemeier, 2005).

Unit-of-use coding is the level of greatest relevance to patient-related within-hospital uses. The fact that bar coding is more common on shipping packages than units of use suggest that bar coding is used more for shipping-related needs than for accurate product identification within the hospital (or, by extension, for addressing patient safety issues). In order for hospitals to rely on manufacturer-supplied automatic identification systems for bedside or other scanning (for patient safety, expanded inventory control, or improved billing accuracy), many more packages will require bar codes or other automatic identifiers. This observation assumes that manufacturer-provided bar codes will provide the basis for bar code use in hospital inventories and that the hospital will not need or prefer its own, internally designed bar code.

Figure 1-1. Percentage of Products 100 Percent Bar Coded by Packaging Level



Source: Advamed, 2004a

The results of other surveys are roughly consistent with the AdvaMed finding that bar code use is widespread but often does not reach the level of unit-of-use packaging. A 1997 report by the Health Industry Distributors Association reported bar codes were used on nearly 70 percent of all cases, but only 26 percent of unit-of-use packages, or eaches, were bar coded (Allen, 2000). Other surveys have provided different figures, although the comparability of the figures is difficult to establish because the packaging levels are not always clearly distinguished.

AdvaMed survey results indicate that use of bar coding will likely continue to rise, but not all manufacturers lacking bar codes plan to use them: only 11 percent of companies not currently using bar codes had plans to begin using them. On the other hand, companies that are bar coding some of their products are expanding their use of bar codes across their product lines.

RFID

In March 2005, ECRI, a nonprofit health services research agency, reported the results of an informal poll of that organization's member hospitals (ECRI, 2005). The results suggest that RFID use is uncommon now, but may rise. Specifically, in response to the question, "Does your hospital plan to implement RFID technology for tracking the location of capital equipment?" hospitals reported:

- Already use RFID--3 respondents (3.5 percent);
- Working on implementing the technology--6 respondents (7.1 percent);
- Plan to implement the technology within the next two years--30 respondents (35.3 percent);
- Do not have any immediate plans to implement RFID--39 respondents (45.98 percent); and
- Did not know what their plans or activities were--7 respondents (8.2 percent) (ECRI, 2005).

OCR

Technically, OCR could be used to identify medical devices. Currently, its use in the healthcare industry is extremely limited, however.

1.3.3 Use of Device Identification in Hospitals

Most hospitals do not have sophisticated inventory systems that use bar codes or other auto-identification technologies; they have not invested in equipment and software needed for auto-identification. One industry expert estimates that only 10 percent of the hospitals are using bar coding systems (Kilzer, 2005). When evaluating the use of UPNs for Medicare in 1999, HHS identified three hospitals that were using UPNs to reduce waste of supplies and equipment and improve patient billing (HHS, 1999). Of hospitals using bar codes for medical devices, most develop and affix their own bar codes because of the lack of uniformity in identification numbering for medical devices and supplies.

Hospital inventory systems are a complex mix of central materials management controls, some decentralized stocking systems, some vendor-provided (i.e., distributor) inventory management assistance and other value-added services, and some informal stockpiling of devices by individual departments or nursing stations. The inventory systems at most hospitals compile what comes into the hospital, but there is limited further tracking of materials. For example, most hospital supply rooms are inventoried using handheld data loggers (after which lists of needed supplies are generated). Even these hospitals only inventory products to the shelf level, not to the unit-of-use level (Kilzer, 2005). Furthermore, most internal hospital labeling systems do not include secondary information (e.g., batch and lot information) on device labels; additional investment might be required to do so.

Hospitals have reasonably thorough inventory systems for capital equipment. Hospitals routinely record receipt of capital assets and monitor their use in the hospital. The Joint Commission on Accreditation of Hospital Organizations (JCAHO) requires adequate maintenance programs, purchasing controls, etc. Thus, hospitals must create and effectively implement appropriate maintenance schedules for capital equipment. Hospitals sometimes use bar code identifiers on medical equipment to help in identifying and locating capital equipment and in performing maintenance programs. Outside vendors are also often used for equipment maintenance, and they might also employ bar code or other automatic identification systems to track equipment use and sustain their maintenance schedules.

Recalls also place some pressure upon hospitals to coordinate and centralize their inventory systems. Hospitals generally initiate recalls by reviewing purchasing and materials management records. Hospital staff must sometimes spend considerable time determining whether recalled devices have been purchased, identifying where the devices have been distributed in the hospital, and then conducting manual searches of the numerous storerooms where devices are distributed. When a widely stocked item is recalled, virtually all hospitals must manually search their numerous distinct stock and storage locations. Nevertheless, while numerous cautions and recall alerts are distributed, ERG judges (based on discussions with industry personnel) that recalls are not so constant that personnel are dedicated to tracking down errant materials.

Hospitals are likely to consider bar-code-based or other automatic identification systems for pharmaceutical dispensing before introducing such programs for medical devices. Bedside bar code checks on pharmaceutical dispensing presumably have a much larger impact on medical error reductions than such checks on medical device systems, based on the apparent evidence of the Institute of Medicine (IOM, 1999) and other studies of medication errors. FDA has encouraged such systems by requiring pharmaceutical companies to place bar codes on all packaging. But—because many drugs are not offered

in unit dose packaging, as is needed for bedside bar coding checks—hospitals still must develop in-house capability for bar coding if they wish to begin bedside bar code checks.

Nevertheless, relatively few hospitals have bedside bar code checks on pharmaceutical dispensing. In 2001 and 2004, the Institute for Safe Medication Practices (ISMP) surveyed hospitals nationally who submitted data for their ISMP Medication Safety Self Assessment (Crowley, 2005b). They found that between 2001 and 2004, hospitals that had fully implemented bedside scanning rose from 1 percent in 2001 to 6 percent in 2004. Partial implementation rose from 2 percent in 2001 to 7 percent in 2004. Also, while only 36 percent were considering implementation in 2001, 61 percent were considering implementation in 2004. Moreover, because pharmaceutical companies are not required to be in compliance with FDA's bar code rule until 2006, the use of hospital bedside bar code checks might accelerate once the bar code rule is fully implemented.

The institution of bedside bar coding capabilities for pharmaceuticals might facilitate use of medical device barcodes. Some of the bar coding equipment purchased for bedside scanning could also be used to scan medical devices, reducing the capital investment needed to make use of UDI.

Case Study: An Advanced Hospital Bar-Code-Based Inventory System—St. Alexius Medical Center

A leader in hospital use of bar coding, St. Alexius Medical Center in Bismarck, North Dakota, has been bar coding medical devices since 1986 and pharmaceuticals since 1987. Based on conversations with the hospital's director of medical device inventory (Kilzer, 2005), ERG developed this case study of bar coding at St. Alexius Medical Center.

St. Alexius Medical Center developed its own set of bar codes for products used in the facility because of the inconsistency of bar coding on incoming products. The director of medical device inventory stated that using an incoming bar code (either the GS1 or HIBCC code) would be better, permitting use of a consistent convention, but bar coding is not sufficiently widespread or consistent to permit use of incoming bar codes. The St. Alexius bar codes capture only primary information (e.g., UPC), but the hospital is working on methods to add secondary data information (e.g., serial number, lot number, batch number).

At St. Alexius Medical Center, about 10 percent of capital equipment has bar codes and 80 to 90 percent of disposal supplies have bar codes. Disposable medical supplies and medical equipment entering the medical center receive a proprietary St. Alexius bar code. A scanner is available in every examination and patient room. When an item, disposable supply, or piece of equipment is used on a patient, it is scanned to record that it has been used. The resulting records are used for billing purposes and for patient safety in the event a product recall is issued. St. Alexius estimated that this system leaves less than 3 percent of disposal materials in its inventory unaccounted for (most of which are misplaced, thrown away, or used without being scanned). Hospital personnel believe that the inventory system has saved the hospital money by keeping better track of disposal supplies and by improving the accuracy of the patient billing system.

St. Alexius has also fully embraced bar-code-based checks on pharmaceutical dispensing. Hospital nurses scan each medication before giving it to a patient; the computer system checks the medication against the patient's medicine record. If the medicine is not on the record or dispensing is contraindicated, the computer alerts the nurse and the medication issue is reviewed for resolution.

If a medical device recall alert occurs, materials management personnel check their database to determine if that device is present in the medical center. If it is, they identify where the devices are distributed in the hospital. (Because only primary information is recorded, not secondary information such as lot number or serial number data, hospital personnel do not know where specific devices are distributed.) A physical check for the lot number of the recalled device is performed in all areas where the device is stored. This is the only hands-on physical inventory check required in St. Alexius.

1.4 OTHER POSSIBLE MODELS FOR UDI

Above we discussed medical device identification systems currently in use. Some of these might well serve as the starting point for a more comprehensive and consistent method of medical device UDI. In this section, we examine the National Drug Code (NDC) as a possible model for medical device UDI. The NDC has been successfully used to standardize product numbering on pharmaceutical labeling.

Created in the 1970s by FDA to streamline out-of-hospital drug reimbursement for Medicare, the NDC number is widely used by industry. The NDC number includes three components identifying the labeler, the product and the package. FDA assigns the first 4 or 5 digits and companies determine the remaining digits. Companies required to register and list with FDA must list the complete NDC number with FDA. Each year FDA publishes a directory of NDC codes free of charge on its website. It currently contains all listed prescription drugs.

A consortium of private companies sells subscriptions to the NDC data linked to other content, including pricing information. The companies also edit the NDC data, addressing errors, to make it more usable by companies. The pricing information makes the data particularly crucial to retail outlets; virtually all have a subscription and frequently upload the latest NDC updates into their computer networks. Manufacturers are also inextricably tied to the NDC consortium companies because of the effectiveness and efficiency with which they can distribute the NDC and link pricing information for their new products.

In February 2004, the FDA required that certain human drug and biological product labels contain a linear bar code to encode the NDC number. At a minimum, the 10-digit NDC number is required (in addition to human-readable format), but encoding of lot number and expiration date information is voluntary. The implementation date for this rule is April 26, 2006. At this time, firms cannot encode the NDC number using another automatic identification technology, such as a radio frequency identification chip or a two-dimensional symbology in place of a linear bar code.

The NDC is intended to be a unique universal identifier of human drugs. One of the challenges of the bar code rule is to ensure that the NDC is indeed unique. Pharmaceutical industry personnel have sometimes cautioned that the NDC system is not perfect and some confusion or discrepancies can occur. For example, in the NDC system, numbers can be used again 5 years after their associated products have been retired. Manufacturers have sometimes reused numbers too quickly, creating confusion among NDC users (Morgan, 2003). Such discrepancies and confusion appear to exist at the very periphery of the system and do not create significant or disruptive problems.

SECTION TWO

POTENTIAL BENEFITS OF UDI AND INTERESTS OF STAKEHOLDER GROUPS

Medical device UDI has the potential to yield several benefits, including reducing medical errors, facilitating recalls, identifying incompatibility with devices or potential allergic reactions, improving inventory control, improving reimbursement, and reducing product counterfeiting. These potential benefits are described in greater detail in Section 2.1 below. In Section 2.2, we take a closer look at the interests of various stakeholder groups in the development and implementation of medical device UDI.

2.1 POTENTIAL BENEFITS OF UDI

2.1.1 Benefits to Patients

Reduction of Medical Errors

One objective of UDI is to reduce medical errors similar to those targeted in bar coding of pharmaceuticals. While there has been considerable discussion in the literature about pharmaceutical medication errors in hospitals, much less is known about the contribution of medical devices to hospital or clinical errors in treatment. Furthermore, the focus of serious mistakes is typically on medical errors by physicians, such as a sponge left inside a patient after surgery or an inappropriate amputation. Much less attention is devoted to detecting nurse, technician, and other product user errors. Although the benefits to patients will depend on the extent that potential medical device errors can be reduced, UDI is essential for efficient patient safety monitoring.

In 2004, FDA received approximately 47,000 manufacturer reports and over 3,000 user facility reports of adverse medical device events (Field and Tilson, 2005). In studies of adverse medical device events, however, researchers have done relatively little to develop taxonomies of the nature of the device difficulties. In most cases, the medical devices are described as having simply failed or malfunctioned in some way.

ERG examined the literature that explores the nature, range, and/or frequency of treatment problems relating to medical device use, although few studies have been performed. Among the most relevant was a study by Samore et al. (2004) that examined whether computer-based surveillance could improve identification of medical device–related hazards and adverse medical device events. For a sample population, the study authors compared the effectiveness of several methods of detecting the frequencies, proportions, positive predictive values, and incidence rates of device-related problems. They examined computer-based flagging systems, telemetry problem checklists, specialized use of *International Classification of Diseases (Ninth Revision)* discharge codes, clinical engineering work logs, and patient survey data. They concluded that adverse medical device events were an important patient safety issue and several detection methods had low efficiency in detecting them, and therefore that further study on optimal detecting methods (e.g., bar coding and radio frequency identification devices) was necessary.

Improvements in Medical Device Reporting

FDA's Medical Device Reporting (MDR) system provides information about patient injuries and deaths resulting from medical devices. Most of these reports are from manufacturers. In considering the

MDR system, ERG noted that while the MDR does not directly benefit patient safety, it is the tool used by FDA for pre-market assessment and post-market surveillance (e.g., recalls) of medical devices. Currently, however, FDA has difficulty using the information provided by manufacturers because information such as lot numbers and even model numbers are not provided. UDI would help manufacturers provide this data in their reports, thus allowing FDA to identify any dangerous devices and device interactions, as well as any situations in which these devices should not be used.

Furthermore, UDI may also improve reporting and understanding of user errors. A recent Harvard study of drug administration errors by nurses in their cardio-thoracic-surgery intensive care unit found that nurses routinely bypassed danger alerts and drug libraries as much as 25 percent of the time, sometimes administering medications such as propofol, insulin and heparin at rates 10 times as high as those ordered. As much as 8 percent of the time nurses gave medications without having a documented order. These errors were discovered only because the hospital installed "smart intravenous pumps" to record dosing information (Wright and Katz, 2005). It's conceivable that if nurses are making errors with simple procedures such as the administration of medication, that these errors are also occurring with the use of devices, especially those that are difficult to use. UDI could improve the information provided regarding such user errors with respect to devices, providing the necessary data to identify and find solutions to such problems.

A 2005 IOM report on safe medical devices for children underscores that problem detection and analyses are limited because of problems with underreporting and incomplete or inaccurate reporting and recommended, in part, that FDA collaborate with industry, health care professionals and organizations to focus more attention on adverse device events; promote linkages between adverse event reporting systems, FDA databases and other safety programs; and update product labeling, patient information and other communications to promptly reflect safety-related findings from analyses of adverse event reports (Field and Tilson, 2005).

Facilitation of Recalls

UDI will help facilitate recalls if sufficient data can be entered and tracked through the hospital inventory. Hospital recall/tracking-related operations will improve to the extent that UDI is entered and used. For example, to the extent hospitals can upgrade their tracking capabilities, UDI should help identify individuals who have received or used devices that have been recalled and must be removed from inventories or other circulation. At present, hospitals generally must search their inventories manually. Unique identification, especially if automated, will help make recalls faster and more complete.

Identification of Compatibility Issues

If detailed medical device information is maintained in electronic health records, UDI holds the potential to facilitate the identification of device compatibility problems. For example, some implantable materials have turned out to be incompatible with magnetic resonance imaging (MRI) devices, resulting in injuries and deaths (see, for example, FDA, 1997). UDI systems might help reduce such episodes by facilitating communication of more information about implants and implant accessories and by helping to get the additional information into patients' medical records. Scenarios such as this are discussed further in Section 4.

Identification of Potential Allergic Reactions

UDI might also improve methods of ensuring that patients with allergies are not treated with or touched by medical devices to which they are allergic. As in the case of the MRI compatibility issue, UDI might help facilitate the placement of relevant information into the patient health records.

Reduction of Product Counterfeiting

Counterfeiting of medical devices is a growing concern that might also be addressed by enhancement of medical device identification. UDI systems, such as bar codes (especially more complex bar codes), might allow better checking on device pedigree by purchasers.

Enhancement in Capabilities for Post-Market Surveillance

At present, healthcare providers often do not have access to objective studies of the relative effectiveness of even fairly significant medical devices. UDI could make it possible to study the performance of alternative device designs; for example, medical researchers could conduct post-operation evaluations of implants if information on implant models was routinely kept in medical records. Hospitals and insurers and others with an interest in medical device research could also undertake a much wider spectrum of retrospective studies of the effectiveness of care.

2.1.2 Benefits to Hospitals

Some of the benefits from UDI that accrue to patients would also benefit hospitals, such as more effective recalls and improved patient safety. Hospitals also benefit in other important ways, as noted below.

More Efficient Purchasing

Industry commentators have noted the difficulty of ordering medical devices because of the lack of standardization for packaging and labeling. Thus, catalogue purchasing can be subject to some uncertainty as to the quantities to be found in package or other product characteristics (Hagemeier, 2005). UDI could reduce this uncertainty. Indeed, as noted in Section 1.3.1, DOD devised the UPN as an effective means of addressing this problem.

Improved Inventory Control

UDI holds considerable promise to reduce inventory management costs for hospitals and other healthcare entities. The 1996 Efficient Healthcare Consumer Response study documented that more than $11 billion in healthcare supply chain costs are avoidable process costs, and that a major contributor to such inefficiency was the absence of bar coding (Pleasant, 2003).

According to Frank Kilzer, director of materials at St. Alexius Medical Center, the hospital's central supply and purchasing department has used bar code technology to reduce lost charges and improve documentation to the point that inventory losses are less than 1 percent, compared with a national average of 15 to 20 percent. Mr. Kilzer also indicates that improved inventory control has paid the cost of the bar code system at his facility (Kilzer, 2005).

Enhanced Medical Device Asset Utilization

A unique medical device identifier might also enhance the utilization of devices. ECRI staff described to FDA the example of a reprocessed device that had a limited life. For example, a reusable laparoscopic electrode is expensive, but has a limited life, though it can be reprocessed. Hospitals try to get the "most" use out of these electrodes before they throw them out. The manufacturer does not present unique device markings and hospitals generally do not track them through reprocessing steps. Hospitals are aware that laparoscopic electrodes can be reprocessed a finite number of times, but they cannot track

the number of times that individual devices have been reprocessed. To reduce unsafe over-reprocessing, hospitals use a calendar life of 12 months, then discard the devices. This only approximates the number of times the device can be reprocessed, however, so some devices are probably discarded prematurely (Crowley, 2005a).

Also, healthcare personnel spend considerable time locating medical devices they wish to use. Many medical devices in hospitals are mounted on wheels for transport to the patient or different departments. Unique medical device identifiers, such as RFID devices, could allow staff to locate equipment assets more quickly, producing an important productivity benefit.

UDI will also facilitate the evolution toward interoperability among medical devices. In some hospital operations, particularly in medical/surgical operations where many devices are employed simultaneously on patients, interoperability can allow for more effective coordination of care. Ideally, medical devices would have standardized communication protocols to allow device operations to be coordinated and for better capture in health records of the monitoring data generated. UDI is one of the precursors of the development of interoperability because it will be necessary to uniquely identify the machines generating and communicating data.

Improvements in these areas would generate productivity and/or cost savings for hospitals that might offset some or all of the expenses of enhanced auto-identification systems for device location and identification. While we lack quantitative estimates, the expense of the medical device assets in question suggests the potential for substantial savings.

2.1.3 Benefits to Insurers

Efficient Reimbursement

Currently, Medicare and Medicaid reimbursement is based on broad billing codes that might not differentiate between inexpensive and expensive medical devices. As a result, Medicare and Medicaid programs might be paying too little or too much for some treatments. UDI provides an opportunity to improve this system by uniquely identifying each product. In addition, UDI will help the Centers for Medicare and Medicaid Services (CMS) to combat other incidences of fraud and abuse. Other insurers may also be able to take advantage of UDI in a similar manner.

2.2 INTERESTS OF STAKEHOLDERS

Several groups hold an interest in the possible development and implementation of UDI for medical devices, including:

- Manufacturers
- Distributors
- Group purchasing organizations
- Hospitals
- Industry consortia
- Food and Drug Administration
- The Agency for Health Research and Quality
- Office of the National Coordinator for Health Information Technology
- Centers for Medicare and Medicaid Services

- Department of Defense
- Veterans Health Administration
- Private initiatives for PDU-type Systems

In this section, we describe the nature of their interest, their stance toward UDI, potential benefits and challenges, and any efforts they have made toward developing UDI.

2.2.1 Manufacturers

The two medical device manufacturing trade associations, AdvaMed and the Medical Device Manufacturers Association, are supportive of efforts to help standardize medical device nomenclature and development of automatic identification systems. Nevertheless, they have stated opposition to any regulatory effort that would mandate bar codes or other automatic identification systems because of the enormous diversity of medical devices and associated safety needs.

Within the medical device industry, manufacturers maintain varied stances relative to bar codes or other automatic identification technologies. One consideration is probably the market-driven demand for bar coded products and the value to the manufacturer and customer of bar coded identification systems. Several companies, such as Becton Dickinson, have advocated wider bar coding and have adopted the UPN as their product identifier. These firms are among those who have participated in and contributed to various industry consortia working on UDI issues. As indicated in the AdvaMed survey, small companies are the least involved in bar coding.

The greatest benefit to manufacturers from UDI is the gain in supply chain efficiencies. UDI, combined with auto-identification technology, can result in more accurate and faster product delivery and improved quality control. Manufacturers will also be able to conduct recalls more efficiently and completely.

Manufacturer associations have argued that medical devices are so diverse that the applicability or usefulness of automatic identification systems has not been established for the entire spectrum. For example, in Advamed's comments submitted for FDA's public hearing on the bar code rule, the industry representatives noted that FDA has already required traceability requirements for those devices most applicable to patient safety (see Section 1.2), and equivalent safety concerns were not established for other devices. They also note that manufacturers and customers are evolving toward enhanced device identification system at the pace warranted by the customers' needs (Advamed, 2002).

Advamed also noted potential technical difficulties, such as:

- Some packaging material might inhibit the use of printable codes
- Small devices with limited packaging might need to rely on two-dimensional symbols or RF technology instead of linear bar codes, or larger, costlier packages
- Most device companies are small firms for whom auto-identification reflects significant investments
- UPN or other identifications at some units-of-use (e.g., throat swabs) appears inappropriate.
- UPN might be used at different packaging levels, but might not be available at the time of use, particularly for multiple use devices sterilized in the hospital (Advamed, 2002).

Manufacturers might also face some concerns about advancements in device identification should that generate greater "commoditization" of medical devices. At present, both professional and non-

professional medical device users can find it difficult to compare medical devices and to judge their relative cost-effectiveness. It remains somewhat problematic to compare devices because of the lack of standardization in the way device packages are described (HCEC, 2005). Also, most medical devices are also not subject to post-market evaluations of their effectiveness or of their effectiveness relative to other devices. Price comparisons are often difficult to make among devices (Abelson, 2005). In this environment, UDI has the potential to allow users and consumers greater capability to pursue various evaluations of devices.

2.2.2 Distributors

Medical device distributors are also generally supportive of efforts to implement medical device identification. The Health Industry Distributors Association (HIDA) encourages manufacturers to bar code or auto-identify their products to help streamline distribution (HIDA, 1999). HIDA recommends that manufacturers place bar codes or other auto-identification on their complete line of shipping cases, inner packs (intermediate packaging), and units of use (eaches). In addition, where relevant, HIDA recommends that manufacturers place secondary bar coded information (quantity, expiration date, and lot number) on packaging above the unit level. HIDA also recommends that manufacturers adopt (for internal operations and for distribution purposes) the bar code formats that make up the UPN initiative, namely the HIBC and the GS1 formats (HIDA, 1999).

Nevertheless, HIDA has also stated opposition to mandatory medical device labeling requirements (HIDA, 2005). They judge that such labeling would add to healthcare costs. A HIDA vice president for industry relations indicated that distributors play virtually no role in determining package labeling or device bar code or automatic identification approaches (Fri, 2005).

Distributors sometimes add bar codes to packaging upon customer request. Where distributors provide extra value-added services, for example, distributors sometimes supplement bar codes with special identification systems. Most notably, DOD has requested bar coding on medical device packaging, and distributors have helped industry respond to this request.

Like manufacturers, distributors could gain supply chain efficiencies from UDI combined with an auto-identification technology such as bar coding. Many steps within the distribution process could be streamlined if computer systems were integrated with auto-identification of products.

2.2.3 Group Purchasing Organizations

Large group purchasing organizations (GPOs) are among the entities most actively campaigning for enhanced medical device identification systems. In a recent letter to FDA Commissioner Lester Crawford, a group of GPOs and hospital associations cited goals of patient safety, improving quality of care, and encouraging cost effectiveness and supply chain efficiency. They also noted the potential for bar coding to improve clinical product and service innovation, as well as the opportunity to improve the effectiveness of bar codes (Reagan et al., 2005).

GPOs have supported industry coalitions that are working toward the development of consensus standards or other agreements. GPOs might be relatively well served by improvements in supply chain efficiencies resulting from bar coding of devices and improved device tracking systems. These systems might also help GPOs verify compliance with their contractual agreements with hospitals, in which hospitals agree to purchase supplies primarily from the negotiated list of manufacturers. UDI would help facilitate this process by clearly identifying products that could be purchased under the agreement.

2.2.4 Hospitals

The American Hospital Association (along with Catholic Health Association of the United States, the Federation of American Hospitals, and the National Association of Public Hospitals and Health Systems) cosigned the recent letter to FDA Commissioner Lester Crawford encouraging the administration's efforts to promulgate a regulation that would require bar codes on medical devices (Reagan et al., 2005).

As noted earlier, very few hospitals have undertaken their own independent bar code or automatic identification operations for medical devices. Bedside bar coding of pharmaceuticals is also not commonplace (Hagemeier, 2005). One recent estimate placed hospital bar coding of pharmaceuticals at 5 percent (Wright and Katz, 2005). However, it is reasonable to expect this percentage to increase, as drug manufacturers have until April 26, 2006 to comply with FDA's barcode rule.

A consistent bar coding or auto-identification system for medical devices would facilitate hospital operations, serving as a tool to reduce medical errors and facilitate device tracking in case of a recall, thereby improving patient safety. Hospitals would also benefit from an increase in supply chain efficiency and the potential for improved inventory control. Purchasing and supply could be more accurately tracked and losses due to theft would likely decrease. CMS also makes a determination of coverage of some medical devices by requiring additional evidence. Coverage with evidence development (CED) puts a great burden on hospitals. A representative for the American Hospital Association noted that this has been difficult to comply with for hospitals, and UDI has the potential to simplify this process (Worzala, 2005).

2.2.5 Industry Consortia

Industry groups supported by some of the largest device manufacturers and GPOs have recommended various steps to allow increased use and reliance upon bar codes or auto-identification systems in medical device distribution and use. In general, these consortia feel that in the current situation, medical device identification systems are so inconsistent and inadequate that they impede use of electronic data interchanges and automatic capture (such as using bar codes) of data.

Coalition for Healthcare eStandards (CHeS).

One group, the Coalition for Healthcare eStandards (CheS), describes its mission as providing leadership to the healthcare industry in the identification, definition, evaluation, adoption, and endorsement of standards that improve the accuracy and efficiency of the supply chain. The vision of CHeS is to accelerate the adoption, implementation and active usage of industry-wide data standards for improving the efficiencies throughout the healthcare supply chain. The CheS Board of Directors includes representatives of GPOs, healthcare hospital networks, healthcare management and support firms, and major federal healthcare purchasing entities, such as the DOD and the Veterans Health Administration (VHA).

Health Care Ebusiness Collaborative (HCEC)

The Health Care Ebusiness Collaborative (HCEC) is a nonprofit group interested in rectifying electronic business deficiencies in the health care industry. HCEC is developing an approach to the development of automatic device identification systems to achieve distribution efficiencies for healthcare institutions. HCEC is working with industry groups on a collaborative method to help medical device manufacturers standardize the means by which they identify their products, thereby facilitating purchasing, distribution, and tracking of devices.

According to Garren Hagemeier of HCEC, the group is working to develop systems for medical devices that are parallel to the NDC for pharmaceuticals. Currently, HCEC is developing a Master Device Index that would help device users identify the manufacturers and characteristics of devices they would like to purchase. The index would include hyperlinks and Internet URLs for device manufacturers. This would make it easier for users to locate relevant specifications and price information about medical devices (Hagemeier, 2005).

HCEC is also working to further the standardization of medical device identifiers to facilitate purchasing and distribution systems. As discussed in Section 1, devices have such varied characteristics and are labeled in such varied ways that purchasers have considerable difficulty ordering products. HCEC is endeavoring to standardize terminology, ideally along with developing an NDC-like numbering system to improve communications in the supply chain. As HCEC judges, the medical device numbering system should be able to distinguish the levels of device packaging, subcategories of devices, and varieties of a given device (Hagemeier, 2005)

Healthcare User Group (HUG)

Another recently formed group, the Healthcare User Group (HUG), is also committed to encouraging the development and utilization of the global healthcare industry, with the primary focus on automatic product identification to improve patient safety. A number of large medical device and pharmaceutical companies participate in this group, which is described as the first time the healthcare industry has combined to develop global solutions to common industry problems. The objectives of the group are to reduce medical errors and to improve product authentication, tracing and tracking, and total supply chain efficiency. The group will work on e-commerce transactions and data synchronization strategies. HUG is also affiliated with the GS1 organization, which inherits the legacy of the UCC in the United States and the EAN International in Europe. They have a working plan for the coming 12 months that includes evaluating and further developing current standards and will provide future guidance on healthcare standards based on their findings.

GHX

To date, the private sector has not developed an accurate and standardized industry-wide repository of manufacturer-provided product data. Nonetheless, organizations, including a variety of consulting and medical services firms, are working to facilitate efficient electronic transactions and data accuracy among healthcare providers. For example, McKesson provides supply chain management consulting products and services to the industry to enable effective management of contract-supply relationships. Some firms also offer consulting services that "clean" device purchasing databases with up-to-date and accurate medical device identification information. These steps help hospitals to reduce their error rates (and reduce costs) in medical device purchasing. Some of these organizations are also partnering with CheS and HIBCC and other groups to support industry adoption of UPNs.

One example of a data exchange organization is GHX, a privately held company providing e-commerce, supply chain automation and buyer-seller data synchronization services to the healthcare sector. Founded in 2000 by major healthcare manufacturers, it is now owned by a group of healthcare device manufacturers, distributors, GPOs, and healthcare provider organizations—companies that represent the entire supply chain (GHX, 2002). Exchange membership is open to all participants in the healthcare supply chain. GHX has compiled the product data necessary to facilitate electronic healthcare transactions. To achieve its goal of improved e-commerce, GHX is working with the healthcare supply chain to build and maintain an accurate repository, called AllSource®, with up-to-date information on manufacturer and distributor offerings. Currently the repository contains information on more than 1.4 million SKUs, covering about 80 percent of medical devices (Wylie, 2005).

As an affiliate member of industry consortia such as CHeS, GHX participates in industry efforts associated with UDI. Moreover, as noted in Section 1, GHX members recently launched a collaborative initiative to expand the use of UPNs. Use of a unique UPN could improve data synchronization between buyers and sellers. Once UPNs are published, members of the medical devices supply chain could synchronize their product data and would be able to transact on the basis of UPNs (GHX, 2004). AllSource® supports both UPN formats (HIBCC and GS1) and all product data in AllSource® are owned, reviewed, and maintained by manufacturers.

2.2.6 Food and Drug Administration

FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. Public health and patient safety are high priorities. To reduce risks associated with FDA-regulated products, FDA patient safety initiatives include seeking continuous improvements in safety reporting systems, in the quality and standardization of the adverse event reports, and communicating information about product risks and benefits.

Among federal agencies, FDA has the most direct interest in medical device labeling because of its potential relevance to its core mission. Enhanced medical device identification systems could potentially further FDA's mission in several ways. First, FDA has learned of recalls in which hospitals had difficulties locating the affected devices or preventing further use on patients, which poses a potential risk to the safety of patients. Automatic medical device identification systems and/or unique identifiers could facilitate hospital tracking of devices in their facility. Improvements in device tracking, however, depend on improvements in device identification systems.

FDA's MDR system also would be enhanced by more consistent and complete information about devices that malfunction or fail. FDA personnel noted that MDR reports often provide limited information about the specific make or model of a device that fails. Many devices are separated from their packaging at the time of their use, so determining even basic model or make information can be problematic. Potentially useful secondary information, such as the lot number, is often not provided. For MDR, better labeling or automatic labeling systems on the device itself might be necessary to allow substantially better reporting of device characteristics. Further, some problems are not identified by FDA or clinicians due to a lack of information. UDI might help better identify the following problems as well:

- Human factors issues
- Device-device interactions
- Manufacturer- or lot-specific problems
- Problems that affect a device type (multiple models and manufacturers)
- Problems due to changes in design, materials, processing
- Problems due to accessory-device interactions

2.2.7 The Agency for Health Research and Quality

The Agency for Health Research and Quality (AHRQ) pursues and facilitates research on healthcare. Within this charge, AHRQ describes reduction of medical errors as a principal area of research. For example, AHRQ has established the Centers for Education and Research on Therapeutics, which is endeavoring to "reduce adverse drug events by conducting state-of-the-art clinical and laboratory

research to increase awareness of both the uses and risks of new drugs and drug combinations, biological products, and devices as well as of mechanisms to improve their safe and effective use" (AHRQ, 1999).

In one of its grant programs, AHRQ is looking fairly broadly at medical error reduction and quality improvement. The agency seeks applications that will demonstrate and evaluate:

- A variety of methods of identifying errors or opportunities for improving safety and reporting them to a database that promotes analysis, understanding, and action to reduce the risk of harm to patients.
- Different concepts of the information needed to reduce risks to patients.
- Effective methods of disseminating information to those who need the information to improve safety through choice of, oversight of, or changes to the delivery system.
- New methods of changing the delivery system in ways that can reduce hazards, including innovations in informatics and education.

In this and other efforts, medical device improvement is useful, but only one of many advancements being sought. ERG confirmed in interviews with AHRQ staff that the agency is principally interested in medical device safety as it pertains to the overall healthcare system. AHRQ has not attempted to take a leading role in examining the benefits of enhanced medical device identification systems or of systems such as bar code advancements. While AHRQ supports any quality-enhancing innovations, one respondent noted that it was unlikely to become a repository for medical device information (Munier, 2005).

2.2.8 Office of the National Coordinator for Health Information Technology

The Office of the National Coordinator for Health Information Technology (ONCHIT) carries out Executive Order #13335 and pursues the implementation over the next 10 years of widely interoperable electronic health records (EHRs) (HHS, 2005). More specifically, ONCHIT will develop and maintain the strategic plan for nationwide implementation of interoperable EHRs. This implementation will encompass the following objectives (HHS, 2004):

- Inform clinical practice with electronic health records.
- Interconnect clinicians so they can share health information.
- Personalize care with consumer-based health records and better information for consumers.
- Improve population health through enhanced biosurveillance and streamlined collection of data for quality measurements and research.

ONCHIT will be addressing a range of issues related to advanced electronic development and portability of patient health records, as well as development of the hospital and clinical environment to provide quality care. In this setting, automatic medical device identification will play some role, but appears to be a second-tier issue. The advancement of the electronic health record is the primary concern and will involve a number of hospital systems. Thus, ONCHIT is primarily focused on monitoring and encouraging the development of electronic standards to facilitate electronic sharing of health information.

The connection of these activities to medical device identification systems does not appear sufficiently robust at this point for ONCHIT to focus resources on this area. However, given that one of the benefits of EHRs will include information about medical product use (e.g., medications, devices, blood), UDI could help facilitate this aspect of EHR and might become of greater interest to ONCHIT as EHRs advance.

2.2.9 Centers for Medicare and Medicaid Services

CMS is monitoring developments in UDI and will potentially stand to benefit from such enhancements. As the largest purchaser of medical services, CMS will benefit from improvements in medical system effectiveness and efficiency. UDI may also be of interest to CMS for the purposes of determining the cost-effectiveness of certain medical devices.

A federal CMS representative indicated that the agency is interested in capturing enhanced information on medical devices, but preferably through changes in claims forms that would add fields to collect that data. Changing claims forms is an extremely arduous process; the last CMS effort along that line was not been well received (Phurrough, 2005).

It appears possible that in the long run better medical device identification would improve reimbursement accuracy in the Medicare and Medicaid programs. For example, the consumption of devices during medical procedures is not always reported or reported with sufficient detail or accuracy in medical records to allow precise billing. In these programs, however, reimbursement is established by diagnosis-related groups, which consider average rates of medical device consumption as well as other use of medical resources. Nevertheless, in response to a question about the accuracy of medical device data capture for the CMS program, a CMS representative stated that improving medical device identification was primarily an issue of quality in healthcare provision (Phurrough, 2005). Presumably better device identification systems would allow better device comparisons, and this would allow better reimbursement practices. In addition to improving the capture of medical device use by adding fields on CMS claim forms, CMS might also be interested in studies of cost-effectiveness of certain devices using UDI.

At the state level, California's Medicaid program (Medi-Cal) is currently in the exploratory stages of adopting the UPN to track medical supplies (Medi-Cal, 2004; Riviera, 2005). They have already received approval from the federal CMS and now will be embarking on a pilot project.

2.2.10 Department of Defense

DOD's Defense Personnel Support Center (DPSC), located in Philadelphia, Pennsylvania, has been working for years to make their huge purchasing operation more efficient. Classic materials resource planning and distribution resource planning software requires businesses to assign internal identifiers or "item numbers" for every product in their inventory. Using latex gloves as an example, with 50 distributors each assigning their own item number to each box of latex gloves, and 50 Medical Treatment Facilities (MTFs) receiving the product and each assigning their own item number to it, there could be 2,500 different item numbers for the same product.

With centralized purchasing and payment functions for the entire system of DOD MTFs, DPSC encountered:

- Duplicate identifiers for different items.

- Costly maintenance of cross-reference tables.
- An inability to filter all product identification errors on documents transmitted by the MTFs, which in turn created other problems, including delayed payments to vendors.

DOD decided to follow health industry and commercial industry business practices. They now require that all packages bear an industry standard bar code, down to and including the single unit package (unit of use, unit dose), although compliance is not perfect. This bar code becomes the single identifier for the item throughout the system of DOD MTFs and DPSC. DoD refuses to purchase items not in compliance with this requirement, and has revoked approval of vendors of those items.

DOD is also developing a system for applying a unique identification number and a bar code to purchases, including medical device assets, that are over $5,000 in value, or when the item is serially managed, mission essential or a controlled inventory piece of equipment (DOD, 2005). For each item, the database includes information on the unique Equipment Control Number, serial number, lot number, model number, and maintenance records. The database includes information about disposable medical supplies, but no unique number is given at the unit-of-use level. If a carton of syringes is in the database, for example, only its stock number and quantity are listed. Eventually an all-DOD inventory system will be organized (Rubio, 2005).

The Navy's Medical Logistics Command has developed a program that utilizes very small 2-D matrix barcodes called microdots on all individual items used in their hospitals. The Navy has to be able to quickly deploy modular field hospitals in the event of a contingency, national emergency, or war operations. This program allows the navy to efficiently manage the stocking of such hospitals, generating immense savings. It has cut down on the need for packaging and generated numerous other benefits, including the ability to scan surgical instruments before and after surgery to ensure that hospital staff can account for all devices. Currently, the microdots are based on unique item identifiers generated by DOD. However, if the UPN was widely adopted as an industry standard, this division might choose to use it to access data through UPN-based databases (Lippert, 2005).

2.2.11 Veterans Health Administration

The VHA was an innovator in the use of bar codes for medication application, and ERG investigated their current practices and levels of interest in medical device identification.

VHA has instituted a National Item File (NIF) that essentially represents an internal UDI system for medical device and other purchases. VHA began work on the system in 2001 and was encouraged to do so by development of an internal Core Financial and Logistical System (FLS). With the FLS, VHA was able to maintain consistent purchasing records across divisions and locations, but lacked consistent means of identifying medical devices. They therefore undertook an effort to standardize identifying data throughout their administrative systems. The internal customers for this development were acquisition offices, material managers, healthcare providers, and maintenance and planning support functions (Hinson, undated).

The goals of the NIF are to allow standardization of existing item files across the VA, provide a clean and complete NIF for the FLS, and identify product availability across the U.S. NIF has a three-tiered structure:

Level 1: Item-Oriented, with information for end-user perspectives

Level 2: Manufacturer-Oriented, with information for industry perspectives

Level 3: Distributor–Oriented, with information for purchasing perspectives

NIF includes many data elements (see Table 2-1). At Level 1, the VHA establishes the functional equivalence of devices based on a comparison of the National Stock Number, a comparison of known attributes, or a determination by the Standardization User Groups of VHA's Clinical Logistics Office. Data files were received from the FLS sites and then compared and cleansed to derive a consistent data file. At Level 2, the VHA links the device information with the sources of that information, namely the manufacturer data. Level 3 provide links to distributor data and other information that relates to the purchasing function.

The VA acted because of the lack of a reliable repository for manufacturer-provided device information. According to a VA executive, it appeared unlikely that a private sector effort would provide the necessary repository or a consistent number for each device that can be referenced for purchasing and logistics purposes. VA expected that a database of accurate device information would be quite valuable and formally calculated the return on investment (ROI) for its NIF project. VA forecast total spending in its first decade (including design and implementation costs and use through the year 2011) to be $22 million. The VA considered only the value of avoided errors, a very conservative interpretation of the possible benefits. VA estimated that without the NIF 12 percent of device purchases cannot be completed because one or more data items supporting each device purchase is incorrect and must then be resolved (Hinson, 2005). Resolving each error is estimated to cost from $15 to $50 in labor, as VA staff must usually contact device manufacturers or distributors to obtain the correct information. VA used only the low end of this range ($15) in its calculations. With these inputs, VA calculated the ROI at 26 percent.

Table 2-1
Level 1, 2, and 3 Data Elements in VHA's National Item File

NIF number	UN Standard Product and Service Code	Reusable indicator code	Lot number
Date effective	National Drug Code number	Latex containing indicator code	MSDS required indicator code
Mandatory source	VA Category Stock Number	Special handling code	Green ID (for recyclables) indicator code
VHA Healthcare Common Procedure Code (HCPC)	Universal Medical Device Nomenclature System Code	Patient tracking indicator code	Energy Star indicator code
Ambulatory Procedure Code	Warranty period	Serial number tracking indicator code	Expiration date
Inactivated indicator code	Life expectancy of device	Sterility requirements indicator code	Federal supply classification number
Replacement item indicator code			
Manufacturer name	National Stock Number	Shipping UPN barcode label (flag to indicate if packaging is bar coded) (Y/N)	Low CF
Manufacturer parent	North American Industry Classification System number	Intermediate UOM	Low UPN
Manufacturer part number	UPN	Intermediate CF	Low UPN replaced
Brief item description	Shipping Unit of Measure (UOM)	Intermediate UPN	Low UPN barcode labeled
Extended description	Shipping Conversion Factor (CF)	Intermediate UPN replaced	Shipping UPN Replaced (the UPN assigned to Outer Pack UOM previous to current shipping UPN)
Trade name	Shipping UPN for (Pack Unit of Measure for item number)	Intermediate UPN barcode labeled (Barcode flag; Y/N)	Low UOM
Standard Industrial Classification			
Item detail number	Distributor reorder number (i.e., vendor/distributor stock number)	Unit price (cost at UOM)	Contract number (national contract number, such as Federal Supply Schedule, prime vendor contract, other)
Distributor name			

Source: Hinson, undated.

SECTION THREE

MEDICAL DEVICE MANAGEMENT SCENARIOS

FDA has identified several scenarios that illustrate issues potentially associated with insufficient identification or tracking of medical devices. These scenarios are outlined in Table 3-1 and discussed further in Section 3.1 below. The presentation summarizes each problem, how it is addressed currently, and potential means of rectifying the problem. When considering these scenarios, common themes emerge regarding how improved identification information would facilitate the work of healthcare institutions. These common themes are explored in Section 3.2.

3.1 SCENARIOS

One of the primary areas where device identification can contribute is in recalls. Some medical device recalls are initiated nearly every month. Although FDA has mandatory recall authority, it has rarely been used because it is in the best interests of manufacturers and distributors to conduct recalls voluntarily. The effectiveness of a recall is largely dependent on the manufacturer's effort, whether healthcare professionals and consumers track recalls effectively, and the help of the media in disseminating recall information. UDI will have the most impact on the second factor—the ability of healthcare professionals to track recalled product.

Recalls are the subject of the first four medical device management scenarios. Following these are six more scenarios addressing other issues relevant to patient safety.

3.1.1 Scenario 1—Recall of Disposable Devices

For disposable devices, information provided during a recall usually includes the name and lot number of the affected product, the name of the recalling manufacturer, the reason for withdrawal, and the volume and geographic distribution of the product. Expiration dates are also provided in some cases. For example, on May 6, 2005, one lot of a disposable infusion set (the LifeShield Latex-Free HEMA Blood PlumSet) was recalled. Only this lot was recalled because the inlet and outlet tubing on the cassette may have been reversed, which would have drawn the blood out of the patient instead of infusing it in.

Hospitals currently do not track the lot number of medical devices, so hospital personnel must conduct manual searches to find the recalled product in the hospital. If the product is separated from the packaging, it might never be located. With manual searching, delays and failures to locate recalled products can occur, potentially affecting patient safety. Electronically readable labeling that includes primary and secondary (i.e., including lot numbers) information on packaging could address this problem.

3.1.2 Scenario 2—Recall of Capital Equipment

Another type of medical device recall involves capital equipment needing to be repaired or removed from service. For example, a recent recall was initiated when it was learned that the power supplies in some Tyco/Nellcor Puritan Bennett 840 ventilator systems could become loose and shut the ventilators down. The information provided in a capital equipment recall usually consists of a model and serial number.

Table 3-1
Summary of Device Identification Scenarios

Scenario 1. Recall of disposable devices	▪ Cannot locate recalled items ▪ Not aware of recall	▪ Manual search	▪ Electronically readable labeling ▪ Model and lot numbers ▪ Equipment that can use this information
Scenario 2. Recall of capital equipment	▪ Cannot locate recalled items ▪ Not aware of recall	▪ Reading serial number manually	▪ Mostly addressed already ▪ Improved handling of recall alerts ▪ Improved asset tracking
Scenario 3. Recall of implanted devices	▪ Cannot locate recalled items ▪ Not aware of recall ▪ Non-powered implants not tracked ▪ Accessories not tracked	▪ Serial number of powered device is written in health records	▪ Electronic capture of primary and secondary device information in the patient health record ▪ Information about device accessories
Scenario 4. Recall of reprocessed devices	▪ Recall notifications do not reach appropriate personnel ▪ Lack information about which patients were treated with devices	▪ None	▪ Electronic capture of device serial numbers for patient records
Scenario 5. MRI-incompatible devices	▪ Implanted materials that are non-compatible with MRIs	▪ Record in medical records ▪ Patient interview	▪ Electronic capture of device serial numbers for patient records ▪ Incompatibility check when product is scanned
Scenario 6. Tracking and documenting device use	▪ Insufficient data available, especially regarding recalled devices	▪ Primary device information is recorded only for some implanted devices ▪ Secondary information on devices is not generally recorded	▪ Electronic capture of primary and secondary device information in electronic patient health record
Scenario 7. Allergic reactions to devices	▪ Patient exposures to allergens	▪ Patient records indicate known allergies ▪ Devices with allergens are labeled	▪ Extension of e-prescribing and electronic health record systems for automatic notification
Scenario 8. Identification/ reduction of product counterfeiting	▪ Hospitals or distributors cannot identify counterfeit product	▪ None	▪ Security or encryption features as part of electronically readable labeling
Scenario 9. Medical errors in surgery	▪ Devices left in patients ▪ Errors involving use of devices ▪ Implanting of incorrect devices	▪ Manual checks ▪ Some use of bar coding software	▪ Electronically readable labeling
Scenario 10. Identifying medical devices associated with an adverse event	▪ MDR reports lack identifying details, such as model or lot numbers	▪ Follow up with reporter of adverse event	▪ Electronic capture of primary and secondary device information in the patient health record

Most hospitals should be able to identify capital equipment by serial number, as they monitor these assets in regular maintenance programs (per JCAHO requirements). Some hospitals already use bar codes to keep track of preventive maintenance programs. However, hospitals might not learn of recalls and in some cases might still not have adequate tracking in place. These issues will need to be resolved with improved recall alerts and tracking.

3.1.3 Scenario 3—Recall of Implanted Devices

Recalls of powered implanted devices, such as pacemakers, are often accomplished by model and serial number. The serial number is usually recorded in a patient's medical record. However, this information might not be recorded for non-powered implanted devices or for accessories to implantable devices.

Currently, healthcare staff must conduct manual searches to identify and locate these products. These manual searches can result in delays in the removal of potentially hazardous devices implanted in patients and from the market, which clearly poses risk to public health. Given the lack of data in patient records on non-powered implanted devices and accessories to powered implants, these products might never be located when recalled. Electronically readable labeling that includes primary and secondary (i.e., including lot numbers) information on packaging would help in locating these devices. This will require a more sophisticated RFID technology, as the devices' serial numbers will need to be read while they are implanted. As noted earlier, hospitals will need inventory systems that electronically read automatic identifiers with primary and secondary information.

3.1.4 Scenario 4—Recall of Reprocessed Devices

Reprocessed devices are devices that may be reused after sterilization. This presents special problems when use of a reprocessed device in patients needs to be traced. For example, in 2001 Olympus America, Inc. bronchoscopes were recalled due to biopsy parts that could loosen. Hospitals did not have enough detail on who had been treated with these devices and had a difficult time completing the recall.

Patient and hospital records do not generally record use of reprocessed devices. When a recall alert for a reprocessed device is received (assuming that specific lots are being recalled), hospital material managers might access data on lot numbers from the purchasing system computer or purchasing files. Very few, if any, hospitals have an inventory system that will inform them of the disposition of the specific lots being recalled. Thus, hospital personnel must manually check the departments where the recalled devices were distributed and seek the boxes or cartons being recalled. If the devices have been consumed (and disposed of), there will typically not be a record of where or how they were used. This presents a major problem, which electronic capture of relevant information (such as lot and/or serial number) in patient records should alleviate.

3.1.5 Scenario 5—MRI-Incompatible Devices

Radiologists and other relevant personnel need to know whether implanted devices are MRI-compatible. FDA has received reports that patients with implanted devices have suffered serious injury during MRI procedures. Passive components can remain even after devices are removed and can also have adverse effects during an MRI procedure. Devices' MRI compatibility might not be known.

Currently, information about device-MRI incompatibility can be recorded in medical records, but might not be complete. As a result, patients need to be questioned about implants, including removal. Electronic medical records could help automate this process if the presence and characteristics of implanted materials are adequately reported. Physician and MRI technician training must emphasize the need for adequate checks in patient records for non-compatible materials; ideally these checks should be achieved automatically when products are scanned.

3.1.6 Scenario 6—Tracking and Documenting Device Use

Tracking and documenting device use helps in adverse event reporting and analysis. It can also help patients and their doctors know which devices have been used, prescribed, or implanted. For example, when a 16-year old with cystic fibrosis arrived in the emergency room complaining of sharp chest pain, neither the child nor the parents thought to let medical staff know about an implanted catheter. The catheter had fractured and was eventually seen on x-ray (Field and Tilson, 2005). Documentation of the implanted device in the child's medical record using UDI would have resulted in a faster identification of the problem causing the chest pain.

Tracking and documenting device use might also aid in disseminating FDA and manufacturer advisories regarding devices, which could be electronically communicated whenever a device is used. Currently, inadequate systems exist for monitoring medical device recalls and advisories; in some cases, hospitals do not receive information due to misrouting or similar mishaps (Field and Tilson, 2005).

Currently, tracking and documentation of device use is not generally available in electronic form. Primary information is recorded for many (but not all) devices used, and secondary information is generally not recorded in patient records. Electronic capture of this information would allow every device to be tracked to its user, as well as improving the level of detail provided in adverse event reporting.

3.1.7 Scenario 7—Allergic Reactions to Devices

Patients can have allergic reactions to devices, such as those that contain latex, titanium or its alloys, or bovine collagens. In addition, past diseases or treatments can contraindicate use of certain devices. Currently, medical personnel have to rely on patient records for allergy information, and they have to remember to check the record and the product for any information on known allergies. Providing these data electronically will help streamline this process: personnel would be able to view past reactions, and allergy information would be provided automatically when patients' records are pulled up. Similarly, scanning the device's bar code or other auto-identification could bring up a reminder to check a patient's records for allergies if the device contains allergens. Automated warnings regarding a possible allergic reaction between a device and a sensitive patient might also be a possibility.

3.1.8 Scenario 8—Identification/Reduction of Product Counterfeiting

Counterfeit product can be very difficult to distinguish from authentic product. Both components and devices have been counterfeited, and the practice appears to be growing. With a high potential profit, counterfeiting medical devices is a huge business. Unfortunately, counterfeit products can seriously compromise patient safety. A recent example is the marketing of counterfeit nonabsorbable propylene mesh used in the repair of hernias. Since sterility could not be guaranteed for this product, FDA issued an alert to healthcare professionals who might have used the product in patients (Field and Tilson, 2005).

Currently, few systems are in place to prevent counterfeiting or to identify and reduce use of counterfeited products. Electronically readable labeling might provide a way for manufacturers to improve protection against counterfeit products. Using an RFID-based solution, products can be given a unique, encrypted serial number that cannot be copied. Both the manufacturer and patient would benefit. Several countries in Southeast Asia have adopted the technology to reduce counterfeit shipments in addition to assisting with inventory control.

3.1.9 Scenario 9—Medical Errors

Medical errors in the use of medical devices are well documented. There have been cases of surgeons implanting the wrong medical devices (e.g., the wrong model of a pacemaker) in patients. Sometimes surgical instruments are inadvertently left in the patient's body. Sometimes similar-looking devices are mistaken for one another; in one example, tubes for an IV pump were confused because their end-fittings looked the same, causing a fatal air embolism in a young child (Field and Tilson, 2005).

While manual methods are in place to reduce these errors, they still occur. Some hospitals use bar coding systems that allow medical personnel to scan surgical instruments and record each time that they are used, protecting against the possibility that an instrument will be left behind in a patient. Bar code or RFID labeling of devices might also provide an automated check that the correct device is being implanted.

3.1.10 Scenario 10—Identifying Medical Devices Associated with an Adverse Event

When an adverse event with a medical device occurs, manufacturers and hospitals are required to report some (but not all) of these events to FDA. For adverse event reports to be most effective, data such as serial and lot number should be provided. Healthcare facilities generally do not keep detailed data (e.g., expiration date, lot number, model number, attached accessories) when doing inventory control. In many cases, if healthcare personnel cannot provide lot numbers, manufacturing data cannot be obtained. For some generic products such as tubing, the information might not be available at all (Field and Tilson, 2005). For example, when an infant heel warmer caused a second-degree burn on a baby, no lot information was available and the product had been discarded (Field and Tilson, 2005). Data are also lost when packaging is removed unless the device itself carries the information. In addition, users of medical devices do not always provide information about model number, accessories, and whether the device has been reprocessed, making it difficult to use adverse event reports effectively in reducing further problems. Electronic capture of all this information would help greatly.

3.2 COMMON THEMES

Looking broadly over all the scenarios, several common themes emerge:

- UDI may resolve or substantially alleviate existing difficulties with medical device recalls (scenarios 1-4), medical errors (e.g., scenario 9), unintended device interaction problems (e.g., scenarios 5, 6, and 7), and completion of MDRs (e.g., scenarios 7 and 10). UDI might also help curb distribution of counterfeit medical devices (scenario 8).

- For these benefits to be realized, UDI would need to be implemented extensively and consistently, and would need to include both primary and secondary information about medical devices.

- For UDI to be implemented extensively and consistently, hospitals would need to invest in systems to capture primary and secondary information, as well as systems to place and check this information in patient health records.

It should be noted that while UDI might resolve some of the difficulties addressed above, no data is available about the frequency with which these scenarios occur. The magnitude of the benefits from UDI will be largely related to this missing data point. In addition, the second and third bullets above identify data and technology needs that must be addressed for UDI to be successful. These data needs and technology issues vary somewhat based on the type of device and scenario involved. To elucidate these further, we analyzed data requirements (what, how, when, and by whom data should be provided) for different situations; these are outlined in Table 3-2.

This analysis also suggests that the potential role of UDI will differ based on the type of medical device involved. This, in turn, raises the question mentioned in Section 1.1 about how different classifications of medical devices might influence selection of a UDI system. Based on our analysis of the scenarios (and other information presented in this document), ERG made preliminary judgments about the importance of UDI based on device classification system, which we summarize in Table 3-3.

In addition to the possible classification systems listed in Section 1.1 and addressed in Table 3-3, FDA also has an existing risk classification system in which devices are classified as Class I, II, or III based on the likelihood that device failure could cause injury. This classification system has some usefulness in evaluating the role of UDI. For Class I devices, which by definition do not pose a risk to patient safety, UDI would probably not improve patient safety. Thus, these devices might be excluded from consideration. UDI might or might not produce a safety benefit with Class II devices, and likely would produce a benefit with Class III devices, although the magnitude is unknown.

To conclude, this analysis generated the following findings:

- Many devices, such as capital assets and most implantables, are generally adequately identified by existing hospital systems.
- Using FDA's existing risk classification system, Class I devices appear to be a low priority for UDI development.
- Some device characteristics, such as whether they are single use, reprocessed, or components of kits or of larger systems, appear to be of secondary importance in considering UDI needs.
- High-risk devices not adequately tracked or identifiable in hospitals appear to be among those of greatest interest for developing UDI.

Table 3-2
Data Requirements and Technology Issues Related to Effective UDI

To execute **recall**—lot or serial number	▪ All devices	▪ Secondary data	▪ After recall is announced	▪ Hospital or clinic ▪ Home healthcare materials management staff	▪ Bar codes or other automatic systems
For **caregiver (1)** —model, size, indicator of possible allergens	▪ Devices directly used on, in, or with patients ▪ Devices that directly affect treatment given	▪ Model ▪ Size ▪ Materials included	▪ Prior to treatment	▪ Caregiver	▪ Scan primary and secondary information into patient health record
For **caregiver (2)**—information on device-procedure interaction concerns	▪ Devices with foreseeable interaction concerns	▪ Information specific to interaction concerns	▪ Prior to treatment	▪ Caregiver ▪ Medical technician	▪ Scan primary and secondary information into patient health record
For **caregiver (3)**—information for complete MDR reporting	▪ All devices	▪ Secondary data	▪ At time of treatment	▪ Caregiver ▪ Medical technician	▪ Scan primary and secondary information into patient health record
To support **tracking**—model, size, lot, or serial number	▪ Devices for which tracking is necessary for patient safety	▪ Secondary data	▪ Prior to treatment	▪ Post-surveillance monitoring staff and/or caregiver	▪ Scan primary and secondary information into patient health record

Table 3-3
Potential Classifications of Medical Devices Relative to UDI Needs

Implantables			
Permanent	High	Adequate	Currently powered devices are identified and tracked
Temporary	High	Adequate	Currently powered devices are identified and tracked
Non-active	Moderate	Not known	Some devices are individually identified and tracked
Accessories or non-active components	High	Inadequate	Evolving technical issue; UDI role might change or be case-specific
Device materials [a]	High	Adequate	Systems other than UDI (e.g., labeling) generally used
Capital assets			
Laboratory	Moderate	Adequate	In-hospital tracking covered by maintenance and inventory controls
Non-invasive	Moderate	Adequate	In-hospital tracking covered by maintenance and inventory controls
Invasive or life-support items	High	Inadequate	Occasional problems in tracking have occurred
In vitro diagnostics	Moderate	Adequate	In-hospital tracking covered by maintenance and inventory controls
High-risk devices (Risk to patient)	Varies with risk	Varies with risk	FDA's Class III devices are of greatest concern
Infectious Risk/Sterility	High	Sometimes inadequate	Concerns have arisen with inadequately cleaned devices
Supplies (Disposables)	Varies	Varies	Disposability might be described in UDI database
Single-use only	Varies	Varies	Single-use feature might be described in UDI database
Reprocessed devices	Varies	Often inadequate	Tracking might require further labeling by reprocessing firm
Reusable devices	Varies	Varies	Reusable feature might be described in UDI database
Interoperability [b]	Varies	Varies	Depending upon issues, might pose problems for UDI
Care setting	Varies	Varies	Uncertain applicability to UDI database
User of device	Varies	Varies	Uncertain applicability to UDI database
Kits vs. components	Moderate	Varies	Characteristics might be addressed in UDI database
Systems vs. components	Moderate	Varies	Characteristics might be addressed in UDI database
Devices requiring expiration dates	Varies	Varies	Device expiration dates would be addressed in UDI database
Devices relating to bioterrorism	Varies	Varies	Characteristics relevant to bioterrorism could be addressed in UDI database

Source: ERG, 2005.
[a] Materials that are allergenic or other have other properties relevant to patient safety (e.g., latex).
[b] Includes mechanical, electrical, and software interoperability.

SECTION FOUR

UDI IMPLEMENTATION: POSSIBLE STEPS AND CHALLENGES

We have discussed potential benefits of UDI and the interests of various stakeholders in advancing the concept of UDI. Moving forward, FDA will need to consider what its role, if any, will be in advancing UDI. To assist in this process, ERG has outlined five steps for consideration in the effective implementation of UDI for medical devices to improve patient safety:

- Select a unique identifier.
- Identify the data needed for patient safety.
- Determine how hospitals will utilize UDI.
- Standardize and synchronize product data (based on the unique identifier).
- Maintain a central repository of the standardized data.

Below we describe each of these steps further. We also note challenges associated with each step. While not insurmountable, overcoming these challenges will require some financial investment and additional research, as well as cooperation from industry.

4.1 SELECT A UNIQUE IDENTIFIER

Currently, medical devices lack a standard and unique identifying system comparable to the NDC system for pharmaceuticals. Implementation of UDI will require selection of a system to uniquely and unambiguously identify medical device products. With no federal or industry standards for standardizing medical device characteristics in place, interested groups will need to collaborate to agree on standards for uniquely identifying medical device products for the purpose of UDI.

One possibility is to extend the use of the UPN. Many bar code systems used in the medical device industry use UPNs. Currently, however, UPNs are primarily used for supply chain management and thus some of the data (e.g., secondary data such as lot number) needed for patient safety is generally not included. UPN use is also not yet industry-wide. Although many initiatives are underway to encourage adoption of the UPN, manufacturers have been slow to do so because of the cost of updating their systems with new numbers. Furthermore, anecdotal evidence suggests that some manufacturers fear that use of a unique identifier like the UPN might "commoditize" medical devices. These issues will need to be addressed to increase rates of UPN adoption.

4.2 IDENTIFY THE DATA NEEDED FOR PATIENT SAFETY

FDA recently held a public meeting (in April, 2005) to survey viewpoints on medical device identification. Participants discussed what types of data elements are needed to achieve an optimal level of patient safety. Data elements that participants suggested are needed to meet minimum requirements for UDI include (FDA, 2005):

- Manufacturer
- Product name

- Make
- Model
- Lot number (as applicable)
- Place of manufacture
- Name of product
- Serial number (as applicable)
- Unique description
- Expiration data
- Address (as applicable)
- Quantity (i.e., unit)

FDA is examining the potential to remove some elements in the list, such as the place of manufacture and address of the manufacturing firm. While the length of this list suggests that identification systems will need to carry more data than is normally seen on product bar codes. Existing bar codes, when present, generally provide only limited primary data (manufacturer, product name, make, and model). In some scenarios, secondary data (lot number, expiration date) are needed. For example, secondary data are needed to identify the specific lots subject to recall and in some cases could identify a product as an allergen or as MRI-incompatible.

The amount of data needed raises a question as to where the data will reside. Physically, it is possible for a bar code or other identification system to contain all of the required data elements. "Two-dimensional" bar codes, for example, such as those used in some DOD unique identification systems, have sufficient capacity to include a large number of data fields (Lippert, 2005). It is also possible to encode data on two bar codes, one for primary data and the other for a limited amount of secondary data.

As an alternative, some of the data could reside in a database. Along with the medical device identifier affixed to a device or its labeling, auto-identification systems generally also serve as pointers to databases that provide additional information. Thus, a bar code or other identifier might serve as a pointer to a database of information about medical devices. Experience with pharmaceutical product bar codes supports this idea; a pharmaceutical bar code points a pharmacist to additional product information, including price data.

The ideal solution will depend on the capabilities of available technologies and how data will be utilized. For example, greater reliance on databases might increase the infrastructure required for a hospital to retrieve the data.

If additional data is to reside in a database, the language used to communicate this data will need to be standardized as well. Industry organizations that have attempted to unify and combine information on medical devices have not yet created overall industry-wide standards. Thus, hospitals or other possible database users cannot yet subscribe to a complete database of device information if they are instituting bar code or other identification systems.

4.3 DETERMINE THE TECHNOLOGY NEEDED TO UTILIZE UDI

To benefit from electronically readable medical device information, hospitals will need to expand their capabilities for capturing the data and using it in hospital networks. In studying the impact of the pharmaceutical bar code on hospitals, ERG identified the purchases needed to capture bar coded package information. Hospitals will need to purchase numerous personal digital assistants with scanners (to be used by nurses or by others with device identification responsibilities), install wireless networks throughout their facilities, and implement bar coding operations for materials that arrive without suitable

bar codes. Hospitals will also need to develop training programs and managerial systems to implement and sustain the systems. Many of these costs might be mitigated to the extent that hospitals are also investing in or have developed bedside bar code systems for pharmaceutical dispensing. Nevertheless, these systems will generally require notable hospital investments, especially if several technologies will be required to make use of UDI.

4.4 STANDARDIZE PRODUCT DATA

Once the first three steps have been completed, manufacturers and distributors will need to modify their internal product identification and packaging practices to match the standards established in Steps 1 and 2. Manufacturers and distributors will need to build a cross-reference from current coding schemes to the new standardized system. This could be quite challenging. For example, adopting new number systems could require extensive changes to existing databases (HCEC, 2005). Furthermore, some data may not be currently tracked. For example, unit-of-measure codes are used to distinguish packaging levels, and unit-of-use codes distinguish unit-dose packages. Currently, however, placement of unit-of-measure and unit-of-use codes on products is inconsistently done (HCEC, 2005). Distributors, GPOs, and health care facilities might face similar challenges in attempting to standardize their data.

The DOD PDU pilot project and the GHX AllSource® catalogue represent ongoing efforts to standardize product data. GHX continues to encourage its participating manufacturers, as well as new suppliers as Content Only members, to continually publish and maintain product data to AllSource®. This product data repository may provide the industry the opportunity for accurate data synchronization among all data consumers; whether they participate as transactional member of GHX. (See discussion in Section 2.2.5). By placing product data for similar products in comparable formats, these types of systems might encourage manufacturers to standardize their data as current inconsistencies are identified.

4.5 MAINTAIN A CENTRAL REPOSITORY OF PRODUCT DATA

After standardization, data will need to be submitted by manufacturers and distributors to a centralized repository (e.g., a PDU) that is maintained on an ongoing basis. This repository will not only house all the data, but will analyze the data for compliance with the agreed upon specifications and report any errors back to the manufacturer or distributor. Data files will also be synchronized to identify any differences between the suppliers of the data (manufacturers and distributors) and the organizations that distribute the data (e.g., GPOs, Integrated Delivery Networks (IDN)). The repository will continue to update and maintain product data and communicate these updates throughout the supply chain.

Efforts to build such industry-wide systems have not yet succeeded, reflecting the considerable challenge of motivating manufacturer participation. Interested organizations, including manufacturers, distributors, GPOs, and hospitals, will likely need to invest in the creation and maintenance of the PDU. HCeC estimates that building and maintaining a PDU can cost more than $1 million and $3 to $5 million annually, respectively, and depend on the number of participants and products. (Hagemeier, 2003). While subscription revenues could cover maintenance costs, interested members of the industry will likely have to pay the startup cost.

4.6 OTHER CHALLENGES TO CONSIDER

UDI will require worldwide cooperation to be completely effective. The U.S. is the largest market for medical devices in the world, both with respect to imports and exports (Medica, 2005). Thus, given the level of supply chain interaction with foreign firms, ideally, these will also need to agree to comply with the new UDI standards.

Another potential challenge may be the small size of many device companies. Smaller companies might find it particularly difficult to undertake costly modifications to their systems. On the other hand, in the PDU pilot managed by the DOD, smaller companies were more compliant than larger companies in providing data (Garvin, 2005), perhaps because the smaller and simpler systems of small companies are more easily changed than the large, complex systems of larger companies.

Figure 4-1. HCEC Recommendations

The HCEC prescription for moving forward includes the following elements:

A common frame of reference: Define and adopt a standard product packaging structure detailing packaging, quantity, and content relationships with comprehensible definitions in order to view, discuss, and exchange packaging information and identification needs from a common frame of reference. HCEC has noted the difficulty of determining how many units are included in some packaging.

A common language. Adopt a common supply data dictionary to ensure that data is clearly communicated and understood between trading partners.

Product and packaging identification specifications and guidelines. Establish specifications and guidelines for correlating unit-of-measure and bar code identifiers at every level of packaging and communicating this information with the item records.

Manufacturer-assigned bar code identifiers. Encourage manufacturers to assign bar code identifiers to the lowest level of product or package detail (the product unit of measure), whether or not the packagers or products are bar coded or bar codable and communicate identifiers with item records to enable end-users to accurately capture point-of-use data with manufacturer-assigned identifiers at the point of care.

Business rules. Establish business rules and requirements to validate compliance with specifications and enable data exchanges to facilitate electronic product and packaging data maintenance from point of manufacture to point of use and back up the supply stream.

An adaptive interface. Adopt and implement a common adaptive interface to create a common cross-reference from internal product and packaging information files to standard component keys (computer field or XML tags), unit-of-measure definitions, and product packaging identifiers in order to accurately exchange product packaging information between disparate computer systems.

Product information management system or service. Each enterprise will need a software system or service to manage and maintain standard product data with trading partners and import/export data with internal non-standard systems.

4.7 RECOMMENDATIONS FROM CHeS AND HCEC

Various industry consortia have also taken an initiative to recommend how UDI could be achieved. CHeS (first described in Section 2.2.5) recommends rapid and widespread adoption of the UPN by all industry participants in the healthcare supply chain. The organization considers UPN the building block of improved supply chain interactions and considers the medical/surgical PDU the most effective way to ensure UPNs and related product data become the cornerstone of electronic commerce. CHeS is committed to working with the industry to bring the UPN and PDU from concept to reality.

Another industry group (also described in Section 2.2.5), HCEC, also supports wider adoption of the UPN and has recommended the following steps as the essential generic process needed for progressing to UDI:

- *Define and consistently use standard unit of measure codes for units of use.* Healthcare providers need to capture usage data on units of use dispensed or applied at the point of care or point of use.

- *Define and use standard unit of measure codes for packages.* Inconsistent use of packaging unit of measure codes creates source confusion and errors across supply processes. All supply chain partners must adopt unit of measure codes in a standard packaging hierarchy.

- *Define and use unique bar codes for unit of use and for each packaging level.*

More specifics about their recommendations are presented in Figure 4-1.

In presenting their prescription for progress, HCEC also recognizes the existence of obstacles. For example, manufacturers are often unwilling to change internal product and packaging unit of measure descriptors because the current terms and values are integral to their business processes and information system functions. Changing and applying the revised identifiers will produce some costs and might pose technological challenges that manufacturers may not be willing to undertake. Furthermore, even if identifiers are revised, some products cannot be bar coded at the unit of use without some technological advancement, which is also likely to be costly. This may be an even greater challenge, given the variety of medical devices that exist. The question also remains whether distributors, group purchasing organizations, and other facilities will be able to change their systems to adopt new standard units of measure and packaging configuration specifications. Further research needs to be done to determine if these challenges can be overcome.

SECTION FIVE

CONCLUSIONS REGARDING THE POTENTIAL GOVERNMENT ROLE IN UNIQUE DEVICE IDENTIFICATION

Considering the wide-ranging activities and interests of the various stakeholder groups, it remains uncertain how and whether UDI will evolve further into a universal standard for the medical device industry. This summarizes characteristics in the healthcare sector regarding UDI.

5.1 PROSPECTIVE PURCHASING POWER INFLUENCES ON MEDICAL DEVICE INDUSTRY BEHAVIOR

Large government entities with healthcare responsibilities, such as CMS, DOD and VA, have not mandated or enforced a complete system of UDI. DOD and VA have created some elements of UDI systems, but these do not create comprehensive requirements for the medical device industry. The healthcare sector lacks the type of organizing presence that exists in some sectors. For example, Walmart has enforced a number of packaging requirements on its suppliers in the private sector. Similarly, grocery and retail industries have also managed to adopt standardized product identification systems.

Industry consortia have also formed, such as GHX, to try to overcome manufacturer hesitancy and create the necessary reference systems for device information. The willingness of some healthcare entities to invest in such organizations suggests that they forecast that an effective device identification system will eventually be put in place. Other healthcare companies and consulting firms also offer various services to hospitals to "clean" their device purchasing databases. While these organizations improve the quality of device information, they do not perform a standardization function.

Overall, industry consortia have now existed for a number of years and it is uncertain whether these efforts at standardization are building toward success. The quality of device information remains quite uneven.

5.2 COOPERATION FAILURE

The current situation in the medical device market represents some of the characteristics of a situation referred to as "cooperation failure" (or "coordination failure") in the economics literature. This refers to circumstances in which parties (such as components of the medical device supply chain) could achieve greater returns through cooperation than they receive without it. Nevertheless, the disparate parties cannot achieve cooperation. (See, for example, the discussion in Chilosi, 2003). Distributors, hospitals, GPOs, and insurers would benefit from a UDI standard. They would capture direct savings in supply chain management if a database could be developed and populated with manufacturer-supplied information on medical devices.

The applicability of the "cooperation failure" term might be questioned because of the uncertain benefits to manufacturers of enhanced device identification systems. As noted in previous sections, manufacturers have concerns about the commoditization of their devices. UDI systems might allow much greater opportunity for price and performance comparability and, in some current medical device markets,

the lack of such comparability probably benefits manufacturers (see Abelson, 2005). The lack of cooperation from some manufacturers might, therefore, reflect rational concerns about the effect of those efforts on future profitability.

5.3 POTENTIAL ROLE FOR GOVERNMENT

Thus, the Federal government might be able to generate net social benefits by providing organizing principals for a UDI system. This is a traditional role for government, i.e., organizing socially beneficial efforts that the private sector will not organize itself. Further, as a leading healthcare provider, the Federal government would capture the supply chain savings from implementation of UDI.

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APPENDIX A

AUTO-IDENTIFICATION TECHNOLOGIES

As noted in Section One of this document, auto-identification is the use of technology to help machines identify objects. The three main types of auto-identification technologies—bar coding, radio-frequency identification, and optical character recognition—are described further in Sections A.1, A.2, and A.3, respectively.

A.1 BAR CODE TECHNOLOGY

A bar code is the graphic representation, in the form of bars and spaces of varying width, of numeric or alphanumeric data that is machine-readable. A machine-readable bar code identification symbol can be used on an extremely wide variety of products and packages, including many products regulated by FDA.

Bar codes encode numbers and letters using one of many available symbologies, or encoding systems. Bar codes can be presented in linear (or one-dimensional) codes, two-dimensional (2D) codes, or composite codes, which combine one- and two-dimensional symbologies.

For medical devices, bar codes are carried on one or multiple levels of packaging. Most existing bar coding helps manufacturers, distributors, and healthcare facilities effectively and efficiently track orders and manage inventory. While bar coding sometimes presents technical or logistics challenges, bar codes generally can be applied for very low costs, such as fractions of a cent per package (Dillon et al., 2001).

Bar coding uses line-of-sight technology. That is, users must orient the code toward a scanner so that the scanner can "see" and read it. Standard bar codes identify only the manufacturer and product, not the unique item. The bar code on one milk carton is the same as on every other, making it impossible to identify which one might pass its expiration date first.

A.1.1 Standard Bar Code Symbologies

Many industry groups have developed their own symbologies to address industry-specific issues, and they maintain inherited or legacy environments for electronic data interchange. Given the variety of existing approaches, domestic and international health industry groups have worked to develop standards on bar code use.

In the retail area, there is widespread acceptance of the GS1 (formerly UCC) bar code guidelines, which include the universal product code (UPC) symbology (HDMA, 2001). The GS1 is a nonprofit voluntary standard-setting group that includes many major retail store chains. The UPC is the industry consensus for retail shelfkeeping units (SKUs). The UPC symbology is an all-numeric, fixed-format number system. To obtain a code, a user registers with GS1 and receives a unique manufacturer identification number. The user then registers products to receive a unique UPC product identification code for each.

For international trade, manufacturers wish to conform to the European counterpart of the GS1: the EAN International symbol, the principal retail bar code symbology in Europe. The EAN and GS1 symbologies are compatible, so a commonly used bar code system is referred to as UCC/EAN. The EAN symbology, however, does vary somewhat from the UPC. Specifically, the EAN symbology adds a 0 to the front of the number, which creates difficulties for products imported from Europe. Thus, standardization is not yet complete among those using the UCC/EAN codes. UCC has recommended the adoption of a 14-digit code on unit-of-sale packages.

Independent of GS1 guidelines, the HIBCC, another nonprofit industry voluntary standard-setting group, developed its own bar code symbology. The original HIBCC bar code recommendations were issued in 1984, before the GS1 (i.e., UCC) guidelines became so widely used among retail establishments. As a result, the HIBCC standards were not made compatible with those guidelines.

The HIBCC Bar Code Standard (HIBC) was designed to meet a substantially higher level of safety and security than the UPC standard. HIBC advocates argue that it is much more precise and, therefore, more appropriate for critical care situations. The symbology incorporates greater use of "check" characters that help ensure accuracy. HIBCC has sponsored studies to compare the accuracy of the two symbologies and found substantially lower error rates with the HIBC.

HIBC is uniformly defined everywhere where it is in use; thus, there is no international variation in how HIBC codes are interpreted or displayed. To obtain these codes, users register themselves and their products in much the same way that they do with UCC to receive UPC codes.

Overall, both HIBC and the GS1 system are standard-based systems with reasonably wide acceptance. As a result, they currently coexist, and they represent a choice of bar code options for manufacturers considering bar code labeling. Further, scanning technology can be programmed to auto-discriminate among codes and accommodate both symbologies simultaneously.

Manufacturers make a variety of choices before selecting bar codes for their business. While these will encompass many technical bar code specifications, the choice between UPC and HIBC symbologies is principally a business decision, according to the GS1 spokesperson for healthcare, John Roberts (UCC, 2001).

For medical device manufacturers, there is no federal or legislated code that uniquely identifies items in a fashion analogous to either the UCC or HIBCC standards. As noted in Section One, the DOD developed a bar code symbology termed the UPN as an identifier for devices sold to the government (Mosher, 1996). The UPN can consist of either the UPC/EAN primary data structure (all-numeric) or the HIBCC primary data structure (alpha-numeric). The UPN is now widely used for healthcare and many other products.

A.1.2 Linear, Two-Dimensional, and Composite Bar Codes

Bar codes can be linear, 2D, or composite. Linear bar codes are the familiar row of vertical lines found on most retail packaging. 2D systems record information both horizontally and vertically. They can consist of several rows of lines or a checkerboard of black and white squares. Composite codes have both linear and 2D components. The linear component includes a signal indicating the presence of additional 2D information. If the scanner is capable of capturing it, it will then read and interpret the additional 2D information.

2D codes compete on their accuracy, extent of information included, compactness, and ease of adaptation in printing and labeling systems. Some also can provide substantial error correction capabilities, with self-checking content. Some 2D codes can be printed on relatively high-resolution industrial printers, which are now widely employed because they do not need to use solid lines or circles to establish read orientation. Others require some upgrading of the supporting technology (Dillon et al., 2001).

The 2D codes offer an array of quality control and product processing advances for data management and product tracking. For example, ultraviolet (UV) 2D bar code markings allow manufacturers to combat counterfeiting of products. The UV 2D codes provide an invisible identifying label that is difficult to copy and does not interfere with the visible labeling eventually added. Some pharmaceutical companies have undertaken UV 2D development projects or have considered them (Packaging-technology.com, 2001).

Composite codes offer some of the advantages of both systems. Virtually all bar code readers can read the linear component, but then 2D readers can also capture the additional material. This research has not examined whether the composite codes are likely to gain popularity relative to other codes.

A.1.3 New Bar Code Symbologies for Healthcare Industries

Until recently, manufacturers were unable to place even linear bar codes on their smallest unit-of-sale products, such as prefilled syringes, due to physical limitations of the product. Two industry standards groups have responded by facilitating agreements about acceptable small bar code symbologies.

DataMatrix Bar Code

The HIBCC moved first to adopt a 2D bar code that requires a very small footprint on the package. HIBCC recommends using DataMatrix 2D symbology to carry the UPN number, lot number, and expiration date. This bar code looks like a square matrix of printed dots and can be made small enough to fit on virtually any label: its square matrix has been prepared in sizes as small as 0.001 inches per side (Dillon et al., 2001). Very dense, this tiny code can store from 1 to as many as 2,000 characters, according to the Barcode Software Center. Thus, assuming that label materials are suitable, and that all associated printing and packaging logistics are addressed, a DataMatrix bar code can be placed on almost every product.

HIBCC selected DataMatrix because it was already in relatively wide use in several industries and was judged to be a viable and robust symbology (Miller, 2001). The electronics and automotive industries have used the symbology for distribution purposes. The pharmaceutical industry and others also make wide use of this symbology in the "nude" identification systems employed for internal distribution (Dillon et al., 2001). These internal systems allow manufacturers to identify their products during internal processing and distribution without having to actually label them.[2]

[2]Manufacturers prefer to label products as late as possible in the production process in order to maximize their flexibility to ship products to where they are most valuable or needed (Packaging-technology.com, 2001). For a multinational pharmaceutical manufacturer, this might mean withholding labeling until the company determines to which country the product will be shipped.

Reduced Space Symbology

The GS1 (then UCC) also considered adoption of a 2D matrix symbology equivalent to or identical to that of the HIBCC. The UCC working group, however, was concerned that the DataMatrix 2D symbology did not allow continued use of existing (and highly prevalent) scanning equipment that can only read linear codes (Sharp, 1999). Manufacturers selling large volumes of material through giant retail chains had substantial incentive to avoid making so much equipment obsolete. Instead of following the HIBCC, the UCC and European industry groups developed a new Reduced Space Symbology (RSS).

In adding the RSS system, the UCC and European industry groups provided a family of coding choices for manufacturers. The RSS group includes linear codes such as RSS-14 Limited and RSS-14 Stacked and a composite code called RSS-14. The Limited and Stacked versions of RSS are designed to fit where only very short or very narrow bar codes can be accommodated—for example, on drug vials and syringes. The composite code can contain additional information, such as the expiration date and lot number. Any member of the RSS family can be printed as a stand-alone linear symbol or as a composite symbol. The accompanying 2D composite component is printed directly above the RSS linear component. RSS symbols encode an indicator of the existence of a 2D composite component (UCC, 2001).

Other Symbologies

Numerous alternative symbologies are in use and could have been selected by the standards organizations of healthcare product manufacturers, but these alternatives are less suitable for medical devices. For example, MaxiCode is a 2D symbology that is perhaps the most widely used code for distribution package tracking. It is used by United Parcel Service (UPS). MaxiCode is a fixed-size code that holds up to 93 data characters. This symbol, however, is slightly more than 1 inch in size along its sides (Dillon et al, 2001).

A.2 RADIO-FREQUENCY TECHNOLOGY

Radio-frequency identification (RFID) systems represent an alternative or complementary system to bar coding. RFID is a generic term for technologies that use radio waves to automatically identify products and/or patients. An RFID system requires an antenna, a transceiver with decoding capabilities (i.e., an RF reader or interrogator), and a transponder (i.e., an RFID tag) that is electronically programmed with unique information. There are several methods of identification, but the most common is to store a serial number that identifies a product and/or patient, and perhaps other information, on a RFID tag. The antenna enables the chip to transmit the identification information to an RF reader. The RF reader emits radio waves that activate the RF tag. The RF reader then decodes the information on the RFID tag and passes it on to the host computer for processing (RFIDjournal.com, 2005).

Because RFID systems are considerably more technologically demanding and costly than bar coding, most research has been oriented to potential high-value-added applications of the technology.

RF tags have some advantages in the healthcare setting. For example, they do not have the line-of-sight limitation of bar codes: they could allow nurses to identify patients without having to physically locate and scan their wristbands.

Selected potential healthcare uses have been noted. For example, RFID has potential uses for tagging and identifying high-value medical device assets. A large mail-order pharmacy has been investigating the use of RFID to verify the contents of a mail order after the package has been sealed,

reducing packing and shipping errors (Pierce, 2001). RFID systems are still being developed, and RFID standards continue to evolve.

A.3 OPTICAL CHARACTER RECOGNITION

Another machine-readable technology is optical character recognition (OCR). OCR is the process of converting images of printed characters (i.e., written or printed text) into machine-readable ASCII codes. The equipment required is essentially the same as that for bar codes, namely a scanner-type device and character recognition software. For the OCR case, the scanner component consists of a digital camera.

There are two main types of OCR "recognology." Topological recognition is a character recognition methodology that relies primarily on the properties of printed characters (machine print or hand print) that endure when the characters undergo distortions. A newer methodology for recognizing "real world" characters and thus enhancing data entry accuracy, called recognition-enhanced data entry, employs neural networks (Schantz, 1996).

As with bar coding, OCR technology could be used to read package information on pharmaceutical or medical device products as an additional safeguard for bedside point-of-care dispensing of medications. OCR equipment has not been employed in this fashion thus far—its use in healthcare in general is very limited, and it is not commonly mentioned as a potential solution in medication error discussions. The technology has been applied primarily in text-intensive environments where automated data entry from lengthy documents or large numbers of documents is required. Check processing systems, tax form data entry systems, and insurance claim processing are among the leading users of OCR.

Noland, Bernice E.

From: Crowley, Jay
Sent: Friday, May 26, 2006 11:52 AM
To: Noland, Bernice E.; Marthaler, Annette L
Cc: Racine, David W.
Subject: RE: UDI ANPRM References

Attachments: UDI ANPRM Reference 1.pdf; UDI ANPRM Reference 2.pdf; UDI ANPRM Reference 6.pdf

Bernice – I didn't attach the references that are already posted on our website (because of their size) – but I can put them in a separate email if you'd like…

UDI ANPRM References

1. Letter from Pete Sessions, Mike Doyle, Tim Murphy, Michael Conaway, Bill Jenkins, Bob Inglis, George Radarovich, Members of Congress to Lester M. Crawford, Acting Commissioner, Food and Drug Administration, dated May 24, 2005

   UDI ANPRM
   eference 1.pdf (90 .

2. Letter from Margaret Reagan (Premiere, Inc.), Rick Pollack (American Hospital Association), Larry Gage (NAPH), Charles Kahn (Federation of American Hospitals), Edward Goodman (VHA). Michael Rodgers (The Catholic Health Association of the United States), Robert Dickler (Association of American Medical Colleges) to Lester Crawford, Acting Commissioner, Food and Drug Administration, dated May 9, 2005.

   UDI ANPRM
   eference 2.pdf (807.

3. The Food and Drug Law Institute / CDRH Report on Meeting to Discuss Unique Device Identification (April 14-15, 2005) (http://www.fda.gov/cdrh/ocd/uid/)
4. ECRI / FDA White Paper: Automatic Identification of Medical Devices (August 17, 2005) (http://www.fda.gov/cdrh/ocd/uid/)
5. The Food and Drug Law Institute / CDRH Report on Meeting to Discuss Unique Device Identification (October 27, 2005) (http://www.fda.gov/cdrh/ocd/uid/)
6. ERG Final Report: Unique Identification for Medical Devices (March 22, 2006)

   UDI ANPRM
   eference 6.pdf (221.

7. Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Safety Program (January 18, 2005) (http://www.fda.gov/cdrh/postmarket/mdpi-report.pdf)

Jay

From: Noland, Bernice E.

Sent: Friday, May 26, 2006 9:32 AM
To: Marthaler, Annette L; Crowley, Jay
Subject: RE: UDI ANPRM

I don't have them. I will need them. Annette is the rin # applied to the document now, or after we send it to Parklawn. If now, I will need that also Jay.

From: Marthaler, Annette L
Sent: Friday, May 26, 2006 9:27 AM
To: Crowley, Jay; Noland, Bernice E.
Subject: RE: UDI ANPRM

Hi, do your folks have all the references pulled together? Bernice will correct me if I'm wrong, but I believe we need all of those for the blue sheet package. Thanks!

From: Crowley, Jay
Sent: Friday, May 26, 2006 8:04 AM
To: Kahan, Linda S; CDRH-OSEL Director's Mailbox; Norcio, Catherine T.; Marthaler, Annette L; Schultz, Daniel; Racine, David W.; Ashar, Binita S
Subject: UDI ANPRM

Attached is the completed ANPRM. Binita has reviewed it – and we are ready to move it forward.
<< File: ANPRM - 25 May 06.doc >>

Who in the regs staff who I work with to create the blue sheeted package?

Linda – you also mentioned making a point of letting Ann Wion know that Scott Gottlieb was anxious to keep this moving, so OCC knows it is a priority – is this is in email or as part of the blue sheet?

Linda – you mentioned that you would like to send it to Diane Maloney.

David – since you have been the primary point of contact with the federal partners, do you want to send it to them?

Jay Crowley
Senior Advisor for Patient Safety
Center for Devices and Radiological Health
Food and Drug Administration
Office: 240-276-2389
Cell: 301-980-1936
E-mail: jay.crowley@fda.hhs.gov