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Task 4

White Paper
Automatic Identification of Medical Devices
Final Version

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1 INTRODUCTION

In 2000, the Institute of Medicine (IOM) published its report, *To Err Is Human: Building a Safer Health System*[1] to understand the causes of medical errors and find ways to prevent them. In the report, a type of automatic identification technology - bar code identification systems – was identified as one of the tools that could effectively be used to help reduce medical errors, in particular medication errors. Since that time, the federal government and others have called for a number of initiatives to improve patient safety. [2, 3]

In 2004, the U.S. Food and Drug Administration (FDA) published a final rule that will require bar codes on human drugs and biologics by 2006[4]; however, this rule did not extend to medical devices. Numerous comments submitted to FDA regarding the bar coding rule for human drugs and biologics raised a number of questions or concerns related to requiring bar codes on medical devices, such as the diversity of medical devices available on the market as well as the lack of a standard, numerical identification system for medical devices.[4-7] While numerous opportunities using automatic identification technologies to prevent adverse events associated with pharmaceuticals have been demonstrated; a similar case for medical devices has not yet been made. [4, 5] At the time it issued the rule, FDA stated that medical devices presented different issues compared to human drug and biological products and while it would not include medical devices in the rule, it would continue to study whether to develop a proposed rule to require bar codes on medical devices and/or issue another type of guidance. [4, 5]

Bar codes are a type of automatic identification technology -- automatic (or "auto") identification is the broad term given to a host of technologies that are used to help machines identify objects or persons. Automatic identification is often coupled with automated data capture. There are a host of technologies that fall under the automatic identification umbrella. These include bar codes, smart cards, voice recognition, some biometric technologies (retinal scans, for instance), optical character recognition, radio frequency identification (RFID) and others. [8-13]

The goal of this white paper is to provide a general overview of some of the most prevalent technologies available to support automatic identification of medical devices, to briefly review the current published positions and standards of various stakeholders in the medical device industry and user community, and to highlight some of the general applications reported in the literature to date involving automatic identification systems for medical devices. The white paper also examines some key issues related to unique identification of medical devices, including standard device nomenclatures.

Existing information identified by ECRI's literature searches completed to date form the basis for this white paper; a de novo analysis of data is outside the scope of this project.

This white paper is intended to assist FDA as it moves forward in considering the many issues related to the area of unique identification of medical devices, and the use of automatic identification technology. It is not intended to provide specific, prescriptive recommendations, but rather, serve as one of the many inputs FDA considers as it continues to study whether it is

appropriate to develop a proposed rule or some other type of guidance related to automatic identification and medical devices.

The information used for the basis of this draft white paper was derived primarily from the published literature. This information was supplemented with information obtained from an FDA-sponsored workshop on automatic identification of medical devices that was held April 14 and 15, 2005. This meeting was convened for FDA by the Food and Drug Law Institute (FDLI), and was attended by key stakeholders from the medical device industry, and research and trade associations, representatives of the Food and Drug Administration, and ECRI. (A complete set of notes from this workshop is available separately.)

A draft of this white paper was circulated to the April 14-15, 2005 workshop participants, and comments were received from the organizations represented by several attendees, specifically, AdvaMed and the Health Industry Business Communications Council (HIBCC).[92, 93] An original set of all review comments received have been submitted to FDA separately; these comments have been addressed as appropriate in the final version of this white paper.

2 METHODS USED TO IDENTIFY THE LITERATURE

ECRI performed a number of searches of the biomedical, public health and industry literature to identify potentially relevant information on automatic identification of medical devices. To identify information for this draft white paper, we searched more than 10 databases. We list these databases, along with key elements of our search strategies, in Attachment A.

In addition to the peer-reviewed literature, ECRI reviewed a number of gray literature resources, as well as the bibliographies and reference lists of relevant articles, standards, position statements and other guides published by various stakeholders such as the Health Information Management System Society (HIMSS), AdvaMed, the Health Industry Distributors Association, HIBCC, the Uniform Code Council (UCC), Premier, and others. (A complete list of organizations is provided in Attachment A.) (Gray literature includes reports and studies produced by local government agencies, private organizations, educational facilities, and corporations that do not appear in peer-reviewed journals.)

While our searches identified some articles published in the traditional peer-reviewed biomedical literature; the majority of information identified by our searches came from the business/industry literature. While there is a growing body of peer-reviewed literature related to automatic identification technologies and pharmaceuticals or transfusion safety, there seem to be very few studies in the peer reviewed literature related to applications for automatic identification of medical devices, particularly with relation to patient safety. The majority of information published regarding the automatic identification of medical devices appears to be derived from the business/industry literature, and is comprised of business case studies, case reports regarding implementation of various automatic identification technologies (e.g., bar code identification systems, RFID), surveys, and white papers from various stakeholder groups such as standards organizations, advocacy groups, professional associations, manufacturers of bar code and RFID technologies, and providers.

We did identify one white paper on patient safety published in 2001 that briefly mentions medical devices as an example, along with medications, blood and patients, in its recommendations to implement bar coding and other information technology solutions to reduce errors in health care. The authors cite an overall evidence level 4 for the recommendations (evidence level 4 is defined by the authors as "case series").[14] However, with the exception of this article, the majority of the patient safety literature ECRI identified appears to be focused on developing and implementing automatic identification systems for the delivery and tracking of medications for the purposes of preventing adverse drug events, and for transfusion safety.[15-20]

3 TECHNOLOGY OVERVIEW

There are many different technologies available to support the automatic identification of medical devices for a number of different applications. These include bar code identification systems, radio frequency identification (RFID) technologies, and others.[8-13] The two most prevalent technologies currently referenced when discussing the use of automatic identification of medical devices for the purposes of patient safety, delivery of clinical care and tracking of clinical outcomes, as well as improving product, supply and material management processes, are bar code identification systems and RFID.[21, 22, 23] These technologies are briefly reviewed below.

3.1 BAR CODE IDENTIFICATION SYSTEMS

A bar code is a graphic representation of data (alpha, numeric, or both) that is machine-readable. Bar codes encode numbers and letters into different types of symbologies. Linear (or one-dimensional) codes, two-dimensional codes (e.g., Data Matrix), and composite codes (a combination of one- and two-dimensional symbologies) are available.[8, 13] The reported advantage of two-dimensional and composite codes is that they can encode more information than one-dimensional bar codes. This may be a significant consideration when examining the utility of applying bar codes to smaller medical devices, such as surgical instruments and implants.[8, 13, 21]

One-dimensional linear bar codes typically consist of a series of dark and light bars, either dark bars on a light background or light bars on a dark background, and are read by scanners such as laser scanners. Two-dimensional symbologies use various combinations of dark and light shapes such as dots or dashes. Essentially, most two-dimensional bar codes function as a series of one-dimensional linear bar codes "stacked" on top of one another. To read these two-dimensional symbologies, a scanner can employ a two-dimensional laser scanning pattern or digital image capture. In two-dimensional laser scanning, a light source 'reads' the top line of the two-dimensional bar code in the same manner as it would a one-dimensional linear code, goes down to the next line of code when it reaches the end of the first line, and proceeds as such until it reaches the bottom "quiet zone." In digital image capture, the scanner snaps a digital picture of the code, and then software orients the picture and decodes the dark and light shapes.

Basic System Components

There are several basic components of a bar code identification system: a bar code printer, a bar code label, a bar code verifier, scanning equipment, and an external database for bar code data capture and relay.[8]

The bar code printer generates the bar code label. The bar code label contains the symbology that identifies the object. There are a number of different printers available, including laser printers and thermal printers, which can transfer an image to labels made of paper or synthetic materials or directly to the item itself.[8]

The bar code verifier is a calibrated device that scans each bar code directly after printing to measure the accuracy and print quality of the bar code. These measurements are based on ANSI Print Quality Guidelines (ANSI INCITS 182) established by the American National Standards Institute. Bar code scanners quickly and accurately read, capture and decipher the information contained in the bar code label. According to the literature, verifiers should be a key consideration when considering bar codes as a means of improving patient safety, as it is essential that any system implemented utilizes high-quality, scannable bar codes that meet existing standards.[8, 21]

Bar code scanners or "readers" also act as decoders that decipher the information contained in the bar code and convert it into a signal that can be understood by a computer system attached to the scanner. There are many types of scanners available, including bar code wands, linear charged coupled devices, laser scanners and image-capture scanners.[8]

The final component of a bar code identification system is the database supported with middleware applications to provide an interface between the bar code readers and the host data management software. Many existing bar code applications use external computer databases as a 'lookup table'- a computer collects and interprets the data transmitted from the scanner and links the unique data in the scanned bar code to a detailed data file on that item in the computer's database. Other applications are able to populate data to a database system directly from the bar code.[8, 81, 93]

Standards

A bar code standard describes what information should be contained in a bar code (data content) and specifies the bar code (symbology) to encode the data. Currently, there are two major developers of bar code standards that are available for use with medical devices: the Health Industry Business Communications Council (HIBCC) Health Industry Bar Code (HIBC) which supports the HIBC-LIC format and the Uniform Code Council (UCC), which supports the EAN.UCC Universal Product Code (UPC) format. In addition, the U.S. Department of Defense, developed the Universal Product Number (UPN) as an umbrella term to encompass both the EAN.UCC and the HIBC bar codes.[8, 21, 24,-31]

Medical device manufacturers can choose to use either standard, and there is evidence from a recent 2004 AdvaMed survey to indicate that there is significant use of both bar code standards among medical device manufacturers.[21] According to the AdvaMed survey results, in some instances, manufacturers have chosen to follow the EAN.UCC system for some products and the HIBC system for others.[21] Hospitals may also use any available standard.[17]

Proprietary bar codes may also be used. The 2004 AdvaMed survey of manufacturing firms noted a potential problem for the medical device industry related to the extent that proprietary bar code standards are used, citing cost as the key issue.[21]

Both HIBC and EAN.UCC formats support a primary data structure (a format for the manufacturer name, product name, and packaging level), as well as a method of encoding additional information, such as lot, batch, serial number, and expiration date. This is called secondary data. Secondary information may be especially helpful as medical devices and supplies move through the supply chain to the provider and reach the point of care.[27, 28, 29, 30, 31] This type of information may be more critical for some products than others. For example, the secondary data structure might be used by those in the supply chain (manufacturers, distributors, and hospitals) that must respond to FDA's Safe Medical Devices Act (SMDA), which requires tracking of certain devices all the way to the patient. Other examples of medical devices for which secondary data may be important include in vitro diagnostics or implants that have expiration dates. In a survey of manufacturing firms completed by AdvaMed in 2004, nearly 68% of the companies responding reported bar coding secondary information, with FDA Class III products most likely to carry a secondary bar code.[21]

One of the key challenges that has been noted in association with bar coding of medical devices is the need to apply a bar code to a potentially small area.[4, 5, 6, 17, 21] Many medical devices are too small for the application of some existing symbologies. Consequently, new symbologies have been developed that have the potential to accommodate more information in a smaller bar code area. These include symbologies such as Reduced Space Symbology (RSS), composite symbologies (such as CC-A, CC-B, and CC-C), and two-dimensional symbologies such as Data Matrix and PDF417 (portable data file). In its 2004 survey, AdvaMed noted that the challenges associated with applying bar codes to very small unit-of-use devices might partially explain why only 25% of FDA Class I, 44% of FDA Class II and, 50% of FDA Class III unit-of-use products are bar coded.[21]

According to AdvaMed, three symbologies -- Data Matrix and Micro PDF under the HIBC Supplier Labeling Standard and RSS under the EAN.UCC system -- are appropriate for use on small packages, where space for a bar code symbol may be limited.[21] According to the responses received by AdvaMed for its 2004 survey of manufacturers, there is a limited use of Micro PDF on shelf packs and a slightly greater use of Data Matrix on unit-of-use items. At the time its survey was published, AdvaMed indicated there was no reported use of RSS on medical devices.[21]

(For more information from the 2004 AdvaMed survey, see Section 4, below.)

3.2 RADIOFREQUENCY IDENTIFICATION SYSTEMS

RFID is a wireless communication technology that utilizes radiowaves for automatic identification and data capture of information for the purpose of identifying and tracking objects or people. The technology uses signals in the radio frequency (RF) range of the electromagnetic spectrum to communicate data either unidirectionally or bidirectionally between transmitter and receiver devices.[13]

Basic System Components

An RFID system typically consists of the three main components: tags, readers, and middleware and host data management software applications. Tags are placed on objects or people; they usually contain information about the object or person. The reader, which may be activated manually (as in the case of a handheld reader) or may function automatically, uses RF energy to interrogate the tag and read the information it contains. In some cases the reader can also transfer data to the tag. Because RF energy can pass through solid objects, RFID doesn't require a direct, unobstructed transmission path between a tag and its reader — that is, it isn't limited to line-of-sight communication. The information obtained from the tag (such as a unique identifier or the object's physical location) can then be transferred to a host data management system.[13]

RFID tag sizes range from fractions of a square inch to many square inches, depending on memory capacity, the size of the antenna, and whether the tag incorporates a battery (tag batteries are typically about the size of a watch-type battery). The size of the tag's antenna will mostly depend on the desired read range (that is, the distance over which the tag and reader can communicate) and operating frequency, as well as on the type of reader that will be used. Some tags function as transmitters only; others can both transmit and receive. A tag's ability to communicate with a reader is based on established protocols.[13]

RFID tags can be categorized into three groups: passive, semi-passive, and active.[13] Passive tags do not have a battery but instead receive all of their energy from the reader. The reader induces energy in the tag's antenna, and the tag uses this energy to power its internal circuits to transmit data back to the reader. Typically, passive tags are read-only and operate at lower frequencies (e.g., 13.56 MHz) but there are also passive tags that can operate at higher frequencies (e.g., 900 MHz). The read range for passive tags is typically a few inches to about 4 feet (ft) (approximately 1.2 meters [m]).

Semi-passive tags contain a battery that powers the internal circuitry. Power for communication, however, is still provided by the reader. Because more of the reader's energy can be used for communication, semi-passive tags provide a longer read range than passive tags do: approximately 10 to 100 ft (3 to 30 m). These tags typically operate at higher frequencies (e.g., 900 MHz, 2.4 GHz), but can operate at lower ones. These tags, which are rather new to the market, are more expensive than passive tags, but less expensive than the active versions.[13] Some stakeholders emphasize that semi-passive tag technology is extremely new and that the price of these tags may be prohibitive; in addition, availability may be an issue.[92]

Active tags are completely powered by their battery. This allows all the reader's energy to go to transmission, providing a greater read range than with passive and semi-passive tags. The internal battery can last from several months to several years, depending on use conditions; frequent or continuous activation can decrease operating time significantly. Active tags typically operate at high frequencies (e.g., 433 MHz, 900 MHz, 2.4 GHz). Their read range is over 100 ft (30 m).[13]

Different RFID tags use different types of memory storage. Some are read-only—information is programmed into the tag at manufacture, based on a customer's specification, and cannot be changed or added to. (Most passive tags are read-only.) Other tags are known as write-once read-many (WORM), allowing users to store information on them once. Still others are read/write, allowing users to store or update information on them as needed. The data storage capacity of RFID tags and power source varies greatly and is a key determinant of the tags' uses.[13] Capacities can range from one byte to 512 Kb.[13]

One-byte tags are typically used for EAS (that is, as antitheft devices), like the tags attached to clothing in retail stores. These tags contain no information — they are simply either detected or not detected. Tags with a capacity of 128 bytes can store small amounts of information, such as a serial number or other unique identifying number. Tags with a capacity of several hundred bytes (e.g., 512Kb) can store a serial or other unique identification number, item contents, or specific handling instructions. Tags that contain EEPROM (electrically erasable programmable read-only memory) chips with a storage capacity of up to 512 Kb can store pages of information.[13]

Some tags can perform additional functions — for example, sensing and recording vibration and temperature to alert users to possible detrimental effects on stored or transported objects. In addition, some RFID applications today use tags that function as wireless network cards and interface to computer networks.[13]

The RFID reader (sometimes called an interrogator) is an electronic device that communicates with a tag to (1) receive data, (2) validate that the data is relevant to a particular application (for certain types of tags), and (3) send data to the tag. A tag reader for a passive or semi-passive tag provides the energy to trigger the tag to transmit its information.[13]

There are two basic types of readers: those that are installed — in a room or entryway, for example — and those that are handheld. The first type may automatically read tags within its read range, either continuously or intermittently, or may wait for a user command. A handheld reader is operated manually. Different types of readers can be deployed in a variety of ways to provide a wide range of RFID architectures and applications.[13]

Some readers are capable of programming WORM or read/write tags, allowing data to be extracted from and written to a tag. Readers capable of programming a tag typically obtain programming instructions and information from a middleware and/or host data management application. When the tag is within the write range of the reader, the user or system initiates transfer of the information to the tag.[13]

As mentioned earlier, RFID systems do not require line-of-sight between the tag and the reader, but instead rely on the proximity between these two components.[13] (Note: although line-of-sight is not strictly required with RFID systems, the orientation of the tag in relation to the reader may be an important consideration to ensure accurate reading of tags. System sensitivity or reading distance may vary with orientation of some systems.[13, 93])

Some RFID readers may be able to read many tags simultaneously. To avoid collisions between tag signals being read, which might disrupt or corrupt the tag data, a reader can send a command to the tag(s) to transmit in an orderly manner based on a unique identification method, called anticollision.[13] Two methods for "anticollision" include bit collision and time slot. The bit-collision method uses a unique binary code of 0s and 1s. For example, a reader requests transmissions from all tags within its electromagnetic field having a binary code starting with 0. If more than one tag in the field starts with 0, the reader then requests all tags that have codes beginning with 01, and so on until all the tags have been read. This process typically takes a couple of milliseconds per tag, so a reader with 1,000 tags in its field will take about two seconds to read all of them. With the time-slot method, a reader transmits a signal requesting any tag in the electromagnetic field to begin counting up to a number provided by a random-number generator contained in the tag. Once the sequence is finished, the tag transmits its information. Each tag will finish its counting sequence at different time intervals, so each tag will transmit its data in a different time slot.[13]

Most readers are only capable of reading a single frequency (e.g., 13.56 MHz), but some suppliers offer readers that claim to be able to read multiple frequencies (e.g., 13.56 MHz, 900 MHz) simultaneously. Also, there are suppliers that offer what they describe as multi-protocol readers that can read more than one tag protocol. In addition, certain suppliers offer readers that incorporate both multi-frequency and multi-protocol technologies.[13] (Note: According to HIBCC, reading of multiple frequencies and/or multiple protocols may be very difficult to achieve, due to many factors. HIBCC states that "readers that claim to [read multiple frequencies and protocols], in fact, can only read one protocol at a time. They simply go through all the possible protocols/frequencies, until they find the protocol to which the tag will respond. Even then, the 'tuning' that is required [depending on the tag antennae size, etc.] to get a positive read is difficult to achieve reliably across the range of possible configurations."[93])

An antenna connected to the reader radiates the electromagnetic energy to communicate with the tag. Most readers can be configured by the manufacturer with various size and shape antennas to accommodate the type of tag, the particular RF used with the RFID system, the proximity of the RFID system to other materials such as metals or liquids (which may block certain transmission frequencies), and the desired coverage area. The read range between the tag and reader depends not only on the tag type (e.g., passive, semi-passive, active), but also on the type of antenna, transmission frequency, and — especially for passive and semi-passive tags — the maximum RF power output of the reader.[13]

The read range between the tag and reader depends not only on the tag type, but also on governmental regulations for the particular frequencies used for RFID. Government agencies,

such as the U.S. Federal Communications Commission (FCC), regulate the maximum output power of radio frequency transmitting devices.[13]

Readers capable of programming a tag typically obtain programming instructions and information from a middleware and/or host data management application. When the tag is within the write range of the reader or programmer the user or system transfers the information to the tag.[13]

Like bar code identification systems, most RFID systems require middleware applications to provide an interface between the readers and the host data management software.[13] Middleware software filters and structures the data read from the tags and integrates it into the host application, which stores the information from the tag or dictates the action to be taken with the information. Middleware and host data management software applications may be provided by an RFID vendor or by third party applications developers. Some examples of host data management software include those for supply chain and pharmaceutical inventory management, as well as tracking software for locating and tracking equipment, staff, and patients.[13]

Standards

RFID systems follow certain protocols for encoding and exchanging information between tags and readers. Generally, each RFID frequency has its own protocol. In the early days of RFID, proprietary protocols were used by individual suppliers, and in most cases, tags from a given supplier could communicate only with readers from the same supplier. Standards were necessary to move towards universal systems, within which any supplier's tags could be read by any supplier's reader.[13]

As RFID technology is becoming more widely diffused, new standards are being developed. Two organizations have established standards that are commonly used for RFID – EPCglobal, Inc. (a subsidiary of the industry association GS1 [formerly EAN International]) with its EPCglobal Network standard (predominantly used in the United States) and the International Organization for Standardization (ISO) with its 18000 series of standards (predominantly used internationally).[13] HIBCC is also considering the development of an RFID standard as well as related position statements.[85, 86]

Both EPCglobal (a subsidiary of GS1 [formerly EAN Internationa]) and UCC have developed standards to address how the tags and readers conduct RF communications (referred to as communications [air] interface protocols). In addition, in December 2004, UCC and GS1 agreed to the Gen2 standard for RFID tag manufacture.

Finally, GS1 and its subsidiaries are working with ISO to harmonize each of their respective standards for universal compatibility.[13]

3.3 DIFFERENCES BETWEEN BAR CODING AND RADIOFREQUENCY IDENTIFICATION SYSTEMS

(Note: The information below is provided as an overview of the basic similarities and differences between bar coding and RFID technologies – it is not intended to serve as a comprehensive comparison of the two technologies.)

Many manufacturers, distributors, suppliers and healthcare facilities are currently using bar code technology for a variety of applications. However, RFID technology is gaining attention for use in these same areas, as well as other applications. Some experts predict that as the costs associated with RFID implementation go down, more manufacturers and healthcare facilities will begin to use RFID. ECRI believes that the two technologies are complementary, rather than competitive, for many healthcare applications.[13]

Bar code and RFID are both identification technologies that hold data that is accessed by some type of reader. They complement each other very well and can be used effectively side by side in many applications. Bar code is an optical technology and RFID is a radio technology. The ways these technologies exchange data account for most of the differences between RFID and bar code and help determine where each identification technology is best put to use.

Because it is a radio wave-based technology, RFID requires no line-of-sight between the reader and the tag to exchange data. RFID tags therefore may be read through material (e.g., packaging, bed linens, patient clothing, surgical drapes) (although, as noted earlier, orientation of the tag and the reader is still an issue to consider in at least some applications). RFID is subject to interference however, particularly from metal or liquid.[13, 92, 93]

The data capacity of RFID tags enables them to carry all the same information as bar codes and more. Just like bar codes, RFID tags are available with different memory sizes and encoding options.[13]

At this point, RFID is still too costly to implement for all automatic identification and data capture applications, particularly for healthcare providers. RFID will likely be the choice where its features offer clear benefits and bar code technology is the choice when this technology allows significant benefit at what is currently a more reasonable cost.[13]

Below, ECRI presents a simple comparison of the different capabilities of bar code and RFID technologies, primarily from the perspective of a healthcare provider.

Table 1. Comparison – Bar Code and RFID Technologies

Parameter	Bar Code Technology	RFID Technology
Transmission Type	Optical	Radio Frequency
Position of label/tag compared to reader).	Line-of-sight, specific orientation	Non-line-of-sight, not typically orientation dependent*
Read Range (Typical)	Up to a few feet	A few inches to 4 feet (passive tags), more than

Parameter	Bar Code Technology	RFID Technology
		100 feet (active tags)
Maximum Read Rate	One per scan	Up to 1000 tags per second
Tag Programmability During Use	No	Yes, if WORM or read/write
Symbologies or Tags Appropriate for Small Items	Yes	Yes
* System sensitivity or reading distance may vary with orientation of some systems.[13]		

From a healthcare provider perspective, RFID and bar code technologies can be used for many of the same applications, but they may serve different roles in those applications. For example, bar code labels applied at the unit-of-use level may be more cost-effective than applying RFID tags because bar code labels are currently less than $0.01 per label – based on quantity purchased – compared to about $0.50 per basic passive RFID tag commonly used for this purpose.[13]

Bar code technology can be used for inventory control and asset locating, although, not in real-time. Bar code technology lends itself very well for supply inventory control especially for disposable items, such as dressings, catheters, and IV tubing, where those items are usually always kept in the same location (e.g., stockroom).[13]

Though both technologies can be used for locating assets, RFID may offer certain characteristics relevant to this application that may justify its higher cost. For example, equipment bar codes can be scanned manually to provide location information, but only up to the last time the device was scanned. RFID can allow automatic scanning in certain locations or simplify more frequent manual scans as the (active) tags can be read from long distances and not in direct line-of-sight.[13]

The ability of bar codes and RFID tags to withstand various environmental conditions varies. Reportedly, RFID tags are less susceptible to damage from exposure to ice, snow, and dirt when compared to bar codes.[13] However, with RFID, there may be issues related to sterilization, as certain types of sterilization methods may cause damage in certain RFID tags. In addition, RFID technology may be susceptible to interference from metals or liquids that can impact the accuracy and reliability of RFID applications.[13, 92, 93]

According to HIBCC, two-dimensional bar code technologies have desirable characteristics that RFID does not. For example, a data matrix symbol can be etched onto metal surfaces whereas most current generation RFID tags are difficult to implement in such applications. As many medical devices are manufactured from metal, HIBCC believes that this is an important issue to consider when reviewing the characteristics of bar code technologies versus RFID in applications involving medical devices.[93]

Another key consideration is the size of the medical device that needs to be identified. Smaller devices may have specific requirements that certain automatic identification technologies are not yet able to accommodate.

In summary, each technology has its own set of strengths and disadvantages that should be considered, depending on the characteristics of the medical devices involved, as well as the intended application. In some cases, one technology may be the preferred solution over the other; in other cases, both technologies may be used in combination to achieve a particular goal.[13]

4 WHO IS USING AUTOMATIC IDENTIFICATION TECHNOLOGY?

Several organizations have published data with regard to the extent to which automatic identification technology such as bar code identification systems have been implemented by the healthcare industry, as well as healthcare providers. (To date, ECRI has not identified comparable data regarding the use of RFID in healthcare.)

According to data gathered for FDA during the development of the bar code rule for human drugs and biologics by the Eastern Research Group, Inc. (ERG), the use of bar code technology in the healthcare provider setting, in particular by hospitals, is growing.[4, 5] According to the American Hospital Association, in 2003 almost half of the hospitals in the United States had explored the possibility of independently installing this technology. At the time these data were collected approximately four percent of all hospitals were currently using some form of computerized systems in their medication processes, and about half of them were using bar codes in everyday practice. As applications such as bar code medication administration technology have become more widely diffused, the number of hospitals using bar code technology has increased.[4, 5]

Stakeholders believe that several initiatives will drive the implementation of bar code identification systems, or comparable technology. According to respondents to a May 2004 survey from HIMSS, these include the FDA rule for human drugs and biologics, as well as a proposed requirement from the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) that links a healthcare facility's accreditation to the implementation of bar code identification systems.[33] (Note: since the time of the HIMSS survey, JCAHO has dropped the specific bar code requirement from its safety goals.[80]) The HIMSS survey results also indicated that a lack of financial resources presents a key barrier to implementation.[33]

On the manufacturer side, a survey published by AdvaMed in 2004 indicates that 78% of the 41 respondents representing 37 different manufacturing firms already apply bar codes at some level of packaging.[21] In addition, 83% of FDA Class I devices, 86% of FDA Class II devices, and 76% of FDA Class III devices made by the respondents were identified as having some form of bar code.[21] More than 80% of firms with more than $30 million in sales per year indicated that they use bar codes, though that figure drops to 54% for companies with revenues of less than $30 million.[21] In addition, more than 80% of the 41 respondents indicated that they apply bar codes on some or all of their products at the unit-of-use level and at the shelf-pack level.[21] About 50%

indicated that they apply bar codes at the shipper-carton level, with less than 20% applying bar codes at the pallet level of packaging.[21]

The AdvaMed survey indicated that the most widespread use of bar coding was by manufacturers was at the level of shelf packs.[21] Over 50% of both respondents who manufacture FDA Class II devices or FDA Class III devices indicated that 100% of their shelf packs already had bar codes.[21] A number of respondents also indicated bar coding was being applied for some FDA Class I devices.[21] There was also some indication from the respondents that they intended to apply bar codes on 100% of shelf packs in the near future.[21]

Although the percentage of manufacturers who applied bar codes to unit-of-use packaging was lower than that reported for shelf packs, the AdvaMed survey indicated that a number of manufacturing firms are applying bar codes at the unit-of-use level. According to the survey results, over 40% of FDA Class I products and approximately 50% of FDA Class II products are bar coded at the unit-of-use.[21]

It is also interesting to note that, according to the AdvaMed survey, 58% of the Class I manufacturers that do not now bar code 100% of their unit-of-use level packages indicated that they are close at 80% to 99% complete.[21] Of the Class II manufacturers 77% of those still working on bar coding this packaging level are at least 75% complete.[21] Results are similar for Class III manufacturers who report that they are between 75% and 95% finished applying bar codes at the unit-of-use level.[21] According to the AdvaMed survey responses, by the end of 2005, a significant amount of unit-of-use products will be bar coded.[21]

The AdvaMed survey was based on three Web-based surveys aimed at medical device manufacturers, distributors, and hospitals.[21] The survey questions were developed with input from AdvaMed's Automatic ID Working Group. (Note, the AdvaMed survey also included 4 responses from 3 distributor facilities, and 9 responses from hospitals; these data were excluded from the final analysis as the population was too small to provide valid data that could be generalized to a larger population.)

Older (2000) survey data from the Health Industry Distributors Association indicated that less than 60% of distributors applied bar codes at the unit-of-use for medical/surgical supplies.[34]

An informal poll recently conducted (March 2005) by ECRI of its Health Devices member hospitals asked the question "Does your hospital plan to implement RFID technology for tracking the location of capital equipment?" The responses received indicated that 3 respondents (3.53%) already use RFID for this purpose; 6 respondents (7.06%) are working on implementing the technology now, 30 respondents (35.29%) plan to implement the technology within the next 2 years, 39 respondents (45.88%) indicated that they do not have any immediate plans to implement RFID, and 7 respondents (8.24%) indicated that they did not know.[35]

In May 2005, ECRI sponsored a teleconference titled "Radiofrequency Identification (RFID) for Medical Devices: Planning for Today and Tomorrow."[91] During this teleconference, participants, the majority of whom came from healthcare provider institutions, were invited to respond to the

same question "Does your hospital plan to implement RFID technology for tracking the location of capital medical equipment?" A total of 117 organizations responded as followed:

- RFID system is already in use - 5.12% of respondents
- Working on implementation now - 5.12% of respondents
- Plan to implement within two (2) years - 45.29% of respondents
- Not in our immediate plans - 29.05% of respondents
- Don't know - 15.38% of respondents

During the April 14-15, 2005 workshop regarding unique identification of medical devices sponsored by FDA and hosted by the Food and Drug Law Institute, participants identified several healthcare providers with solid experience in using automatic identification technology, in particular, bar code identification systems, with medical devices. One particular workshop participant claimed that these institutions find benefits for patient safety, controlling costs, and providing reimbursement information for third party payors.[82]

5 HOW IS AUTOMATIC IDENTIFICATION TECHNOLOGY BEING USED WITH MEDICAL DEVICES?

One of the key reasons FDA declined to include medical devices in its 2004 rule on bar coding was the diversity of medical devices available on the market, and the potential challenges of implementing a program of automatic identification for medical devices.[4,5] In addition, not all potential uses of automatic identification technology may show the necessary benefit to justify the costs of implementation.[4,5,6]

One key question to be answered is "Which medical devices will benefit from automatic identification technology?" The answer may differ depending on the perspective, whether one is looking at the question from the view of improving patient safety or from the view of streamlining supply chain, inventory control, and asset management processes, for example.

It is important to note that there are limits to what FDA can implement within the definitions of its statutory authority, because, insofar as medical devices are concerned, its authority is premised on product safety and effectiveness. Some potential benefits resulting from automatic identification of medical devices may not be directly linked to that statutory authority. The white paper, and the workshop held April 14-15, 2005 both viewed the issue of what medical devices could benefit from automatic identification technology from a broad perspective; consequently, some of the applications discussed may fall outside the purview of the FDA.[82]

As stated earlier, there is a paucity of evidence in the literature regarding the application of automatic identification technology and medical devices. Cost-benefit studies are also absent from the literature. The information ECRI has identified to date is mostly limited to various case examples presented in the healthcare business and trade literature. A selection of these case examples are summarized below.

Tracking and/or tracing of objects such as medical devices using a unique symbol such as a bar code or a RFID tag is being used in a number of applications, including tracking and/or tracing of medical devices. The concept of tracking involves controlling the shipping and receiving process for medical devices, as well as managing assets and inventories within healthcare facilities. Tracing relates to building a history – an audit trail – for manufacturing, shipping, and receiving medical devices, as well as the use of devices and supplies in patient care.[13, 17, 21, 34, 37, 38, 39, 40, 41]

According to the literature ECRI reviewed, automatic identification technologies can be used to track and/or trace a product through the supply chain and clinical workflow.[13, 17, 37, 41] They may be used to link a product to a particular patient and also can identify the clinician who used it with the patient. Automatic identification technologies can also be used to track or trace a particular medical device or supply back to a given manufacturer or distributor.[13] The information contained in bar code labels and RFID tags can also be used to control and streamline medical device returns and recalls/safety alerts, and to support the implementation and management of the medical device requirements specified under FDA's Safe Medical Devices Act.[13, 25]

Not having equipment available may result in delays in patient care. For patient safety initiatives, it is important that the right device be available at the right time for the right patient. The literature contains various examples of these types of problems that could be addressed, at least in part, by automatic identification technology, such as surgery delays due to instruments not being available, delays in administering medications and intravenous fluids because of the inability to locate and obtain an infusion pump, and quickly tracking down a ventilator in an emergent situation. The need for tracking portable equipment such as ultrasound scanners and telemetry packs have also been illustrated in case examples in the literature.[13, 17, 37, 41-46]

Tracking equipment and supplies, while predominantly described in the literature as a nonclinical application for automatic identification of medical devices outside the purview of patient safety initiatives, can also be viewed as a part of an effective and efficient approach to ensuring patient safety. Experiencing delays in finding critical patient care devices, such as infusion pumps, or not being able to find these devices at all, can contribute to adverse events or near misses.

Using automatic identification technology to capture unique information about the patient and the medical devices used on that patient during the course of a health care encounter in an electronic medical record is another example in the literature of how this technology can be used. Various groups such as the National Committee on Vital and Health Statistics (NCVHS) and the Institute of Medicine have indicated that information regarding devices should be included in a standard for the electronic medical record.[3] However, although there is a evolving body of literature on the electronic medical record, ECRI did not identify any studies that examined the implementation/benefit of using automatic identification technology to capture medical device information for this purpose.

Use of automatic identification technology, including bar code identification systems as well as RFID, to manage patients and equipment in specific settings, such as emergency rooms and operating rooms has been also been described in the literature.[47, 48, 49]

Recently, Radianse, Inc., (Lawrence, MA) recently received a $1.5 million grant from the U.S. National Institutes of Health to conduct an implementation study of its RFID technology designed to track medical equipment, surgical patients and staff at Massachusetts General Hospital (Boston).[50] This study is expected to be performed over an 18-month period; early results of the study are expected in late 2005. Massachusetts General is also using technology from Mobile Aspects (Pittsburgh, PA) to track its medical equipment, drugs and supplies.[50]

Several case examples in the literature illustrate the use of automatic identification technology to help track and trace surgical instruments and other supplies through the decontamination and sterilization process.[36, 39, 43, 44, 51, 52, 53] One hospital reports implementing automatic identification technology after an event occurred where nonsterile instruments made their way into the operating room.[52, 53] In addition, use of automatic identification technology has been suggested for processes designed to track and trace devices back to a particular patient in cases of inadvertent contamination and/or increased risk for exposure to disease such as hepatitis or Creutzfeldt-Jakob disease (e.g., implants, surgical instruments, endoscopes, blood processing equipment, dialysis units).[54] While it is not large, there is a body of literature dealing with contamination of various devices posing a risk to patients who have been expose to such devices.[57-69]

Some stakeholders, as well as case examples in the literature, have identified the use of automatic identification technology such as bar codes and RFID as a key tool for improving medical device recall and alert processes.[4, 5, 7, 55] In testimony presented to FDA at a 2002 public meeting on bar coding, one hospital described the numerous challenges it encountered with respect to successful tracking and recalling of a bronchoscope, and asserted at that time that bar coding of this medical device, along with the appropriate inventory management system, would have greatly facilitated the tracking and identification of the affected devices.[7, 55, 56] These devices had been identified as the source of an unexpectedly high rate of *Pseudomonas aeruginosa* infections among a group of 410 patients. A total of 41 infections were reported in 39 patients.[57, 58]

Validating that an action has occurred or that a particular item is available has been another function of automatic identification technologies used with medical devices that has been reported in the literature. The ability to validate an action by a bar code or RFID scan could help reduce errors and waste, provide a management check on productivity, and/or could help construct the necessary documentation to meet requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).[13, 17]

Findings from a survey conducted by the Patient's Association (a UK-based patient advocacy group) focused on potential benefits of tracking medical devices for improved patient safety in Great Britain's hospitals.[36] The survey, which was the basis for the report "Tracking Medical

Devices and the Implications for Patient Safety" was carried out with the support of GS1 (formerly EAN International) and represented a collaboration between the Patient's Association, the Institute of Decontamination Sciences (IDSc), the Infection Control Nurses Association (ICNA) and the National Association of Theatre Nurses (NATN). Results were compiled from the responses of 125 members of IDSc, ICNA and NATN during December 2004. According to the survey: 97% of respondents indicated that off-site sterile service decontamination facilities should have tracking/tracing systems for individual medical devices; 78% of respondents indicated that improved medical device tracking/tracing would impact patient safety; 39% of respondents indicated that they thought it would be impossible to track a single instrument back to an individual patient. Less than 50% of the respondents indicated that they actually tracked individual surgical instruments, as opposed to tray sets, in sterile services.[36]

While not yet available, the UK National Institute for Clinical Effectiveness (NICE) is currently working on an evidence-based guideline titled "Creutzfeldt-Jacob Disease (CJD) - Patient Safety and Reduction of Risk Transmission Via Interventional Procedures" that will include recommendations related to sterilization and the tracking/tracing of reusable surgical instruments and endoscopes. This guideline is planned for release in 2006. (NICE is an independent organization responsible for providing guidance to the UK National Health Service on the promotion of good health and the prevention and treatment of ill health.)

Innovision Research and Technology (United Kingdom) has reportedly developed a range of RFID tags that are small enough to be embedded in many medical devices, according to the company's news reports available from its Web site.[70] The intention behind the technology, according to its developers, is to prevent single-use equipment from being used again, to trace and identify specific devices that may be needed in an emergent situation involving patients, and to track medical equipment or implants suspected in the transmission of disease, such as Creutzfeldt-Jakob disease or hepatitis.[70] (Note: at least one stakeholder has noted that the tags available from Innovision should be considered proprietary; in addition, they are not currently widely available. This stakeholder also noted that "there are too many unanswered questions to reference/endorse this company or technology."[92]) Another reported example of smaller RFID tags are those developed by Maxell Corp. (Fair Lawn, NJ). Maxell Corp. has developed the Coil-on-Chip RFID system, a 2.5-mm^2 chip with built-in antenna coil and rewritable memory that ranges from 128 bytes to 4 Kb.[87]

There are few older, published reports that describe successfully embedding automatic identifiers into medical devices such as dental appliances, instruments and implants. For example, Milward and colleagues described successful implementation of an approach for reliable automatic identification of dental appliances using bar and matrix codes in printed and laser engraved forms.[71] Experiments with both bar codes and matrix codes were attempted, and the authors report being able to reliably incorporate laser-etched matrix codes into various dental appliances.[71] Shepherd and his colleagues,[72] as well as Jones and a similar group of researchers[73] described a process for automatic identification of surgical and orthodontic instruments using the same matrix coding system described by Milward that is intended to ensure instrument

identification, as well as documentation of every clinical use and sterilization, and can be used to establish when instruments are likely to require servicing or replacement.

Finally, some reports have stated that automatic identification technologies might be able to prevent counterfeiting of healthcare products such as medical supplies and implants.[13] To date, ECRI has not identified any published examples of such applications for medical devices.

During the FDA-sponsored workshop on automatic identification of medical devices that was held April 14 and 15, 2005, participants identified a number of potential applications for automatic identification technologies with medical devices intended to improve patient safety, as well as related to other areas such as inventory control, asset tracking, etc.. Many of the issues discussed at the workshop mirrored the examples ECRI found in the literature. Potential patient safety related examples raised by the workshop participants included activities such as improved tracking of recalled devices and resolution of medical device recalls and safety alerts, tracking/tracing of implanted devices, tracing of patients exposed to potentially contaminated devices, prevention of counterfeit devices entering the supply chain, and improved adverse event surveillance.[82]

Workshop participants also noted there are many unanswered questions involving automatic identification technologies and medical devices, particularly as it relates to defining the problem, and examining the costs and logistics associated with implementation of any solution as they relate to the intended benefits. This should be a key focus for FDA as it moves forward in considering the issue of automatic identification of medical devices.[82]

6 POSITION STATEMENTS

There are numerous stakeholders in the issue of automatic identification of medical devices. Some industry groups, such as Advamed[12] and the Health Industry Distributors Association[25] have developed specific position statements advocating the voluntary adoption of bar codes, RFID, and other technologies that include specific statements regarding components of an automatic identification program. Others, such as HIMSS[10] have issued more general position statements, along with detailed guides on how to implement programs at the supplier and/or provider level.[8] Some groups, such as the National Health Service (United Kingdom; NHS),[74] have endorsed specific coding standards, while most have left the option open to the user. In Table 2, below, we present several position statements from key stakeholder groups, and compare/contrast the basic information discussed across the various groups.

Table 2. Comparison of Position Statements from Various Stakeholders

	AdvaMed (2002)[12]	**HIMSS (2004)[10]**	**HIDA (1999)[25]**	**NHS (2004)[74]**	**EUCOMED (2004)[75]**	**PREMIER (2005)[55]**
Scope	"Automatic identification" technology including bar code identification systems and radio frequency identification technology	Automatic identification technology, including but not limited to bar coding technology	Bar code technology	Automatic identification technology, including but not limited to bar code identification systems	Bar code technology	Bar code technology
Voluntary versus Manda-tory System	Supports a voluntary system where it is "economically and technically feasible, and where it is clinically practical"	Not stated	Not stated	Supports a voluntary system that includes all products supplied to the NHS	Not stated	Supports a federally required program for standardized bar code labeling on all appropriate hospital-administered/ implemented medical devices and implants
UPN, HIBC, UCC.EAN	Supports voluntary use of UPNs on	Not stated	Supports bar code formats that comprise	Supports the use of UCC.EAN,	States that both UCC.EAN and HIBC are	Not stated

	AdvaMed (2002)[12]	HIMSS (2004)[10]	HIDA (1999)[25]	NHS (2004)[74]	EUCOMED (2004)[75]	PREMIER (2005)[55]
	medical devices, which include UCC.EAN or HIBC standards		the UPN initiative: HIBC and UCC.EAN. HIDA recommends that manufacturers/ distributors establish a policy of UPN bar coding the complete product line shipping cases, inner packs (intermediate packaging) and units of use ("eaches"). Add UPN bar codes as labels are changed, or as packaging supplies are replenished.	unless a supplier is already using HIBC. If a supplier is already using the HIBC set of standards, they may continue to do so for the foreseeable future.*	adequate.	
Level of packaging to be labeled	Not stated	Not stated	All levels of packaging	Not stated	Not stated	Not stated

	AdvaMed (2002)[12]	HIMSS (2004)[10]	HIDA (1999)[25]	NHS (2004)[74]	EUCOMED (2004)[75]	PREMIER (2005)[55]
Repro-cessed, repack-aged, refur-bished devices	States that the same consideration regarding automatic identification should be made for these devices as other medical devices	Not stated	Not stated	Supports the use of UCC/EAN	Not stated	States that benefits exist for requiring bar codes for certain medical devices, regardless of whether they are "original," "reprocessed," "repackaged," "refurbished," or "multiple-use"
Inclusion of reimburse ment coding/ informa-tion, such as ICD or CPT codes (U.S.)	Recommends against including reimbursement coding/information in automatic identifiers for medical devices	Not stated	Not stated	Not stated	Not stated	Not stated
Suggested Compon-ents of a Unique	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated

	AdvaMed (2002)[12]	HIMSS (2004)[10]	HIDA (1999)[25]	NHS (2004)[74]	EUCOMED (2004)[75]	PREMIER (2005)[55]
Device Identifier						

* According to one stakeholder, NHS is in the process of changing their position to include HIBC as equally acceptable to UCC.EAN.[92]

To date, only AdvaMed, HIMSS, and the UK NHS have incorporated positions involving a broader scope of implementation for a range of automatic identification technology, versus bar code technology only.[10, 12, 74] The majority of the position statements available indicate that either of the two predominant bar coding standards, HIBC or UCC.EAN, can be used.

Most of the position statements call for voluntary programs. According to AdvaMed, in a letter dated May 19, 2005, to FDA Acting Commissioner Les Crawford, the unique diversity of medical devices is such that only a voluntary automatic identification program should be considered.[94] The exception is the group purchasing organization, Premier, which advocates for a legislation or regulations from the federal government that will facilitate application of automatic identifiers, specifically bar codes, to medical devices, citing equivalent rationale to that which supports the application of such identifiers to drugs or biologics.[55]

In addition to Premier, there are a number of other groups that advocate for action from the federal government, in particular, FDA, that would require bar codes on medical devices. Other hospital groups such as the American Hospital Association and the Federation of American Hospitals, as well as selected members of Congress, have encouraged FDA to revisit the issue of bar coding of medical devices in an effort to improve the quality of health care, as well as cost-effectiveness and supply chain efficiency."[88, 89, 90]

7 WHAT MEDICAL DEVICES MIGHT BENEFIT FROM AN AUTOMATIC IDENTIFICATION PROGRAM?

One of the key reasons FDA cited for not including medical devices in the final rule on bar coding of drugs and biologics was the diversity of medical devices available on the market, and the variety of unique challenges this diverse group of items presented.[4, 5] In order to develop an effective program for automatic identification of medical devices, we must identify those medical devices and their applications that would best benefit from being used with such technologies.

Among the various stakeholders, there is a diverse set of opinions over which types of medical devices, if any, should be tagged with an automatic identifier such as a bar code or RFID tag.[4, 5, 56] When FDA issued its proposed rule for bar codes, comments submitted from various stakeholders indicated that many healthcare professionals and hospital groups supported requiring bar codes on medical devices, while others preferred to defer action on medical devices because different device classes present different levels of risk.[4-7, 56] Device manufacturers generally opposed the inclusion of medical devices in a bar coding proposal.

As stated earlier, in terms of automatic identification technology programs, medical devices present different issues compared to drugs and biological products. For example, there are different classes of medical devices, and each class represents a different degree of risk, so, for a low-risk device (such as a bandage), an automatic identifier such as a bar code or RFID tag might not have an impact on patient safety. Other examples demonstrating the diversity of the

issue included the fact that some medical devices may be reconditioned by parties other than the original manufacturer, presenting complex implementation and tracking issues. [4,5,56]

While the relationship is more clear-cut for drugs, demonstrating a relationship between automatic identification technology and improved medical device safety through the prevention of adverse events is a challenge. Most adverse device events occur from multiple causes and/or devices. This further complicates the issue. Human factors are more important when examining medical errors for devices than they are for drugs because devices have to be operated by a person, and proper use depends on optimal design and instructions, as well as user adherence to instructions related to use and maintenance.

In trying to identify which devices present the most risk, and offer the most benefit from implementation of automatic identification technologies, a further challenge is the lack of formal published investigations and analyses of adverse device events. Public resources for device safety issues are available from FDA; however, there are many opportunities for improving the usefulness and utility of the reported information (for related information, see Section 9, below.) In addition, ECRI has published thousands of problem reports involving medical devices that have been fully investigated.[35] And some recent studies may indicate the current lack of formal studies may be changing.[76, 77, 78] Recent studies published in *JAMA*[77] on the application of computer-rule–based methods for screening and detection of adverse events involving medical devices, and in the *Journal of Biomedical Technology*[78] that focus in particular on the magnitude and causes of errors when using medical devices are evidence of this trend.

Some stakeholders have suggested that automatic identification technology may be more appropriate for certain risk classes of devices, such as FDA Class II or III devices, as the use of automatic identification technology on these devices are more likely to have significant impact on patient safety. [4, 5, 6, 21, 56] Other opportunities to identify those devices that will show the largest benefit from automatic identification and data capture could come from an analysis of the various types of injury from medical errors involving medical devices and their associated subcategories. For example, there are numerous categories in the FDA Form 3500A Device Coding Manual used by medical device manufacturers and healthcare facilities to comply with the Medical Device Reporting regulation at 21 CFR Part 803. In addition, ECRI has historically employed five broad categories which, based on our experience, are at the heart of all medical errors involving a medical device. These broad ECRI categories, are (1) device factors, (2) user errors, (3) external factors, (4) tampering and sabotage, and (5) support system failures. We further break these five categories into additional subcategories, such as software deficiency; packaging error; improper maintenance, testing or repair; poor incident/recall reporting procedures; or improper cleaning, sterilization, storage. A complete list of ECRI categories can be found in Attachment B.

While using automatic identification technology to prevent adverse events associated with medical devices may be difficult to demonstrate, the information available to date highlights opportunities for using automatic identification technologies in the tracking and/or tracing of medical devices, e.g., to ensure that the right device is available to right patient at the right time, to track certain high-risk devices (e.g., types of implants), to track/trace contaminated

instruments or equipment back to patient(s), or to facilitate tracking of recalled or obsolete products. The case examples presented in the literature to date present opportunities to improve patient safety through tracking and tracing initiatives.

Regardless of which medical devices will benefit from automatic identification technology, it is also important to note, that assigning an automatic identifier to a medical device is only part of a system that can provide benefits to patient safety or inventory management. Establishing, maintaining, and sharing data is also an essential component.

Further information from stakeholders attending the April 14-15, 2005 FDA workshop hosted by the Food and Drug Law Institute (FDLI) regarding which medical devices are most likely to benefit from automatic identification and data capture is available in the workshop notes titled "Report on Meeting to Discuss Unique Device Identification"[82]. Workshop participants identified a number of opportunities for automatic identification technology and medical devices; however, as recognized by ECRI in this white paper, not all of these opportunities fall directly under the purview of FDA. Specifically, with regard to the types of medical devices that might benefit from automatic identification, the workshop participants identified implants, devices that contain certain types of materials (e.g., latex), capital equipment, devices that are determined to pose a "serious" risk to the patient (e.g., Class III devices), devices that might pose an infection risk or that are exposed to sterilization processes, and others.[82]

8 UNIQUE DEVICE IDENTIFIERS

One of the barriers to implementing automatic identification for medical devices cited in the comments submitted to FDA in response to the bar code rule for drugs and biologics was the lack of a standard, unique device identifier accepted by all stakeholders. FDA and other federal agencies, such as the Agency for Health Research and Quality (AHRQ) have asserted that there is an urgent need for a unique identifier for medical devices, as it would encourage industry use of automatic identification technologies such as bar codes, and facilitate the implementation these technologies.[3,79]

The National Health Related Items Code (NHRIC) is a system for identification and numbering of marketed device packages that is compatible with other numbering systems such as the National Drug Code (NDC) or Universal Product Code (UPC). The code consists of two elements: a labeler code plus a sequential number assigned by a manufacturer to identify a device. In the NHRIC system, the manufacturer or distributor assumes responsibility for maintaining the unique number. NHRIC data is not actively maintained by FDA, as is the NDC; this may limit its usability as standard identifier.

When considering the unique device identifier, a key question that should be addressed is whether the unique identifier for medical devices should be include only product level information, such as catalog number, part number, model number or lot number, or whether the identifier should incorporate a generic level descriptor that identifies the product as a member of

a discrete group of similar devices. These generic descriptors would be based on a standard device nomenclature (see Section 9, below).

During the April 14-15, 2005 workshop, participants seem to express general support of some type of universal unique identification system for at least some classes of medical devices. However, industry representatives expressed their concerns for how the parameters of such a system might be established. Manufacturers, for example, reportedly object to the idea of having to comply with any technology-based standards, because the technology is constantly changing. Instead, they advocate for performance-based standards. According to the workshop participants, performance-based characteristics could be established without specifying how they should be accomplished (for example, necessary data elements for a particular type of device could be established without specifying that the identification technology should be a linear bar code).[82]

In other words, the workshop participants emphasized that the essential data elements should be specified, but not the data carrier. Further, it was suggested that industry could help FDA to determine how to implement a performance standard. For example, participants suggested that there could be different performance standards for different types of medical devices (e.g., magnetic resonance imaging units versus an implantable device), because different classes of devices have different identification needs.[82]

It was also noted by the April 14-15, 2005 workshop participants that identifying devices or drugs for reimbursement purposes in electronic health care records may need to be taken into account when performance-based unique identification standards are developed.[82]

(Note that FDA's previous experience gained via public comments to the bar code regulation that hospitals and other potential end-users of a unique identification system advocated specification of a particular technology to facilitate equipment purchases; this same attitude may carry over to device identification.).

Regarding the unique identification of implants, several workshop participants felt that at least a lot number and a unique serial number are necessary. (For one large company, each of their products has a bar code with a lot number and/or serial number.) For example, according to participants, all hip manufacturers identify their hips with a UPN (universal product number), which involves using either a Health Industry Business Communications Council (HIBCC) or a Uniform Code Council (UCC) number.[82]

The workshop participants emphasized that not all devices would benefit to the same extent from a unique identification system in terms of patient safety (e.g., an implant versus a bandage); consequently, the patient safety benefit has to be evaluated for each type of device.[82]

9 STANDARD MEDICAL DEVICE NOMENCLATURES

A key problem related to medical device surveillance, risk assessment and related activities is the inconsistent manner in which the relevant data are captured and organized. For example, while

FDA maintains numerous databases and reporting systems related to medical devices, within these databases, significantly different devices are linked to the same category (e.g., FDA Product Code), or different categories are used to index information on the same device. Another issue is the lack of denominator data related to medical errors with medical devices, which complicates the ability to conduct useful analyses.

Numerous stakeholders, including FDA, AHRQ, NCVHS, ECRI and others have recognized that in order to address these issues, a rigorously developed and internationally recognized medical device nomenclature is needed.[3,79] Not only would a standard have significant implications for patient safety, but would also be extremely useful in purchasing, business inventory control, and other applications, such as the electronic medical record.[3,79]

Further, the combination of a unique device identifier and a standard medical device nomenclature can offer a number of opportunities to improve the overall knowledgebase with regard to medical errors, patient safety and medical devices, improve processes related to inventory control, asset tracking and related applications, and improve the current capabilities in medical device surveillance, recall tracking, and related activities.

Currently, there are several well-recognized medical device nomenclatures available, including the Global Medical Device Nomenclature (GMDN) maintained by the European Union, the Universal Medical Device Nomenclature System (UMDNS) maintained by ECRI and a dedicated portion of the UNSPSC terminology maintained by the Uniform Code Council on behalf of the United Nations. FDA also maintains its Standard Product Nomenclature; however, it is currently working with GMDN and ECRI on a harmonized system.

As we move towards the goal of a single standard medical device nomenclature, there are a number of quality indicators or criteria that should be considered.[83, 84] Adherence to these quality indicators will insure that any nomenclature used to support medical device surveillance, risk assessment and related activities can support its information needs. In addition, these criteria have been adapted for use in evaluating the appropriateness of a given nomenclature for inclusion in the standard for the electronic medical record.

- Nonredundancy – A terminology can not contain two or more formal concepts with the same meaning. (This does not exclude the incorporation of synonyms to improve usability.)
- Nonambiguity – Within a given terminology, no formal concept identifier can have more than one meaning.
- Internal Consistency – Relationships between concepts should be uniform across parallel domains within the terminology. For example, if component devices are related to the overall system in one case, this should be present across the terminology.
- Mapping – Concept information (e.g., definitions, entry terms) should support the cross-mapping from one nomenclature to another. This is particularly important in a domain (e.g., medical devices) where there is more than one accepted terminology. y
- Definitions – Definitions should be explicit and ideally, available to all users.

- Multiple Hierarchies -- Concepts should be accessible through all reasonable hierarchical paths (i.e. they must allow multiple semantic parents), e.g., an implantable cardiac pacemaker can be viewed as an active implantable device as well as a specific type of stimulator. A balance between number of parents (as siblings) and number of children in a hierarchy should be maintained. This feature assumes obvious advantages for natural navigation of terms (for retrieval and analysis), as a concept of interest can be found by following intuitive paths (i.e. users should not have to guess where a particular concept was instantiated).
- Context Free Identifiers -- Unique codes attached to concepts must not be tied to hierarchical position or other contexts; their format must not carry meaning. Because health knowledge is being constantly updated, how we categorize health concepts is likely to change. For this reason, the "code" assigned to a concept must not be inextricably bound to a hierarchy position in the terminology, so that we need not change the code as we update our understanding of, in this case, the disease. Changing the code may make historical patient data confusing or erroneous.
- Persistence of Identifiers - Codes must not be re-used when a concept is obsolete or superseded. This encompasses the notion of Concept Permanence.
- Version Control -- Updates and modifications must be referable to consistent version identifiers.

In Table 3, below, we present a basic comparison of the three most commonly available medical device nomenclatures.

Table 3. Comparison of Key Standard Medical Device Nomenclatures

	GMDN	**UMDNS**	**UNSPSC**
Scope	Medical devices, as defined by the European Union Medical Devices Directives	Medical devices, clinical laboratory equipment and supplies, and other equipment and supplies found in healthcare delivery settings	Medical devices and clinical laboratory equipment, as well as other patient care items purchased by hospitals
Terms	7000 preferred terms	7500 preferred terms	3000 commodity-level terms
Code	5-digit, with no inherent meaning	5-digit, with no inherent meaning	10-digit, with embedded meaning
Definitions	Yes	Yes	Yes
Maintenance Approach	Consensus-based	Consensus-based	Consensus-based
Hierarchy	2-level	Up to 5 levels, depending on device concept	5-level
Polyhierarchy	No	Yes	No

	GMDN	UMDNS	UNSPSC
Concept permanence	Yes	Yes	Unknown
Entry terms, including synonyms	Yes	Yes	No
Search Options	Code Term Keyword(s)	Code Term Keyword(s)	Code Term Keyword(s)
Have codes been cross-mapped to codes in other vocabularies?	The basic development of GMDN began with a mapping of six different vocabularies. However, these mappings are not actively maintained.	Yes. ECRI maintains cross-mappings between UMDNS and the existing FDA Product Codes, GMDN, UNSPSC, HPIS. Partial mappings to clinical terminologies such SNOMED-CT, CPT and ICD-9 are maintained via the National Library of Medicine's Unified Medical Language System (UMLS)	No
Copyright Owner	CEN (European Union standards organization)	ECRI	United Nations
Users	Manufacturers, Regulatory Agencies (e.g., Canada, Australia, Japan). GMDN is mandated as the standard nomenclature for European Union. FDA is currently working towards possible adoption of GMDN harmonized with UMDNS	Hospitals, Manufacturers, Regulatory Agencies. UMDNS is used in 80 countries, endorsed by the World Health Organization and the Pan American Health Organization, and is incorporated into the National Library of Medicine's UMLS	Hospitals, Group Purchasing Organizations, Health Systems

GMDN and UMDNS are very similar in scope and coverage, while UNSPSC has a significantly fewer number of concepts related to medical devices. In terms of meeting the various established quality indicators for standard nomenclatures,[83, 84] each of the systems has different strengths and weaknesses.

9.1 CROSS-MAPPINGS

A single system used by manufacturers, distributors, suppliers, providers, regulatory agencies and other stakeholders may not be a reality, at least in the near future. Given this, cross-mapping amongst the various device vocabularies may be a key tool. At this time, ECRI is aware of the following cross-mappings between various medical device nomenclatures:

- UMDNS:FDA Product Codes – A current mapping of UMDNS to the 1999 version of FDA's Product Codes is available from ECRI as a separate dataset, as well as through the U.S. National Library of Medicine's Unified Medical Language System (UMLS). Equivalent terms between the two systems, as well as related terms (broader than, narrower than, other related) are included in these mappings.
- UMDNS:GMDN – UMDNS was one of the original nomenclatures used to develop the GMDN. There are a number of equivalent relationships between UMDNS and GMDN currently embedded in the GMDN; however, ECRI and FDA are not convinced that these relationships are correct. Consequently, ECRI and FDA are working together to identify and resolve the problems, in an effort to harmonize the two systems. The UMDNS:GMDN mapping is not available as a separate dataset at this time.
- FDA:GMDN – The FDA Product Code system was one of the original nomenclatures used to develop the GMDN. There are a number of equivalent relationships between the FDA Product Codes and GMDN currently embedded in the GMDN; however, ECRI and FDA are not convinced that these relationships are correct. Consequently, ECRI and FDA are working together to identify and resolve the problems, in an effort to harmonize the two systems. The FDA:GMDN mapping is not available as a separate dataset at this time.
- UMDNS:UNSPSC – In 2004, ECRI completed a pilot effort that identified all equivalent, as well as other (broader than, narrower than, other related) relationships between UNSPSC and UMDNS. This cross-mapping is currently maintained as an internal dataset at ECRI.
- UMDNS:HPIS – HPIS (a subsidiary of Neoforma), which maintains a nomenclature of supplies and other items found in the medical device distributor arena, utilizes UMDNS as the basis for its vocabulary. In 2004, ECRI and HPIS updated the current cross-mapping between the two vocabularies. This cross-mapping is currently maintained as an internal dataset at ECRI and HPIS. Opportunities for revisions are considered at least quarterly.

- UMDNS:HCPCS – A portion of UMDNS has been linked to selected device concepts from the Centers for Medicare and Medicaid's Health Care Common Procedure Coding System (HCPCS) under the auspices of the NLM UMLS.
- UMDNS:SNOMEDCT -- A portion of UMDNS has been linked to selected device concepts from College of American Pathologists Systematized Nomenclature of Medicine (SNOMED) under the auspices of the NLM UMLS. ECRI is currently reviewing the device concepts in the most current release of SNOMED-CT to determine if a more rigorous cross-mapping is needed.

10 CONCLUSIONS

In 2004, the U.S. Food and Drug Administration (FDA) developed a rule that will require bar codes, a common type of automatic identification technology, on human drugs and biologics; however, this rule did not extend to medical devices. At the time it issued the rule, FDA stated that medical devices presented different issues compared to human drug and biological products and while it would not include medical devices in the rule, it would continue to study whether to develop a proposed rule to require bar codes on medical devices.

While the rule for drugs and biologics focused specifically on bar codes, FDA should recognize that the automatic identification technology arena is rapidly evolving; newer technologies, such as RFID, should be considered when developing a program involving automatic identification and medical devices. These technologies offer a number of unique capabilities separate and apart from the many established capabilities of bar code technology, and are demonstrating a wide range of uses for automatic identification of medical devices.

There are a number of challenges and complexities associated with implementing bar codes or other automatic identification technologies for medical devices, including, but not limited to, the diversity of medical devices available on the market, as one approach will not effectively support all things that are considered medical devices.

In this white paper, ECRI identified a number of case reports using automatic identification technology with medical devices that have been published in the literature that may serve as a basis for FDA's further study of the issue of automatic identification programs involving medical devices. Additional information has been captured in the proceedings from an April 14-15, 2005 workshop titled "Report on Meeting to Discuss Unique Device Identification."[82]

Key issues not considered within the scope of this white paper that FDA should address moving forward include cost and logistical considerations. It is not clear what it would cost the average hospital to deliver automatic identification of medical devices, and while certain changes are already being implemented in the area of drugs and biologics, some stakeholders emphasize that it should not be assumed that these same measures could also be used for automatic identification of medical devices.[82,92] In order to properly examine the potential benefits of an automatic identification program for medical devices, FDA should be able to demonstrate that the benefits justify the associated costs.

In addition, it is important to note that FDA needs to continue to seek input from a broad set of stakeholders regarding the use of automatic identification technologies with medical devices, and the related area of unique identification. Among the various stakeholders there is a diversity of opinion as to what action, if any, FDA needs to take with regard to these issues. The April 14-15, 2005 workshop sponsored by FDA and hosted by FDLI represented an opportunity to receive input regarding unique identification of medical devices from stakeholders from the medical device industry and research and trade associations as well as representatives of the Food and Drug Administration and other federal agencies. Additional workshops between FDA and stakeholders from healthcare provider groups, clinical and biomedical engineering groups, patient safety groups, and others are warranted as FDA continues to explore the issues.

The lack of a universal, unique device identifier is a key barrier to implementing automatic identification and data capture technology, particularly as it relates to medical device surveillance and risk assessment activities. This will be an essential focus as FDA moves forward to develop a program for automatic identification involving medical devices. A unique device identifier that incorporates, or that is used in tandem with a standard medical device nomenclature offers a number of opportunities for improving patient safety and medical device surveillance at a number of levels, as well as supporting initiatives such as the electronic medical record.

The use of automatic identification technologies also raises a number of potential issues related to privacy of health information that fall outside of the scope of this white paper. For example, electronic transmission of health information must comply with the Health Insurance Portability and Accountability Act (HIPAA) enacted by the United States Congress in 1996.

Finally, there are opportunities to develop a research agenda relating to automatic identification technologies and medical devices, both in the broad arena of medical device surveillance as well as patient safety. Identifying components of such an agenda is currently outside the scope of this white paper; however, FDA and other stakeholders should work together to define the key research questions that are essential to the implementation of automatic identification technologies for medical devices, particularly as it relates to patient safety.

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Attachment A

Methods Used to Identify the Literature

Electronic Database Searches

To date, the following databases have been searched for relevant information:

- ABIInform (through February 2005)
- Cochrane Database of Systematic Reviews (through 2005, Issue 1)
- ECRI Health Devices (through February 2005)
- ECRI Health Devices Alerts (1977 through January 2005)
- ECRI Healthcare Standards (1975 through January 2005)
- ECRI International Health Technology Assessment (IHTA) (through January 2005)
- PubMed (includes MEDLINE and HealthSTAR) (through January 2005)
- U.S. Centers for Medicare & Medicaid Services (CMS) Web site (through January 2005)
- U.S. Food and Drug Administration Web site (through February 2005)
- U.S. National Guideline Clearinghouse™ (NGC™) (through January 2005)
- U.S. National Library of Medicine (NLM) LocatorPlus (through January 2005)

The search strategies employed a number of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts: “medical errors,” “device*” “equipment,” “suppl*” “instrument*” “bar cod*” “barcod*” “RFID” “radio frequency identification,” “automatic identification” “tracking” “supply chain” “patient safety” “electronic medical record” “information technology” “automatic data processing” “Equipment and Supplies, Hospital”

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI’s collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

Organization Resources

ECRI reviewed the Web sites and related publications from the following organizations.

Below is a list of organizations ECRI included in its efforts to identify relevant literature and related information:

American Hospital Association
One North Franklin
Chicago, IL 60606
http://www.aha.org

AdvaMed
1200 G St NW, Suite 400
Washington, DC 20005-3814
http://www.advamed.org

Association for Automatic Identification and Data Capture (AIM)
634 Alpha Drive
Association for Automatic Identification and Mobility
125 Warrendale-Bane Road,
Warrendale, PA 15086
http://www.aimglobal.org/

Coalition for Healthcare eStandards (CHeS)
3300 Washtenaw Avenue, Suite 222
Ann Arbor, MI 48104-4250
http://wwwchestandards.org

GS1 (formerly EAN International)
Blue Tower
Avenue Louise 326 - Bte 10
1050 Brussels, Belgium
http://www.gs1.org

EPCglobal, Inc.
Princeton Pike Corporate Center
1009 Lenox Drive, Suite 202
Lawrenceville, NJ 08648
http://www.epcglobalinc.org/
http://www.epcglobalus.org/

EUCOMED
Place St Lambert 14
1200 Woluwe St Lambert
Brussels, Belgium
http://www.eucomed.org

Health Care eBusiness Collaborative
1405 North Pierce, Suite 100
Little Rock, Arkansas 72207
http://www.hedic.org

Health Distribution Management Association
1821 Michael Faraday Drive, Suite 400
Reston, VA 20190
http://www.healthcaredistribution.org

Health Industry Business Communications Council (HIBCC)
2525 E Arizona Biltmore Circle, Suite 127
Phoenix, AZ 85016
http://www.hibcc.org

Health Industry Distributors Association
310 Montgomery St.
Alexandria, VA 22314-1516
http://www.hida.org

Health Information and Management Systems Society (HIMSS)
230 East Ohio Street, Suite 500
Chicago, IL 60611
http://www.himss.org

International Organization for Standardization
http://www.iso.ch

Joint Commission for the Accreditation of Healthcare Organizations
601 13th Street, NW
Suite 1150N
Washington, DC 20005
http://www.jcaho.org/

National Alliance for Health Information Technology (NAHIT)
One North Franklin Street
27th Floor
Chicago, IL 60606
http://www.nahit.org

The Patients Association
PO Box 935
Harrow, Middlesex HA1 3YJ
United Kingdom
http://www.patients-association.com

Premier, Inc.
700 Commerce Drive
Suite 100

Oak Brook, IL 60523
http://www.premierinc.com

Uniform Code Council (UCC)
8163 Old Yankee Street, Suite J
Dayton, OH 45458
www.uc-council.org

Attachment B

ECRI Taxonomy of Healthcare Technology Related Injuries and Causes of Related Accidents

In its 30 years of investigating patient injuries from errors and accidents involving healthcare technology, instruments, devices, and systems, in both the hospital and laboratory settings, ECRI has developed the following list of mechanisms by which patients are injured in.

Healthcare Technology Related Injuries

- Barotrauma
- Burn (electrical, thermal, chemical)
- Coagulopathy
- Electrical Shock/Electrocution
- Embolism (gaseous/particulate)
- Exsanguination
- Extravasation
- Failure to deliver therapy
- Fire
- Hemorrhage
- Hypothermia
- Hyperthermia
- Infection
- Infiltration
- Ischemia
- Mechanical (puncture, laceration, tear, etc.)
- Misdiagnosis
- Monitoring failure
- Overdose
- Pressure Necrosis
- Suffocation

- Underdose
- Wrong Drug

Beyond these mechanisms of injury, ECRI has historically employed five broad categories which, based on our experience, are at the heart of all medical errors involving a healthcare technology. These broad categories and their additional subcategories are listed below.

Causes of Healthcare Technology Accidents

Device Factors

- Device failure
- Design/labeling error
- Manufacturing error
- Software deficiency
- Random component failure
- Device interaction
- Failure of accessory
- Invalid device foundation
- Packaging error
- Improper maintenance, testing, repair
- Lack of incoming inspection

User Error

- Labeling ignored
- Device misassembly
- Improper ("bad") connection
- Accidental misconnections
- Incorrect clinical use
- Incorrect control settings
- Incorrect programming
- Inappropriate reliance on an automated feature

- Failure to monitor
- Abuse
- Spills
- Pre-use inspection not performed
- Maintenance or incoming inspection error

External Factors

- Power supply failure (including piped medical gases)
- Medical gas and vacuum supplies
- Electromagnetic or radio-frequency interference (EMI and RFI)
- Environmental controls (Temperature, humidity, light)

Tampering/Sabotage

Support System Failure

- Poor prepurchase evaluation
- Poor incident/recall reporting systems
- Failure to impound
- Lack of competent accident investigation
- Failure to train and credential
- Use of inappropriate devices
- Lack or failure of incoming and pre-use inspections
- Improper cleaning, sterilization, storage
- Error in hospital policy

These categories and terms have proven useful in application during clinical and laboratory investigations of medical device accidents. They are complimentary to, but more succinct than the terminology used in the 2,180 coded categories in the FDA Form 3500A Device Coding Manual used by medical device manufacturers and healthcare facilities to comply with the Medical Device Reporting regulation at 21 CFR Part 803.