

November 8, 2006

The Honorable Andrew C. von Eschenbach, M.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Parklawn Bldg., Rm 14-7
Rockville, MD 20857

RE: Unique Device Identification Request for Comments [Docket No. 2006N-0292]

Dear Acting Commissioner von Eschenbach:

On behalf of Novation and its alliance partners, I am writing to provide comments on the importance of unique device identification for medical devices. Novation is the health care contracting services company representing two hospital alliances, VHA Inc. and the University HealthSystem Consortium (UHC). These alliances include more than 2,500 community-based health care organizations and academic medical centers across the United States and represent roughly 30 percent of the occupied hospital beds in the country. Both organizations work with Novation to improve member hospitals' clinical, operational and financial performance through industry-leading supply chain management services.

We are very interested in supporting initiatives that will help us better serve our alliance member hospitals. Given the significant impact that a mandatory unique device identification system would have in the health care industry, we greatly appreciate the opportunity to provide comments on the topic and we are grateful that representatives from the agency are carefully weighing the advice of all contributors.

As representatives for America's leading hospitals we recognize safety, quality patient care and good stewardship of resources are top priorities, and we will work in cooperation with regulatory agencies and suppliers to further the adoption of a universal identification system for medical devices.

Benefits of Industry Standards

Novation has a history of supporting the adoption of industry standards. For example, we were an active member of the initial coalition of health care group purchasing organizations and industry experts to publicly support bar coding on drugs. Novation strongly endorses the use of a unique device identification system for medical devices. While there are many other benefits to be gained, below are several areas that would benefit from the implementation of a consistent device nomenclature.

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Unique Device Identification – Recall Management

The increasing number of medical device recalls, the lack of consistent medical device nomenclature and the manual and labor-intensive tracking systems for device recalls within the health care arena provide a fertile environment for error. According to ECRI, more than 600 device recalls are issued every year; however, this statistic may be understated. Recorded in the FDA Recall Database, there are 1,549 device recalls for the period of January 1, 2005 to December 31, 2005. Of the total, 67 were Class I recalls. This means that a facility would conceivably have to manage nearly 30 device recalls every week with at least one of those being a Class I recall. This does not even consider the drug, biologic or food recalls that a facility may need to manage.

In order to ensure that affected products are taken out of service, it is imperative to know the product, brand, lot, location and in some cases the serial number. While health care facilities have processes to manage recalls, it is usually through a manual rather than automated method, which can lead to inaccuracies. Many VHA and UHC hospitals have expressed concern over the possibility of overlooking a device that has been recalled or withdrawn from the market. Creation and adoption of a UDI nomenclature is a necessary first step to implementing a consistent and accurate recall system for the health care facility, the FDA, the manufacturer but most importantly, the patient.

Unique Device Identification - Counterfeit Medical Devices

Counterfeit medical devices are on the rise. An example of this is in the October FDA warning about counterfeit blood glucose strips that were identified in the market. When counterfeit surgical mesh entered the US market, one hospital reported that 30 patients had been implanted with the counterfeit product. A consistent and unique method of identifying medical devices would enable the prevention of counterfeiting and early detection should such product pass into the supply chain.

According to the U.S. Census Bureau's, *Annual Survey of Manufacturers, 2004*, the medical device market generated \$82.7 billion in purchases. This industry was estimated to grow at 6 percent per annum, which equates to more than \$90 billion dollars annually by the end of 2006. A market of this dollar volume in an ever-expanding global economy and the multiple points of manufacturing of medical devices and their components, require a unique device identification nomenclature to deter entry of counterfeit product into the health care supply chain.

Unique Device Identification - Product Substitution and Product Shortages

All health care facilities have experienced product shortages for one reason or another including but not limited to: raw material shortages, recalls, market withdrawals, national and international disasters. A consistent identification device nomenclature would facilitate identification of products that are therapeutically or functionally equivalent enabling continuous patient care with minimal disruptions. This is accomplished readily with various drugs because there is a consistent and regulated method of identifying

identical or equivalent products from different manufacturers. At this time, there is not a similar system for medical devices.

Unique Device Identification – Adverse Event Monitoring, Post Market Surveillance, Reprocessing of Single Use Devices

When a procedure does not have a desired outcome, it is often difficult to determine if the device was in any way responsible or contributory. The FDA reports difficulty in tracking and trending data submitted by manufactures and end user facilities. In 2004, FDA received approximately 47,000 manufacturer reports and more than 3,000 user facility reports of adverse medical device events. Currently, there is not a common nomenclature or vocabulary for identifying the specific product. There have been situations where the product being reported by the facility into the database was incorrectly identified causing incorrect data collection and analysis.

Post market surveillance is further hampered when a failed medical device cannot be identified as a new or reprocessed single use device (SUD). Currently, reprocessors have implemented systems to track and trend items; however, these systems are intended to track inventory, not necessarily device failure. Often hospital staff cannot tell if a failed device was new or reprocessed, thereby impeding the accurate reporting of device failure. In order to evaluate the role, if any, of a reprocessed device in the event of a negative patient outcome, a unique device identification nomenclature is necessary.

Unique Device Identification – The Electronic Health Record, Item Master and Charge Master

According to HIMSS, “the Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. The EHR has the ability to generate a complete record of a clinical patient encounter, as well as supporting other care-related activities directly or indirectly via interface - including evidence-based decision support, quality management, and outcomes reporting.”

With the recent focus on and call for implementation of the EHR, data standards for all aspects of health care will be required. This includes the products used to treat patients as well as the ability to track and trend outcomes related to the use of a particular product. It also includes the call for transparency related to patient outcomes and the charge for various procedures and health care products. UDI is essential to ensure that the right product is used on the right patient for the right procedure, is charged at the right price and recorded accurately in the EHR.

Response to Request for Comment

As you know, hospitals are under tremendous pressure to provide unlimited care on a limited budget. They face uninsured patients, an aging population, reimbursement cuts, staff shortages and now many are faced with the challenge of spending millions to

develop internal tracking systems for medical devices. The implementation of a regulated, mandatory global nomenclature, similar to the FDA's National Drug Code System, would help improve patient safety, reduce medical errors, facilitate device recalls, improve device adverse event reporting and enable hospitals to focus on what they do best – provide quality care for patients.

In response to the FDA's request for comments on a unique device identification system published in the August 11 *Federal Register*, Novation, VHA, UHC and some of our alliance member hospitals offer the following collaborated comments on unique device identification for medical devices:

I. Developing a System of Unique Device Identifiers

1. How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

A unique device identification system should be developed with input from manufacturers, packagers, wholesalers and end users and overseen by the FDA.

The attributes/elements of a device should include at a minimum:

- Manufacturer
- Description of the product
- Size
- UOM
- Lot number
- Serial number unique to the device if appropriate
- Expiration date if appropriate
- Reprocessed if appropriate

In addition to the above attributes, specific information related to material content such as latex or mercury content; country of origin; components; versions of software or firmware; flammability characteristics were cited by members.

Selected member comments:

“A suggestion might be to look into a system similar to a network MAC address. A MAC address is composed of a sequence of 12 numbers (similar to 01-23-45-67-89-AB). The first six numbers [of a MAC address] (01-23-45-??-??-??) are unique to each manufacturer and manufacturers request these from IEEE. Manufacturers can request more than one if necessary. Each manufacturer is responsible for integrating a tagging system: serial number, RFID, etc that reflects the unique id assigned to every product sold. The system works in the networking world to identify millions of Internet Protocol (IP) enabled devices around the world and allows all of those devices to interact.”

“A system should be developed along lines with ECRI and CHES or any formal Bio-Medical association. All ID numbers should be bar-code readable.”

“By the company that makes the device, maybe assign a group of numbers to each company.”

"Don't reinvent the wheel; utilize the ECRI Universal Medical Device Codes (UMDC)."

"Each device should be identified by unique label i.e.; defibrillator, ventilator followed by a unique model number. These are common labels that everyone can quickly identify instead of product codes and such."

"For consideration: invasive versus non-invasive, involved with drug delivery versus not, lot# or manufacturer date, manufacturer, manufacturer's site ID, manufacturer's recommended service interval (every mo, qtr,...), MR compatibility, reusable versus disposable versus limited reusable."

"Having a specific uniqueness to every product which details all the needed information about that product or any similar type of product would allow selection based on specific need for the patient. Criteria such as latex containing, flammability, hazardous material, and disposal are all necessary."

"Incorporate some identifier for manufacturers and use UNSPSC codes if possible for the device type. There are systems already developed that we could use as a standard without need to create yet another system for this purpose."

"UDI should follow existing GDSN standards. I perfectly workable framework is available. Multiple standards are not efficient and effective."

"Use a common name for all devices of same name. It should have size, description, packaging information, outdate or event date consistent throughout system."

"Use a system like the NDC listing for drugs."

"Use and expand HCPCS C-codes since they are already used for most devices in OPPTS."

"Yes, manufacturer/device name/number. Number needs to be universal. Everyone uses the same identifier numbering system so it is not the individual order number or lot number or serial number."

2. What should be the role, if any, of FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?

The FDA should be the arbiter and gatekeeper of information received in discussions with stakeholders such as manufacturers, packagers, wholesalers and end-users. In addition, the FDA should determine which nomenclature is the most suitable and serve as the regulator for ensuring compliance with the requirements. Currently, there are multiple and varied product numbering and coding systems, such as GS1, UNSPC, HIBCC, UMDNS to name a few. Many are in use but because the FDA does not require a particular nomenclature or vocabulary, there is no consistency. If a voluntary system were going to work, there would be a usable system already affixed to devices like the NDC is to pharmaceuticals. Therefore, we support a regulated, mandatory UDI with a global nomenclature.

VHA and UHC member hospital respondents recommend the FDA provide oversight, development and adoption of the requirements for a standard identifier

system before the manufacturers create their own. End user facilities cited the need for a specific implementation date with regulatory and enforcement guidelines.

Novation, as well as a majority of survey respondents from VHA and UHC member facilities, support a mandatory system. If a voluntary system worked, there would be one in place currently. One can look to the implementation of RFID drug pedigrees to see that a voluntary system may not be the best solution.

Selected member comments:

“The FDA would likely be a candidate to act in the same role that IEEE does in issuing IDs to manufacturers of IP enable devices. The system should make the vendors then responsible for matching the unique # to a device. Vendors should also be required to keep elements of the manufacturer database accurate, such as contact information. The FDA should then maintain the database open to the public in a completely unrestricted fashion just as IEEE does with MAC address assignments.”

“They should be the clearing house that ensures no duplication of identifier and a source for consumers to reference to ensure our databases match for quick and accurate reference in the event of a recall or alert.”

“It would be very useful if the FDA could mandate or encourage manufacturers to maintain user relevant information on web sites so that only a UID would need to be entered and all of the above elements/attributes are provided or expounded upon. For example, it would be useful to see UL test report results, or verification and validation testing results that are applicable to a particular device, also instructions for use, maintenance info, technical bulletins, advisories, recommended cleaning/ sterilizing methods.”

3. What are the incentives for establishing a uniform, standardized system of unique device identifiers?

The incentives for establishing a uniform, standardized system of unique device identifiers include:

- Efficient product recalls for health care facilities and manufacturers thereby providing a positive impact on patient safety
- Improved adverse event reporting
- Prevention of errors related to device use such as using a recalled product
- Catalyst for harnessing the power of health information technology (for example, accurate entry of information into the electronic health record related to medical devices used on or in a patient)
- Implementation of a uniform, reliable credible system of product identification will be recognized globally similar to the National Drug Code (NDC) in drug products

VHA and UHC member hospital respondents consistently stated that UDI implementation would provide incremental benefits in the area of device recalls and patient safety.

Selected member comments:

"Collection of all information regarding a defect or failure of a product. An example would be a staple line on a surgery that has failed. Data would be submitted regarding the device used and a search could be done to see if it is a repeat problem or a one time issue (user error instead of device failure)."

"Ease of recalls and identifying who has the devices."

"In the event of a recall or alert everyone can quickly and easily identify the device in question. Too often you get a notice from a manufacturer with some obscure product code that means nothing to me. Whenever anyone refers to any product there should be a common I.D. that everyone can quickly identify and or locate."

"Recalls and hazard notices."

"Reduce overall cost of data/pricing management; promotes asset tracking; promotes preventative maintenance practices."

"Safer environment! Better product recall process, thus helping to ensure patient safety & staff safety."

"Improvements in efficiency and safety; ordering would be easier; recalls more efficient."

"Streamlining of product charge masters and product acquisition to reduce expenses within the supply chain."

"The manufacturing industry would benefit from a standard format/length ID--easier to specify as part of the design, standardized UDI might mean less expensive methods for applying the ID to the device. Clinical engineering departments would not have to establish unique identifiers for equipment management, and could use web based management systems since the UDI would be unique within the entire database. The industry might benefit from greater transparency between the developers, manufacturers and maintainers of devices/equipment by using this type of system. UDIs would facilitate cradle to grave tracking, proper disposal of items with hazardous materials."

"This should not need incentives beyond this being deemed best practices in the realm of delivering safe care to the customers of the medical community. The unique tagging system offers a way for healthcare organizations to relate defective or equipment that may need hardware, firmware or software upgrades. It is most effective for all parties to support a common solution. After the standard is constructed and supported by a number of major manufactures, customers of biomedical devices will then have a tendency to seek out "certified" vendors that use the standard."

4. What are the barriers for establishing unique device identifiers?

The barriers for establishing unique device identifiers include: the lack of a standard unique device identifier accepted by all stakeholders; inability to come to consensus about appropriate technology; additional cost to suppliers.

VHA and UHC member hospital respondents stated barriers to creating a UDI system include: lack of agreement on the identifier, cost, lack of manufacturer

compliance and lack of IS capability to implement. A few respondents suggest a UDI system should be mandatory.

Selected member comments:

“Existing serial numbers and asset tracking numbers used by manufacturers and clinical engineering departments. An adequate transition period would be useful to help, ensuring the UDI is machine readable would help implementation, and perhaps coming up with a way for owners/maintainers of items that were not manufactured with a UDI to assign a UDI that conforms to the established requirements would also help.”

“Getting people to agree on what it needs to look like then getting all to be compliant. Only way to overcome barriers is to mandate the need for this process. Care needs to be taken though as manufacturers will send forward the cost of this to the hospitals and patients. This should not be allowed as the manufacturing community has a huge profit margin and many hospitals are barely keeping their heads above water.”

“Manufacturers fear of identity loss, cost; manufacturers sell on the premise that they have the BEST. An identifier number might be threatening to their perception/advertising.”

“If the regulation is mandatory, every manufacturer will be in the same situation. I doubt the users will even recognize the number, however the purchasing entity will and this would make comparison eminently easier.”

“The assumption that there is a quick fix; identifying an organization that is willing to foster communication and establish a standard that is effective and they are committed to follow.”

5. Have you implemented some form of UDI in your product line? Please describe the extent of implementation, type of technology used, and the data currently provided.

While not a manufacturer of products, Novation does contract with manufacturers for medical devices. Novation currently requires manufacturers to place a bar code on all medical devices in the NOVAPLUS[®] private label. Novation requires the use of a nomenclature recognized in the United States and requires the symbology of the bar code is machine-readable. In addition, the product must have a human readable product code.

Currently, it is difficult to implement fully UDI systems or measure the positive impact because there are multiple methods of product identification. Facilities are faced with having to create or adopt identifiers for the tracking of capital equipment requiring inventory and preventative maintenance. In addition, inventory management and purchasing systems have various product coding or product master files.

While this appeared to be a question for manufacturers, several VHA and UHC member hospital respondents said they have implemented some form of UDI in their facilities in order to manage product inventory, charges and preventative maintenance.

Selected member comments:

"BioMed department assigns their own identifying number and tracks the equipment in their database. All equipment coming into the facility through BioMed receives a number before being released for use."

"We are not a manufacturer. We are a hospital system that uses unique asset tracking numbers for medical equipment items."

"We assign a Lawson number to each item purchased and have a central organization surrounding item master management."

"We have a partial system. CMH puts a unique number on pieces of equipment used within our facility. I cannot say this is done with every piece of equipment but it is on most pieces."

"We use the ECRI nomenclature."

6. Should unique device identifiers be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?

Yes, unique device identifiers should be considered for all devices; however, the data elements within the UDI for various classes of devices may vary. For example, having a UDI down to the individual exam glove is not necessary; however, being able to identify the manufacturer, product description, size and lot number are essential. Capital equipment and implanted devices such as pacemakers, stents, and joint implants as well as some products that are used in an invasive manner, such as intravenous catheters or central venous catheters, may require additional elements that enable unique identification of a particular device. This could be accomplished through product serialization.

Well over a majority of VHA and UHC member hospital respondents believe unique device identifiers should be considered for all devices. Those that responded yes cited ease of product recalls, safety issues and tracking as the reasons why UDIs should be considered for all devices. In addition, there was a trend in the responses expressing concern about data integrity if some devices had UDIs and others did not.

Selected member comments:

"This will enable either barcodes or RFID readers to identify products for ease in user inventory (stores receiving stocking and dispensing). Users can scan the device and the patient armband and instantly charge the right patient for the right product. See significant savings in lost charges for health care providers. [UDI] will be a great help in inventory, audits, stocking, dispensing, product identification, identification of all items used for specific DRG treatments. This will assist in more reasonable reimbursements from all 3rd party payers. It will allow easier review of items used for treatment and ability to identify excessive use, loss of products, evaluate if all products used are really beneficial to the treatment, enable treatment comparisons for the improvement of therapy regimens."

"Ease of product identification for cost savings, standardization, patient charging, recalls, safety improvements, etc."

"You cannot just do a part of this or the data will not be correct or accessible in only certain areas that have this identifier."

"Any medical device item can be recalled. Therefore all should have a standardized labeling system."

"Standardization in ordering, tracking, recall notification would all be easier and more efficient with an identifier that is understood by all."

"As a consumer of devices, a consistent system will simplify our needs to track, organize, maintain and replace various devices. If it is not used on all devices, the entire process will be of limited value to the consumer of the various devices. It will be just another number and the device consumer will still have to derive a proprietary way to track and maintain devices."

"In the personal computer world, Gartner Group demonstrated in their studies that total cost of ownership maintenance expenditures exceeded by an order of magnitude the purchase cost. So lower the TCO with automated management programs. Pumps and even beds now have network connections so they can be monitored remotely. It is a small step to UDI."

"So no matter who refers to any device they will always be talking about the same device without question."

"For the purposes of making specific comparisons and the ability to track recalls."
"Recalling a device is easier when you have this kind of data."

"We should strive to synchronization on as much product information as possible and practical. All devices that have an impact on patient safety need to be tracked for patterns of malfunction. "

7. At what level of packaging (that is, unit of use) should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, what should be the minimum data requirements?

As with pharmaceuticals, the smallest packaged size should be considered. The level of packaging should be based on the type of device. It is not practical to have a UDI for every item; however, it is not practical to have a UDI down to the box or case. When appropriate, individual products should be serialized, and these would include but not be limited to infusion pumps, implanted cardiac defibrillators, stents, joint implants, MRI equipment and pacemakers.

The minimum data requirements should include at a minimum:

- Manufacturer
- Description of the product
- Size
- UOM
- Lot number
- Serial number unique to the device if appropriate
- Expiration date if appropriate

- Reprocessed if appropriate

VHA and UHC member hospital respondents frequently mention that UDIs should be considered at the individual unit of measure level.

Selected member comments:

“At the level of product itself and the packaging of the product. Cases get discarded. The packaging itself and possible the product itself.”

“Everything from a packing slip to the box it's delivered in, to the equipment case itself should have exactly the same UDI.”

“For equipment labeling needs to be on the equipment. For sterile items labeling needs to be on the outside package and on the inside package. If this could be bar code technology that would facilitate use.”

“For equipment, eaches; for disposables at package level.”

“In computer networking a Media Access Control address (MAC address) is a unique identifier attached to most forms of networking equipment. Most layer 2 network protocols use one of three numbering spaces managed by the IEEE: MAC-48, EUI-48, and EUI-64, which are designed to be globally unique.”

“It should be at a level of packing that will quickly and effectively identify a (or more) device as compromised. Depending upon the device, the manufacturer is already doing this with serial numbers or lot numbers.”

“Lowest unit of measurement is level I would want. Not to different levels of packaging. Just adds to confusion. One number, one item.”

“Should be on the "Each" level. Packaging size indications would also be helpful. Permanent labeling on hard surface reusable devices.”

“Since many items are removed from boxes, all individual items should be labeled.”

“UDI/GTIN is at the package level. If you do not do this you will continue to have UOM issues.”

8. What solutions have you developed or could be developed for addressing the technological, equipment, and other problems that might arise in developing and implementing a UDI system (e.g., solutions for packaging issues)?

There are several solutions for addressing the potential issues with implementation. Once the UDI methodology is determined for each product or product category, a method of placing the unique identifier on the product will need to be determined. Based on the type of product a bar code may be the best method however, for other products; RFID, etching or an attached plate may be the better choice.

Some VHA and UHC member hospital respondents suggest bar coding, while others have implemented whole system RFID to track equipment. There is a trend in the member responses citing a collaborative effort based on electronic

standards for health care. The ability to affix the UDI to the device may be an impediment, but one that could be overcome with consideration of the nuances of the specific device. If every battery, every printer cartridge and vehicle has a unique identifier, then it is feasible that this could also be accomplished for a hip implant.

Selected member comments:

“RFID based solutions would help with some issues, as would other machine readable UDIs.”

“An overseeing group (combination of manufacturers, consumers, & purchasing alliances) that represents the best interests of the UDI project should receive all suggestive issues and collectively issue a “best practices” ruling. The collective of the “best practices” should be easily accessible either for free or through affordable “membership” to the overseeing group.”

“Bar coding is available in many places so this would help with implants. If the codes (UDI’s) have to be manually entered into an EMR then they need to be big enough to be read easily and simple enough to get entered.”

“(Our facility has) developed an electronic item master. Can track manufacturer’s re-order numbers, place all orders via EDI. Have specific contracts for each item. Can track area of use, volume used, alerts to change in price daily. (It) would be helpful if each identifier had a code that addressed its unit of measure. Each individual item should have a UDI as well.”

II. Implementing Unique Device Identifiers

9. What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set improve patient safety? What other data would improve patient safety?

The attributes/elements of a device should include at a minimum:

- Manufacturer
- Description of the product
- Size
- UOM
- Lot number
- Serial number unique to the device if appropriate
- Expiration date if appropriate
- Reprocessed if appropriate

VHA and UHC member hospital respondents suggest the minimum data set should include manufacturer, lot number, product description, size, quantity and manufacture/expiration date. In addition, a serial number would be appropriate for specific products such as equipment and implantable devices.

Several members identified additional elements such as software or firmware versions, and RFID information. For example, if a device requires a FCC license due to use of RF signals, this should be a required element. If the device does not use RF, then the elements should not be required for the device. Other examples

should be acceptable software or firmware elements like version, nuclear regulatory compliance, FDA compliance, EPA compliance, to cite a few.

A majority of the respondents believe a minimum data set would improve patient safety and would facilitate management of recalls and product alerts.

Selected member comments:

“An identifying code for the type of device followed by a unique number to differentiate the model.”

“Date manufactured, identification of manufacturer in an abbreviated way, size if it comes in multiple sizes, name/category/type of equipment, model #, lot #.”

“Device Description, Device Category, Manufacturer, ID Number.”

“GTIN, description, packaging, dimensions, weight, brand owner, seller, bar code.”

“In computer networking a Media Access Control address (MAC address) is a unique identifier attached to most forms of networking equipment. Most layer 2 network protocols use one of three numbering spaces managed by the IEEE: MAC-48, EUI-48, and EUI-64, which are designed to be globally unique.”

“Manufacturer ID, date or lot#, MR compatibility code, fluid ingress protection rating, leakage current rating, device class. “

“Manufacturer’s catalog number in a standardized format and a lot/serial number.”

“The actual device should contain at a minimum a unique identifying manufacturer number, a unique identifying product “serial number”. Don't complicate the device with special technology. Require a “best practices” method for correlating the unique identifier to a non-restricted source that supply chain management vendors and device consumers can obtain the details they need about the device. The source “database” should then have required elements on file based upon the class of the device in question.”

10. How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?

It is our recommendation that the FDA, in collaboration with other organizations such as GS1, ECRI, UNSPSC, and/or HBICC, determine the method and requirements for the UDI nomenclature. Based on the requirements, the responsibility for ensuring that the UDI meets the requirements resides with the manufacturer of the device. One consideration is that some of the data elements could be determined as part of the PMA or 510k process. For those products that are exempt, another method would be determined such as accessing the information from a UDI clearing house such as one of the companies cited above. The same organizations would provide public access to the information, similar to the NDC system.

Some VHA and UHC member hospital respondents believe the manufacturer should provide and maintain the UDI and others believe the FDA or a group such as ECRI should be the keeper of the information. Many suggest having the data available through electronic means such as the Internet and that the information should be publicly available on all devices.

Selected member comments:

"The FDA."

"ECRI."

"Brand owner/seller."

"It should be the responsibility of the manufacturer of the device to obtain and maintain the information to remain a "UDI" certified manufacturer. The vendor should also be responsible for making this information publicly available in a form accessible to most world markets and in compliance to accepted best practices to be developed jointly by the device manufactures. In effect, they should not (disown) the product after it is sold, but support the appropriate dataset for the life of the product they have either manufactured or obtained through acquisition of another manufacturer."

"First manufacturers must submit the UDI's for all products that fit the criteria for submission. Then the mandatory end user reporting of device events will associate to the manufacturer's data. The integrity of the data must be absolute and verifiable. Put it out there on the web for everyone to look at."

"Manufacturers should apply the UDI and maintain logs. User facilities should track what equipment they are using to match lists. Data should be available electronically by internet."

11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?

UDI should be both human readable and encoded in an automatic technology. The UDI should be on the devices, especially the implantable devices. Automation is a wonderful adjunct to practice; however, if there is a failure of automation, it becomes essential to revert to manual processes.

VHA and UHC member hospital respondents indicated the UDI should be both human readable and encoded in automatic technology. They also believe the UDI should be on the device itself when appropriate.

Selected member comments:

"Both [the UDI should be human readable and encoded]- on the device itself with scanning or manual reading capability."

"Build a small handheld capable of reading a device MAC Address or develop software for PDAs that can perform this task."

"For non-computer devices use bar code technology etched into the device with the same reading devices as above so the information can be part of the same data base."

"Readable by both technology and humans."

"The greatest potential benefits are with use of machine readable encoding. The methods should be established as a preferred ranking to allow manufacturers flexibility. For example, some may need to use nanotechnologies.

"With all the electronic systems available, I believe we do not need human readable [UDIs]. An electronic system would make it much simpler to make changes in codes quickly and more accurately."

"Yes, a barcode would be nice and UDIs would be entered into databases the same way every time with no differences - such as dash or no dash, commas, capital letters and so forth."

"Yes, an effective and usable dataset may fall outside of parameters in effect when the product was made. For example, if a firmware upgrade is necessary for a device, it would not be reflected in the laser-etching at manufacturing time."

"Yes, [the UDI should be] human readable and barcodable."

"Yes - not all facilities have barcoding yet. Yes--the UDI should be on the device itself."

- 12. Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a barcode is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the bar code be "compatible" with those used for the drug bar code rule? If yes, why? If not, why not?**

The first step to UDI is the "what" or nomenclature. Then, the next step is to determine "how" to place the UDI on the device or packaging. This may be different for different products. At a minimum, a bar code that is human and machine-readable is feasible and this would be compatible with those used for the drug bar code rule. One potential issue in using a symbology may be the limit on the amount of data that can be tracked. Once the minimum data elements are determined, a symbology selection may be necessary.

The majority of VHA and UHC member hospital respondents stated the UDI should be based on specific technology (e.g. linear bar code). The majority of the respondents also stated that if a bar code is recommended, a specific type of symbology is preferred and the bar code should be compatible with those used for the drug bar code rules. Respondents mentioned the process should be kept simple to increase compliance. In addition, it would allow for the use of existing equipment.

Selected member comments:

Non-specific

"But this has to be a standardized approach not requiring proprietary technology to access."

"Category and usage should be encoded in the UDI, but not delineate the UDI assigned number."

"Not all facilities have the ability to read bar codes. Requiring them to do so could pose financial exposures that they had not planned for. Nonspecific would allow everyone to participate."

Specific

"Barcode assists in safety."

"Standardization lowers costs - the Japanese have proved this in manufacturing. Standardization is key - same formula for everything."

"If everyone has one thing to work from then consumers won't have to purchase multiple technologies to perform what should be a simple task."

"Actually both would have been my choice. Unless you choose bar code and give people time to get the devices in place you will also need a number that can be read."

"If it is non specific technology, there will be too many options and no standardization of processes."

"The group of manufacturers, consumers and purchasing alliances that are developing the standard should recommend the most appropriate technology that they and their peers should be implementing."

"Use existing standards if at all possible."

"If allowed to be variable, then it is not standard."

III. UDI Benefits and Costs

- 13. From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify.**

A centralized, universally recognized system for standard identification of medical devices will help to reduce errors, and assist in recall and adverse event reporting. While it has been said that there should be more evidence that UDI would improve patient safety prior to regulation or mandate, it is difficult to measure the impact of something that does not exist. In consideration of the 1,500 or so device recalls issued in 2005 with 67 of those being Class I recalls, it is not a huge leap to determine that UDI would positively affect patient safety through the efficiency gained in identifying and removing recalled equipment from service.

Currently, there are no unique identifiers to differentiate a new single use device from a reprocessed single use device. When a product fails, is it new or

reprocessed? With the implementation of UDI, all reprocessed products would be uniquely identified, thereby clearly identifying which device failed.

VHA and UHC member hospital respondents often mentioned that recalled products could be located faster, with less human error. It would make the process more efficient (ordering, tracking, inventory, and recall management), from manufacturer to patient.

Selected member comments:

"A common methodology will greatly improve the effectiveness and efficiency of those responsible for maintenance of devices."

"Encoding device compatibility or compatibility with cleaning methods would lead to fewer application errors and device failures. UDIs would facilitate more economical asset tracking hardware and software, improving device readiness/availability/usage, reduce losses, save costs for replacing lost assets."

"Faster notifications for patient safety."

"I am a CIO. All our devices have MAC Addresses. Our help desk software allows automatic inventorying of network devices. We monitor, at almost no cost per device, all incidents on devices. Each month we review these records to rid ourselves of lemons. We are also able to electronically monitor Mean Time to Repair. We could add on to this system and any other device with a MAC Address at no additional cost. Most hospital IT shops have these monitoring tools in place. I am not sure except standardization seems to reduce confusion that sometimes contributes to an adverse event."

"I believe that we underreport issues we have with equipment and supplies. This would require detection and reporting early and thus make available info to all users that there is a product problem. I think that many manufacturers do not have the ability nor do they have the interest in doing forensic evaluations of failed products. You send it in and get back that it must be user error. If there are many of these happening, then it will cause the identification of serious issues with a product to happen quicker, thus exposing fewer patients to poor products."

"I would not have to deal with the confusion of each manufacturer having different product codes. This would make ordering, tracking, inventory and recall management easier. It would also help manage costs better since I wouldn't have to know each manufacturer's codes to pull usage and cost information."

"Increased knowledge regarding a recall is directly proportional to increased compliance with getting affected product recalled. If it is easy to track, it is pulled much faster."

"System would remove transposing of numbers, human error issues and when then reduce errors to patients due to being able to scan item rather than key in and possibly have human error."

"There would be no devices missing when a recall occurs, eliminates a person's opinion as to whether their device applies."

"Track and trace from manufacturer to patient [and make it a] part of the patient's record. How else are we going to secure the supply chain?"

"[A UDI] would enable users searching for recalled products a much easier method to find these items rather than a manual search. Could part of the code be an expiration date so you could search electronically at the end of every month for all items expiring?"

"Would facilitate recall, adverse event reporting and verifying five rights of administration for drugs; reduce medical errors by linking specific devices to patient care activity."

14. From your perspective, what are the setup costs measured in time and other resources associated with the development implementation, and use of a UDI system? Please submit detailed data to support these cost estimates.

VHA and UHC member hospital respondents are unsure about setup costs. A few respondents indicated the cost could be minimal if an existing database such as ECRI, GS1 or UNSPSC is used.

Selected member comments:

"Development of the identifiers will be first up front cost. Then each manufacturer would have to add to their current labeling systems. I have no cost information available to me on cost of labeling changes. I would think that maintenance and administration of the database will be the largest expense in the long run. Hospitals will have to set up a system to collect data. If there is an electronic medical record in place this will not add to costs. If not then alternatives will need to be put in place. The cost will be dependent on how extensive the UDI process is."

"Set up costs for a new device would be insignificant. For transitioning an existing device, it would take about two years. Implementation costs for the IEEE symbols should be looked at for baseline estimates."

"Setup time for an item file would take considerable time, but some GPO's and other companies are offering this as a benefit. GHX will add UNSPEC codes to our database for those vendors we are currently using EDI technology. This may be a method to get compliance. Many institutions are already using bar code technology or are moving towards it. Investments in software could be expensive; another reason for a common numbering system that would allow all users to access same software/hardware system."

15. If you have already implemented a form of unique identification on your medical device labeling, what investments in equipment, training, and other human and physical resources were necessary to implement the use of UDIs? What factors influenced your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since the institution of UDIs?

Members of VHA and UHC frequently cite the biomedical department as the implementer of UDI in order to track and inventory medical equipment. In addition, many facilities have inventory management systems through materials management or central supply that may or may not link to reimbursement and the electronic medical record.

Selected member comments:

"We have had to use unique identifiers for equipment tracking for as long as I can remember. Costs are minimal, but our system will always miss some equipment items since it is dependent on 100 percent knowledge of what is brought into the facility. A UDI could be something that automatically comes into our system once a purchase is received through our materials management system."

"It is done manually by the biomed department."

"Our biomed has established codes."

16. From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?

Acceptance begins when the UDI system is determined and clearly becomes the consistent method of recognizing and tracking products throughout the supply chain. The most efficiency is to be gained through methods of automatic identification; however, the rate of adoption of a specific technology will vary based on the health care setting. VHA and UHC member hospital respondents indicated the rate of technology acceptance could be high if the cost to implement is low (for example, upgrading systems to accommodate new technology versus using current systems.)

Selected member comments:

"Fast for vendors to implement. Slower for users to upgrade their technology in order to read the bar coding."

"From a materials perspective, acceptance would be as soon as one could find the money to implement."

"If it is a recognized standard, then acceptance would be as vendors support the technology."

"It could be high if low cost and possible within current existing systems; meaning few manual steps."

"Moderate. The health care industry must be convinced that it is the right thing to do."

"Next fiscal year they should change. This isn't rocket science."

"Technology systems would be developed quickly within the first 2-3 years that take advantage of UDIs. Ideas would washout and systems would mature in 5-8 years."

"We have computer Physician Order entry, computer based documentation, and this goes along with the same expectations."

17. From your perspective, what are the obstacles to implementing or using a UDI system in your location?

One of the greatest obstacles is consensus about the UDI nomenclature as well as the best method for associating the identifier with a device. Additional obstacles include legacy device identification, variability and complexity of different devices, data synchronization and health care facility readiness for change.

VHA and UHC member hospital respondents stated the following barriers to implementation: changing existing database and/or systems, cost, and cooperation between the end-users and the manufacturers.

Selected member comments:

"Changing our database from what is entered now to what it may change to would be time consuming. However it would be greatly beneficial."

"Changing over from our existing equipment identifiers and perhaps any needed changes within our materials management systems."

"Cooperation has proved to be the major problem; review the history of HL7 in the interface world."

"Cost of developing, implementing and maintaining."

"Expense."

"Getting all parties to agree on a standard system. Manufacturers do not want to have a common # for their individual products as they feel any such item such as a band aid would then be open to a "number" and there would not need to be a certain mfg's product, but whatever band aid would work."

"I believe our medical center and distributor would be very excited to do this."

"Prioritization"

"Vendors charging significant premiums associated with the standard or certified methods (of UDI)."

18. For hospitals and other device user facilities considering technology investments, what would be the relative priority of developing UDI capabilities compared to other possible advancements, such as Electronic Health Records, bedside barcoding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities and other possible advances?

The VHA and UHC member hospital respondents indicated a varied level of priority of developing UDI ranging from low to high.

Selected member comments:

"As current devices must be replaced, those with automated UDI would have an edge in the marketplace as well as those vendors offering Internet monitoring and management."

"As related to patient safety, this would be a medium priority unless we could justify a higher priority based on cost savings/avoidance. It depends on how you justify the expense."

"It is relative to the cost, but the effort for UDI is focused more toward the materials management, bio-medical, and facility management departments that are not as directly impacted by the efforts to implement clinical software capabilities."

"Low if the technology level is pre implementation of the EMR."

"Part of the same system. Data on EHR must be accurate."

"Probably low on the list until some of the above (UDI consensus) are accomplished."

"Relative priority would be lower than the initiatives stated, but would still be significant."

"Same level if not higher since this could potentially be a patient safety issue."

"Very high priority."

"We already have most of these in use. UDI is just the next step"

"We are currently about half implemented with EHR, [and we] are implementing a system for 5 point verification and barcoding at bedside and dispensing. My feeling is most hospitals are ahead of us or are moving in same direction at different speeds."

19. What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes? How costly are these advancements?

VHA and UHC member hospital respondents mentioned that barcode readers and software capabilities are needed to capture and use UDI. Some respondents indicated the facilities would need wireless networks.

Selected member comments:

"Advancements are costly. Infrastructure costs may be in place or being planned already such as wireless networks."

"Broader use of barcoding [and] equipment management."

"EHR are a must in order to follow with bar codes."

"Everything exists for those devices that are network aware. The bar coded devices would take some development and [can] be slower to adopt."

"Most hospitals already have medical equipment databases through their biomedical/clinical engineering departments."

"Organization, technology and process. It is expensive but the ROI is there."

"RFID, barcode readers and interface w/ our IS technology would be required"

"Simply manpower to change the database. We currently have barcode technology that would make it even easier if that was implemented as well."

"Software capable of support whatever standard methodologies are needed."

"We have wireless technology throughout the medical center, [an example includes] robots to deliver supplies. It doesn't seem the costs would be as much as these previous systems cost."

20. Referring specifically to completing medical device recalls in your hospital or other device user facility, for what share of the most serious (Class I) or next most serious (Class II) recalls would having Access to and an ability to capture UDI information help you to respond?

The vast majority of VHA and UHC member hospital respondents agree that UDI information would help them respond quickly to most Class I and Class II recalls.

Selected member comments:

"All, our current ID system is cross referenced to manufacturers information. Because our current ID is a primary data field, we can only track down items through the cross referencing which can be incomplete."

"Both Class I and II."

"Everyone from the purchaser to the clinical technician would easily be able to know what device is at question. Now you just about have to get a committee to try and determine what (device is recalled) and do we or don't we have that device?"

"I can now look up the manufacturer item number quickly. However it is much harder to track down capital hard equipment, one time buys, and trial equipment. We would need to require a log in electronically of all these items in order to be able to capture them."

"If a standard number system was implemented, the data for recall would be in the keepers system and would be easily accessible for recalls."

"[This would be] invaluable - especially if driven by the vendors over the existing Internet connections."

"It would be a great help."

"[It would help] track and trace accuracy. We could respond more quickly and know more definitively what we had purchased and could then track it down proactively rather than waiting for response from our users."

In closing, we hope the information shared will prove useful to the FDA as it moves forward with this important initiative. Thank you for the opportunity to provide comments and to reiterate our strong support for a regulated, mandatory unique device

Andrew C. von Eschenbach, M.D.
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identification system with a global nomenclature, similar to the FDA's National Drug Code System. We look forward to working with you on this important issue that will improve patient safety, reduce medical errors, facilitate device recalls and improve device adverse event reporting, and positively impact supply chain operational efficiency.

If you have questions or comments, please contact Novation's Cathy Denning, R.N., M.S.N., senior director of contract and program services at 972-581-5041 or cdenning@novationco.com.

Sincerely,

Jody Hatcher
Senior Vice President
Novation