

DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006

1. *How should a unique device identification system be developed?*

Choose an existing UDI technical model, that would incorporate UDI interoperability with the patient Healthcare Record (PHR), Infection control, reporting of adverse events and resolving UDI database security issues. Preference UNSPSC

The UDI Model should have five major components:

- a. Allow for variable data fields on an Auto-ID label (RFID tag, 2D Barcodes, etc.)
- b. Universal translator: Nomenclature Sequence Code (NSC): Bridges and Maps the 11 different medical device naming databases by establishing a relational universal number for each device.
- c. Privacy Preserving Index (PPI): provides confidentiality, data integrity and user authentication.
- d. Nomenclature Sequence Server (NSS). This is a secure relational database that directs queries and retrieves information through the PPI creating a de-registered database environment.
- e. A model for a rules based semi-automated mandatory reporting system of adverse medical device related events.
 1. Mandatory for electronic medical devices : Device remote maintenance (DRM)
 2. Voluntary reporting with incentives for medical device non- electronic instruments and supplies.
 3. Primary UK Study: *Winning ways: working together to reduce healthcare associated infection in England* (DH, 2003)

1a. *What attributes or elements of a device should be used to create the UDI?*

Tag UDI Elements:

- Manufacturer or distribution company
- Make
- Model
- Lot Number and Serial number in the same line/ field
- Expiration Date
- Software version
- Universal Translator Number (NSC, PDU, UDEF, PLDS)
 - The key will be setting up variable fields to include pointer information to a database.

Database Elements:

Items that would reside in a UDI database reference system:

- Manufacturer (from UPN- EPC)
- Make (from UPN-EPC)
- Model (from UPN-EPC)
- Distributor
- Contract Manufacturer
- Original Equipment Manufacturer VS the Distributor
- Labeler (use the GS1 or UPN definition) HIBCC - Healthcare bar code (**medical/surgical & devices**)
- Places of Manufacturer (this can be more than one)
- Date of Manufacturer
- Number of uses allowed (reprocessing etc. These can be used)
- Number of uses so far (added by Bill Newcum)
- Expiration date
- Component, Kit, Parent/Child Relationship
- FDA Approval or marketing basis (Good Practice Marketing, BPM, 21CFR802)
- Adverse event reporting (history)
- Regulatory Compliance
 - Software compliance
 - CPT compliance
 - Maintenance compliance, post-approval (??)

DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006

- Safety alarmed compliance
 - Device instructions/ Labeling
 - Returns & Recall Management
 - Service and Warranty Authorizations Maintenance
 - Company generic model name
 - Version, especially software (needed for device remote maintenance)
 - Models within version
 - Method of reprocessing
 - Date of last update and by whom Software
 - Device may contain patient identifiable information (Y/N)
 - SNOMED procedural nomenclature, clinical term (CT), must be tied to patient's episode and procedure
 - Include clinical attributes (CT) such as allergens, adverse reactions.
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?*
- a. The FDA should intervene and resolve the political warring factions between the 11 public global nomenclatures.
 - a. Here are some suggestions in the hopes to ending this impasse.
 - i. One offers money in exchange of licensing IP from the other, receiving an on going annuity.
 - ii. Find a non-bias intermediary organization where both to hand over IP for on going annuity.
 - iii. The respective governments will trump both organizations and both will have to follow a mandate and deal with the resulting outcome.
 - iv. Either organization can politically trump the other by yielding its code to an existing accepted data standard organization, thus elevating the problem from their level to a more politically internationally active level.
 - v. Either organization can run a PR campaign and try to sway public opinion. (costly and ineffective)
 - b. The FDA should design a plan that compensates the losing non-nomenclatures as a 10 year pay out for their cooperation in conversion/ mapping to the universal translation number/ code
 - c. The FDA should allow a 3-5 year voluntary compliance
 - d. The FDA should be the major vote in an industry-provider- government compliance council.
 - a. This government group to involve
 - i. CDC
 - ii. NHIN
 - iii. FDA
 - iv. Bill ([S 3678](#)) : Department of Homeland Security Funding for biosurveillance systems and Public safety networks

DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006

Expectations for Government

The key desired actions of government are to:

- Facilitate development of national standards and code sets (57 percent cited as an "extreme" expectation; 22 percent cited as a "high" expectation)
- Provide grant funding (45 percent extreme; 35 percent high)
- Provide payment incentives (38 percent extreme; 32 percent high)
- Simplify the Medicare payment system (37 percent extreme; 26 percent high)
- Accelerate investment in regional networks (26 percent extreme; 37 percent high)

3. *Should a system be voluntary or mandatory?*

The UDI model should be written as a 3-5 year voluntary recommendation, followed by a 2-5 year mandatory standard

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

Incentives

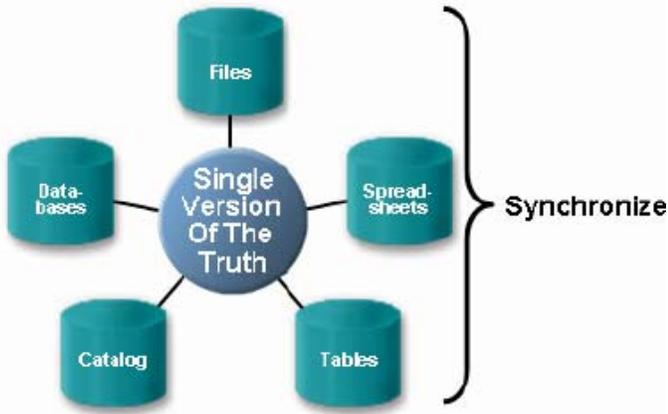
- a. Reduction of hospital associated infections, reducing mortalities through ensuring sterilization and proper device usage on the correct patient.
- b. Matching patient data records to diagnosis, treatment and device to patient schedule/ procedure and infection cause.
- c. Device maintenance and increase regulatory compliance reporting – in cases where infections have been passed from patient to patient due to improper device maintenance
- d. Reduce theft and counterfeiting of medical devices
- e. Enable a process to track the reprocessing, recalls, rentals and loaning of medical devices
- f. Increase supply chain asset visibility resulting in, increased productivity, administrative efficiencies and billing accuracy

**DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006**

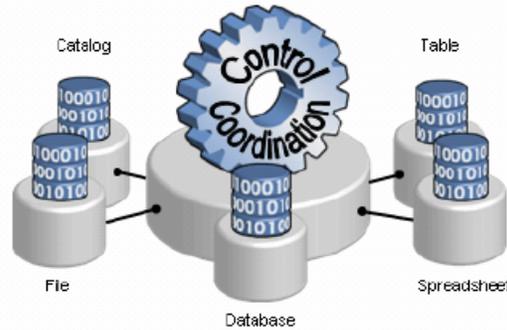
4. What are the barriers for establishing unique device identifiers? Diagrams A B and C

A. EXTERNAL Synchronization

B. Internal Synchronization



**Internal Synchronization
Data Use: Option Three**



C. Internal Synchronization

**Internal Synchronization
Data Cleansing**

What suggestions would you have for overcoming these barriers?



1. Establish UDI recommended Standard
2. Allow 2-5 years for standard to be phased in from a systems and voluntary standpoint.
3. Move at the speed of market IT system adoption. For example current PHR and EMR initiatives time frames 2010.
4. Only make UDI adoption mandatory after a full inventory turn of Medical Devices, the industry average is 8 years.

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.

No- I have consulted to companies who are planning to develop a UDI.

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 all devices need to have a UDI and if there are usage cycles, those cycles need to be tracked

- a. Rentals Cycles
- b. Loaners - Consignment
- c. Tracking of Sterilization Cycles
- d. Distributor re-labeling
- e. Most difficult; Reprocessing of medical devices and the associated regulations (FDC 502.u, SUD's and seven others regulations)

**DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006**

- f. The key will be designing a tag/ label that points to the data base containing the additional information.
 - i. The DoD uses a cognizance symbol (commonly referred to as cog) is a two-digit alpha numeric code prefixed to a national stock number to identify the cognizant inventory manager, the stores account and the type of material.

7. At what level of packaging (that is, unit of use) should UDIs be considered?

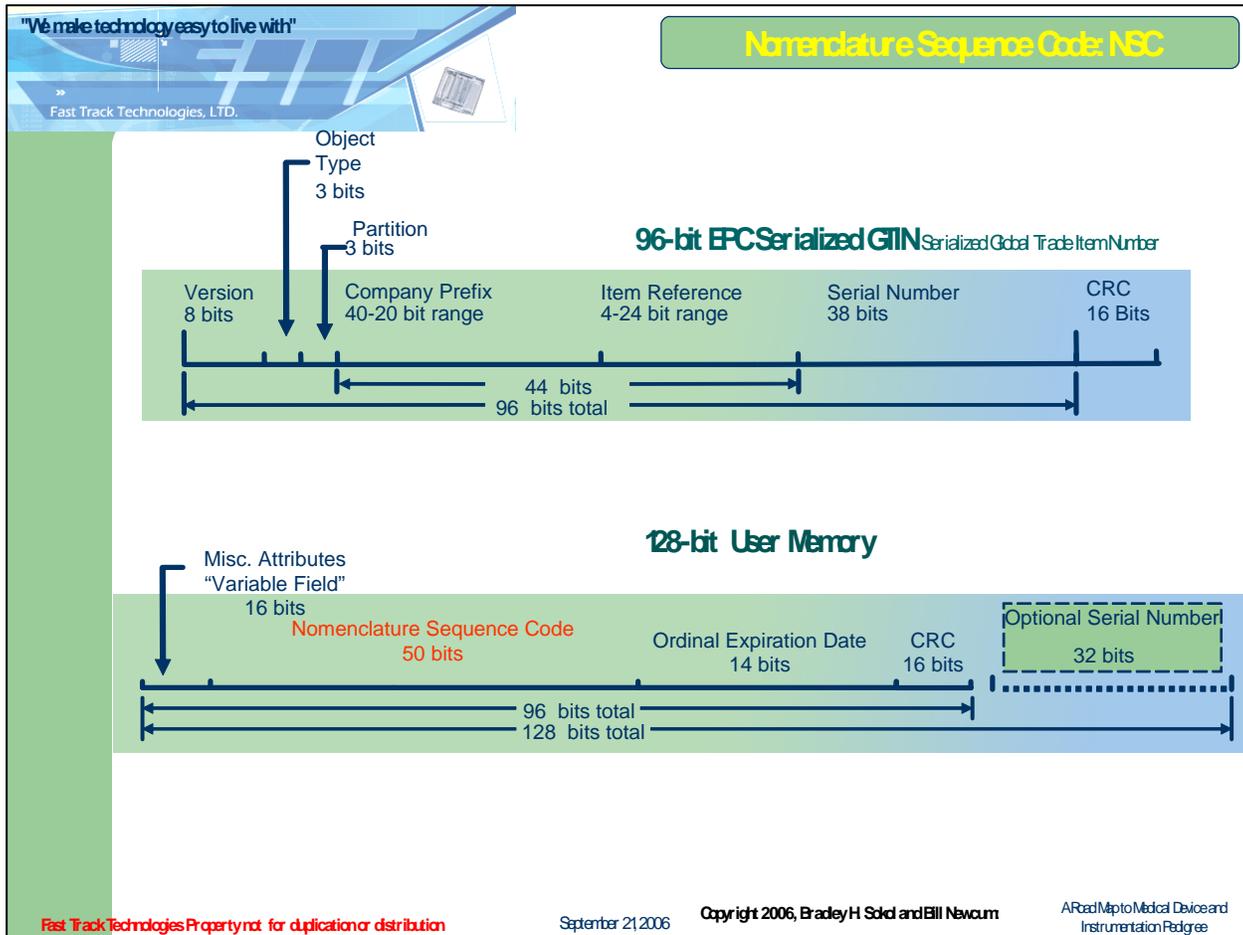
A phased in approach is necessary Starting with:

- a. Case
- b. Item
- c. Serialization
- d. Pedigree tracking

Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device? Why or why not?

The basic information on the UDI should remain the same at any level. It is important to make sure that the trackID media used has enough space for additional field pointers to notate specific events and features required by that device. i.e. SUD or Reprocessed.

With basic UDI elements, even the smallest medical device manufacture could comply with the initial voluntary standards.



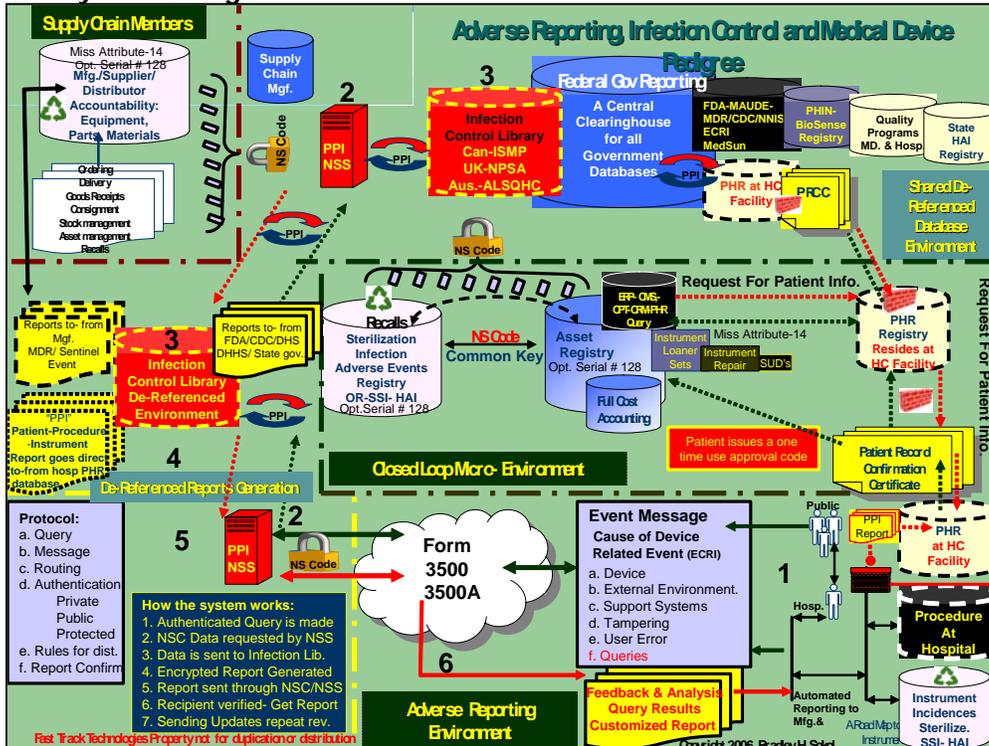
DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006

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)? Implementing Unique Device Identifiers.*

The solutions I have empirically tested are RFID solutions down to the item level.

1. Development of a test universal translator database:
2. Test following scenarios:
 - a. Test recall
 - b. Test Reprocessing
 - c. Test Consignment and rental cycle
 - d. Test Data transfer speed
3. Test Following Materials
 - a. Metal
 - b. Liquid
 - c. Cardboard Box
 - d. Overall conclusion 13.56 Mhz or ISO 18000.3 Mode 2 is the best all around solution: BUT NOT PERFECT!
4. Test following environments:
 - a. Sterilization
 - i. Autoclave
 - ii. Cold- Flash Sterilization
 - iii. Gama radiation
 - iv. Vapor Sterilization
5. Technology Methods (Patient information, EHR, Cost Capturing)
 - a. New Thermographic Sensory Measurement Tags 125 Mhz with visual nano-coating.
 - b. Time/Temperature Indicators (TTI) RuBee 333Mhz -450Mhz
 - c. 402- 405 Mhz wireless implants
 - d. MEMS **M**icro **E**lectro-**M**echanical **S**ystems
 - e. SAW- Sound Acoustical Wave 2.4 GHz

The System Design



DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006

1. 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?

Covered in question 1a. Therefore, I will address existing standards that we must keep in mind when establishing UDI.

Int'l Related standards

- a. Nomenclature is published in Europe as CEN report - CR 14230 - (which is identical to ISO Technical Specification – ISO - TS 20225).
- b. Sub categories are additional to the terms included in nomenclature and are for specific purposes to simplify the data exchange purposes and certification purposes.
- c. These "Sub Categories" will be applied to regulatory procedures within the Global market, as being addressed within the Global Harmonisation Task Force (GHTF)

US Related Standards:

- The ANSI/INCITS 389-393 collection of standards, commonly referred to as the URC standard or the V2 standard (the name of the INCITS group that initiated the standard) defines protocols for describing a target and its properties that are implemented by XML (eXtensible Markup Language) files.
 - a socket file, expressed in XML, that presents the signals and their properties, including what signals are available to be controlled and the types of data the signal variables accept or tolerate (ANSI/INCITS 390), see also code fragments below,
 - a presentation (PreT) file, expressed in XML, which gives details of the URI references for each of the variables defined in the socket file, including the form of interactors and how variables are grouped (ANSI/INCITS 391),
 - a target description file, expressed in XML, which points to locations for all the target files and other discovery information (ANSI/INCITS 392), see also code fragments below,
 - a target-based resource description framework (RDF) file, that gives information about what labeling information is available for the controls, help content, alternative formats, etc. (ANSI/INCITS 393), refers to code fragments.
- Data Submission Standard: XML ONLY for Healthcare due to HL7 and SNOMED
- **True healthcare Interoperability is not possible, without a Universal Medical Device Nomenclature Standard.**

9a. Would this minimum data set differ for different devices? **NO covered in question 7**

9b. If so, how? How would the data in the minimum data set improve patient safety?

Procedure Efficacy (Patient safety, Limit liability, Tracking product life cycle, Product efficiencies and Unified reporting)

9c. What other data would improve patient safety?

2. 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?

- Example 1: **The Food and Drug Administration's National Drug Code (NDC) for pharmaceutical products and the National Health Related Item Code (NHRIC) for medical/surgical devices are directly incorporated into the GTIN.**

DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006

- **Example 2:** Using the May 2nd 2006 example of the FDA's announcement to standardize drug information and requiring a standard vocabulary for electronic prescription drug labels starting June 30 2006.
<http://www.eweek.com/article2/0,1895,1956775,00.asp>
- The FDA will use the National Library of Medicine as a "clearing house for the existing medical device terminology standards (UNMDS, GMDN and IEEE 1073), SNOMED_CT/ HL7 will serve as the Data Exchange and interface buss.
- **We expect the same action to evolve with Medical Device Nomenclature within the next 10 months, if the UNMDS and GMDN do not work out an agreement.**
- **Case Study:** The electronic drug labeling terminology solution was given as an alternative in July 2004. **Twenty two months** later with healthcare interoperability deadlines approaching, the FDA made the proposal Mandatory.

10. 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?

The UDI should be human readable and could be encoded on the packaging. Due to new requirements federal and state on repossessing and reuse of devices and SUD's, the only feasible long term answer is an encoded technology given the form factor and material of some medical devices.

Laser Etched ID is dangerous due to the inability for absolute sterility assurance.

11. 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 bar code 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? UDI Benefits and Costs

Based on the answer in question 11, we should phase in the marking technology.

- a. Human Readable on Labels and Packages -
- b. 2D Bar Code- on Labels and Packages and device items large enough to support a 1"x1" label
 1. QR Code- Japan Capacity 4K
 2. Aztec- US Capacity 2.8 K
 3. Print Matrix – US and Europe Capacity 2K
- c. RFID or MEMS chips embedded into supply and instrumentation Items.

12. From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system?

The "Postmarket Transformation Initiative" will develop an electronic reporting system for adverse reactions, standardize the identification process, obtain the medical records of patients who use the devices and increase communication with professional organizations and the medical device industry the [New York Times](#) reports (Meier, *New York Times*, 1/21)

- **There is an absolute need for the UDI system to have the ability to trace back the source of infection to the specific medical tool(s), procedure and patient.**

Please refer to my submission on 10-17-06

Threat Detection (Patient Safety and Increase Sales)

- Detecting exposure of hazardous materials
- Safety of opened product
- Counterfeit Instruments
- Pedigree Laws will directly control the reuse and recycling of SUD's devices by an electronic handshake.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006**

- o Currently at least 11% of the hospitals reuse SUD's. (Increase sales)

Error reduction through technology (Patient Safety New Standard)

- Tracking surgical tools and consumables
- Medical device Visibility Wrong procedure, Wrong Patient.

Document management (EHR and Interoperability)

- Product Recalls
- Eliminates the manual effort required to count and reconcile inventory
- Provides accurate, real-time inventory records
- Locates inventory with pinpoint accuracy
- Increased Government compliance: Easy reporting along the supply chain.
- Increased reimbursement through proper cost coverage in charge capturing and applicable new CPT and CMS codes

Procedure Efficacy (Patient safety, Limit liability, Tracking product life cycle, Product efficiencies and Unified reporting)

- Improved clinical trials reports and reduced cost of development
- Increased recovery Time
- Reduced need of second procedure
- Verifiable Decontamination: Sterilization and decontamination
- Reduce Liability
- Ensure proper Preventative Maintenance as set forth by manufacturer and healthcare provider

"We make technology easy to live with"

128KBits of USER MEMORY for Sterilization in a Closed Loop

A method for sterilization verification and pedigree tracking using a passive tag

- Reader with controller getting info from autoclave conditions.
- Smart label with this autoclave sensitive material printed on it.

Basic system

1. Passive tag, read/ write
2. Reader/ writer: reads and writes tags, 2-way communication with controller.
3. Controller: acquiesces data from autoclave, makes decisions and puts data into a format, passes the data in the right format to the reader when the reader says "something is coming out, what should I write to it".
4. Database: the database resides on a network and the controller feeds it information that the reader writes to the tag with time stamps, conditions, tag ID, etc
5. Autoclave Mfg. could install a controller to streamline the process of data retrieval.
6. The system can be made up of a PC, i/o cards for autoclave, i/o for reader/ writer, and software for writing to a database.

User Memory

Misc. Attributes	Serial Number
16	32 avg.
65,535-64K	2 to the 28 th

↓ Regulatory Compliance Verification

Variable fields, up to 3 separate, event entries - denoted by Y/N flags or numeric flags for Sterilization Cycle #, Recall, Rented, Loans Reprocessing

↓ Cost of Data Ownership

For individual item tracking
 Allows for 5 alpha numeric characters
 4 Billion numeric.
 1st 3 digits for Sterilization Cycle Verify.

Fast Track Technologies Property not for duplication or distribution
September 21, 2006
Copyright 2006, Bradley H. Sold
ARoad Map to Medical Device and Instrumentation Pedigree

DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA

Unique Device Identification; Request for Comments

11-09-2006

13a. How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error?

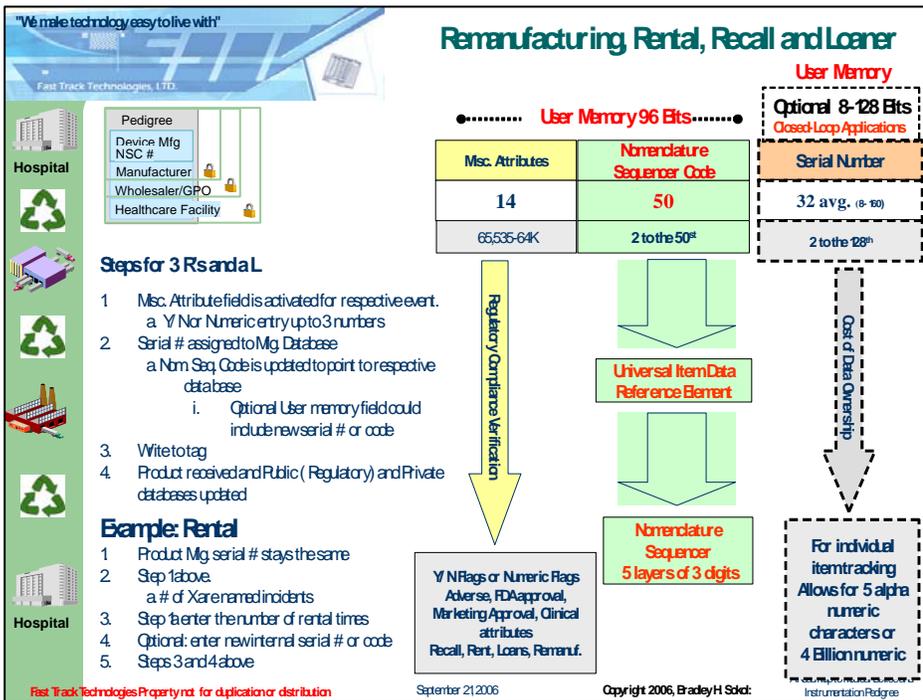
Please refer to my submission on 10-17-06 "Medical Device pedigree with Notes".

A recall is an action taken to address a problem with a medical device that violates FDA law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective *and* a risk to health.

A medical device recall does not always mean that you must stop using the product or return it to the company. A recall sometimes means that the medical device needs to be checked, adjusted, or fixed.

Actions that may be considered recalls:

- Inspecting the device for problems
- Repairing the device
- Adjusting settings on the device
- Re-labeling the device
- Destroying device
- Notifying patients of a problem
- Monitoring patients for health issues



The above chart addresses the following:
Class I recall:

DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006

The company notifies their customers (i.e. distributors or vendors), and directs them to notify the intended recipients of the device (i.e. other vendors, hospitals, nursing homes, outpatient treatment facilities, doctors, or individual patients). The notification usually contains the name of the device being recalled, identifying lot or serial numbers, the reason for the recall, and instructions about how to correct, avoid, or minimize the problem. It should also provide a telephone number for questions related to the recall.

MDR reporting requirements for manufacturers include reporting deaths, serious injuries, and malfunctions to FDA within 30 days; reporting events that require immediate remedial action to FDA within 5 days; and filing baseline reports to communicate basic data about each device that is the subject of a report.

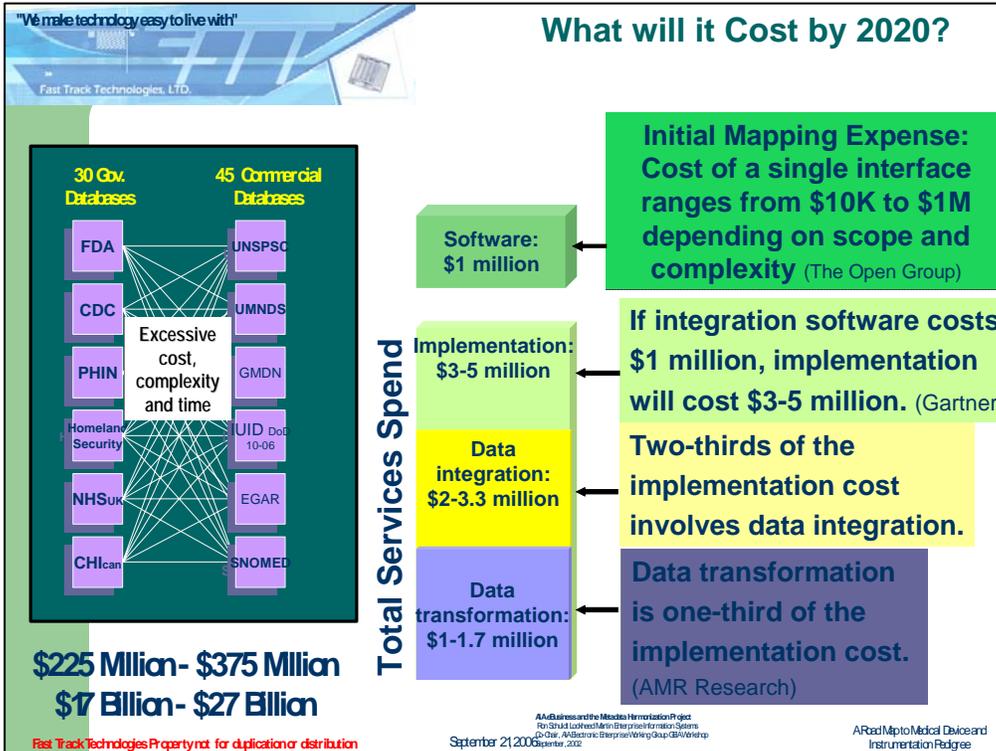
13b. Please submit detailed data to support benefits you identify.

BENEFITS

- 5.1 billion dollars are spent and/or wasted in medical device and Instrumentation errors a year.
- Medical Device and instrumentation Pedigree will reduce liability exposure by 5.1 Billion a year. *Burke JP. Infection control – a problem for patient safety. NEJM 2003; 348: 651-656 and three*
 - 13,000- 26,000 cases a year involving medical device and instrumentation errors
 - Reduce hospital stay by 3 to 7 day per case (33,000 to 147,000 Hospital days)
 - <http://www.showmenews.com/2003/Jan/20030116News024.asp>
- The rapid development of Medical Device connectivity has opened the opportunity for an add-on RFID module.
- 15% of HAI's are preventable: "by the decontamination of surgical instruments": Feb 2001 Report to Scottish dept of health working group. www.decontamination.nhsestates.gov.uk
- The FDA estimates that problems with medical devices result in 300,000 deaths and injuries annually as reported by the Boston Globe. (Kerber, *Boston Globe*, 7/14/05)
<http://www.medicalnewstoday.com/medicalnews.php?newsid=27451&nfid=rssfeeds>
- Aug. 2, 2006 RFID Journal: In more than 10 million surgical procedures each year in the United States, ClearCount reports, registered nurses spend 15 to 30 minutes per procedure counting surgical sponges and instruments to make sure none are missing. This costs U.S. health-care institutions more than \$1 billion annually. Whenever an item is not present and accounted for, the hospital often X-rays the patient to see if the lost object can be found, adding another \$375 million in annual costs (NEJM 1/16/2003).
- Critical care is a complex, non-linear system. As such, it requires systematic redundancy, and rapid and effective feedback control. Application of these principles to the critical care model is necessary to reduce medical errors and provide the kind of patient safety that we need. [Csete ME, Doyle JC. Reverse engineering of biological complexity, Science, 295:1664, 2002.](#)

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.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006**



Supporting detail:

"We have a board of directors that is balanced and a product and pricing committee that is split between hospital and suppliers." He says that GHX operates on a \$35 million cost structure generated by a combination of \$20,000 per hospital integration fees plus an ongoing software maintenance fee depending on the GHX services a hospital uses, along with an annual fee paid by each participating supplier. He says GHX is open to any supplier for unlimited use. http://findarticles.com/p/articles/mi_m0BPC/is_3_27/ai_99121147

1. The parties to each transaction own the data relating to that transaction. The parties are the buyer (e.g., the hospital) and seller (e.g., the manufacturer). If a distributor is legally an agent, then its rights to data are governed by its agreement with the seller, If a distributor is legally the seller, then the manufacturer's rights to data are governed by its agreement with the distributor.
 2. The exchange will not disclose transaction specific data to anyone without the consent of the buyer or seller.
 3. The Exchange may sell aggregated data. Aggregate data may not identify participants, individuals or particular transactions. Aggregate data will only include data from buyers and sellers who consent.
- Curt Werner "[Post-merger Global Healthcare Exchange seeks a balanced market - News](#)". Healthcare Purchasing News. March 2003.

MedSun: Costs about \$20,000 to add a hospital to the system (Kerber, *Boston Globe*, 7/14/06).

September 19, 2006

<http://www.ihealthbeat.org/index.cfm?action=dsplItem&itemID=125063&changedID=125043>

Hospitals in England during the last four months experienced more than 110 "major incidents" after the National Health Service went live with parts of its \$23.4 billion IT upgrade, [Computer Weekly](#) reports. The NHS IT project, which includes an online booking system, electronic prescriptions and an electronic health records

DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006

system for 50 million patients, aims to connect more than 30,000 physicians to 300 hospitals by 2014, [BBC News](#) reports. The online booking system already is a year behind schedule, and the EHR system is at least two years behind schedule ([BBC News](#), 9/18).

Total system cost for the USA: 17 to 27 Billion

Manufactures:	15 Billion	15,000 x \$100,000
Hospitals	2 Billion	6,000 x 33,000
Government	.5 Billion	100 x 5,000,000
Organizations	.5 Billion	200 x 2,500,000

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?

I have not personally implemented a form of unique identification on your medical device labeling

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

The rate of technology acceptance is based on four factors:

- a. Technology confident: General age averaging of staff population : 7 years 35-45 year old employees will be in senior management position who accept technology;
- b. Replacement of legacy systems as mandated by the PHR Patient healthcare record by 2010-2014: 7 years
- c. Inventory turn of old devices. We can plan to inventory over three years if mandates are in place. 3-6 years
- d. Proper funding and profitability are required to undertake this project.

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

- a. Standards
- b. IT Infrastructure
- c. Legacy Systems
- d. Personal Reluctance to change
- e. Government Funding
- f. Tying UDI to Patient safety
- g. Current Devices are fairly new, how do we account for them under the new UDI
- h. Will my GPO have the same UDI?
- i. Who will help pay for this system upgrade?
- j. Training Personal

18. For hospitals and other device user facilities considering technology investments, what would be the relative data sharing capabilities across hospitals and other device user facilities, and other possible advances?

There are several areas of investment:

- a. Internal and external database interoperability
 - i. HL-7
 1. XML
 2. SOA
 - a. SOAP
 - i. Integrated Delivery Model
 - ii. Rules
 - iii. Query

DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006

- iv. Applications
- v. Databases
- vi. Tables
- vii. Catalogues
- viii. Spreadsheets
- ix. Files

b. Passwords and firewall security

- i. PPI – Privacy Preserving Index – **Advancement**
- ii. 128 encryption
- iii. Patient record security

1. One time **Patient Record Confirmation Certificate– Advancement**

- a. In the case of Patent Registry and Patient Record Information:
- b. The Patient Record is kept at the HC Facility
- c. A notification goes out to the patient record file and patient, anytime there is a request for information on the record.
- d. The record can only be updated and accessed by the facility after the patient gives approval or the patient gives a directory of authorized users
- e. The above applies to all government agencies inquiring in the patient record so that privacy issues are protected

Removal of Patient Identifiers in de identified data: Protection of patient confidentiality by removal of personal identifiers from data sets is possible. An excessive concern in this area can remove so many potential identifiers, e.g. regional area of residence in the UK and hospital dates, that the data becomes of no value for research. The development of a concept of reasonable limitation where sufficient identifiers are removed to protect the subject broadly but not in such excess that no useful data remains would be helpful

Application feasibility: The Patient Record Confirmation Certificate can be distributed by Windows mobile-Smart Phone 2005 (Built in certificate security)

c. **Shared De-Identified Anonymity Database Environment**

- i. **An environment that is safe to transfer high security and privacy information between databases.**
- ii. Currently being implemented in UK on a regional basis
- iii. This system structure will allow Anonymity and security (PPI) for both the patient and the manufacturer.
 - 1. **Manufacturer de-identified database:** Manufacturer's of medical devices could also use the de-identified database concept allowing the public to view "near miss" events without fear of retribution.
- iv. The importance of Anonymity for the manufacturer is to motivate them through a Veil of secrecy to voluntarily comply with reporting all adverse events within 5 days.

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?

I covered this over the course of this submission.

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?

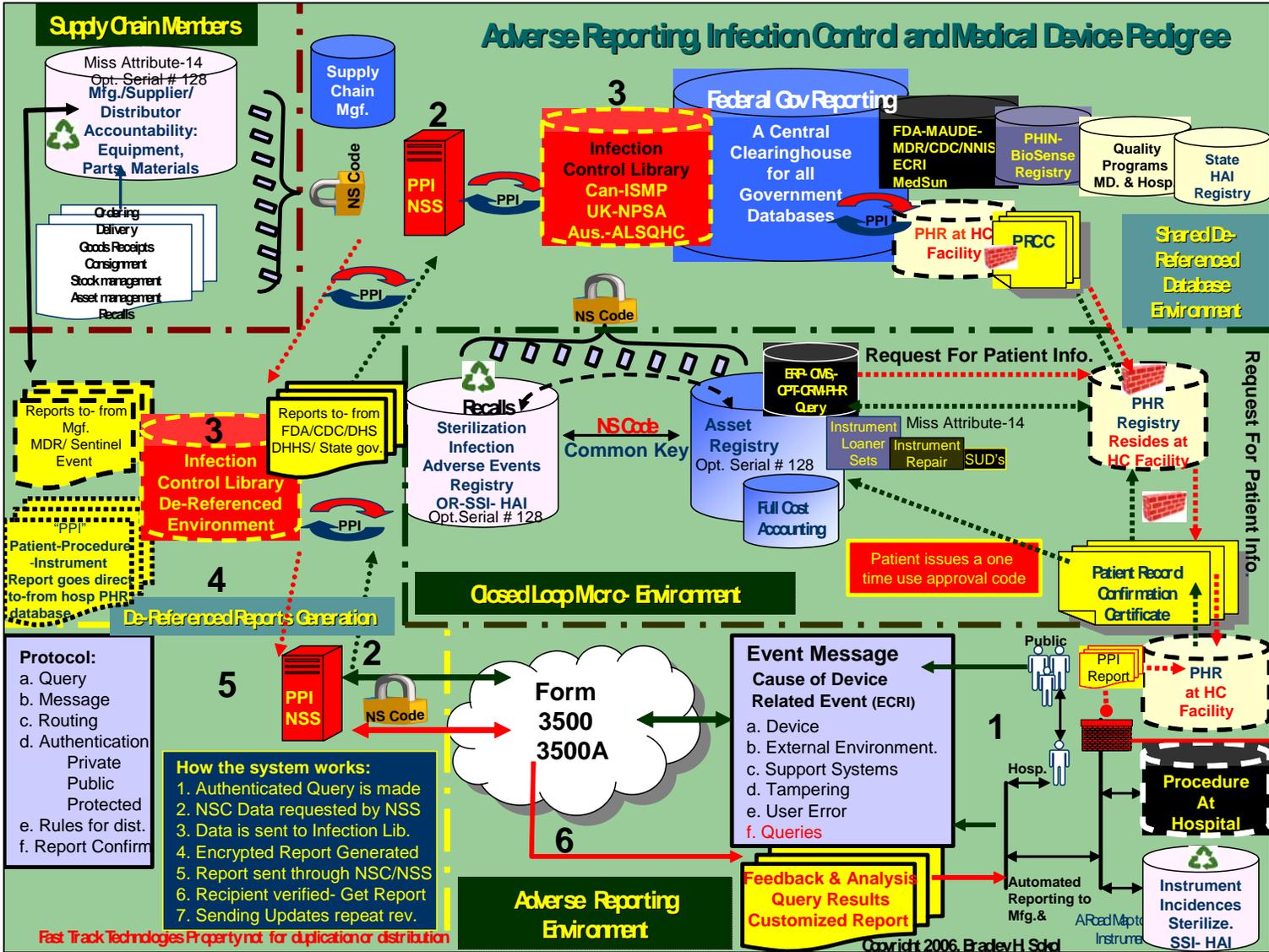
DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
Unique Device Identification; Request for Comments
11-09-2006

- a. Answered in question 13 and question 18c. (Shared De-Identified Anonymity Database Environment)
- b. Additional thoughts are:
 - i. SunMed program ported over to scanning RFID cell phones or PDA's
 - 1. Develop 5 -10 question electronic reporting form
 - 2. A Scanning PDA could interface with UDI database and fill out the MHR and MDR
 - 3. Then a transmission will be initiated to state HAI programs, Homeland Security bio-terrorism database, CDC-PHIN- National Healthcare Safety Network and FDA-MAUDE

CONCLUSION

- 1. Linked the significance of Pedigree, sterilization- instrument-procedure-patient.
- 2. Explained the NSC and it's importance to pedigree and privacy
- 3. Highlighted the security exchange between the NSS- De-registered Database Environment and Privacy Preserving Index (PPI)
- 4. Established a case for Medical Tool Pedigree based on reducing 26,000 mortalities annually through automating systems, procedures and workflow
- 5. Demonstrated how to protect the privacy rights of Individuals and Manufacturers
- 6. Paralleled the EPC data construct and explained how the 128bit User Memory would be applied throughout a medical device life cycle in Sterilization, Maintenance, Remanufactured, Recall, Rental and Loaner scenarios
- 7. Established a case to Incorporate Medical Device Pedigree in the Interoperability Healthcare Model
- 8. Provided resources available today to investigate the implementation of a closed loop Medical Device Pedigree.

DEPARTMENT OF HEALTH AND HUMAN SERVICES : FDA
 Unique Device Identification; Request for Comments
 11-09-2006



Please refer to my submission on 10-17-06 "Medical Device pedigree with Notes".