



"Rationale for a Medical Device Unique Identifier"

A Rationale for a Medical Unique Device Identifier will provide "A Roadmap to Medical Device Pedigree"

This presentation focuses on three areas of opportunity

1. Why a UDI is needed in order to complete the Interoperability healthcare Model and the general benefits realized from UDI

Benefits:

- 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

2. How the UDI can be used to reduce HAI Hospital Associated Infections and increase adverse event reporting through process improvement by automating the closed loop (Healthcare facility).

- a. The key process order events are the 8 L's: last manufacturer, last maintenance, last sterilization, last instrument, last location, last user, last procedure, last patient.

3. Present an overview of one possible technical model, incorporating UDI interoperability, Infection control and reporting of adverse events and resolving UDI database security issues.

The UDI Model has five major components:

- a. Placing additional variable data fields on an Auto-ID label (RFID tag, 2D Barcodes, etc.)
- b. Nomenclature Sequence Code (NSC): Bridges 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



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Differentiating factors versus other similar proposals:

- Focus is infection control: The model has been designed to increase our abilities to detect and have better control over infections.
- The Variable Miscellaneous Field in the user memory that acts as an event definition and pointer having a 2 digit counter. Below are some of the events this field addresses:
 1. Rentals
 2. Loaners
 3. Sterilization
 4. Distributor re-labeling
 5. Most difficult; Reprocessing of medical devices and the associated regulations (FDC 502.c, SUD's and seven others regulations)
 6. FDA MDR/MHR reporting
 7. Adverse Event Reporting
- The De- Referenced Database environment where all queries must flow through a Privacy Preserving Index (PPI is a 2003 theory from Stanford and IBM labs).
- The model offers Patient privacy though several security check points culminating in the patient issuing a one time access code to the inquiring party.
- We have empirically tested the Philips tag with this data construct **and it works!**

Concluding remarks:

- Recommendation on the next steps toward UDI
- Drilled down summary of cost to implement the presented UDI Model
- 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.
- The presentation culminates by integrating the UDI solution with the recently developments in the patient record systems.

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