Nothing is more difficult to undertake, more perilous to conduct or more uncertain in its outcome, than to take the lead in introducing a new order of things. For the innovator has for enemies all those who have done well under the old and lukewarm defenders amongst those who may do well under the new.

Niccolo Machiavelli (1523)
The Road towards UDI – Where are We Now..???

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Current Device Identification

- Non-standard device identification systems; standards used in different ways
- Not necessary unique or unambiguous
- Does not include all necessary levels of uniqueness
- Manufacturers’ own number/catalogue number
- Distributors’ – apply different, proprietary number; lot or serial number not captured
- Hospital – yet different identification number/code
  - Information on use not usually captured
  - Control numbers rarely captured
National Drug Code (NDC)

- Developed to identify drugs for reimbursement
- Identifies the manufacturer, product and package size
- FDA took over in 1972 (The Drug Listing Act)
- Pharmaceutical barcode rule – NDC in linear barcode
- Ubiquitous use has facilitated...
  - Analysis of claims in a large database
  - Retrospective chart review
  - Drug interaction checking and decision support
  - Identifying inappropriate prescribing and dispensing
  - Avoiding confusion with look/sound-alike drugs
  - Reporting adverse events
UDI Can Improve… Visibility

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion
- Comparative effectiveness (e.g., registries)
- Disaster/terror preparation and shortages/substitutions
- Reduce medical errors
- Documenting medical device use in patient’s EHR/PHR, hospital information systems, claims data
- Sentinel Initiative - strengthening FDA’s ability to query data systems for relevant device information
UDI to Network Devices

Networking devices offers a host of benefits, including:

- Tracking devices
- Making sure devices are configured correctly
- More effective device used requiring less inventory.
- Increases in patient safety by having safer, more reliable equipment available to clinicians
- Reducing failures through proactive maintenance
- Managing the risk associated with networked devices
- Evidence based maintenance planning with automated, electronic reporting of maintenance information
Medical Device Identification

Develop a system to identify medical devices, which is:

- Consistent
- Unambiguous (differentiates among all dimensions)
- Standardized
- Unique at all levels of packaging
- Harmonized internationally

And facilitates the:

- Storage,
- Exchange, and
- Integration of data and systems
Future Information Lifecycle

Re/order

Hospital

Distributor

Clinical Use

UDI
Device X
Lot/serial Y
Exp Date Z

EHR

Recall

AE reporting

Surveillance

Recalled?

Safe?

Recalled?

Effectiveness

Expiration date?

Reimbursement

Counterfeit

Registries

Population databases
September 27, 2007, the FDAAA signed into law:

- The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.
UDI Public Workshop

12 February 09 - 300 people attended; 4000 webcast

4 Panels addressed issues related to:

• Developing standardized UDIs
• Placing the UDI in human readable and/or AutoID on a device, its label, or both
• Creating and maintaining the UDI Database
• Promoting adoption and implementation

Received 60 written comments.
GHTF UDI ADWG

• Formed October 2008
• EC Chair (Laurent Selles)
• Members US (FDA, AdvaMed), Europe (EC, Eucomed, EDMA, Matthias Neumann), Japan (Hiroshi Ishikawa)
• AHWP recently joined
• Last meeting Berlin 25-26 August 2009
• Final recommendations to SC at Nov 09 Meeting
Establishing a UDI System

Combination of 4 distinct steps:

1. Develop a standardized system to develop the unique device identifiers (UDI)
2. Place the UDI in human readable and/or AutoID on a device, its label, or both
3. Create and maintain the UDI Database
4. Adoption and Implementation
Develop UDI code according to ISO 15459 [GS1, HIBCC]

- Created and maintained by the manufacturer
- Concatenating Device and Production Identifier

**Device Identifier (DI):** [static] Manufacturer, make, model [i.e., each catalogue number]

**Production Identifier (PI):** [dynamic] if currently serialized – serial number; if currently identified at the lot, the lot number, and expiration date

Risk based approach – DI; DI + lot; DI + serial (or lot and serial)
UDI Application - DPM

• Ceramics, titanium, plastics and stainless steels can all be direct part marked.
• Marks are durable enough to withstand harsh environments, including cleaning with disinfectants and steam sterilization.
• 2D data-matrix codes allow the marking of 20 or more characters onto spaces only a few millimeters across
2nd – UDI Application

- Applied at all levels of packaging, down to the lowest level (the patient use level or unit of use)
- Human readable and/or encoded in a form of automatic identification technology
- Direct Part Marking (DPM) for some devices
- No specific technology would be identified (technology neutral)
- Identify a series of standards (linear barcode, 2-dimensional barcode, RFID)
UDI Application Example

[Image of UDI label]

- **LOT**: H612
- **Sterile**: R
- **Length**: 122 cm (4 ft)
- **Use By**: 2009-01-15 (YYYY-MM-DD)
- **Manufacturing Date**: 2007-01-15 (YYYY-MM-DD)
- **Manufactured for**: Medtronic, Inc.
  Minneapolis, MN 55432 USA
- **PIN**: 082104004

Attention. See accompanying documents.
### 3rd - UDI Database Development

- Device Identifier Type/Code [GTIN, HIBCC]
- Make/model; Brand/Trade Name; Description
- Device model number (or reference number)
- Size; Unit of Measure/Packaging level/quantity
- Control – Lot and/or Serial Number; Exp. Date
- Contact name, phone, email
- GMDN Classification code/term
- Storage condition; Single Use; Sterility; Restricted Use
- Contains known, labeled allergen (e.g., latex)
- URL for additional information – Web address
- Special Instruction for use
FDA’s UDI Database

The label of Medical Device 123 Size 45:
- Device Identifier (Device XYZ123)
- Production Identifier (Lot #ABC)
- Expiration date (MMDDYYYY)
- Sterile; Latex free

Manufacturer (Acme)

Minimum Data Set
For each Device Identifier:
- Manufacturer and model
- GMDN Code
- Other attributes

GSI GDSN
or
HIBCC UPN
or
FDA eList

Other options

FDA Managed

Business Rules

FDA’s UDI Database

Public User Interface

FDA
• Device Identifier: GS1 2081090010024
• Endopath Dextrus Finger Mounting Locking Forceps
• Ethicon Endo-Surgery Inc, Cincinnati, Ohio
• Jane Smith; 1-888-888-8888; JSmith@JNJ.com
• Controlled by Lot; Expiration Date
• Packaged sterile; Single Use; Prescription
• GMDN code: 12345; Manufactured in Israel
• Package of 1; Storage conditions: between 0-24° C
• Does not contain latex or PVC
UDI Database Pilot

• Purpose: Assess the feasibility of collecting, storing, and retrieving UDI data from initial creation (manufacturer) to point of use (hospital).

Learnings:

• Data suppliers (manufacturers) had concerns about data definitions, obtaining the data from various sources and manipulating for UDI upload.
• Participants confused about the purpose/use of UDID.
• Users (hospitals) liked UDID – it provided data they regularly need - e.g. information related to recalls and identifying alternate products/manufacturers for recalls.
Adoption and Implementation

• Technology issues/role of technology – barcodes, RFID, DPM
• Distributor uptake and use
• Hospital uptake and use
• Use of UDID
• Medical error reduction (e.g., latex)
• Integration issues – MMIS-Clinical
• EMR
• Reimbursement
• Privacy
UDI – Foundational Element

UDI will provide the foundation for:

• more efficient and effective device recalls,
• improved postmarket surveillance,
• better adverse event reporting,
• better device identification in registries,
• ability to document specific device use in patient’s Electronic Health Records,
• collection of device information in population-based data sets.

BUT – only if UDI is captured, stored, integrated and exchanged by ALL stakeholders.
Data Integration

- UDI will facilitate the integration of data across disparate systems – including supply chain, clinical, and reimbursement.

- With this integration comes insight and visibility to assess the cost and clinical effectiveness of:
  - devices in certain patient populations,
  - of similar technologies, and
  - of particular environments and users.
Comparative Effectiveness

“What if it finds that some brand-new and incredibly expensive treatments are wildly effective… That could raise spending…” [TWP, 9/20/09]

- Will visibility will lead to the commoditization of all devices and less reimbursement…?
- Insight could lead to better (higher) utilization and reimbursement for those devices with a proven track record of better patient outcomes and lower overall healthcare costs.
Unique Device Identification

www.fda.gov/MedicalDevices/
DeviceRegulationandGuidance/
UniqueDeviceIdentifiers

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