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)
FDA’s Unique Device Identification Program

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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
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
Future 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
UDI Can Improve… Visibility

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion (location systems)
- 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
FDA Amendments Act of 2007

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.
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
1st – Developing the UDI

- 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 and/or manufacturing date
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
Risk-based Approach

• Production identifier reflects current control (label) – not requiring serialization.
• Granularity of marking based on risk of device - UDI for some devices on multi-packs or higher levels of packaging
• Not all devices require production identifiers
• Take into account realities of retail environment
• Implementation based on risk – premarket class III first; then class II, and finally class I.
3rd - UDI Database Development

• Device Identifier Type/Code [GTIN, HIBCC]
• Manufacturer; Contact name, phone, email
• Brand/Trade Name; Make/model
• Size (e.g., diameter, length)
• Packaging level/quantity
• Control – Lot/Serial Number; Exp., Manuf. Date
• GMDN Classification code and term
• Storage condition (e.g., temperature; humidity)
• Single Use
• Sterility; Restricted Use
• Contains latex
4th – Adoption and Implementation

- Resolve technology issues – barcodes, RFID, DPM
- Develop appropriate UDI Database
- Combination products/kits
- Facilitate distributor uptake and use
- Facilitate hospital uptake and use
- Facilitate use of UDI throughout device lifecycle
- Drive integration – MMIS-Clinical
- Drive appropriate use of UDI in EMRs
- Determine appropriate role in reimbursement
- Address privacy concerns
Data Integration

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

• Focused on documenting device use in EHRs.

• Allows linking of health-related information with device-specific information to conduct risk-benefit and comparative effectiveness assessments.

• Improves the accuracy reimbursement and reduce fraud by allowing payers to more accurately link payment with specific devices.
Limitations of UDI and UDID

- UDI is a foundational element – it unambiguously identifies a specific device (at its unit of use).
- Benefits accrue only if used by all stakeholders.
- UDID contains only “static” identifying and product information.
- UDID does NOT contain production information, such as lot or serial numbers – and is NOT track/trace or other similar purposes requiring the full UDI.
- UDID provides link to product information- not a replacement for Recalls/Adverse Event Databases.
Unique Device Identification

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers

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