Unique Device Identification
FDA and UDI

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Background and History

- 1999 – IOM publishes report “To Err is Human: Building a Safer Health System”
- 2004 - FDA issues final rule requiring bar codes of NDC numbers on drugs and biological products to help reduce medication errors
- Devices specifically excluded from bar code rule because devices lack a unique numbering scheme
- 2005 - FDA receives letters from Congress and a consortium of hospital groups asking that we revisit the issue of bar coding medical devices.

Three Stakeholder Meetings

- April 2005 - meeting with representatives of the medical device industry
- September 2005 - meeting with Federal Partners including DOD, CMS, AHRQ
- October 2005 - meeting representatives of health care related organizations

Stakeholder Meetings told us…

- The majority of stakeholders support the development of a uniform system of unique identifiers as a way to improve patient safety and recognized other ancillary benefits such as better management of the purchase, distribution, and use of medical devices.
- “Throughout the meeting, and in subsequent communications with participants, it became clear that many organizations clearly favored a mandatory approach to this issue”

FDA believes that UDI can…

- Reduce device related medical errors - identify compatibility and interoperability issues:
  - right device for right patient (latex allergy)
  - right accessory for right device
  - MRI compatibility
- Improve identification of specific device in adverse event reports and provide more “denominator” data
- Facilitate more effective device recalls – identify and locate recalled devices in a timely fashion

UDI can also…

- Facilitate the population of device use information in Electronic Medical Record Systems (HIT)
- Provide ancillary benefits for a wide variety of stakeholders:
  - Improve materials management and associated healthcare cost savings
  - Help track devices and identify counterfeit devices
  - Identify similar or substantially equivalent devices to avoid shortage
  - Emergency preparedness – national, military

Federal Register Notice

- 11 August 2006 – request comments to help FDA understand how the use of a unique device identification system may improve patient safety.
- Comments due 9 November 2006
- Notice focuses on 3 broad areas:
  - Developing a System of Unique Device Identifiers
  - Implementing Unique Device Identifiers
  - UDI Benefits and Costs

Combination of 3 Distinct Ideas

1. Developing a uniform, standard system of device attributes—which, when combined, would uniquely identify a particular device at the unit of use.
2. Place human readable UDI on device labeling. UDI could ALSO be encoded in any of a number of different automatic identification technologies.
3. UDI could also interface with a database that would access an additional data set with information related to safe use (a “minimum data set”).

1. UDI System

- At the “unit of use” – create a unique identifier by combining these device elements and attributes:
  - Manufacturer, make, and model;
  - Unique attributes (e.g., size, length, quantity, software version); and
  - Serial number, identifying lot number, manufacturing, or expiration date.
- Any change to the above criteria would necessitate a new UDI.
- “Unit of use’’ would vary for different device types.

2. Automatic ID Technologies???

- Any number of different automatic identification technologies – 1D, 2D barcode, RFID
- Do we specify one technology of different for different device types?
- Or be non-specific and allow different technologies depending on the stakeholders' needs and uses?
- Should it be the same as the drug barcode rule?
- What about direct part marking?

3. Minimum Data Set

To promote safe device use – data would reside publicly and include:

- Manufacturer, make, and model
- Unique attributes (e.g., size, length, quantity)
- Serial number, lot number, or expiration date
- Product type
- Indications, contraindications, warning, precautions
- The accessories needed to operate the device
- If the device is an accessory to another device, the specific device with which it operates.

Public Meeting

- 25 October 2006 – Gaithersburg, Maryland, USA
- Meeting will focus on:
  - Benefits and costs of a UDI system
  - Design and implementation of UDI system
  - Data repository – design, maintenance, use
  - Automatic identification technologies

Realities of the Device World

- Diverse industry
  - 28,000+ firms (many are small < 20 employees)
  - Global marketplace – international harmonization
- Diverse population (of devices):
  - 100,000+ brands/models of devices
  - Vary in size, complexity, packaging and use
  - High volume, low volume
  - Kits; components; systems
  - Implants
  - Reprocessed devices

Next Steps

After Public Meeting and docket closes…

- Analyze Comments
- Determine FDA's role
- Mandatory/voluntary? Guidance/regulation?
- Standards?
- On all or some devices – risk based?
- One format or flexible?
- Auto ID Technology?
- Issues of data ownership?
- What minimal information will be needed?

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