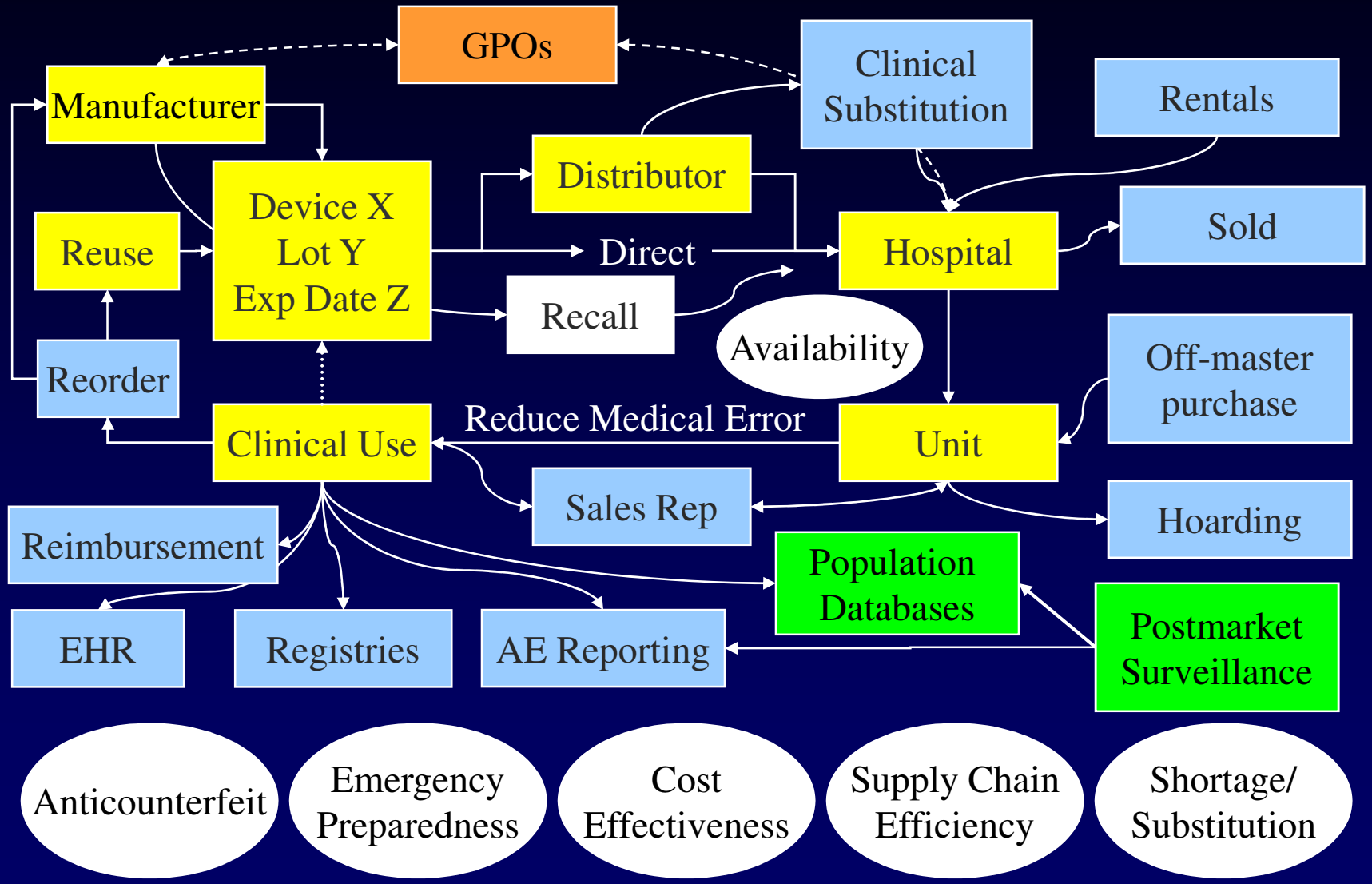
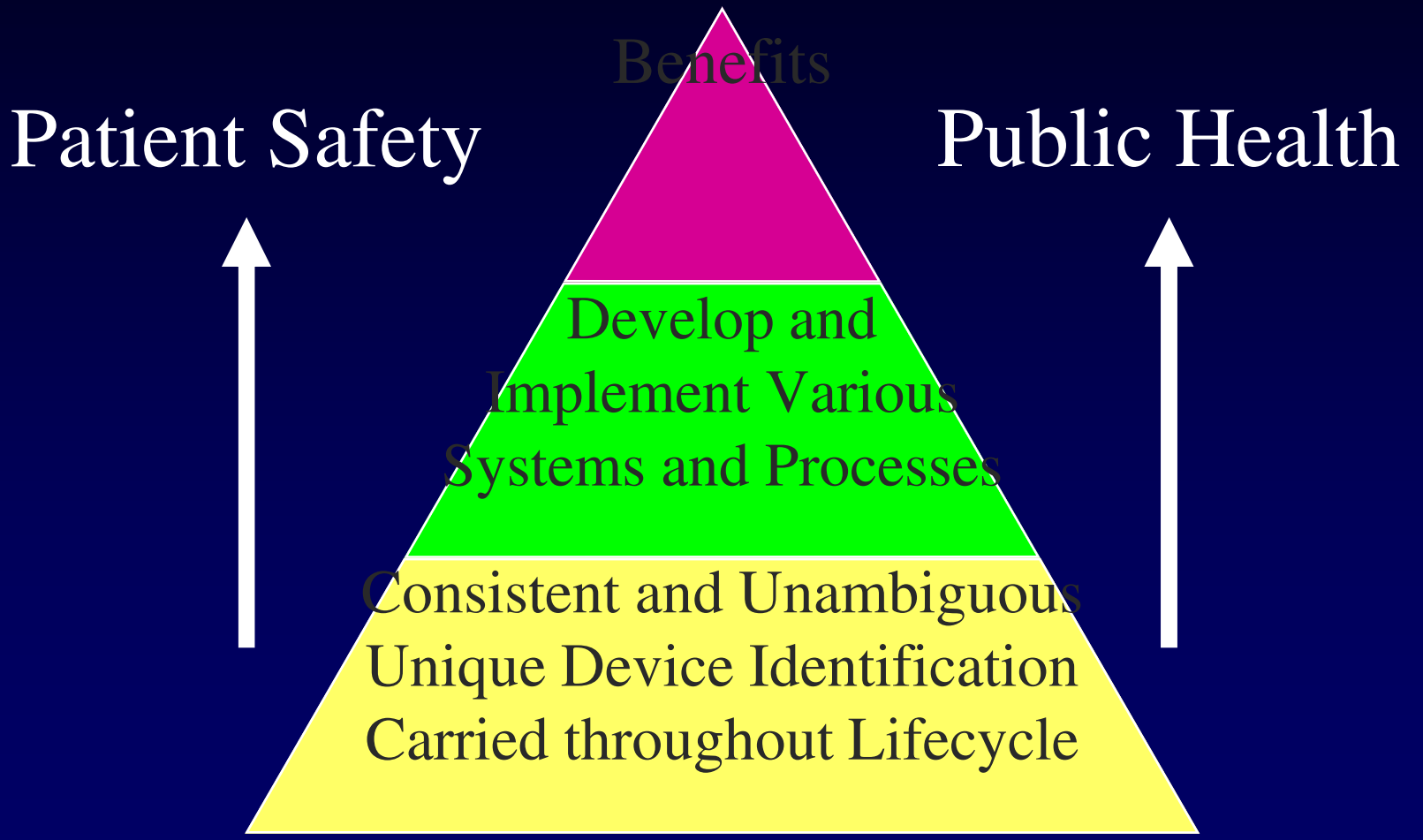
Unique Device Identification

Jay Crowley
Senior Advisor for Patient Safety
Food and Drug Administration
jay.crowley@fda.hhs.gov
(W) 240-276-2389
(C) 301-980-1936

Device Information Lifecycle



UDI as Foundational Element



UDI Can Improve…

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion
- Disaster/terror preparation and shortages/substitutions
- Systems to reduce medical errors
- Assisting clinicians in identifying appropriate device
- 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.

FDA Amendments Act of 2007

Establish a unique device identification system:

- Requires that the label of devices bear a unique identifier ["Label" is defined as "…a display of written, printed, or graphic matter upon the immediate container of any article."];
- Allows FDA to describe an alternative placement (e.g., on the device itself or its packaging) for a particular device or device type;

FDAAA of 2007 (continued)

Establish a unique device identification system:

- Allows FDA to exempt a particular device or type of device from the UDI requirements;
- The UDI must adequately identify the device through distribution and use; and
- The UDI includes information on the lot or serial number.

Establishing a UDI System

Combination of 3 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

1st – Developing the UDI

- ISO/IEC 15459-4:2006 "Information Technology – Unique Identifiers, Part 4: Unique identifiers for supply chain management" [e.g., GS1, HIBCC]
- Created and maintained by the manufacturer
- Concatenating Device and Production Identifier
- Device Identifier: [static] Manufacturer, make, model [i.e., each catalogue number]
- Production Identifier: [dynamic] if currently serialized – serial number; if currently identified at the lot, the lot number, and expiration 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

ENDOPATH®

dextrus™

Finger-Mounted
Locking Forceps

REF	FMF02	LOT	1Q34
	080100	QTY	4

(01) 2 081019001 002 4

(17)080100(10)1Q34

T.A.G. MEDICAL PRODUCTS
ת.א.ג. מכשירים רפואיים

CE 0344

Manufacturer
T.A.G. Medical Products
Kibbutz Gaaton 25130 Israel
Tel: 972-4-9858400, Fax: 972-4-9858404

EC REP

EU representative
MEDNET GmbH
Borkstrasse 10 48163 Muenster, Germany
Tel: +49 (251) 32266-0
Fax: +49 (251) 32266-22

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Distributor
Ethicon Endo-Surgery Inc
Cincinnati OH
45242-2839 USA

Do not use if package is open or damaged

Single patient use only

Does not contain latex or PVC

STERILE R

℞ Only

0-45

D150PPLB02 Rev.D

ENDOPATH®

dextrus™

Finger-Mounted
Locking Forceps

REF	FMF02

UDI Application Example

3rd – UDI Database

Minimum Data Set for each **Device Identifier**:

- Manufacturer, make/model (catalogue number)
- Description
- GMDN/UNSPCS Category/code
- Control mechanism
- Packaging level/number of items
- Country of origin/manufacture
- Labeled as single use or reusable
- Sterility
- Contains known, labeled allergen (e.g., latex)
- Storage conditions (e.g., needs to be refrigerated)

Other UDI Issues

- AutoID technology issues
- Kits; combination products; legacy devices
- Re/marking (legally) reprocessed SUDs
- Maintaining dynamic information
- Hospital and other healthcare facility uptake
- Remanufactured and refurbished devices
- Triggers requiring a new UDI
- Maintaining “dynamic” device information
- Complex, multi-system (“capital”) devices
- Harmonized/international database

Unique Device Identification

www.fda.gov/cdrh/ocd/udi/

Email: cdrhudi@fda.hhs.gov