ENGELBERG CENTER for Health Care Reform at BROOKINGS

Unique Device Identification (UDI) Implementation Webinar

Improved Access to Device Information: What a UDI System can do for Patients and Consumers

Jay Crowley, Senior Advisor for Patient Safety, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, U.S. Food and Drug Administration

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February 26, 2013

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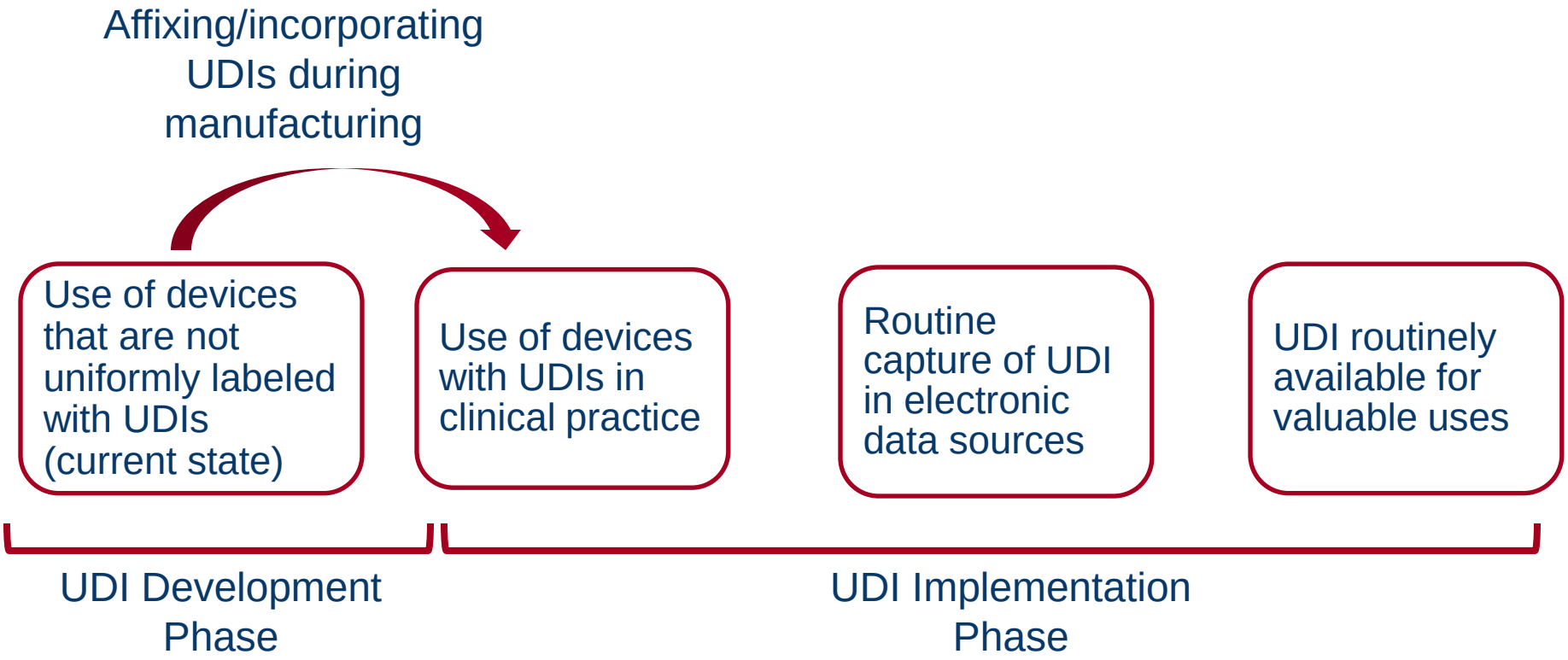
Overview of Unique Device Identification (UDI) Implementation

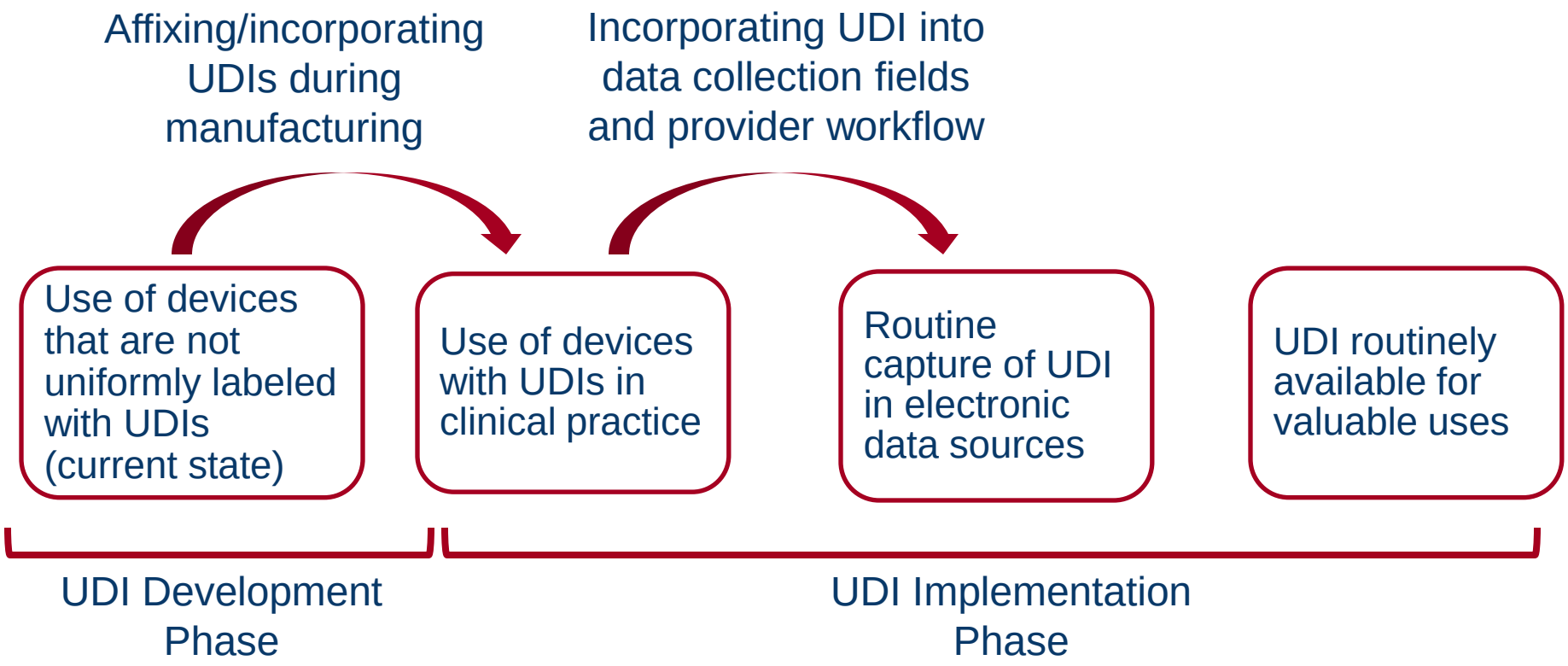
Gregory Daniel

The Brookings Institution • Washington, DC
Tuesday, February 26, 2013

UDI Development and Implementation



UDI Development and Implementation



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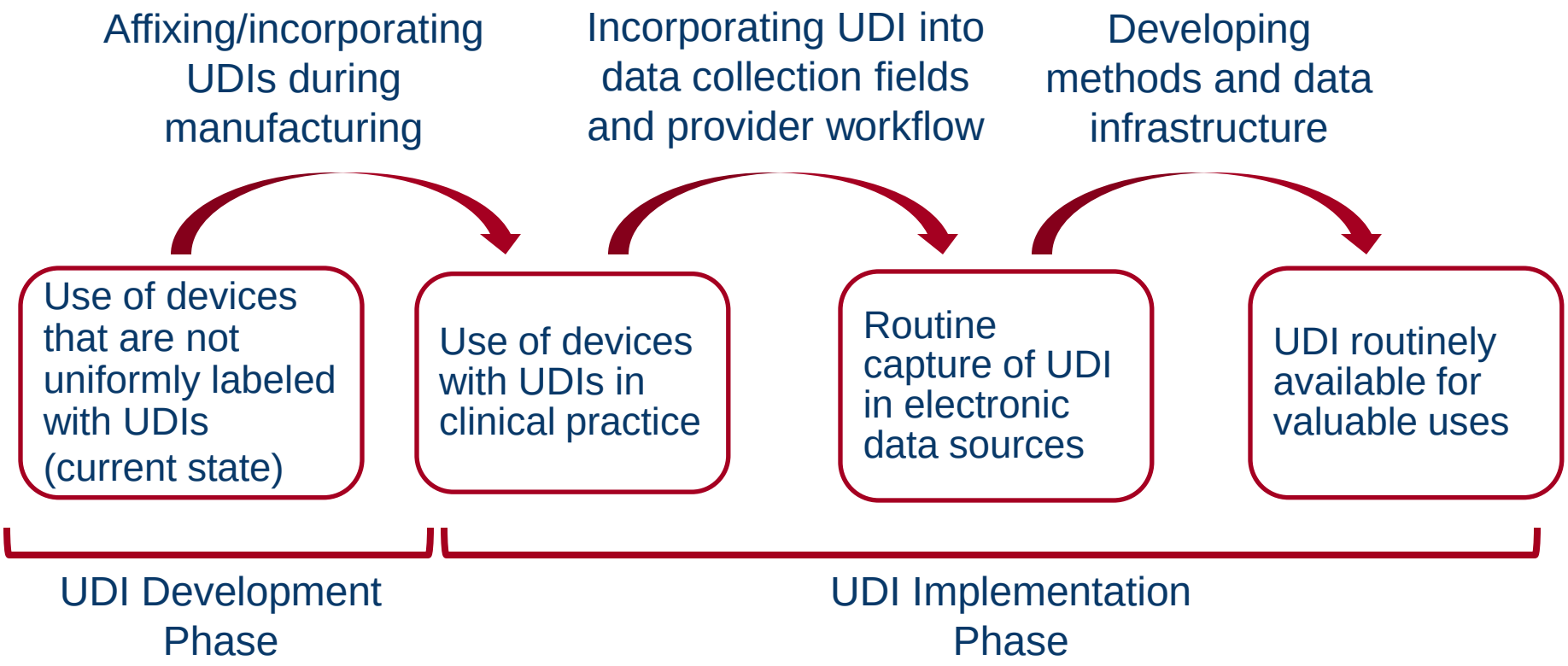

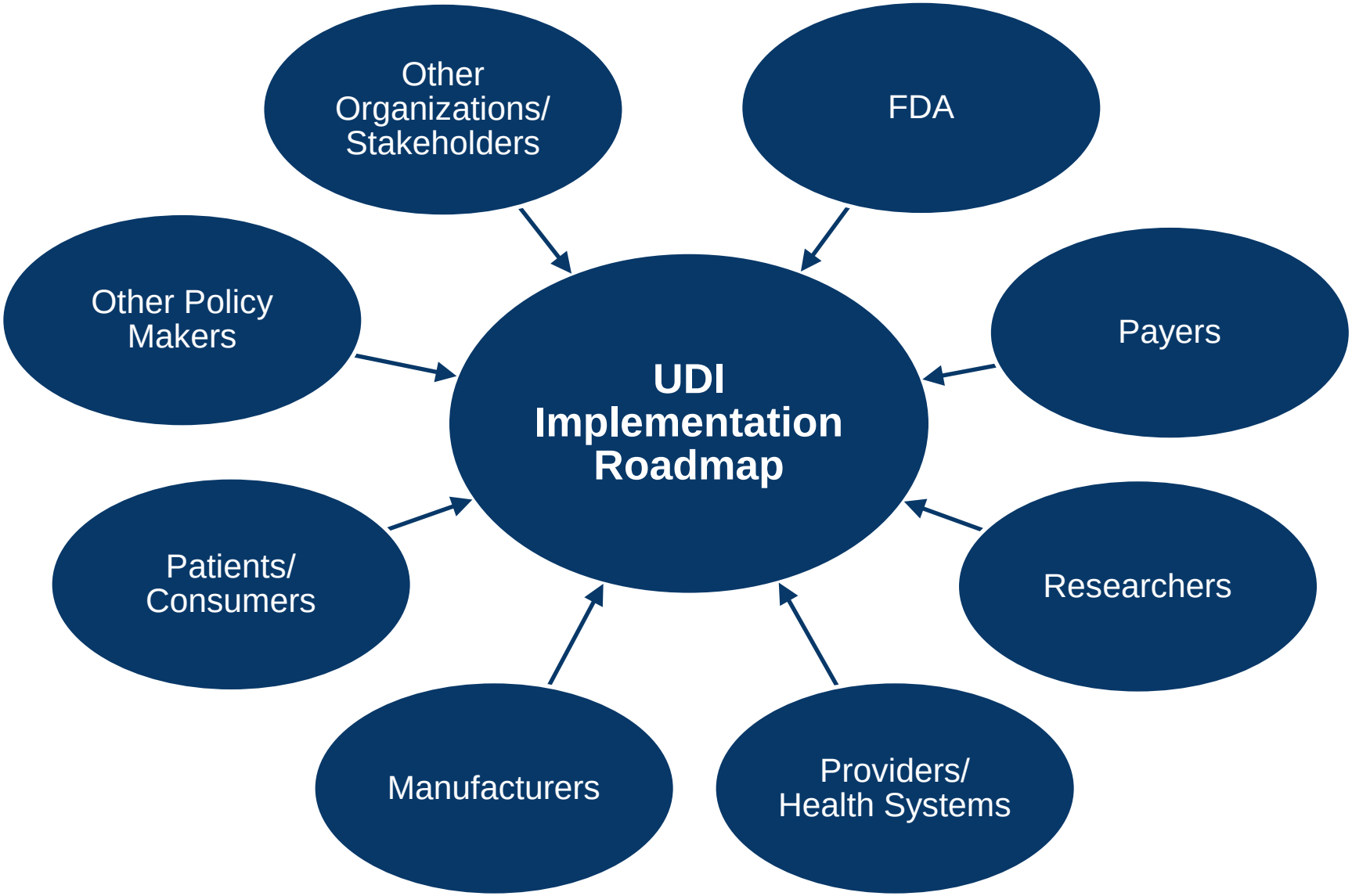

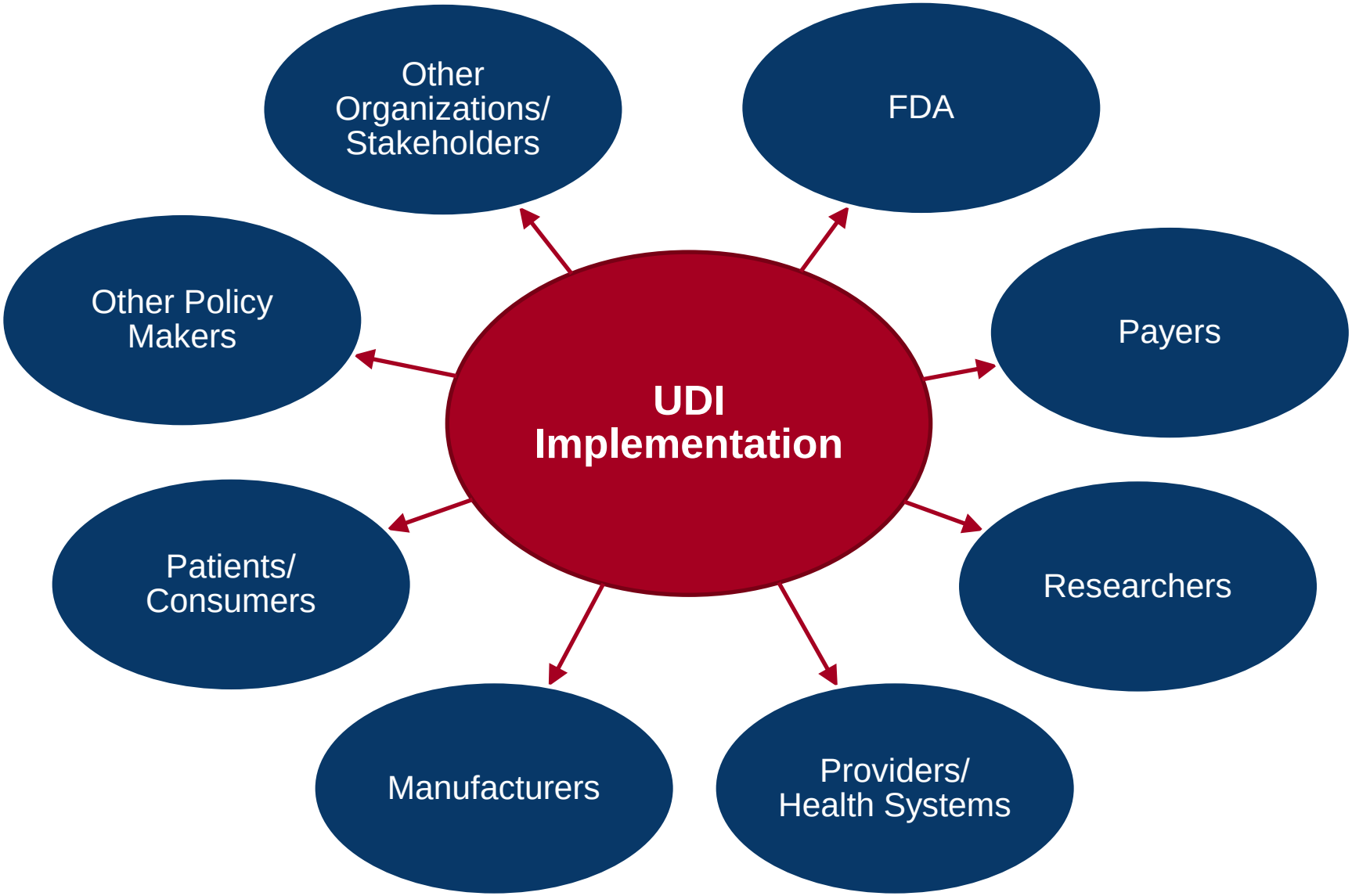

Housekeeping

- To unmute your phone, press 66.
- There will be several opportunities for questions and discussion throughout today's session. **Please use the Q & A tab on the top of your screen to submit your questions into the queue at any point** and we will call upon you to state your question.
- Call the Level 3 Conferencing at 1-888-447-1119 with technical problems.

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“The inadequacy of the current postmarketing surveillance system and the resulting lack of data make it impossible to confidently draw broad conclusions about the safety and effectiveness of products that are on the market.

The lack of standardization in clinical and device-specific data among existing non-FDA data sources and insufficient detail in administrative and clinical health records impede the evaluation of the performance of medical devices.”

IOM Report “Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years”

Unique Device Identification (UDI) – Transforming the Global Medical Device Landscape

Jay Crowley
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History of FDA's UDI Project

- 1999 IOM Report – To Err is Human
- 2007 FDA Amendments Act of 2007
- 2007-2009 – UDI Database Pilots
- 2012 July 10th - UDI Proposed Regulation Publishes
- 2012 FDASIA provisions added
- 2012 November 7th – comment period closes
- 2012 November 19th – FDASIA amendment (Dec 19)
- 2013 June – expect UDI Final Rule

Legislation (FDAAA 07; FDASIA 12)

Not later than December 31, 2012, the Secretary shall issue proposed 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. *The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.*

Current Device Identification
1/2 mL insulin syringe/28 G needle

Business Name	Item Number Type	Item Number
BD	**Mfg Catalog Number**	**329461**
BD	**GTIN**	**00382903294619**
BD	**GTIN**	**30382903294610**
BD	**GTIN**	**50382903294614**
Cardinal Health	**PV Order Number**	**BF329461**
Owens & Minor	**PV Order Number**	**0722329461**
Owens & Minor	**PV Order Number**	**0723329461**
American Medical Depot	**Vendor Catalog Number**	**777127217**
American Medical Depot	**Vendor Catalog Number**	**777127218**
Government Sci Source	**Vendor Catalog Number**	**FSC1482679CS**
Government Sci Source	**Vendor Catalog Number**	**FSC1482679PK**
Alliance Joint Venture	**Vendor Catalog Number**	**888021932**
Thomas Scientific	**Vendor Catalog Number**	**8938M25**
Thomas Scientific	**Vendor Catalog Number**	**8938M28**
VWR International	**Vendor Catalog Number**	**BD329461**

Problems with Device Recalls

GAO showed that device firms do not remove all unsafe medical devices from the market because:

- The firm cannot locate all customers or devices, or
- Customers cannot locate the recalled devices.

In a review of class I recalls, in 53% of the cases – firms were unable to correct or remove all of the faulty devices from the market.

Clinical Use of UDIs in EHRs

Record device use in the EHRs using UDIs would allow:

- Identification/tracking of patients with recalled devices
- Knowledge of prior implants for revision surgeries
- Knowledge of implanted stents when restenoses occurs
- Identification of proper ICD programmer
- Identification of devices for registries and other comparative/cost/clinical effectiveness activities

Public Health Benefits

UDID provides global visibility and supports:

- Medical device recalls
- Adverse event reporting
- Tracking and tracing
- Supply chain security
- Anti-counterfeiting/diversion
- Disaster/terror preparation
- Shortages/substitutions
- Reduction of medical errors (e.g., bedside scanning)
- An easily accessible source of device information for patients and clinicians

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 AIDC-format 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, ICCBBA]
- 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] however product is currently controlled – serial, lot number; expiration, manufacturing date

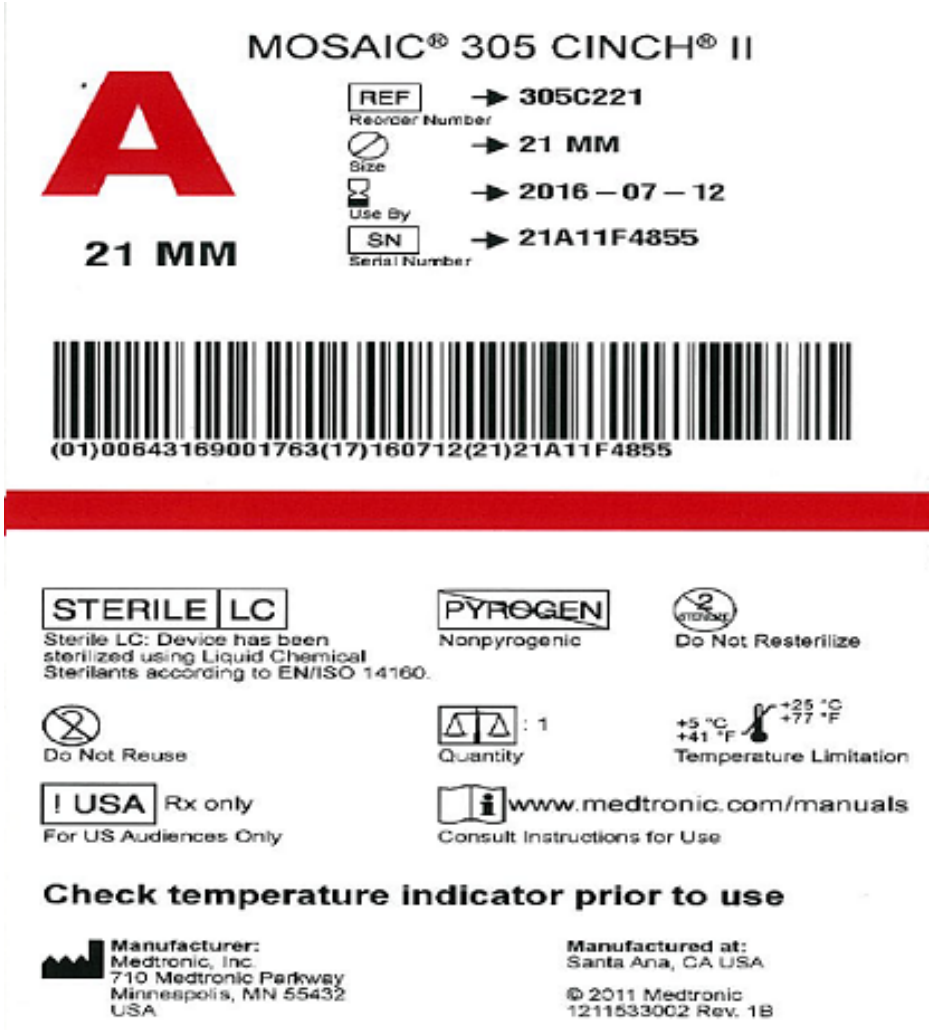
2nd – UDI Application

- Unique UDI applied to “base package” AND higher levels of packaging
- Default location is the label
- Human readable and encoded in a form of automatic identification technology
- No specific technology (technology neutral)
- ALSO Direct Part Marking (DPM) for
  - an implantable device (>30 days)
  - intended to be used more than once, and intended to be sterilized before each use
  - stand-alone software

General Exemptions

- Class I Devices do not need to include Production Identifiers in UDI.
- Devices, other than prescription devices, made available for purchase at a retail establishments, (aka OTC devices, regardless of where distributed).
- GMP-exempt Class I devices
- Individual class I, single-use devices, all of a single version or model, that are distributed together in a single device package, which are not intended for individual sale – the UDI is on the package
- And others…

UDI Application Example



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

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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

D150PPLB02 Rev.D

ENDOPATH®
dextrus™
Finger-Mounted
Locking Forceps

REF FMF02

3rd – Global UDI Database

For each Device Identifier:

- Manufacturer, Make/model, Brand/Trade Name
- Clinically relevant size
- Contact information
- Sterility information
- Contains latex
- FDA premarket authorization (510k, PMA)
- FDA product code (procode)
- Marketing Status/date
- For single-use
- Higher levels packaging
- Rx - OTC

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 for track/trace or other similar purposes requiring the full UDI.
- UDID provides link to product information- not a replacement for Recalls/Adverse Event Databases.

4th – Implementation

- Based on premarket risk class after publication of final rule:
  - class III – 1 year
  - class II implants and life-supporting/life-sustaining devices – 2 years
  - the rest of class II – 3 years
  - class I – 5 years
- Phase out national numbering system (NDC/NHRIC)
- Direct part marking requirements are effective 2 years after class effective date

Unique Device Identification

www.fda.gov/UDI

Email: cdrhudi@fda.hhs.gov

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The Value of UDI Implementation for Patients & Consumers

Kate Ryan, MPA
National Women's Health Network
February 26, 2013

Ensuring Patient Safety

- Implementation of the Unique Device Identification (UDI) system will improve patient safety by ensuring:
  - Quick & efficient device recalls
  - Detailed device information for patients
  - Accurate adverse event reporting
  - Improved post-market device surveillance

Know Your

- Address the CSI problem
- Public awareness and education campaign needed

→ People need to ask their providers for the UDI so that they have that information in case of a problem or recall

Prevent Unnecessary Harm

- Without a UDI system, device recalls are inefficient and incomplete
  - Companies are unable to remove 53% of faulty medical devices from the market because there is no uniform way to track devices electronically

→ Incomplete recalls expose people to dangerous devices that have already been recalled

Know When to Worry

- Currently, many people who learn about a device recall don't know whether or not it includes their device

- With a UDI system, people should be able to quickly check the recall status of their device

Reporting a Problem

- If a patient has a problem with their device, she should submit an adverse event report to the FDA; however…

- Adverse event reports currently submitted to the FDA often lack device-specific information

→ Knowing the UDI will allow people to more accurately report problems with their device to the FDA

Identify Problems Early

Food and Drug Administration
MEDWATCH

Sentinel Initiative

Improving Post-Market Surveillance

- The UDI system has the potential to improve post-market safety surveillance if we…
  - Create a field for UDI on the consumer MedWatch form
  - Integrate UDI into electronic health records and claims data
  - Ensure the Sentinel Initiative and device registries include UDI to facilitate active post-market surveillance

Making UDI Work for Patients

- For patients and consumers to fully benefit from the UDI system, the UDI must be a gateway to more information about the device, such as:
  - Recall status
  - Type/extent of recall
  - Recall date
  - Safety warnings
  - Approval date
  - Market status

User-friendly UDI Information

- Where will patients leverage their UDI for device information?
  - The Global Unique Device Identification Database (GUDID)??
  - A Patient & Consumer UDI portal on the FDA website
- How will the agency ensure that this information is understandable and user-friendly?
  - Focus groups?
  - Beta testing?

Conclusion & Next Steps

- Full implementation of the UDI system has the potential to improve patient safety and provide people with better information about their medical device

- But the UDI system must:
  - Be user-friendly and understandable to patients and consumers
  - Provide information that is relevant to patients and consumers

Thank you!

Kate Ryan, MPA

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ConsumersUnion®

POLICY & ACTION FROM CONSUMER REPORTS

Lisa McGiffert

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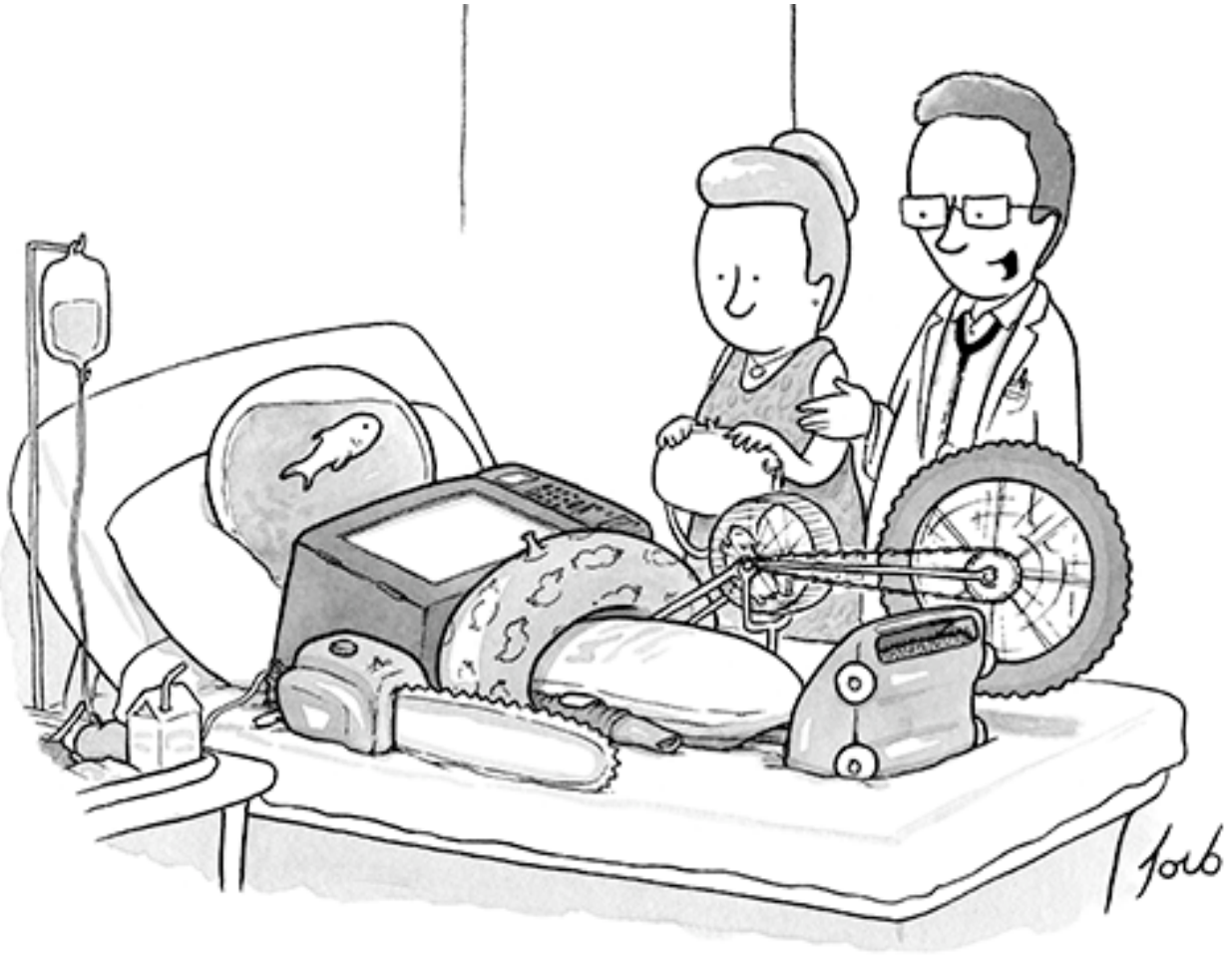
“We began with a hip replacement and just sort of riffed off that”



FDA regulations only cover manufacturers

Consumers must drive use of UDIs

No consumer “rights” relating to information about one’s implant

- Consumers/patients SHOULD have the right to know:
  - What exactly is being implanted in their bodies
  - The UDI associated with their implant
  - The guaranteed lifespan of the implant
  - The post-market history of the implant

UDI checklist
for people getting medical implants

(before surgery) Ask your surgeon for information in writing:

- brand, model and maker of the implant intended to be used
- characteristics of the implant such as materials included in implant – type of metal, coatings, other substances; raise any issues about allergies
- cautions re interactions with x-ray, MRI, CT, etc.
- Surgeon's infection rate

UDI checklist for people getting medical implants

- (before surgery) Tell your surgeon that you want the unique device identifier of your implant, in writing;
  - ask for the UDI to be recorded in your medical record
- (after surgery) Remind to give you UDI
  - Ask for a copy of your medical record to ensure the UDI has been recorded

UDI checklist
for people getting medical implants

- Look the device up in MAUDE and recall databases on FDA website
- Look the UDI up in the GUDID database
- Go back for discussions with your surgeon regarding any conflicting information you find or questions raised by FDA information

UDI checklist
for people getting medical implants

Notify your surgeon and the FDA if your UDI is not in the GUDID

Consumers should push FDA to:

- Create links or a portal that connects the UDI with information about the implant in FDA databases – GUDID, MAUDE, recalls
  - Essential for consumers and health care providers
- Include implant materials in the GUDID
- Create feedback loops for consumer experiences with UDIs

Consumers should push FDA to:

- Create a system to keep interested consumers informed about implementation – progress and barriers
- Reach out to key professional organizations – such as orthopedic surgeons – to enlist in efforts to educate physicians on the benefits of UDIs and encourage their use.

Consumer Orgs can:

- Create the expectation that doctors and hospitals use and give patients UDIs
- Educate the public on the patient role in getting providers to use UDIs
  - actions to our lists, media outreach with stories
- Reach out to professional medical groups about the importance of using UDIs in records

Make UDIs work for us.

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