Realizing the Benefits of the Unique Device Identifier in Health Care

December 9, 2014

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Welcome

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UDI Roadmap

- Terrie Reed, Project Leader, Clinical Research Informatics, Duke Clinical Research Institute
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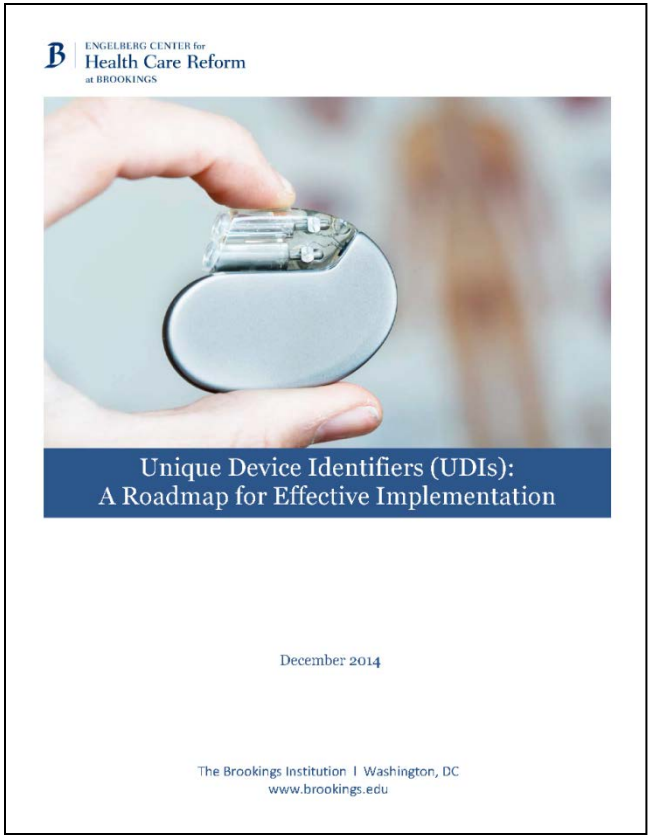
Unique Device Identifiers:
A *Roadmap for Effective Implementation*

Gregory Daniel, PhD, MPH
Fellow and Managing Director
December 9, 2014
The Brookings Institution

Brookings and UDI Implementation

- UDI Implementation Work Group
  - First convened July 2012 in collaboration with FDA and CNI Technical Services, LLC, focused on exploring broad strategies for UDI implementation
  - "Exploring the Opportunities and Challenges Associated with Capturing UDIs in Claims" – Oct 15, 2012
  - "Identifying Steps for Implementation and Integration of UDI within Electronic Data Infrastructure of Care Delivery Sites" – Dec 13, 2012
  - "Accessing and Communicating Device Information: UDI as a Tool for Improved Patient and Provider Connectivity" – Mar 18, 2013
- Began work on UDI Implementation Roadmap late 2013 and held several small roundtable discussions on technical strategies throughout 2014



UDI Implementation Roadmap: Released December 5, 2014

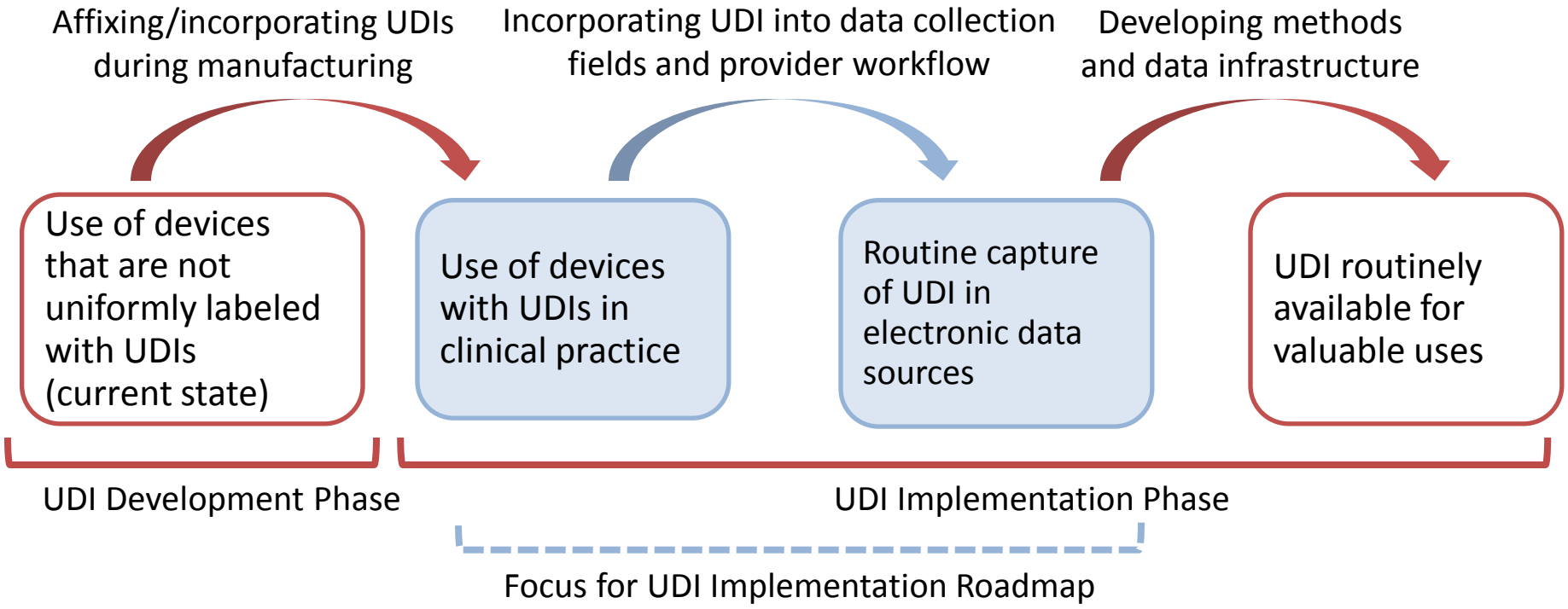
Available at www.Brookings.edu

Benefits of Successful UDI Implementation

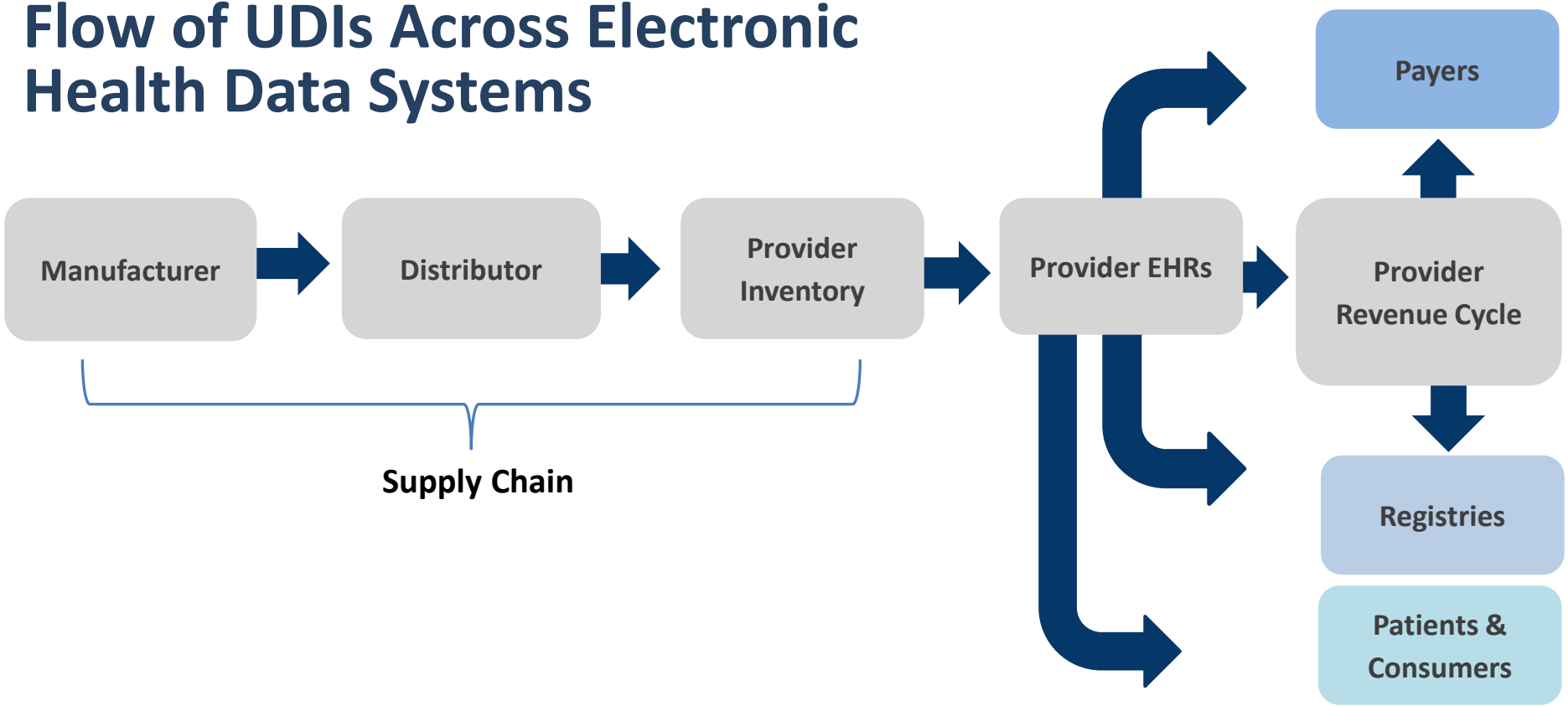
- The value of UDIs derives from their role in “unlocking” and enabling the transfer of critical information about medical devices
  - Similar to the way vehicle identification numbers (VIN) help a consumer make more informed decisions before purchasing an automobile, support consumer access to specific safety and recall information, and facilitate reporting of potential safety problems
- As the standard for communicating information about specific devices across the health care system, UDIs can link specific devices to attributes, quality, safety, performance, and cost to support safer and higher quality care

BENEFIT THEME	ADVANTAGES	
Enhanced Ability to Deliver Safe and High Quality Care to Patients	• Provider access to critical device information • Patient access to device information and shared decision-making	
Improved Recall Management	• Improved recall process • Efficient communication of safety info. to patients and providers	
Evidence Development to Support Safe and High Quality Care	• Medical device safety surveillance • Medical device CER and PCOR • Tracking device utilization patterns and appropriateness of care	• Improved ability to support ongoing quality initiatives • Support for medical device innovation
Improved Transparency, Reimbursement and Value	• Increased medical device reimbursement transparency • Opportunities to support enhanced value	
Improved Efficiency in Health Operations Management	• Improved supply chain integration and management • Identifying networked and telemetric medical devices	• Emergency preparedness and response • Fraud detection • Anti-counterfeit detection

UDI Development and Implementation



Flow of UDIs Across Electronic Health Data Systems



Transmission and Use of UDI Across the Health Care Ecosystem

Flow of UDI

FDA and GUDID

1 Manufacturers submit DI to FDA GUDID to create a master data source

Care Delivery System

Hospital System

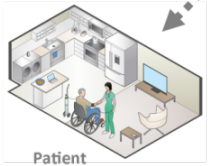
4 UDI is captured and used cross provider system clinical care

2 UDI affixed to medical devices

3 UDI integrated into supply chain

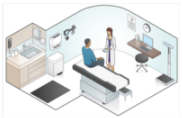
Manufacturer

6 Patient education and engagement improves with UDI capture



Patient

5 Outpatient providers have access to UDI via EHR



Outpatient Clinic

7 Payers capture UDI across provider systems and settings

Payer

Clinical Research

8 Routine recording of UDI enables population-based evidence development that informs practice

Patient-Directed Tools

9 Patient-directed tools facilitate communication of medical device information with UDI

Integrate UDIs into Provider Systems

Recommendations

- Provider systems should incorporate UDIs into their EHRs
- Adopting automatic identification and data capture (AIDC) technology can facilitate more efficient and accurate UDI capture in clinical settings
- Executive leadership champion UDI implementation within their own systems
- Automate safety reporting with UDIs
- Deploy pilot studies to demonstrate ROI for integration across major data systems (e.g. supply chain, clinical, and revenue management)
- ONC and CMS should support the incorporation of UDIs into EHR Certification Criteria and Stage 3 Meaningful Use

Integrate UDIs in Administrative Transactions

Recommendations

- Overall recommendation is to incorporate UDIs into administrative transactions via the claims form
  - Incorporate UDI in ASC X12N 837 Institutional and Professional Claims Transaction forms at claim line detail level with situational rule
  - Incorporate UDI in ASC X12N 835 payment and remittance advice to supplement information provided by the claim
  - Pursue the development of the DI as a HIPAA code set to replace/work in conjunction w/ CPT codes and HCPCS for medical devices
  - Link medical device registries to claims data integrated with UDIs
  - Commission a payer-led pilot project to demonstrate the primary and secondary benefits of UDI within claims

Integrate UDIs Into Patient-Directed Tools

Recommendations

- Patient advocacy orgs. and others should motivate patient patients to request the UDIs from providers (i.e., “Know Your UDI” campaign).
- Patient and provider checklists and questionnaires for high-risk implantable medical devices could help increase UDI use
- PHR developers should integrate UDIs into PHRs.
- Advocacy groups, NLM, FDA should collaborate to develop tools and increase openness of federal databases containing UDIs and device information, including GUDID.
- Consumer medical application developers should develop tools to facilitate patient use of UDIs

Conclusion

- UDI implementation across the system is complex & will take much effort
- Straightforward steps can be taken now to begin realizing the benefits
  - Patients with implantable devices should ask their surgeon for the UDI and communicate this with their other providers
  - Provider systems should be able to scan UDI barcodes and have UDIs automatically recorded into EHRs for implantable devices
- Additional broad strategies for implementation include
  - Stakeholder buy-in; Demonstrate the ROI from early pilot projects;
  - Continued interoperability of HIT infrastructure will support improved value; and
  - Standardization of data formats and specifications will be essential.
- Roadmap conclusion also articulates clinical scenarios depicting how UDIs can benefit patients and their care when UDIs are implemented

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A Special Thanks to Many Others

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Break

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Lunch

- Jon White, Acting Deputy National Coordinator for Health Information Technology

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USE CASES: Clinical Applications

- Support patient safety
- Enhance clinical decision support and care coordination
- Enable analyses of device safety and quality
- Inform other hospital systems (supply chain, billing, etc)

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USE CASES: Support Patient Safety

UDI adoption as part of EHRs and clinical software can:

- Identify patients implanted with recalled devices
- Alert clinicians of clinically-relevant information
  - The device being implanted is expired or recalled
  - The patient has a device that is non-MRI compatible

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USE CASES: Enhance Clinical Decision Support & Care Coordination

Integrating UDI into clinical suite software and EHRs can:

- Display detailed device information in the EHR
  - Listing the device name, expiration, etc… can help clinicians quickly know what devices are implanted
- Provide patients and physicians with needed information
  - Useful for patients seeing multiple clinicians
  - Helpful when adverse events occur years later

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USE CASES: Enable Analyses of Device Safety & Quality

Enabling clinical suite systems or EHRs to support UDI can:

- Easily populate data registries by requiring less manual data entry by clinicians
- Facilitate accurate adverse event reporting through built-in capabilities
- Allow large health systems to conduct their own analyses of device performance

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USE CASES: Inform Other Hospital Systems

UDI integration can enable the EHR to:

- Inform supply chain systems when devices are used
- Notify billing departments to inform accurate claims/billing
- Supply reporting systems (registries, quality measures, etc) with key information

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USE CASES: Clinical Applications

- **Support patient safety**
  - Identify patients with recalled devices & alert clinicians
- **Enhance clinical decision support and care coordination**
  - Provide quick access to key information
  - Support sharing of information among doctors and patients
- **Enable analyses of device safety and quality**
  - Populate data registries & large health system analyses
  - Report adverse events
- **Inform other hospital systems (supply chain, billing, etc)**

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Clinical Applications of UDI

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Break

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Next Steps

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Thank You for Your Participation

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