Realizing the Benefits of the Unique Device Identifier in Health Care

December 9, 2014

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Welcome

- Allan Coukell, Senior Director, Health Programs, The Pew Charitable Trusts, @coukell
- Jeff Shuren, Director, Center for Devices and Radiological Health (CDRH), FDA
Welcome

• Josh Rising, Director, Healthcare Programs, The Pew Charitable Trusts, @joshrising

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UDI Roadmap

- Terrie Reed, Project Leader, Clinical Research Informatics, Duke Clinical Research Institute
- Greg Daniel, Managing Director for Evidence Development & Innovation, Engelberg Center for Health Care Reform, Brookings Institution

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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
<table>
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<th>BENEFIT THEME</th>
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| 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

- Use of devices that are not uniformly labeled with UDIs (current state)
- Affixing/incorporating UDIs during manufacturing

- Use of devices with UDIs in clinical practice
- Incorporating UDI into data collection fields and provider workflow

- Routine capture of UDI in electronic data sources
- Developing methods and data infrastructure

- UDI routinely available for valuable uses

UDI Development Phase

UDI Implementation Phase

Focus for UDI Implementation Roadmap
Flow of UDIs Across Electronic Health Data Systems

- Manufacturer
- Distributor
- Provider Inventory
- Provider EHRs
- Payers
- Registries
- Patients & Consumers
- Supply Chain
Transmission and Use of UDI Across the Health Care Ecosystem

1. Manufacturers submit DI to FDA-GUID to create a master data source

2. UDI affixed to medical devices

3. UDI integrated into supply chain

4. UDI is captured and used cross provider system clinical care

5. Outpatient providers have access to UDI via EHR

6. Patient education and engagement improves with UDI capture

7. Payers capture UDI across provider systems and settings

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

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

Flow of UDI

Care Delivery System

Clinical Research

Patient-Directed Tools
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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Break
Supply Chain and Materials Management Implementation of UDI

- Leigh Anderson, Informatics & Technology Services Chief Operating Officer, Premier
- Joe Dudas, Vice Chair, Category Management, Mayo Clinic
- Dennis Orthman, Senior Director, Strategic Marketplace Initiative
- Mike Schiller, Supply Chain Director, Association for Healthcare Resource & Materials Management
- Moderator: Karen Conway, Executive Director, Industry Relations, Global Healthcare Exchange

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Lunch

• Jon White, Acting Deputy National Coordinator for Health Information Technology
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)
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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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)
Clinical Applications of UDI

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Additional Uses of UDI

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Next Steps

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Thank You for Your Participation

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