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UDI as the Cornerstone to Medical Device Data Capture

Presentation to:
27th Global GS1 Healthcare Conference

April 23, 2015

Mexico City

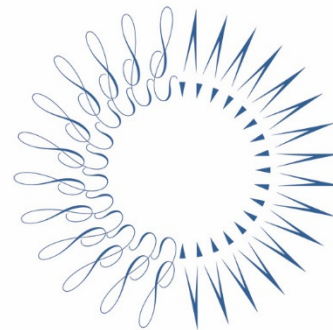


The Pew Charitable Trusts

Pew is an independent, non-profit research and public policy organization.

Pew seeks to enhance medical device safety and foster device innovation that benefits patients.

- Unique device identifier (UDI)
- Medical device registries
- Accelerating device innovation





UDI has Great Potential to Improve Care

- Improve the efficiency of health care operations
- Quickly identify problems with medical devices
- Locate products and patients in the event of a recall
- Enhance care coordination across providers

**Without the adoption of UDI by providers,
UDI has only just that—potential**



Foundation: Standards Development and Uptake

- Supply chain & materials management
- EHRs & clinical systems
- Revenue cycle, billing & claims
- Other applications



Dec. 9 Meeting: Realizing the Benefits of the UDI in Health Care



The Office of the National Coordinator for
Health Information Technology



- 1) What capabilities do hospitals, providers, health plans and patients need?
- 2) What systems need to capture and exchange UDI?
- 3) What standards are needed?
- 4) Identify and build momentum for the development of these standards



Panel 1: Interoperability of UDI

Benefits

- Seamless transmission of UDI among disparate systems
- Scan one, use often

Necessary Standards

- Disparate systems that are not currently interoperable must have improved capabilities to exchange data
- Solutions exist to address three different formats of UDI
- Hospitals must have automatic identification and data capture capabilities

Panel 2: The Supply Chain and UDI Capture

Benefits

- Know exactly what devices are in stock to prevent over-ordering of unneeded products
- Locate all products on hospital shelves when there is a recall or shortage
- Alert personnel to pending product expirations
- Automate reordering of products following their use

Necessary Standards

- Field for UDI in supply chain management systems
- Incorporation and use of UDI in item master as the single source of truth



Panel 3: UDI Capture in Clinical Systems & EHRs

Benefits

- Helps providers identify patients implanted with recalled products
- Enables patients and providers to submit more precise adverse event reports
- Supports care coordination by providing physicians with precise information on the devices implanted in patients.
- Allows hospitals to perform analyses comparing devices used in that facility



Panel 3: UDI Capture in Clinical Systems & EHRs, cont.

Necessary Standards

- *EHR Certification Criteria:*
 - Creates an implantable device list
 - Supports linking with GUDID to document information in the EHR
 - Adds UDI as a data element to the Common Clinical Data Set (CCDS) for transmission among providers
- *Meaningful Use Stage 3:*
 - Encourages the transmission of the CCDS, including UDI

Comments to ONC and CMS on both rules are due on May 29



Panel 4: Additional Uses of UDI

Benefits exist for:

- Registries
 - UDI can streamline data entry on the product used
 - Improve patient matching
- Quality Measures
 - Enhance algorithmic efficiencies
- Patient-centric applications
 - Discharge summaries; Blue Button+
- Claims

What are the Benefits of UDI Capture in Claims?

Benefits to safety & quality

- Sentinel could conduct device assessments
- Longitudinal analyses (especially if linked with registries)
- Provides information on the number of devices used

Benefits for payors

- Innovative payment models and benefit designs
- Utilization analyses
- Outcomes analyses
- Ensure appropriate follow-up care & assist with recalls

UDI capture in EHRs alone does not yield these same benefits



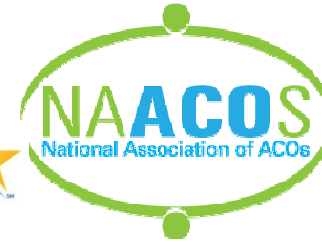
Support for UDI Capture in Claims Transactions



The Society of Thoracic Surgeons



The Office of the National Coordinator for Health Information Technology



POLICY & ACTION FROM CONSUMER REPORTS



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... and counting.



Standards Needed for UDI Capture in Claims

National Committee on Vital and Health Statistics

- Recommended an evaluation of UDI transmission between providers and health plans

Several multi-stakeholder efforts evaluated

- WEDI Foundation
- UDI Roadmap
- National Postmarket Surveillance Planning Board

ASC X12 evaluating revising standards to support UDI

- Convened a workgroup to evaluate
- Email info@disa.org to join this workgroup



Key Outstanding Questions on UDI Capture

- For which devices or procedures should UDI be captured in EHRs and claims? Are there devices other than implants?
- What are the rules, and who should determine them, for defining the right devices or procedures?
- How will hospital workflow change to accommodate UDI?
- How will UDI data be exchanged among hospital systems (MMS, EHRs, billing, clinical suite, etc...)?
- How can hospitals build systems and processes to capture UDI data from EHRs and claims to conduct their own analyses?



Challenges & Questions to UDI Capture in EHRs

- Who will enter the data into the EHR?
- What workflow changes are needed to include UDI in the EHR?
- How will EHRs link with FDA's UDI database (GUDID) or other sources of device information?
- What device attributes should be listed directly in the EHR?



Challenges & Questions to UDI Capture in Claims

- How will claims-based analyses differ among drugs and devices?
- How can UDI improve the accuracy and transparency of billing?
- How will payers utilize UDI data once received?
- Should UDI be in the claim, claim attachment, pre-authorization or another transaction?
- How can we ensure that hospitals can access the information and analyses?

UDI Adoption Guide for Hospitals

- Premier released an implementation guide for hospitals (work funded by Pew)
- Based on experiences of hospitals who have already done work in this area

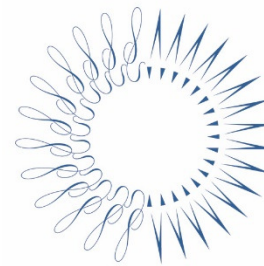


What can you do? Stay Informed and Engaged



Available at:

pewtrusts.org

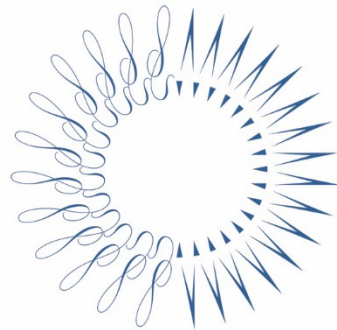


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Thank you

Ben Moscovitch
Officer, Medical Devices
The Pew Charitable Trusts
bmoscovitch@pewtrusts.org



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