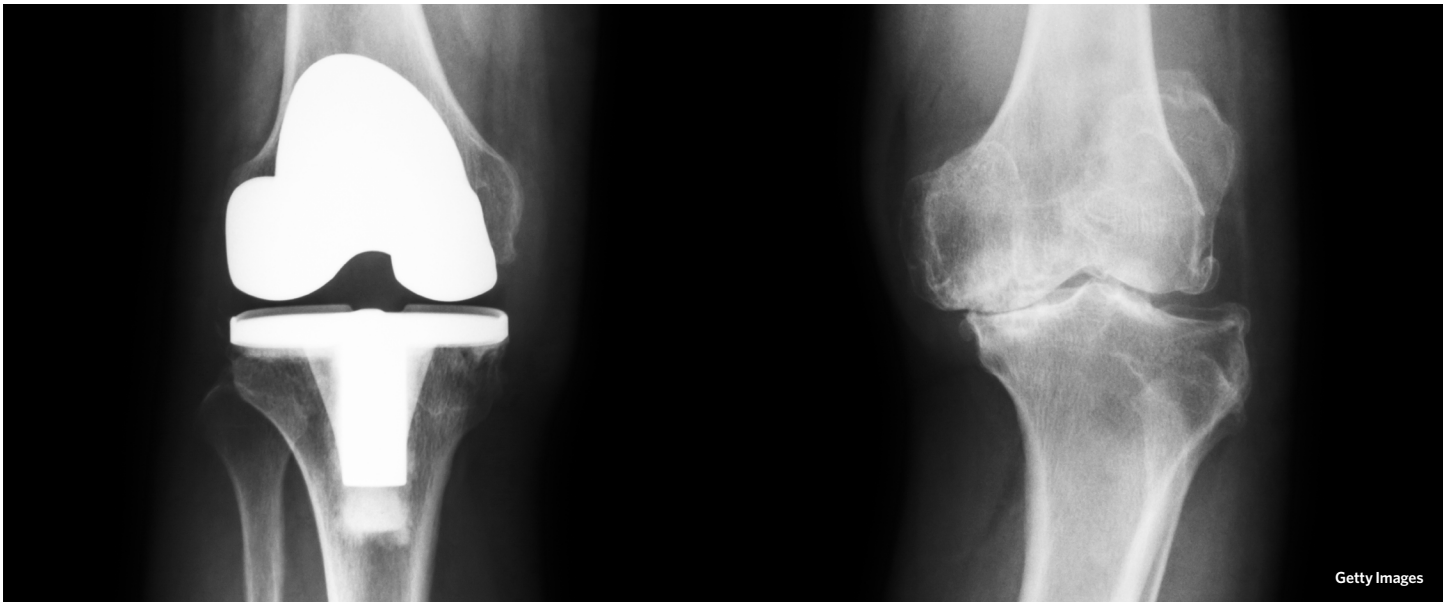
A fact sheet from THE PEW CHARITABLE TRUSTS | June 2016



Unique Device Identifiers Improve Safety and Quality

Why patient health records and insurance claims both must include UDIs

Overview

Patients rely on medical devices to replace failing joints, fix irregular heart rhythms, test blood sugar, diagnose diseases, and improve their health in other ways. While millions of people use these devices on a daily basis, researchers—including those in the federal government and at private organizations—lack an efficient way to track the performance of these products and quickly detect safety problems.

To address this concern, Congress required the Food and Drug Administration (FDA) to create a system to provide medical devices with a unique device identifier (UDI) that corresponds with the product's manufacturer and model type.[1] The UDI system can provide patients and physicians with key information on the devices used in care, such as the precise model of a hip implant that is causing pain and may require revision surgery.

FDA, the National Medical Device Postmarket Surveillance System Planning Board, and many public health organizations, hospitals, and clinical societies agree: The new UDI system can only deliver on Congress' vision once it is actually used throughout the health care system, including in both electronic health records (EHRs) and insurance claims. Documenting UDIs in these data sources offers distinct and complementary benefits. Each is insufficient on its own to effectively realize the potential of this new device identification system.

UDIs in electronic health records will give providers important patient-specific data

Incorporating the UDIs of implanted devices in EHRs can enhance care for individuals as well as enable clinicians to better treat their patients.

Benefits of UDIs in EHRs

- **Support patient safety.** Device-specific information in EHRs can help clinicians identify patients implanted with recalled devices and ensure that they obtain appropriate follow-up care. It can also alert clinicians at the bedside about clinically relevant information, such as a device that has expired or is not MRI-compatible.
- **Enhance clinical decisions and care coordination.** UDI information can help ensure that clinicians have detailed information on what devices have been used or implanted in a patient. This is especially helpful when patients see multiple clinicians or when adverse events occur years after implantation.
- **Inform other hospital systems.** Incorporating UDIs into EHRs and other health information technologies that clinicians use will provide the supply chain, billing, and other systems with product information.

Progress made to advance UDIs in EHRs

Given the importance of UDIs for patient care, federal regulations issued in 2015—with the support of many hospitals, clinical societies, patient organizations, and public health groups—will ensure that EHRs can incorporate the identifier and send it from one provider to another.[2]

However, the inclusion of UDIs in EHRs alone is insufficient because this measure will not effectively support large-scale population health analyses to detect problems quickly. The inclusion of UDIs in insurance claims can fill that gap.

UDIs in claims will enhance population health data on device performance

To better understand care quality, researchers track data on patients over many years, often using claims for this purpose because they contain data for nearly every encounter with the health care system for a specific individual. For example, claims information collected over many years may contain data showing that a patient received a specific prescription drug, had surgery, and visited the emergency department. When used across millions of patients, researchers can begin to understand whether a particular medical intervention, such as a drug, correlates to a particular outcome, such as stroke. Claims data have already been used to detect an association between a vaccine and an intestinal disorder in infants,[3] compare mortality and readmission rates among hospitals,[4] and evaluate preventive services, including cancer screenings.[5]

Given these benefits, the Centers for Medicare & Medicaid Services (CMS) has recently launched several initiatives to increase the use of claims data for research to improve care quality and reduce costs.

Claims cannot be used to study medical devices for one simple reason: Claims currently list only the procedure—such as hip replacement surgery—and lack any specific information about the product implanted in the patient. Adding UDIs to claims would provide that specificity and allow researchers to use this data to assess devices more effectively.

Benefits of UDIs in claims to researchers, FDA, and health plans, including Medicare

- **Data-driven analysis.** If claims contained UDI information, researchers could use these databases as they already do for drugs—comparing, for example, the performance of two models of cardiac stents or determining whether a particular brand of hip implant fails at a higher rate. Health plans could also improve modeling of expected outcomes and costs based on all factors that influence care, including device selection.
- **Sentinel surveillance.** FDA's Sentinel Initiative postmarket surveillance program relies predominantly on claims data to assess drug and vaccine safety. Adding UDI data to claims would allow FDA to use Sentinel to conduct large, longitudinal analyses on device safety, as Congress required it to do in 2012.[6]
- **Demonstrating value.** As Medicare, private health plans, and hospitals increasingly prioritize value, better information about devices can help health systems demonstrate that they are providing cost-effective care to patients without sacrificing quality. This information can help identify when lower- or higher-cost products may be clinically appropriate.
- **Follow-up care and recalls.** Health plans could use UDI information to ensure that their members obtain appropriate follow-up care, such as rehabilitation, which may be required for patients with specific implanted devices. In the event of a recall, UDI data could allow a health plan to notify affected members.
- **Fraud and abuse detection.** Health plans could use UDI data to detect fraud and recoup payments owed to them when products fail.

> "Incorporating the UDI into claims forms could allow quick identification of poorly performing devices and alert relevant stakeholders earlier when defective devices need to be replaced or monitored. As a result, beneficiaries implanted with recalled products could receive appropriate follow-up care more quickly. Finally, CMS could use the data to make better coverage and reimbursement decisions."
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> **Daniel R. Levinson**, U.S. Department of Health and Human Services inspector general, in a September 2015 letter to Senators Elizabeth Warren (D-MA) and Chuck Grassley (R-IA)

EHRs and claims offer different benefits

Because of EHR interoperability challenges, certain FDA postmarket surveillance goals can be accomplished only using claims data. EHRs code information in varying ways and cannot easily exchange information. As a result, researchers face many challenges in combining EHR data across providers to understand quality and value. Claims, on the other hand, are already standardized across providers and payers, resulting in easier aggregation of information throughout the health care system. Adding UDIs would allow regulators and researchers to use claims to evaluate devices in the way in which they already evaluate drugs and procedures.

Broad support for UDIs in claims

Given the many benefits, organizations across the health care ecosystem—including several multistakeholder groups of experts—have emphasized the importance of UDIs in claims. Organizations that have expressed support include:[7]

- Aetna
- Alliance of Community Health Plans
- Geisinger Health System
- Intermountain Healthcare
- Mercy
- National Medical Device Postmarket Surveillance System Planning Board
- American College of Cardiology
- The Society of Thoracic Surgeons
- American Academy of Orthopaedic Surgeons
- Food and Drug Administration
- National Association of Accountable Care Organizations
- American Joint Replacement Registry
- Pacific Business Group on Health
- Leapfrog Group
- Premier
- Nebraska Medicine
- West Health Institute
- Altarum Institute
- Brookings Institution
- National Health Council
- AARP
- Trust for America's Health
- HL7 International
- First Databank

> "Currently, billing data contain the most comprehensive records on individual patient encounters. Due to the lack of interoperability within and across provider systems, patient EHRs are not capable of communicating events such that devices can be tracked over time as patients move between providers. Therefore, the capture of UDIs through claims data provides useful information linking patients to specific devices across provider systems and over time."
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> Unique Device Identifiers (UDIs): A Roadmap for Effective Implementation, The Brookings Institution

Congress must act to add UDIs to claims

Hospitals and health plans cannot unilaterally add a field to claims for UDI information. The claims form, regulated by CMS, is standardized across health plans and providers and is updated infrequently. As a result, plans and providers that want to document UDIs in claims are unable to do so until a change is made. The last update took effect in 2012, and the form might not be revised until 2021 or later.[8] Given that changes for the next update are decided well in advance to allow for an implementation period, the window for adding UDIs to claims is rapidly closing.

Congress should require that CMS—as part of the next claims form update—support the creation of a field to document the UDIs of implanted devices. This common-sense solution would help protect patients from unsafe products and provide clinicians, researchers, and regulators with the data they need to improve quality for the millions of Americans who rely on medical implants.

Endnotes

1 Unique Device Identification System, 78 Fed. Reg. 58785 (Sept. 24, 2013).

2 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and the Office of the National Coordinator for Health Information Technology, Health IT Certification Program Modifications, 80 Fed. Reg. 62601 (Oct. 16, 2015).

3 Mini-Sentinel, "Intussusception Risk After Rotavirus Vaccination in U.S. Infants" (June 13, 2013), http://www.mini-sentinel.org/assessments/medical_events/details.aspx?ID=190.

4 Centers for Medicare & Medicaid Services, "30-Day Unplanned Readmission and Death Measures," accessed June 8, 2016, https://www.medicare.gov/hospitalcompare/Data/30-day-measures.html.

5 National Cancer Institute, "SEER-Medicare: Brief Description of the SEER-Medicare Database," accessed June 8, 2016, http://healthcaredelivery.cancer.gov/seermedicare/overview.

6 U.S. Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112–144, 126 Stat. 993 (2012).

7 Aetna et al., letter to U.S. Representative Kevin Brady at the Committee on Ways and Means, June 11, 2015, http://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2015/06/pew-thanks-representative-brady-for-supporting-medical-device-identifier-system; Brookings Institution, "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System" (February 2015), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM435112.pdf; Food and Drug Administration, Center for Devices and Radiological Health, "Strengthening Our National System for Medical Device Postmarket Surveillance: Update and Next Steps" (April 2013), http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf; American College of Cardiology et al., letter to FDA, the Office of the National Coordinator for Health Information Technology, and CMS, May 29, 2014, http://www.pewtrusts.org/en/about/news-room/letters/letters/2013/05/29/groups-urge-onc-fda-and-cms-to-support-new-field-in-health-insurance-claims-for-udi; David D. Teuscher, letter to Stephen Ostroff at the Food and Drug Administration, Oct. 26, 2015; Clif Gaus, letter to Stacey Barber at Accredited Standards Committee X12, March 2, 2015; Patricia P. Smith, letter to Health and Human Services Secretary Sylvia Mathews Burwell, Nov. 5, 2015; AARP et al., letter to Margaret Weiker at Accredited Standards Committee X12, April 7, 2014; Lincoln T. Smith, letter to Secretary Burwell, Sept. 2, 2015; Joseph M. Smith, letter to Secretary Burwell, Aug. 17, 2015; John Windle and Michael Ash, letter to Secretary Burwell, July 28, 2015; and Blair Childs, letter to Accredited Standards Committee X12's Margaret Weiker, April 9, 2014.

8 Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards, 74 Fed. Reg. 3296 (Jan. 16, 2009).

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