



# Implementing Unique Device Identification

Recommendations for Integrating Medical Device Data Throughout the Health Care System



## The Pew Charitable Trusts

**Susan K. Urahn**, *executive vice president*

**Allan Coukell**, *senior director*

## The Medical Device Initiative team members

**Josh Rising**, *director*

**Angela Franklin**, *senior officer*

**Ben Moscovitch**, *officer*

**Anqi Lu**, *associate*

**Lyana Pearson**, *administrative assistant*

## Acknowledgments

The Medical Device Initiative team would like to thank everyone who participated in the December 2014 Realizing the Benefits of the Unique Device Identifier in Health Care meeting and contributed insight to inform this report. A detailed list of individuals can be found in Appendix B.

We want to express our gratitude to our Pew colleagues Demetra Aposporos, Erin Davis, Linda Paris, Gaye Williams, Laurie Boeder, Bernard Ohanian, Kodi Seaton, Jennifer Peltak, Liz Visser, and Marjorie Connolly for their work preparing this report for publication.

---

## For further information, please visit:

[pewtrusts.org](http://pewtrusts.org)

---

**Contact:** Marjorie Connolly, associate, communications

**Email:** [mconnolly@pewtrusts.org](mailto:mconnolly@pewtrusts.org)

**Project website:** [pewtrusts.org/projects/medical-device-initiative](http://pewtrusts.org/projects/medical-device-initiative)

---

**The Pew Charitable Trusts** is driven by the power of knowledge to solve today's most challenging problems. Pew applies a rigorous, analytical approach to improve public policy, inform the public, and invigorate civic life.

# Contents

- 1 Overview
- 4 Adopting UDIs to improve outcomes and reduce costs
  - Structure of the UDI 5
  - Development of UDI standards 6
- 7 Utilizing UDIs to generate health system efficiencies
  - The need for a single source of product information 8
  - Enhanced supply chain management 11
- 12 Providing better information to doctors and patients
  - Other patient-centric tools require UDI integration 14
  - Standards and next steps needed to give clinicians and patients better information 17
- 18 Improve evaluations of quality with better data
  - Quality improvement benefits of UDI adoption 18
  - Using claims data to improve care 21
  - Standards updates needed to support quality improvement efforts 22
- 26 Ensuring the seamless capture and transmission of UDIs
  - Preventing errors through automated capture 26
  - Standards needed to support UDI interoperability 28
- 29 Critical next steps for UDI adoption
  - Government can support collaboration and standardization 29
  - Vendors and the private sector should drive adoption 31
- 32 Conclusion
- 33 Appendix A: Agenda
- 36 Appendix B: Acknowledgments
- 38 Endnotes

## Overview

Patients rely on medical devices to replace failing joints, fix irregular heart rhythms, test blood sugar, unblock clogged arteries, diagnose disease, and improve their health in other ways. Yet for many years these devices have lacked industrywide standard identification numbers, a shortcoming that hinders hospital efforts to track inventory, prevents physicians and patients from having complete information on the products they use, and limits analyses of the real-world performance of medical devices.

Now there is a new system, developed by the Food and Drug Administration at the direction of Congress, to provide medical devices with a unique device identifier, or UDI, that corresponds to the product's manufacturer, model, and other clinically relevant information, such as expiration date. These codes already appear on an increasing number of product packages, allowing doctors, nurses, hospital staff, patients, and others to read the information. They also appear as bar codes—like the ones used in supermarkets—or other electronic depictions so the identifier can be easily scanned and entered into different databases.

This new UDI system can help hospitals locate recalled devices before they're used in care, develop better data on new technologies, dispense up-to-date information on available items, support patient safety, and facilitate the reordering of supplies as stock on hand drops below a specified level. To obtain these efficiencies and reap associated savings, hospitals should incorporate UDI codes and other related information into their item masters—computerized databases that serve as a catalog of products a facility can purchase—and into supply chain systems that track product orders, monitor utilization, and manage the inventory on institutions' shelves.

The UDI system offers many other benefits to patients and clinicians as well, particularly if included in electronic health records (EHRs). New capabilities to incorporate UDIs into patient records can ensure that more accurate information is available to improve coordination among doctors, facilitate more detailed and accurate reports of device failures, support physician-patient decision-making, and locate individuals when there is a recall. EHRs should also have new fields to record the UDIs of implanted devices and list other product information—such as the name of the manufacturer and product size, if available—to more promptly give clinicians and patients key data on the devices used. Because implanted devices are an integral part of a patient's health history, any summary-of-care documents used to exchange information among health care providers should also include UDIs of implanted devices.

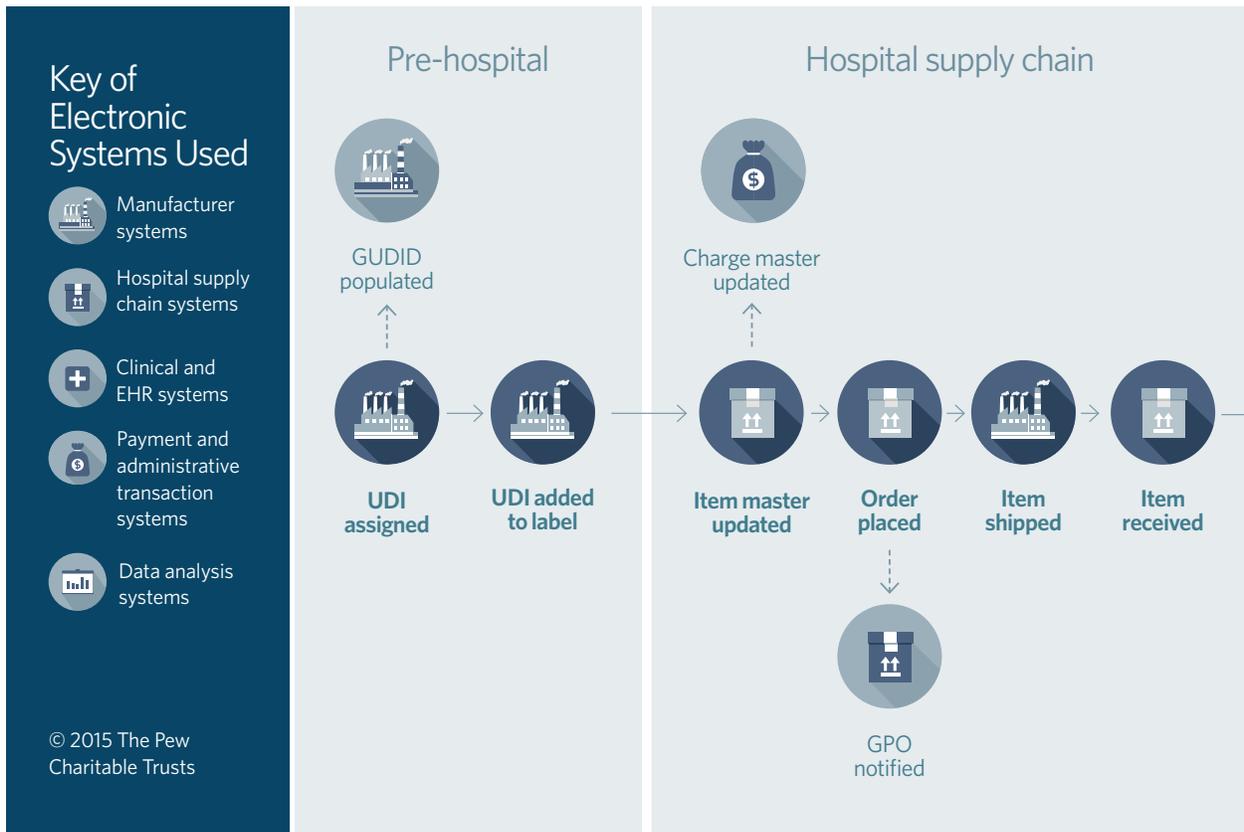
Additionally, UDIs can help improve the quality of information on a device's safety and performance over time by incorporating it into the data sources already used by health plans, hospitals, and researchers to analyze patient outcomes. Including UDIs in registries and health insurance claims, in particular, can support more robust assessments of medical device performance in large patient populations.

And to efficiently facilitate these uses, the electronic systems currently used by hospitals, clinicians, product distributors, health plans, registries, and other stakeholders should be able to collect UDIs through automatic scanning—via tools such as bar-code readers—to prevent error-prone manual data entry and expedite the exchange of UDIs across databases.

To ensure the efficient collection and exchange of UDIs, the federal government, hospitals, health information technology vendors, clinicians, manufacturers, health plans, registries, and patients should now coordinate implementation of this new tool. This report—which was informed by independent research and a 2014 conference with experts from government agencies, hospitals, clinical technology, and medical device companies—outlines key ways to help facilitate and encourage the adoption of UDIs, address challenges to adoption, and enable the entire health system to realize the UDI's full potential to improve care while reducing costs. (See Figure 1.)

Figure 1

# How UDIs Could Flow Through Patient Care



## Glossary of Steps

**UDI assigned.** Manufacturer assigns device a UDI.

**GUDID populated.** Manufacturer records UDI in the Global Unique Device Identification Database.

**UDI added to label.** Manufacturer adds UDI to device's label.

**Item master updated.** Hospital updates its item master with device information as necessary.

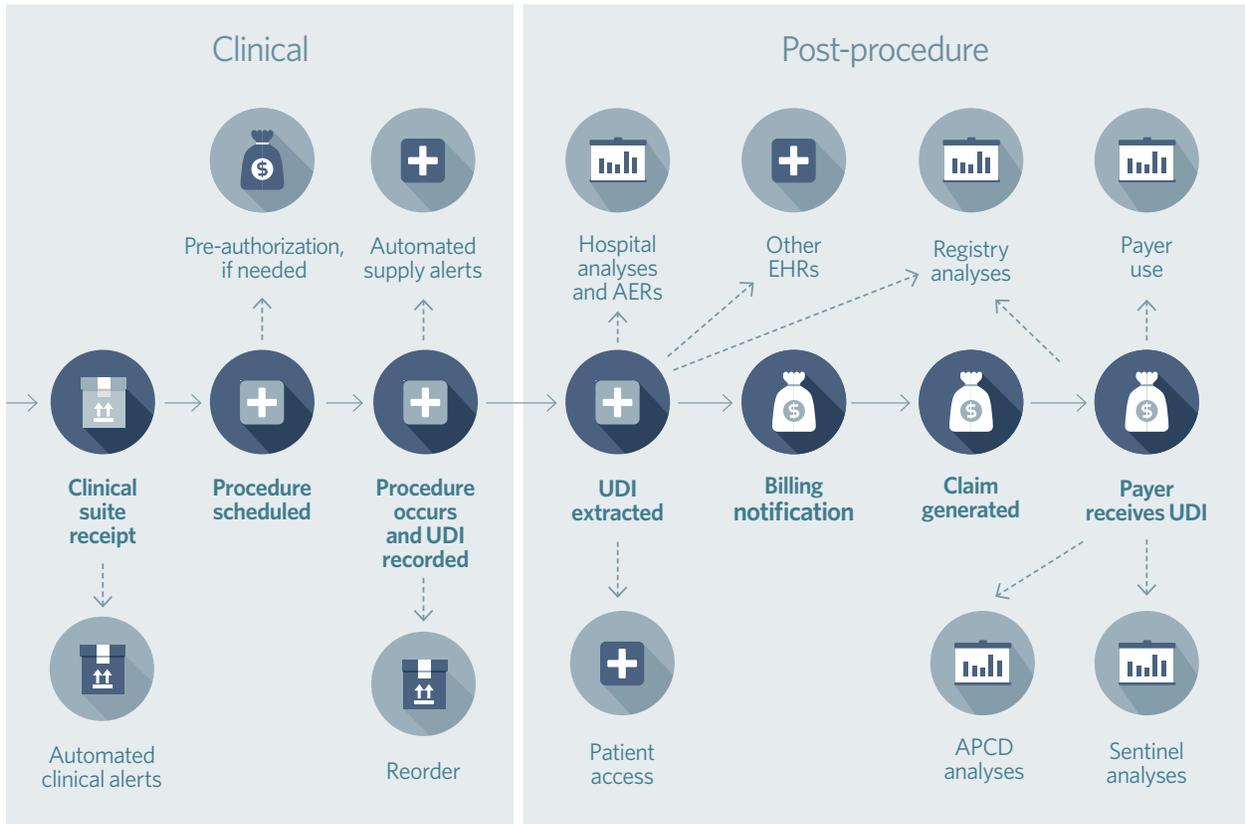
**Charge master updated.** If needed, hospital updates its charge master to reflect UDI-associated billing changes.

**Order placed.** Hospital places medical device order with the manufacturer or distributor.

**Group purchasing organization notified.** Hospital sends its GPO a summary of products purchased, if required.

**Item shipped.** Manufacturer or distributor ships the medical device order.

**Item received.** Hospital receives the item ordered on its loading dock and updates supply chain and procurement systems to reflect receipt.



**Clinical suite receipt.** The hospital unit using the product scans individual devices into its clinical suite inventory management system.

**Automated clinical alerts.** Clinical suite system automatically identifies any recalled or expiring devices before implantation.

**Procedure scheduled.** Patient's procedure is scheduled.

**Pre-authorization, if needed.** If necessary, hospital sends device information to the health plan through its administrative transaction system.

**Procedure occurs and UDI recorded.** UDIs of devices used in the procedure are recorded in the patient's electronic health record (EHR) and the clinical suite system.

**Reorder.** Hospital supply chain system automatically reorders products from the manufacturer to replenish inventory.

**Automated supply alerts.** Hospital receives automatic alert when devices expire or are recalled.

**UDI extracted.** EHR extracts pertinent information, including UDIs, in a standardized format to send to other clinical and administrative systems.

**Patient access.** The EHR sends UDI information to patient portals and Blue Button+, allowing patients to access it.

**Hospital analyses and adverse event reports.** Hospitals can analyze device performance with EHR data and submit AERs to FDA if a problem occurs.

**Other EHRs.** Providers receive UDI.

**Billing notification.** Hospital's clinical suite system relays when a device is implanted, and must be paid for, to the billing system.

**Claim generated.** Billing system generates a claim with device-specific information that is sent to the health plan for payment.

**Payer receives UDI.** Hospital sends payer UDI in claim.

**Payer use.** UDIs allow health plans to contact patients for follow-up care related to implanted and recalled devices or to conduct their own analyses.

**Registry analyses.** Using EHR and claims data information, clinical registries can analyze device performance.

**All-payer claims database analyses.** Health plans submit data to APCD.

**Sentinel analyses.** Sentinel uses claims to assess device safety.

This report will examine how the UDI works, how it is captured in electronic data systems, and how it can benefit the medical system to:

- **Generate health system efficiencies.**
  - Enhance supply chain management and product tracking through hospitals.
  - Alert staff to pending product expiration dates.
  - Support more efficient recall resolution of items in stock.
- **Provide better information to patients and clinicians.**
  - Support coordination of care for patients seeing multiple clinicians.
  - Locate patients implanted with recalled devices.
  - Allow for more precise adverse event reports when devices fail.
- **Improve the information available on the quality and cost of care.**
  - Support robust assessments of medical devices' safety performance in large patient populations.
  - Enhance long-term analyses of registries to track patient outcomes.
  - Help health plans model expenditures and better understand factors influencing the cost of care.
- **Facilitate transmission of standard device data among disparate systems and throughout the health care system.**
  - Ensure more specific documentation of devices used in care.
  - Support interoperable exchange of device information among hospital systems and institutions.
  - Reduce errors encountered in manual data entry by automating documentation of device information.

---

Achieving these benefits requires that a health system utilize this new tool throughout a product's life cycle—from the time it is ordered and received by a hospital, to its use in patient care, to long-term monitoring for safety and efficacy.

---

## **Adopting UDIs to improve outcomes and reduce costs**

Patients and physicians rely on medical devices—including cardiac stents, implantable joints, drug infusion pumps, and other surgical tools—to improve and prolong lives, yet the inability to track and identify these products in a standard way has increased safety risks and the costs of care. To address this deficiency, FDA has established a system to assign each medical device a UDI corresponding to key information about the product, including its manufacturer and model type.

This system can help hospitals, physicians, patients, health plans, and manufacturers identify products that are recalled, develop better data on the performance of different technologies, and decrease the costs of procuring products and managing inventory. Achieving these benefits requires that a health system utilize this new tool throughout a product's life cycle—from the time it is ordered and received by a hospital, to its use in patient care, to long-term monitoring for safety and efficacy.

To accelerate the realization of the many benefits UDI offers, The Pew Charitable Trusts—in conjunction with FDA and the Office of the National Coordinator for Health Information Technology, or ONC—convened representatives from hospitals, health plans, device manufacturers, technology vendors, standards bodies, and other health organizations in December 2014 to explore the additional steps needed to support and help facilitate UDI adoption. The meeting built on findings from several other multistakeholder efforts, including hospital, payer, and postmarket surveillance experts who were organized through the Brookings Institution to develop a UDI road map for FDA.<sup>1</sup> All of these findings are incorporated into this report and its determination of key next steps.

## Structure of the UDI

The unique device identifier system provides each device with a standard code that will enable doctors, patients, and other stakeholders to determine the product’s manufacturer, make, and model, and additional information such as lot number and expiration date.<sup>2</sup>

UDIs appear on a part of the product’s label, and some devices also have the UDI marked on them directly. The UDI must appear in both human and machine-readable formats, such as the numbers on bar codes or radio frequency identification tags.

Figure 2  
Components of UDIs

The unique device identifier consists of two parts, both represented in an alphanumeric code and in an automatic scanning method, such as a bar code. The UDI appears on the device packaging or label, and in certain cases on the device itself.



---

## History of the UDI

**September 2007:** Congress requires FDA to develop the UDI system as part of the Food and Drug Administration Amendments Act.

**July 2012:** Congress requires FDA to publish the UDI rule by the end of the year and incorporate medical devices into the postmarket surveillance Sentinel Initiative.

**September 2013:** FDA publishes the final UDI rule to require medical device labels and, where applicable, to add a unique identifier on the product itself.

**September 2014:** High-risk (known as Class III) devices are required to have UDIs.\*

**May 2015:** The National Library of Medicine and FDA make publicly available the Global Unique Device Identification Database, which provides information on each product based on its device identifier. This database also includes information about whether products contain latex or are compatible with MRI scans.

**September 2015:** All implantable, life-supporting, or life-sustaining devices, regardless of class, must have UDIs.\*

**September 2018:** All devices not exempt from the regulations will have UDIs.\*

---

\* Following each of these UDI compliance dates, FDA regulations allow a three-year sell-off period for the use of devices already in inventory, even if they lack a UDI. Sources: Food and Drug Administration Amendments Act, Pub. L. 110-85, 121 Stat. 823 (2007), <http://www.gpo.gov/fdsys/pkg/PLAW-110publ185/pdf/PLAW-publ185.pdf>; Food and Drug Administration Safety and Innovation Act, Pub. L. 112-144, 126 Stat. 993 (2012), <http://gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>.

---

## Development of UDI standards

Manufacturers obtain UDIs for their products by working with FDA-accredited issuing agencies. Each issuing agency has a standard UDI format that depicts the different elements of the UDI, such as the device and production identifiers, which include the expiration date, lot number, and other information.

Some devices may have multiple UDIs, one from each issuing agency, if the manufacturer chooses to obtain more than a single identifier to, for example, accommodate requests from hospitals that prefer a certain format.

Multiple issuing agencies means that infrastructure supporting UDIs—such as bar-code readers and electronic databases—should be able to differentiate among their formats.<sup>3</sup> For example, software developers can program electronic systems to parse the UDI based on its configuration, including through the use of delimiters, which are characters that divide the sections of each UDI. For example, the device identifier in one FDA-approved UDI format begins with “(01),” while the product expiration date is preceded by “(17).”<sup>4</sup>

# Utilizing UDIs to generate health system efficiencies

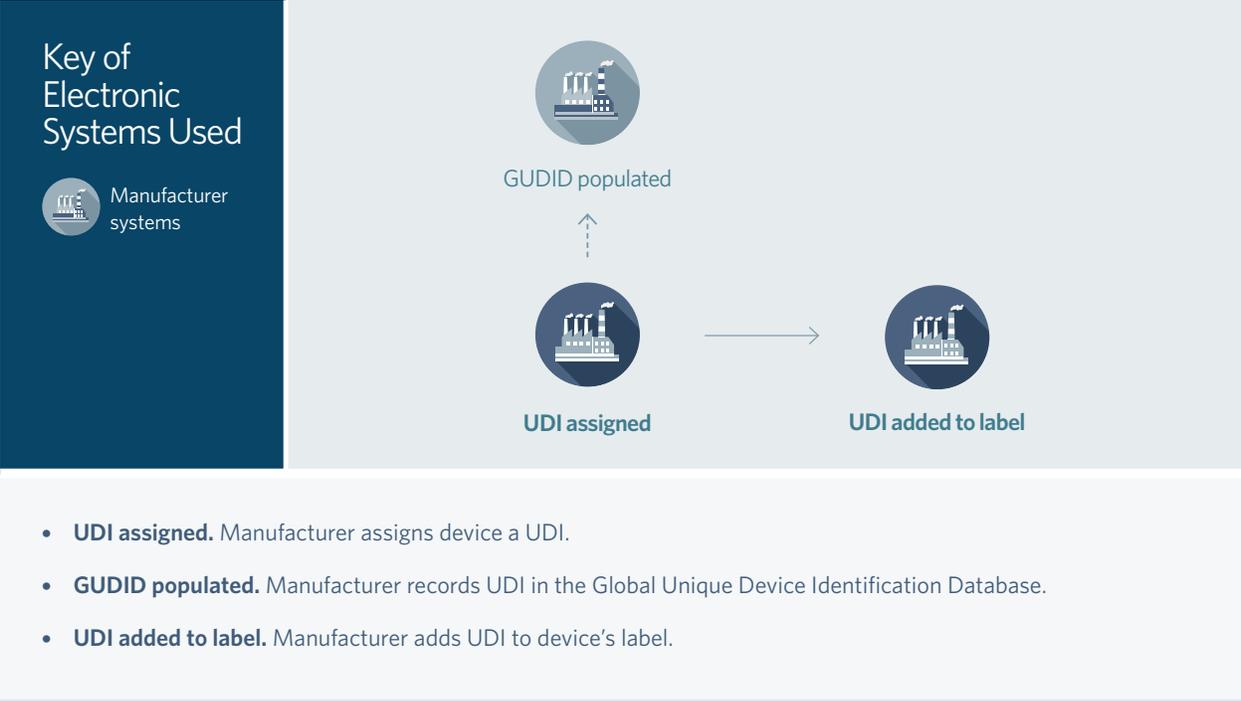
## Key principles

- The UDI can help ensure that a hospital’s item master, a catalog of the products used by a facility, has up-to-date and accurate information on medical devices.
- Supply chain systems—including those used to track product orders and monitor utilization in clinical suites—should integrate UDIs for more precise information on the devices that need reordering and to identify recalled or expired technologies.
- The item master and supply chain systems must be able to link with each other and external databases to exchange information.

The current supply chain information system—where hospitals buy and monitor the products they use—often uses proprietary numbers or other nonunique methods to identify devices. Without UDIs, some products (such as intraocular lenses) could have the same identifying numbers as other vastly different devices (such as knee implants), leading to confusion.

This lack of standard product identification within supply chain systems hinders the ability to effectively track products, including monitoring the products in stock, locating recalled products, using devices before their expiration dates, and ensuring up-to-date data on available products. Modernizing the supply chain to more effectively address these issues requires the use of a standard device identifier.

Figure 3  
How UDIs Could Flow Through Patient Care  
Pre-hospital



The UDI system can improve the way devices are identified and help hospitals, physicians, and manufacturers improve the efficiency of the supply chain, better manage inventory, and generate associated savings. Obtaining these efficiencies from utilizing UDIs requires their use as the unique identifier for products and integrating this new tool into supply chain management systems.

---

## FDA-ONC-Pew Meeting Panel

### Supply chain and materials management implementation of the UDI

These participants helped to inform these principles on providing better information to doctors and patients:

- **Leigh Anderson**, chief operating officer, informatics and technology services, Premier
- **Karen Conway**, executive director, industry relations, Global Healthcare Exchange
- **Joe Dudas**, division chair, enterprise analytics, Mayo Clinic
- **Dennis Orthman**, senior director, Strategic Marketplace Initiative
- **Mike Schiller**, supply chain director, Association for Healthcare Resource & Materials Management

---

## The need for a single source of product information

Hospitals keep internal electronic catalogs of products they use that can include packaging—such as whether a product comes in a case—and other details, including the manufacturer and vendor. This catalog, known as the item master, often provides product information that is shared throughout the hospital for many purposes, such as to aid in ordering replacements or provide clinicians with information on the devices they use. The item master is much like a restaurant menu, listing the different products that authorized hospital employees can order from manufacturers or distributors.

This database is often used to share information with other systems within a hospital. For example, a physician needing to document in a patient's EHR which product was implanted can find that information in the hospital's item master. Similarly, if an inventory management system requires the unit of measure, such as box or case, for device reordering, the item master can provide that, too.

Because item masters may contain information on many products, they can be extremely large. They should be accurate and up-to-date, or incorrect data will enter other systems. For example, if the item master entry contains incorrect information, the hospital could order the wrong device or the wrong quantity, resulting in the need to reorder with additional rush and overnight freight charges or to cancel scheduled procedures.

Manually entering information into item masters can result in incomplete and inaccurate data, while electronically updating item masters from third parties, such as data exchange organizations, can ensure that item masters are up-to-date.

Figure 4

## How UDIs Could Flow Through Patient Care Hospital supply chain



- **Item master updated.** Hospital updates its item master with device information as necessary.
- **Charge master updated.** If needed, hospital updates its charge master to reflect UDI-associated billing changes.
- **Order placed.** Hospital places medical device order with the manufacturer or distributor.
- **Group purchasing organization notified.** Hospital sends its GPO a summary of products purchased, if required.
- **Item shipped.** Manufacturer or distributor ships the medical device order.
- **Item received.** Hospital receives the item ordered on its loading dock and updates supply chain and procurement systems to reflect receipt.

Using the device identifier portion of the UDI can help guarantee accurate information for each product in the item master, which could then be the single source of data on its characteristics across applications.<sup>5</sup> If information associated with each UDI is entered correctly and continually updated, the item master can be used as the main source of data, so that subsequent references to the device identifier will be correct.

With the use of UDIs, the item master could provide information to other systems to assist clinicians, including, for example, whether the product contains latex or is compatible with MRI scans. Many of the product attributes needed in the item master are in FDA's UDI database, which could become a one-stop source for

key, standardized device data from manufacturers. Based on the information that providers need in their item masters, additional data may originate from several sources.

Creation of a supplemental UDI database with additional details about each product may be necessary; a virtual industrywide item master to link product details from manufacturers may serve this purpose.

Figure 5  
Sample Hospital Item Master With UDI

Device Identifier	1060329500	0571560813	0028241923
Manufacturer	WalkEasy Ortho Inc	Heartcare Inc	Valves for All
Model	Strider	Leader	Accel
Unit of measure	Each	Each	Box
Description	Acetabular shell	Drug-eluting stent	Aortic heart valve
Size	78 mm	2.4 mm	22 mm
Latex	No	No	No
Expiration date	No	Yes	No
MRI-compatible	No	Yes	Yes

■ UDI-supported data elements that may not be in a typical item master

© 2015 The Pew Charitable Trusts

“ Our inventories are bloated. Although we are not going to solve a health care financial problem alone by lowering our inventories, it is a contributing factor. It is just one of the many benefits that we think that we can see.”

—Dennis Orthman, senior director, Strategic Marketplace Initiative, a consortium of provider, manufacturer, distributor, and information technology executives dedicated to modernizing the supply chain



You don't want to be grabbing disparate pieces of information across different systems. You want to have it in one centralized location. That centralized location, from a supply chain standpoint, is the item master."

—Mike Schiller, supply chain director, Association for Healthcare Resource & Materials Management

---

## Enhanced supply chain management

The electronic systems used to order, receive, and track inventory should also incorporate UDIs.<sup>6</sup> Doing so can help hospitals:

- Know exactly what devices are in stock to prevent ordering too many.
- Locate all products on hospital shelves when there is a recall<sup>7</sup> or shortage.
- Alert personnel to pending product expirations to ensure prompt utilization.
- Automate reordering of products after they are used.

To achieve these benefits, procurement and inventory management systems should first establish fields for product UDIs or the components of the UDI. Some benefits, such as the ability to reorder products, require only the device identifier portion of the UDI. Other uses, however, such as the ability to efficiently conduct product recalls, require the full UDI.

Second, health care providers' supply chain systems should be able to electronically synchronize their data with those of third parties to keep their product information up-to-date, reduce errors from manual data entry, prevent duplicate entries, and avoid other challenges that compromise the data.<sup>8</sup>

Finally, additional functionality in inventory management systems can reduce the time staff spends managing products on the shelf. These functions could include alerting staff when certain products near their expiration dates, reordering devices when they are used, or notifying providers of recalls.

---

## Lack of Transparency Hinders Ebola Product Management

The UDI system will help hospitals definitively know how many products are in stock and where those devices are located. This information will reduce the perception of product shortages—particularly in emergency situations—by giving health care providers an accurate count of the products on hand.

For example, a speaker at the Dec. 9 conference mentioned that in 2014, fears of the deadly Ebola virus spreading in the United States led many hospitals to order too much additional personal protective equipment for staff because they lacked an adequate accounting system for inventory. The unnecessary orders increased costs and reduced the availability of supplies to facilities that had shortages.

---

## Providing better information to doctors and patients

### Key principles

- UDI inclusion in electronic health records can ensure that patients and physicians have information on the specific products implanted to improve care coordination, facilitate more precise adverse event reports, and locate patients when there is a recall.
- Electronic health records must have fields to record the UDIs of implanted devices and list other information about the product to more promptly give clinicians and patients key data on the products used.
- Providers should not need to manually input UDIs into patients' records; interfaces with other electronic systems and scanning capabilities should automate UDI capture, which would also reduce the possibility for entry errors.
- UDIs for implants must be included in standard reports, such as discharge summaries, that support the exchange of information among providers to facilitate care coordination.

The UDI system can also 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.<sup>9</sup>

To ensure that patients and physicians have the information they need, UDIs should be incorporated into electronic health records and other systems utilized in clinical suites—such as emergency departments, operating rooms, and cardiac catheterization laboratories. It's important that documentation of UDIs also be incorporated into providers'

---

### FDA-ONC-Pew Meeting Panel

#### Clinical applications of UDI

These participants helped to inform these principles on providing better information to doctors and patients:

- **David Bates**, chief quality officer and senior vice president, Brigham and Women's Hospital
- **Hans Buitendijk**, senior expert, R&D, Cerner Corp.
- **Denise Downing**, perioperative nursing specialist, informatics, Association of periOperative Registered Nurses
- **Joe Drozda**, director of outcomes research, Mercy
- **David Hunt**, medical director, Health IT Adoption and Patient Safety, Office of Clinical Quality and Safety, Office of the National Coordinator for Health Information Technology
- **Jon White**, acting director, Office of Clinical Quality and Safety and acting chief medical officer, Office of the National Coordinator for Health Information Technology

workflow to ensure the efficient collection of device data. Additionally, clinical data systems should collect UDI-based information in a seamless and structured manner from other sources, including the supply chain.

While providers may eventually document the UDIs of many types of products in patients' records, hospitals should focus first on documenting identifiers for implanted products at the time of the procedure, as these devices will remain with the individual for many years, have been associated with recent dangerous failures, and are not visible to the human eye for identification if a problem develops.

Documenting the UDIs of implanted devices in patients' health records has several benefits.

- **Supports patient safety:** The UDI can help identify patients implanted with recalled devices and alert clinicians at the bedside to clinically relevant information, such as a device that has expired or is not MRI-compatible.
- **Enhances clinical decision support and care coordination:** UDI information can help ensure that clinicians have detailed device information that quickly shows what devices are used or implanted in a patient. This is especially helpful when patients see multiple clinicians or when adverse events occur years after implantation. Preoperatively, for example, UDIs can help clinicians know what specific implants their patients need removed or revised—a process that currently takes hospital staff approximately half an hour per patient and doesn't always succeed.<sup>10</sup>
- **Informs other hospital systems:** Incorporating UDIs into EHRs and other health information technologies utilized by clinicians will provide the supply chain, billing, and other systems with information when products are used.

To achieve these benefits, patients' health records should:

- List the UDIs of each implanted device and the date the patient received each product.
- Display meaningful information beyond the product UDI so that patients and clinicians have sufficient product data at their fingertips, without needing to look up the UDI on an external database. For each UDI, the EHR should be able to display the manufacturer and model type, serial number, expiration date, and whether the product is MRI-compatible. Other fields are probably needed in EHRs to enable support for clinical decisions, though identifying those product characteristics requires additional collaboration among device manufacturers, providers, federal agencies, and clinical societies.
- Alert clinicians to problems with devices—such as when products are recalled or are MRI-incompatible when physicians order an imaging scan.
- Automate functions for clinicians and patients to easily submit UDIs, and relevant clinical data, in adverse-event reports to FDA when problems occur with the device. Currently, adverse-event reports are underreported and often lack complete and accurate product information;<sup>11</sup> the transmission of UDIs would ensure more comprehensive and precise reports. Automated reporting functions would help hospitals, ambulatory surgical sites, and other provider facilities to adhere to FDA requirements to report suspected medical device-related deaths and serious injuries. Through an automated adverse-event reporting pilot program, ASTER-D, FDA demonstrated that EHRs can help clinicians identify certain situations when adverse events occur and populate reports to FDA using data from the patients' health record.<sup>12</sup>

---

## The Mercy Pilot Project

Mercy, a multistate health system, launched a pilot project to integrate device identifiers into the supply chain and electronic health records systems used in cardiac catheterization labs. The pilot project—which took six months to implement—helped Mercy reduce inventory on hand by approximately \$400,000 (from a starting point of nearly \$2 million) in a single hospital’s cardiac catheterization lab.

More importantly, the integration of UDIs helped Mercy’s clinicians spend less time on inventory management and provided patients and physicians with better information on the devices implanted.

By analyzing data from the pilot, Mercy could also evaluate differences in patient outcomes between bare-metal and drug-eluting stents, finding that the higher mortality rates associated with one device were due to its more frequent use in sicker patients.

---

## Other patient-centric tools require UDI integration

In addition to the electronic health record, several other patient-centric tools can help ensure that patients can access UDI-related information.

### Summary-of-care documents

Summary-of-care documents, such as discharge summaries sent from hospitals to primary care physicians, should include information on any devices implanted in patients. These types of documents often exchange information through the Consolidated-Clinical Document Architecture (C-CDA) developed by Health Level Seven International (HL7), a standards development organization.

Information in the C-CDA is extracted from a patient’s health records in a standard format, and is uniformly structured so that it can be easily accessed by and transmitted to different systems—both within and across institutions.

Including the UDI as a standard element in applicable C-CDAs would ensure that all the systems utilizing this tool would be able to access a list of the devices implanted in patients. This key piece of clinical data would then be available for transition-of-care documents, registries, and systems that require specific information on a patient’s health history.

---

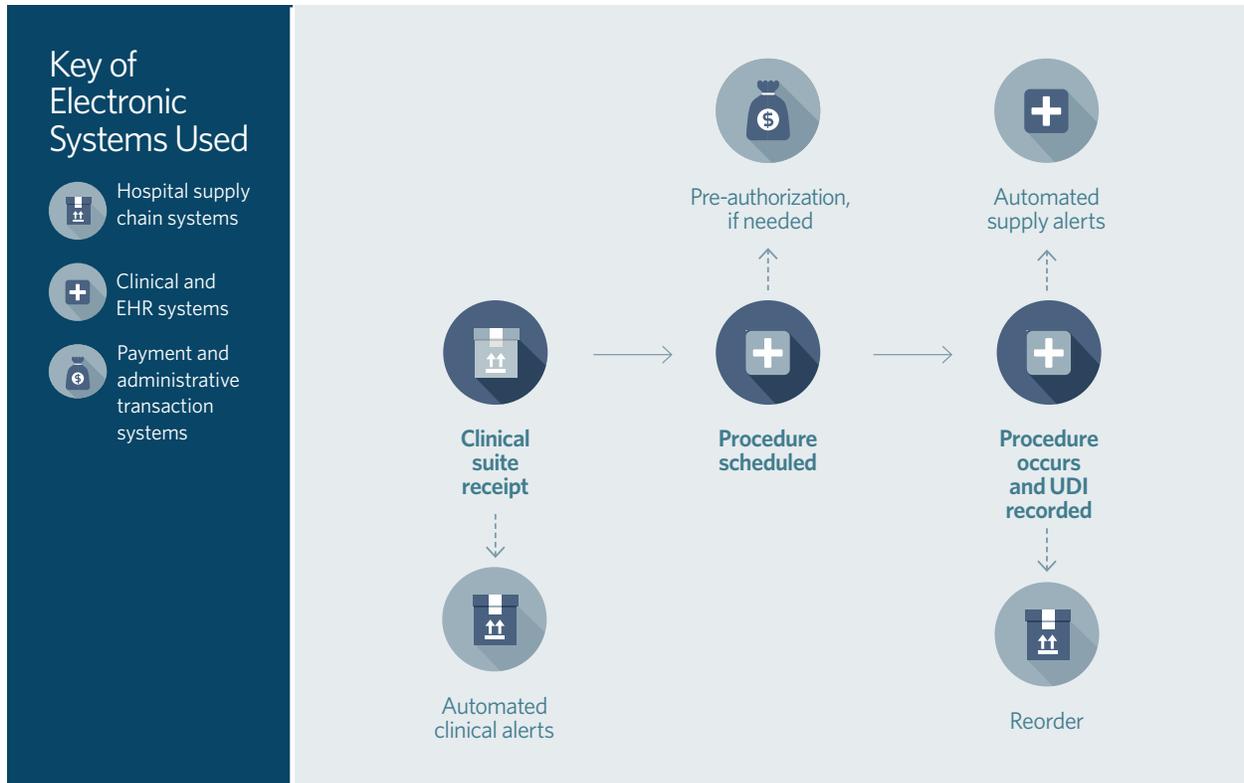
“ The wonderful aspect of this opportunity with UDI in the electronic health record is that the device information is available well beyond the clinicians that are directly responsible for the insertion of the device. That information can now be made available to all members of the care team, including the patient and his or her family.”

—David Hunt, *medical director, Health IT Adoption and Patient Safety, Office of Clinical Quality and Safety, Office of the National Coordinator for Health Information Technology*

---

Figure 6

## How UDIs Could Flow Through Patient Care Clinical



- **Clinical suite receipt.** The hospital unit using the product scans individual devices into its clinical suite inventory management system.
- **Automated clinical alerts.** Clinical suite system automatically identifies any recalled or expiring devices before implantation.
- **Procedure scheduled.** Patient's procedure is scheduled.
- **Pre-authorization, if needed.** If necessary, hospital sends device information to the health plan through its administrative transaction system.
- **Procedure occurs and UDI recorded.** UDIs of devices used in the procedure are recorded in the patient's electronic health record (EHR) and the clinical suite system.
- **Reorder.** Hospital supply chain system automatically reorders products from the manufacturer to replenish inventory.
- **Automated supply alerts.** Hospital receives automatic alert when devices expire or are recalled.

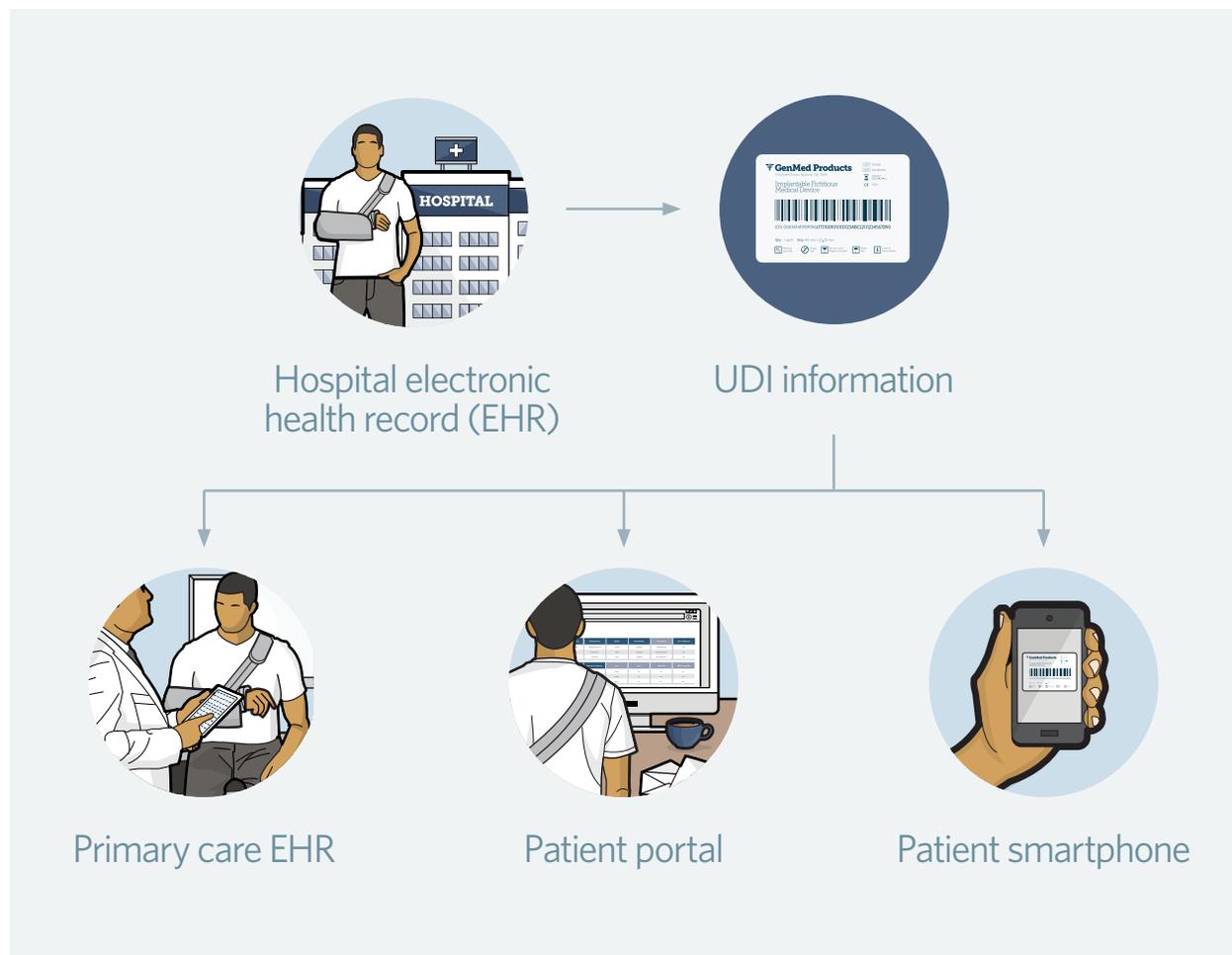
## Blue Button+

The Blue Button+ initiative—which leverages a program originally launched by the Department of Veterans Affairs—supports the use of data from EHRs to provide patients with their own medical history.

Blue Button+ allows patients to aggregate information from disparate doctors' offices, pharmacies, and other health care providers so that all their data—such as medications—are in one place. Blue Button+ capabilities should ensure that patients can access lists of all devices used—regardless of the provider implanting or prescribing the product. This information, for example, will ensure that patients know the model of device implanted in their bodies even if they lose the implant cards they received after surgery.

Figure 7

## Accessing Health Data With UDIs From Patients' Electronic Records





In the future, you are going to carry around your device list on your phone when you go to the emergency room and you have got a problem. They can look and know exactly what device you have in you, what the attributes are, and whether there is a recall on it.”

—Joe Drozda, director of outcomes research, Mercy

---

## Standards and next steps needed to give clinicians and patients better information

Incorporating UDIs into patients’ health records and other clinical systems is achievable through several public and private initiatives.

- **Certification criteria:** The Office of the National Coordinator for Health Information Technology develops standards for the fields and capabilities of electronic health records. The proposed 2015 update includes a new field for the UDIs of implanted medical devices and requires EHRs to parse the different components of UDIs. In addition, it would require EHRs to synchronize with FDA’s UDI database or another data source to list certain human-readable information on the product directly in the patient’s record. This would include, for example, the device description. Last, these criteria create a Common Clinical Data Set that outlines key elements of a patient’s medical history—such as a medication list and the UDIs of implanted devices—for transmission among different electronic health records.
- **Meaningful Use:** Obtaining the benefits of a field for UDIs in patients’ health records requires hospitals and providers to utilize this capability to document and share information on the devices implanted in patients. Stage 3 of the Meaningful Use program, as proposed in 2015, would encourage providers to share the UDIs of implanted devices as part of the Common Clinical Data Set.
- **Standards for UDI incorporation into the Common Clinical Data Set:** The data contained in the Common Clinical Data Set should be displayed in standardized formats, such as through HL7 messages, and accommodate UDIs.
- **Software development:** Along with federal standards describing the creation of a field for UDIs and associated capabilities, software vendors and hospitals should identify the other requirements needed by patients and clinicians to improve care. These capabilities could include, for example, standards to synchronize EHRs with supply chain and other ancillary systems.
- **Blue Button+:** Software vendors should develop Blue Button+ capabilities to enable patient access to their electronic health information and share that data with third parties, including applications that can analyze the data. Software vendors should develop innovative means to utilize UDIs to keep patients informed about the devices they use. These efforts should deliver value to patients beyond existing implantable device cards by helping them adhere to rehabilitation schedules, learn whether their product is MRI-compatible, obtain information on complications, report problems with their products, and contact the manufacturer with questions, etc.

## Improve evaluations of quality with better data

### Key principles

- Transmitting UDIs to FDA, manufacturers, registries, and health plans can support the development of large data sets that help to more quickly identify problems with medical devices.
- To reduce manual data entry requirements, registries must be able to electronically capture UDIs and utilize them to automatically populate several registry fields.
- Incorporating UDIs into health insurance claims can enable FDA's Sentinel Initiative to conduct analyses, facilitate research by payers, and enable health plan innovation based on the specific products used.
- New fields in registries and health insurance claims are necessary to enable these data sources to contain UDIs.

Along with generating health system efficiencies and equipping patients and clinicians with better information on medical devices, the UDI system also has the potential to vastly improve the data available on product performance.<sup>13</sup> UDI-based evaluations of product safety and effectiveness can inform decisions by patients and their doctors, give health plans more information on the quality of care received by their members, equip manufacturers with data on their products, and support FDA's regulatory decisions on its evaluations of marketed technologies.<sup>14</sup>

### FDA-ONC-Pew Meeting Panel

#### Additional uses for UDIs

These participants helped to inform these principles on improving evaluations of quality with better data:

- **Leslie Kelly Hall**, senior vice president of policy, Healthwise
- **Phillip Lerner**, vice president and national medical director, Aetna
- **Brendan Mullen**, vice president of strategy and development, National Quality Forum
- **Josh Rising**, director, health care programs, The Pew Charitable Trusts
- **Art Sedrakyan**, associate professor, Weill Cornell Medical College

## Quality improvement benefits of UDI adoption

### Registry efficiencies

Registries—large databases that house information on patients with similar medical conditions or procedures—are important quality improvement tools for tracking product performance. They have several limitations, however, including the lack of detailed information on long-term outcomes and inefficiencies in data collection. To obtain device data, registries often require clinicians to manually enter information or registries must develop direct links with each type of electronic health record system.<sup>15</sup>

The use of UDIs in registries can help in several ways. First, the UDI will provide detailed information about the device and facilitate registry links with other databases—such as claims, if they also contain UDIs. Storing the same UDI information in both the registry and the claims databases can help researchers reduce the errors in linkages between registry and claims, such as by better matching patients.

Second, UDIs can support the automatic population of multiple data fields that separately list, for example, the product manufacturer and model. Instead of requiring providers to manually enter information on the product in each data field, the UDI can help auto-populate these registry fields by linking the device identifier with standard data in an external database, such as the Global Unique Device Identification Database.

Documenting UDIs in the registry should rely on automated extraction tools from patients' health records and clinical suite software to prevent errors associated with manual entry and reduce how often clinicians need to scan the UDI. For those registries that do not extract data from electronic health records, clinicians should be able to scan the UDI directly into the registry.

---

Documenting UDIs in EHRs can also allow large health systems to analyze their data to evaluate product performance, device utilization, and other hospital-specific trends.

---

### Large health system analyses

Documenting UDIs in EHRs can also allow large health systems to analyze their data to evaluate product performance, device utilization, and other hospital-specific trends. In fact, Mercy health system integrated device identifiers into its EHR system to evaluate the performance of stents and found that variation in outcomes among products reflected differences among patients and not device quality.<sup>16</sup>

### Enhanced quality reporting

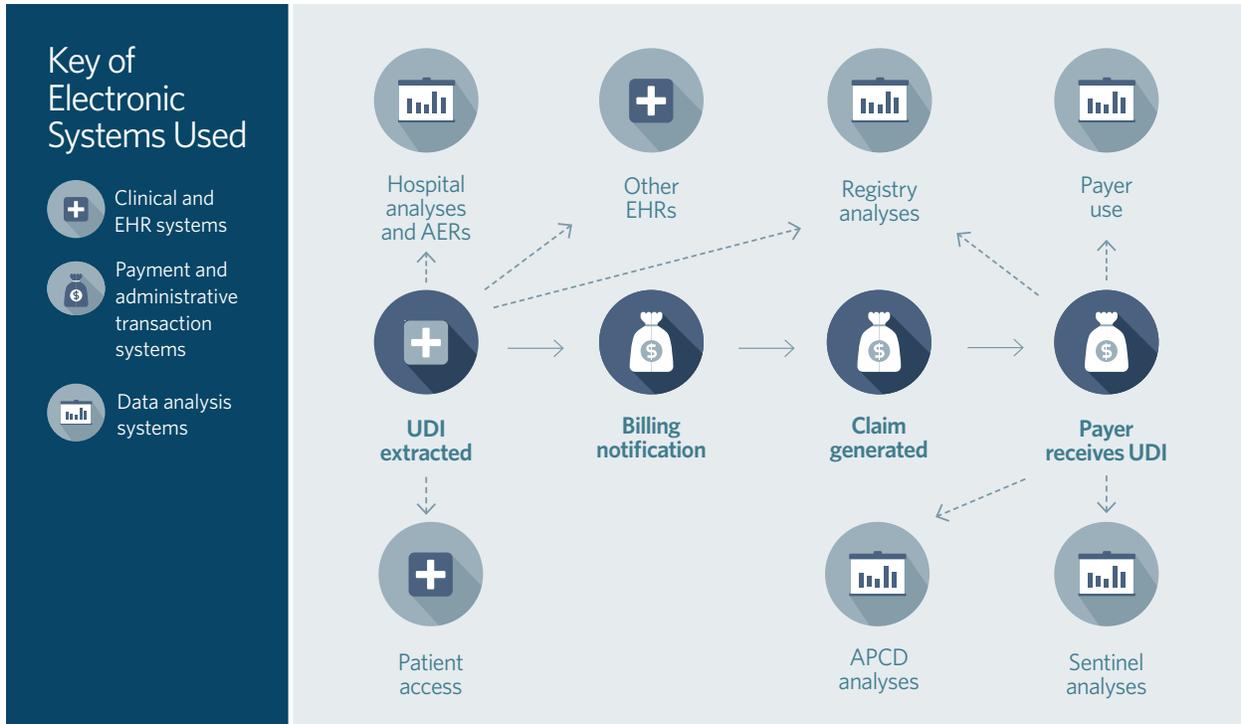
Physicians and hospitals often participate in quality evaluation programs intended to assess the care given by providers. These programs, such as quality measures used by health plans, often analyze data from registries, EHRs, and claims.

For procedures involving implanted medical devices, three primary factors influence outcomes: the patient, the provider, and the device. Without the addition of the UDI to systems that inform quality assessment programs, there is no information on the device used and an inability to determine whether worse—or better—outcomes reflect the product implanted, the severity of the patients' illnesses, or the skill of physicians.

In addition, quality measures based on EHRs or claims can have difficulties identifying the correct group of patients to analyze. For example, quality measures that evaluate care for patients with heart failure may not be able to cull the data to identify all patients with this condition. Using UDIs to indicate that a patient received a specific cardiac implant can remove some ambiguity from these quality measures.

Figure 8

## How UDIs Could Flow Through Patient Care Post-procedure



- **UDI extracted.** EHR extracts pertinent information, including UDIs, in a standardized format to send to other clinical and administrative systems.
- **Patient access.** The EHR sends UDI information to patient portals and Blue Button+, allowing patients to access it.
- **Hospital analyses and adverse event reports.** Hospitals can analyze device performance with EHR data and submit AERs to FDA if a problem occurs.
- **Other EHRs.** Providers receive UDI.
- **Billing notification.** Hospital's clinical suite system relays when a device is implanted, and must be paid for, to the billing system.
- **Claim generated.** Billing system generates a claim with device-specific information that is sent to the health plan for payment.
- **Payer receives UDI.** Hospital sends payer UDI in claim.
- **Payer use.** UDIs allow health plans to contact patients for follow-up care related to implanted and recalled devices or to conduct their own analyses.
- **Registry analyses.** Using EHR and claims data information, clinical registries can analyze device performance.

Continued on the next page

- **All-payer claims database analyses.** Health plans submit data to APCD.
- **Sentinel analyses.** Sentinel uses claims to assess device safety.

## Using claims data to improve care

Health plans utilize insurance claims data to monitor what treatments their patients receive, ensure the use of effective products, and analyze the cost and quality of care. Insurance claims submitted to Medicare, Medicaid, and private health plans are also considered a valuable resource used by researchers and regulators—such as FDA—to evaluate patient care and product performance.

Claims are particularly effective at helping researchers analyze costs and quality because they are standardized across all providers and payers. As a result, researchers and health plans can aggregate claims and evaluate outcomes for patients who see multiple providers over many years.

Claims already include the National Drug Code of medicines patients use; this information clearly identifies the pharmaceuticals, dosage of each, and manufacturer. However, claims lack any information on the specific device used and list only procedures—such as hip replacement surgery or cardiac stent insertion. For procedures involving implants, adding a field for the UDIs of these products would add specificity on the devices used and would equip health plans, researchers, FDA, and other stakeholders with the information they need.

---

Claims are particularly effective at helping researchers analyze costs and quality because they are standardized across all providers and payers.

---

### How health plans can utilize UDI data from claims

- **Comparative effectiveness research:** The lack of data on specific device types prevents health plans from comparing the safety and effectiveness of implants to other devices, surgery, drugs, lifestyle changes, and other interventions. Health plans' receipt of UDI information can help support these types of comparisons and help identify safety or effectiveness problems with particular devices.
- **Follow-up care and recalls:** Health plans lack information outlining the follow-up care required by patients based on the device implanted. Because products may have different physical therapy or checkup requirements, knowing the device model can help health plans ensure that beneficiaries receive coverage for appropriate care. In the event of a recall, the health plan could also notify members.
- **Modeling, cost calculations, and payment:** By knowing which devices their members obtain, health plans can better understand all the factors that influence the cost of care—including the devices implanted in patients. UDIs would help indicate if plan members are typically obtaining higher- or lower-cost products or better-quality devices. This information can improve modeling of expected expenditures and payment rates for procedures, including the development of device formularies similar to those of drugs.
- **Fraud and abuse detection:** Health plans could utilize the UDI to detect fraud when providers bill for the use of products or request add-on payment for utilizing new technology.

## How researchers and hospitals can use UDI data from claims

- **Claims databases:** Large databases that aggregate information from multiple health plans (including all-payer claims databases and private-sector collaborations that pool information) often lack information on the specific device model used. Should claims contain UDIs, researchers could then utilize these databases to evaluate product performance.
- **Sentinel:** FDA's postmarket surveillance Sentinel Initiative, which assesses drug and vaccine safety, cannot efficiently analyze device performance because this system relies predominantly on claims. Adding the UDI to claims would enable Sentinel to conduct large, longitudinal analyses on device safety, as required by Congress in the Food and Drug Administration Safety and Innovation Act of 2012.
- **Demonstrating value:** With the shift in health care to alternative payment models based on quality and value, better articulation of the devices used can help health systems demonstrate that they are providing more cost-effective care to patients without sacrificing patient care. This information can also support claims for costly care by demonstrating the use of higher-quality—and more expensive—products.
- **Improving registries:** Registries often collect information on patients for a set period—such as until hospital discharge. As mentioned, UDI information can help registries link with claims data sets for long-term outcomes.

---

“ One of the sorts of decisions that doctors have to make is, ‘Should I use a \$15,000 prosthesis or a \$5,000 prosthesis?’ They often have little or no sort of scientific basis for making that call. ... We find enormous variability among device performance. There are very clear relationships in that one surgeon prefers one sort of device. Yet they may or may not have any rationale for doing that.”

—David Bates, chief innovation officer and senior vice president, Brigham and Women's Hospital

---

## Standards updates needed to support quality improvement effort

Several revisions to existing standards are necessary to improve the data available on device quality and performance.

- **Registries:** The inclusion of UDIs in registries first requires the development of a standard way for electronic health records to document and transmit this information to the registry. The different fields required by registries must be uniformly mapped to a standard field in electronic health records that document UDI.

Second, in the event that registries cannot automatically extract data from patients' health records, registry input software and hardware should support the automated capture of UDIs—such as with bar-code scanning—to prevent manual entry errors.

Third, registries must be able to utilize UDIs to auto-populate various registry fields on the product. For example, the American College of Cardiology's CathPCI Registry on heart disease patients requires that data on the diameter and length of each stent inserted be recorded. Through auto-population, clinicians would need only to input the UDI into the registry instead of entering information into multiple registry fields.

---

“ I think it is inconceivable that a payer of any kind, from CMS to Aetna, would pay for a device not knowing what it is. Why is that OK? It is not OK for the patient. It is not OK for the taxpayer. It is not OK for the plan long term.”

—Leslie Kelly Hall, senior vice president of policy, Healthwise

---

This auto-population requires that registry linkages with an external database—such as FDA’s UDI database—be able to decipher the product manufacturer and model based on the device identifier and insert that information in the appropriate registry fields.

Last, registries should be able to link their data with external sources—such as claims or Social Security data that list additional outcomes, including revision surgeries or death. Use of the UDI as part of that linkage can facilitate better longitudinal data on patient outcomes linked to particular implanted devices.

- **Claims:** Many of the UDI’s benefits—including better analyses through registries and Sentinel, as well as other quality improvement efforts—hinge on one key data set: insurance claims. Capturing UDIs in claims requires standards development organizations to update transactions with a field for UDIs and the associated rules for how providers and payers should utilize this field.

The National Committee on Vital and Health Statistics—a federal advisory committee to the U.S. secretary of health and human services—recommended in 2014 that standards organizations explore the benefits of UDI capture and transmission to health plans and determine what transactions must be updated to accommodate this information.

The Accredited Standards Committee X12, a standards development organization that governs the electronic claims that hospitals submit to health plans, must update its transactions to accommodate UDIs for implanted medical devices. Similarly, the National Council for Prescription Drug Programs has considered the addition of UDIs to claims submitted for devices purchased at pharmacies—such as diabetic testing strips.

These committees—in consultation with providers, health plans, and other stakeholders—should also examine the transmission of UDIs in lieu of the Healthcare Common Procedure Coding System, used in claims to identify groups of products but not specific model types.

- **Supplementary databases:** Some device analyses will require additional information about products or procedures that are not otherwise standardized in a single database. Health plans and large health systems may need to develop supplementary databases that list information on products, outcomes, or patients that is not otherwise listed in the EHR or claims. These databases could help explore outcomes associated with patient subpopulations, physician practices, or product risks that are not already included.

---

“ If you end up having bad results as a surgeon, and you drill down and find that it is because of the implant, it has implications for quality.”

—Art Sedrakyan, associate professor, Weill Cornell Medical College

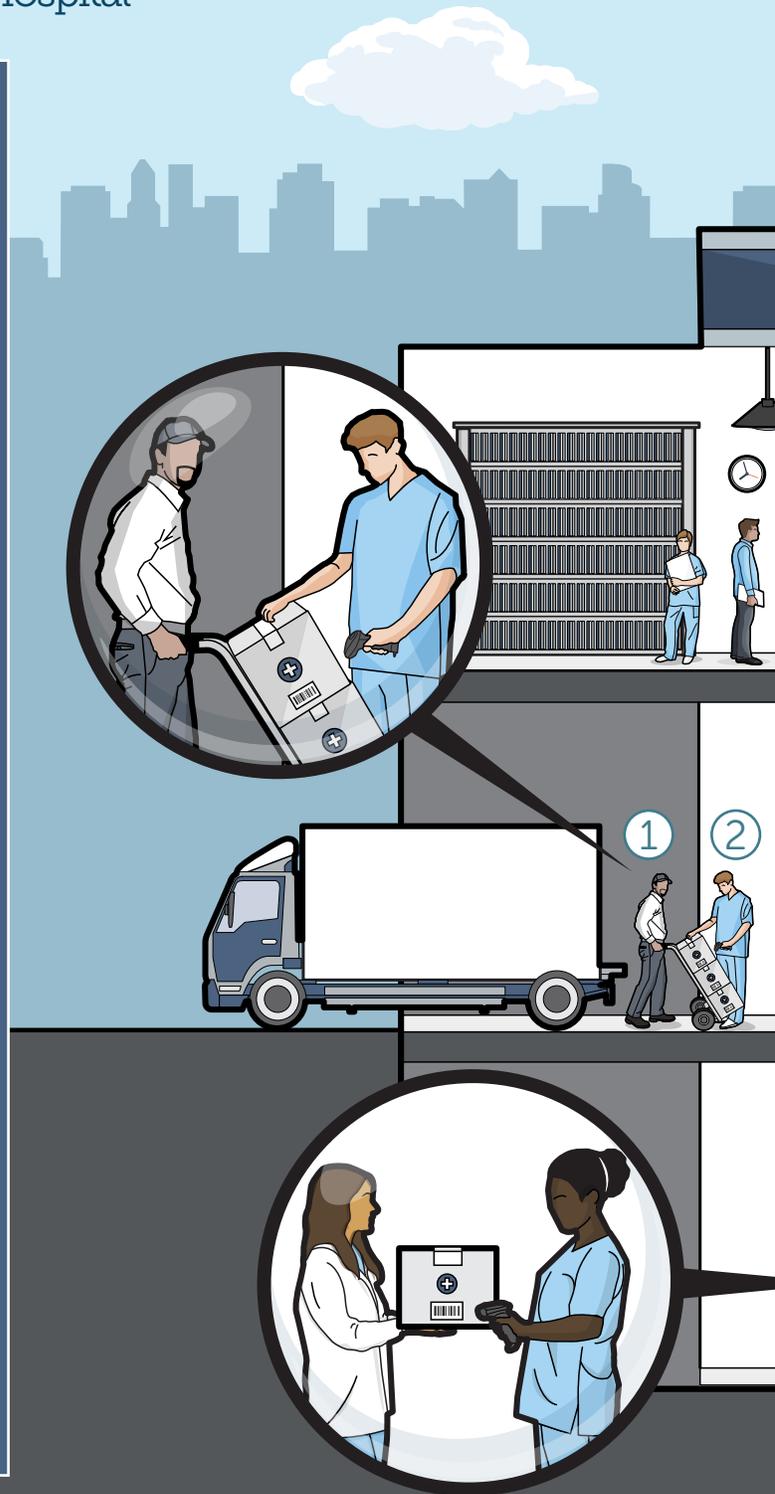
---

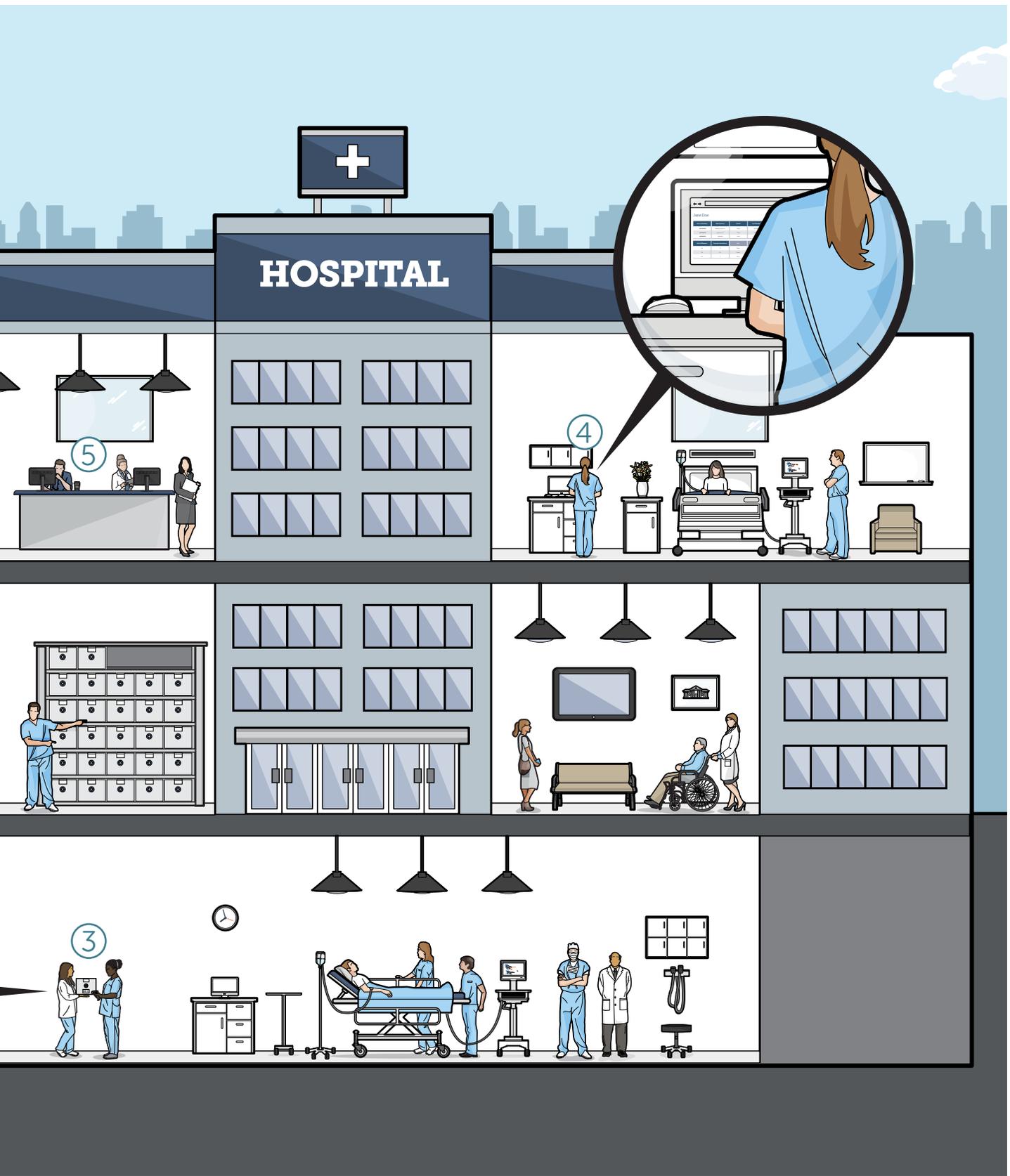
Figure 9

## UDI Movement Throughout the Hospital

As hospitals receive and use medical devices, they will scan the unique device identifiers of those products in certain locations and transmit that data electronically to several other departments for various purposes.

- 1 Loading dock**  
The hospital receives a medical device. Hospital staff scan the UDI on the device package at the loading dock to document its receipt.
- 2 Clinical inventory**  
The device is moved from the loading dock to the unit within the hospital where it will be used. The product's UDI is scanned again and placed into the clinical inventory ahead of a patient procedure.
- 3 Operating room**  
Hospital staff remove the device from inventory for a procedure and scan the UDI to indicate its use.
- 4 Patient room**  
The UDI of a used device is electronically uploaded to the patient's medical record. The UDI is then available for electronic transmission along with other clinical data to a registry, a patient portal, or another care provider.
- 5 Administrative office**  
The UDI is electronically transmitted to the administrative and billing offices, where it is incorporated into the claim sent to a payer.





# Ensuring the seamless capture and transmission of UDIs

## Key principles

- Hospitals must use automated electronic capture capabilities—such as bar-code scanners—to document UDIs and prevent errors associated with manual entry.
- Standards must be developed and adopted for UDI transmission among the systems used within each facility.
- New solutions must ensure the transmission of UDIs across institutions and among electronic health information sources.

Patients, clinicians, hospitals, health plans, manufacturers, FDA, and Congress have identified key opportunities for utilizing UDIs to improve the quality, efficiency, and cost of care. While integrating UDIs throughout the health care system is essential to achieving the program's full benefits, these supply chain management, patient record, and billing systems should all be able to capture and exchange this information.

---

## FDA-ONC-Pew Meeting Panel

### UDI interoperability in electronic health information

These participants helped to inform these principles on ensuring that UDIs can be captured and transmitted seamlessly:

- **Russell Branzell**, president and CEO, College of Healthcare Information Management Executives
- **Jamie Ferguson**, vice president of health information technology strategy and policy, Kaiser Permanente
- **Chuck Jaffe**, CEO, Health Level Seven International
- **Chantal Worzala**, director of policy, American Hospital Association
- **Steve Posnack**, director, Office of Standards and Technology, Office of the National Coordinator for Health Information Technology

---

## Preventing errors through automated capture

To prevent errors associated with manually documenting UDIs—which can reach several dozen characters in length—clinician and hospital staffs should use bar-code scanners and other automatic identification and data capture (AIDC) methods to ensure the accurate documentation of products used.<sup>17</sup> Although FDA did not specify the type of AIDC capabilities required to meet federal regulations, bar codes are expected to become common soon.

## Standards needed

Because many health systems already have automatic data capture capabilities, hospitals and the developers of these technologies should update the software to support documentation of the UDI. This software should be able to distinguish among various formats of the UDI, based on the issuing agencies, and parse the device and production identifiers.

In locations within health care facilities that lack AIDC capabilities, providers should consider purchasing the new scanners that are needed to capture the UDI. For example, some health care facilities may already have the scanning technology needed to document the receipt of a new product, but they may lack bar-coding capabilities in the surgical suite to capture the UDI at the time a device is implanted.

In addition, the AIDC capabilities should support multiple bar-code formats to reflect the many ways that UDIs are displayed. Although FDA requires some form of automated capture capabilities, the agency does not mandate a particular format in which the UDI must appear. Therefore, scanning capabilities should be able to capture the UDI in various formats, including linear bar codes, two-dimensional codes (such as a data matrix), and others.

## Interoperable transmission of UDIs among systems

Once supply chain databases, patient health records, and other systems capture the UDIs, the data should be electronically and seamlessly transmitted within and among health care facilities.



Patients receive care across many of our institutions. That is why standardization is so important. We have to identify medical devices in a standard way so that when you go to any hospital, the physician knows exactly what has been implanted.”

—Joe Dudas, *division chair, enterprise analytics, Mayo Clinic*

---

The two types of interoperability necessary to support UDI transmission are:

- **Intrahospital interoperability:** For hospitals to utilize the UDI, these data should be transmitted among systems within each facility. This interoperability should ensure the transmission of the UDIs and other necessary data—such as information from the item master or clinical data listed in the EHR. For example, supply chain management and clinical systems should be able to exchange a UDI to support automated product reordering or transmitting UDI-based information from the item master to patient health records.
- **Interhospital interoperability:** Hospitals should also be able to transmit the UDI to entities outside the facility, such as other health care providers, registries, payers, and patients. To achieve this exchange, fields for the UDI should be reserved in different databases and transactions used to transmit information outside of hospitals. Dedicated fields ensure that various systems can easily locate and identify the UDI without confusing them with other information.



## Standards needed to support UDI interoperability

Enhancements to the overall interoperability of health information—including existing efforts by ONC—will help resolve some of these challenges to facilitating UDI transmission. However, some smaller steps can be accomplished in the interim to support UDI transmission among systems.

### Clinical summary documents

As mentioned, the Consolidated-Clinical Document Architecture (C-CDA) helps exchange clinical data by extracting information from patient health records in a standard format. Adding the UDIs of implanted devices as a standard element of these transactions will ensure that information contained in EHRs is accessible to other clinical systems that read C-CDA data.

Because ONC recommended inclusion of UDIs in the summary-of-care document known as the Common Clinical Data Set, UDI integration into C-CDA formats will be essential to fulfilling this requirement.

Applicable HL7 standards to support this exchange include Version 2 and other C-CDA documents, such as discharge summaries and reports for transmission to some registries. Finally, HL7's newest standard, Fast Healthcare Interoperability Resources (FHIR), enables disparate systems to quickly mine other databases for information—much like Internet search engines locating information on Web pages. HL7 is already working to support the identification and transmission of the UDI in its existing and future standards, including FHIR.

### Additional clinical standards

Once added to clinical and other systems that collect information on patient outcomes, the UDI can facilitate advanced analyses comparing outcomes across device types and allow problems to be identified more quickly. To further enhance the utility of the UDI to conduct large-scale analyses, systems must also use standard terminology to describe clinical outcomes and adverse effects. FDA already encourages the use of these types of standards—developed through the Clinical Data Interchange Standards Consortium to describe clinical outcomes associated with drugs. Similar standards for devices would ensure that outcomes described by one institution are captured the same way by other providers to facilitate UDI-based research on device performance.<sup>18</sup>

## Critical next steps for UDI adoption

### Key principles

- Several federal agencies have opportunities to advance UDI adoption by providers, patients, health plans, registries, and other stakeholders.
- Hospitals, software developers, health information technology vendors, and standards development organizations all have roles in advancing UDI adoption.
- Coordination of UDI activities is essential to ensuring that the full benefits of the UDI are achieved.

Realizing the many benefits of UDI capture and transmission requires both government and private sector-led efforts to develop the necessary standards and encourage the adoption of this new tool to improve patient safety, enhance quality, and generate efficiencies.

---

### FDA-ONC-Pew Meeting Panel

#### Wrap-up and next steps

These participants helped to inform these principles on critical next steps needed for UDI adoption:

- **Tom Gross**, director, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, Food and Drug Administration
- **Chuck Jaffe**, CEO, Health Level Seven International
- **Rebecca Kush**, president and CEO, Clinical Data Interchange Standards Consortium
- **Steve Posnack**, director, Office of Standards and Technology, Office of the National Coordinator for Health Information Technology
- **Josh Rising**, director, health care programs, The Pew Charitable Trusts

---

## Government can support collaboration and standardization

The federal government has a unique role as both a regulator of some health information technology systems and a convener of experts to develop a national, unified approach to these platforms.

### Role of ONC

- **Develop a framework:** The Office of the National Coordinator for Health Information Technology should leverage its role as a coordinator to bring health information technology vendors, software developers, clinicians, hospital leadership, standards development organizations, and patients together to ensure that the necessary standards are developed to support UDI capture in and transmission among disparate systems and stakeholders, including FDA. ONC could convene these stakeholders through a Standards & Interoperability

Framework, which is used to bring software developers and users together to design tools and standards to support data exchange as part of the supply chain, clinical care, and billing. These frameworks support hands-on collaboration among stakeholders to develop the standards. The agency could also foster less interactive roundtable discussions to regularly monitor private sector efforts to develop and implement necessary standards.

- **HIT Standards Committee:** ONC could task the Health Information Technology Standards Committee—a federal advisory group composed of experts from vendors, hospitals, and other stakeholders—to oversee the development of standards to support UDI capture.
- **Applicable regulations:** As mentioned, ONC can facilitate UDI capture and transmission into certain clinical systems—particularly electronic health records—through the certification criteria program. The creation of a field for the UDI and its incorporation into the Common Clinical Data Set is a start, and ONC should work with stakeholders to expand these criteria as needed.

### Role of other federal agencies

- **Centers for Medicare & Medicaid Services regulations:** CMS can issue multiple regulations that would support UDI adoption. First, as previously mentioned, financial incentives through the Meaningful Use program can encourage the exchange of the UDI among providers. CMS has proposed to facilitate UDI transmission by providing financial incentives for the exchange of the Common Clinical Data Set. Second, CMS can issue regulations to adopt new standards for administrative transactions, such as claims. As part of updates to these standards, CMS should ensure the creation of a field and other standards needed to support the capture and transmission of the UDI. Finally, CMS requires the submission of data via quality measures and registries; for those efforts involving implanted devices, the agency should consider using the UDI to provide additional information on the products selected.
- **Existing FDA forums:** While FDA's primary responsibility centers on manufacturer compliance with the UDI regulations, the agency can still play an integral role to advance better device identification in electronic data systems. For example, the Medical Device Epidemiology Network has already convened expert stakeholders to explore next steps and potential pilot projects that would foster further UDI integration into the health care system. These efforts could demonstrate the utility of the UDI in various applications and help bring stakeholders together to identify gaps in adoption.
- **Pilot projects:** Several federal agencies have grant funding available to help support innovative pilot projects for the use of health care data. These agencies—including FDA, the National Institutes of Health, the Office of the Assistant Secretary for Planning and Evaluation, the Agency for Healthcare Research and Quality, and ONC—can explore new ways to utilize the UDI to improve patient care and examine the feasibility of including this information in different systems. For example, an agency could fund a pilot supporting the capture of the UDI in claims and evaluate a health plan's use of that information.

## Vendors and the private sector should drive adoption

Although the government can support structures to facilitate UDI adoption, the private sector—including hospitals, health information technology vendors, and standards development organizations—should ultimately develop and implement technology solutions to achieve the benefits of the UDI.

However, these organizations will not incorporate the UDI into their processes and systems without a strong business value—such as significant improvements to patient care or financial benefits—to integrating this new tool.

**Hospitals:** Health systems and hospitals should prioritize UDI integration as part of regular systems upgrades. As UDIs will often initially enter hospital data through inventory and procurement systems, modernizing the supply chain to utilize the UDI is essential to the efficient and effective use of this new tool. By adopting the UDI alongside other wholesale changes to their systems, hospitals can avoid challenges and additional costs associated with integrating the UDI as a stand-alone update.

**Private certification programs:** Physicians and hospitals often seek certifications from private organizations to demonstrate that the provider conforms to best practices. These private certification programs should consider including UDI capture and adoption as criteria they examine. The evaluation of UDI adoption would parallel other criteria evaluated in these programs. For example, the Joint Commission criteria on human tissue tracking outlines best practices for identifying bone marrow, skin, therapeutic cells, embryos, and other similar transplants and implants.

**Standards development organizations:** The organizations that develop many of the standards previously mentioned should promptly determine how to efficiently and effectively transmit the UDI among the many electronic systems used throughout the health care system. Resolving challenges associated with UDI capture and transmission might require further collaboration among standards development organizations to identify the most efficient means of integrating this new information into existing or new standards. HL7, for example, has launched a working group on UDI standardization.

## Conclusion

### UDI's value hinges on adoption and standards development

The UDI has the potential to revolutionize the way medical devices are identified and tracked throughout the health care system—from product procurement, through the revenue cycle, to patient use. Once adopted, this tool can improve the efficiency of hospital operations, equip clinicians and patients with information on products they use, and improve the quality of care.

The potential of the UDI is achievable only through robust infrastructure and revised standards to support the documentation, use, and transmission of this information. Specifically, with UDI incorporation, the following systems will be bolstered:

- Item masters will give hospitals an up-to-date and accurate catalog of the products that are used.
- Supply chain systems will give health care providers easier ways to reorder, track, and locate devices, including when there is a recall.
- Electronic health records will ensure that patients and providers know what devices are implanted to improve care coordination, notify individuals affected by recalls, and submit more accurate adverse event reports.
- Discharge summaries and other similar abstracts of patient health records will ensure that the UDI—along with other key information from the patient health history—can be exchanged among providers caring for the individual.
- Registries will support better long-term analyses of patient outcomes.
- Health insurance claims will enable FDA's postmarket surveillance Sentinel system and payers to analyze device performance.
- In addition, hospitals should prepare to capture the UDI in these various systems through the use of electronic capture capabilities—such as bar-code scanners—and the adoption of standards to ensure the accurate exchange of the UDI among the many databases that may house this information.

Through the development of these standards and capabilities, all stakeholders—including government, hospitals, health plans, standards development organizations, clinicians, and patients—have the responsibility and ability to ensure that the promise of the UDI is achieved.

# Appendix A

## Realizing the Benefits of the Unique Device Identifier in Health Care

Dec. 9, 2014

JW Marriott Washington

1331 Pennsylvania Ave. NW, Washington, DC

### Agenda

8–8:30 a.m. **Coffee and Light Refreshments**

8:30–8:55 a.m. **Welcome, Introductions, and Review Work to Date on UDIs**

- Allan Coukell, senior director, health programs, The Pew Charitable Trusts
- Jeff Shuren, director, Center for Devices and Radiological Health, Food and Drug Administration

8:55–9:25 a.m. **UDI Road Map**

A moderated discussion of the Brookings Institution's UDI road map

- Greg Daniel, managing director for evidence development and innovation, Engelberg Center for Health Care Reform, Brookings Institution
- Moderator: Terrie Reed, project leader, clinical research informatics, Duke Clinical Research Institute

9:25–10:30 a.m. **UDI Interoperability in Electronic Health Information**

Assess the state of interoperable standards to transmit UDIs throughout the health care system

- Russell Branzell, president and CEO, College of Healthcare Information Management Executives
- Jamie Ferguson, vice president of health information technology strategy and policy, Kaiser Permanente
- Chuck Jaffe, CEO, Health Level Seven International
- Chantal Worzala, director of policy, American Hospital Association
- Moderator: Steve Posnack, director, Office of Standards and Technology, Office of the National Coordinator for Health Information Technology

10:30–10:50 a.m. **Break**

10:50 a.m.-noon **Supply Chain and Materials Management Implementation of UDI**

Identify the benefits and standards needed for UDI integration in supply chain and materials management systems

- Leigh Anderson, chief operating officer, informatics and technology services, 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

Noon-1:15 p.m. **Lunch and Remarks**

- Jon White, acting director, Office of Clinical Quality and Safety, and acting chief medical officer, Office of the National Coordinator for Health Information Technology

1:15-2:25 p.m. **Clinical Applications of the UDI**

Evaluate how capturing UDIs in patients' medical records and other data systems used by providers and clinicians can improve care and affect workflow, and identify standards revisions that are needed to obtain benefits

- Use case review: David Hunt, medical director, Health IT Adoption and Patient Safety, Office of Clinical Quality and Safety, Office of the National Coordinator for Health Information Technology
- David Bates, chief quality officer and senior vice president, Brigham and Women's Hospital
- Hans Buitendijk, senior expert, R&D, Cerner Corp.
- Denise Downing, perioperative nursing specialist, informatics, Association of periOperative Registered Nurses
- Joe Drozda, director of outcomes research, Mercy
- Moderator: Jon White, acting director, Office of Clinical Quality and Safety, and acting chief medical officer, Office of the National Coordinator for Health Information Technology

2:25-2:45 p.m. **Break**

2:45-4 p.m.

### **Additional Uses for UDIs**

Examine other potential uses of UDIs—for implants and other types of devices—by hospitals, clinicians, payers, and researchers, and the necessary standards needed to support those efforts

- Leslie Kelly Hall, senior vice president, policy, Healthwise
- Phillip Lerner, vice president and national medical director, Aetna
- Brendan Mullen, vice president, strategy and development, National Quality Forum
- Art Sedrakyan, associate professor, Weill Cornell Medical College
- Moderator: Josh Rising, director, health care programs, The Pew Charitable Trusts

4-4:30 p.m.

### **Wrap-Up and Next Steps**

Identify key next steps that FDA, ONC, and other stakeholders need to take to advance standards for UDI adoption

- Tom Gross, director, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, Food and Drug Administration
- Chuck Jaffe, CEO, Health Level Seven International
- Rebecca Kush, president and CEO, Clinical Data Interchange Standards Consortium
- Steve Posnack, director, Office of Standards and Technology, Office of the National Coordinator for Health Information Technology
- Moderator: Josh Rising, director, health care programs, The Pew Charitable Trusts

## Appendix B

### Acknowledgments

We gratefully acknowledge the contributions of the many people who helped plan or participated as a speaker at the December 2014 meeting or provided helpful suggestions on drafts of this manuscript. The conclusions and recommendations herein are those of The Pew Charitable Trusts and may not reflect those of individual sources or reviewers.

Note: The titles or affiliations of some individuals may have changed since they provided feedback or participated in the December 2014 meeting. The affiliations and titles of individuals are listed to reflect their roles at the time they provided input to Pew.

- **Leigh Anderson**, chief operating officer, informatics and technology services, Premier
- **David Bates**, chief quality officer and senior vice president, Brigham and Women's Hospital
- **Russell Branzell**, president and CEO, College of Healthcare Information Management Executives
- **Bill Brewer**, product manager, Global Healthcare Exchange
- **Hans Buitendijk**, senior expert, R&D, Cerner Corp.
- **Kevin Capatch**, director, supply chain technology and process engineering, Geisinger Health System
- **Karen Conway**, executive director, industry relations, Global Healthcare Exchange
- **Greg Daniel**, managing director, evidence development and innovation, Engelberg Center for Health Care Reform, Brookings Institution
- **Denise Downing**, perioperative nursing specialist, informatics, Association of periOperative Registered Nurses
- **Joe Drozda**, director of outcomes research, Mercy
- **Joe Dudas**, division chair, enterprise analytics, Mayo Clinic
- **Jamie Ferguson**, vice president, health information technology strategy and policy, Kaiser Permanente
- **Tom Gross**, director, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, Food and Drug Administration
- **Leslie Kelly Hall**, senior vice president, policy, Healthwise
- **David Hunt**, medical director, Health IT Adoption and Patient Safety, Office of Clinical Quality and Safety, Office of the National Coordinator for Health Information Technology
- **Chuck Jaffe**, CEO, Health Level Seven International
- **Salil Joshi**, senior director, industry development, GS1
- **Rebecca Kush**, president and CEO, Clinical Data Interchange Standards Consortium
- **Phillip Lerner**, vice president and national medical director, Aetna
- **Behnaz Minaei**, policy analyst, Food and Drug Administration
- **Brendan Mullen**, vice president, strategy and development, National Quality Forum
- **Dennis Orthman**, senior director, Strategic Marketplace Initiative
- **Steve Posnack**, director, Office of Standards and Technology, Office of the National Coordinator for Health Information Technology

- **Anita Rayner**, associate director, policy and communications, Food and Drug Administration
- **Terrie Reed**, senior adviser, UDI adoption, Center for Devices and Radiological Health, Food and Drug Administration
- **Steven Rosenberg**, director, electronic commerce, GS1
- **Mike Schiller**, supply chain director, Association for Healthcare Resource & Materials Management
- **Art Sedrakyan**, associate professor, Weill Cornell Medical College
- **Jeff Shuren**, director, Center for Devices and Radiological Health, Food and Drug Administration
- **Linda Sigg**, associate director, informatics, Food and Drug Administration
- **Lauren Thompson**, associate director, initiatives and coordination, Office of the National Coordinator for Health Information Technology
- **Karen Van Hentenryck**, associate executive director, Health Level Seven International
- **Jon White**, acting director, Office of Clinical Quality and Safety, and acting chief medical officer, Office of the National Coordinator for Health Information Technology
- **Chantal Worzala**, director of policy, American Hospital Association

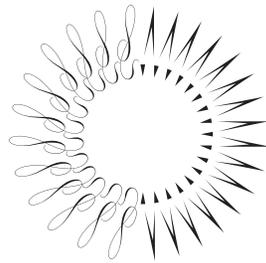
We would also like to thank the following Pew staff who provided assistance during the meeting and made the event a success.

- **Amy Allen**
- **Emely Amaya**
- **Sallyann Bergh**
- **Erin Bongard**
- **Naomi Herz**
- **Colleen Kennedy**
- **Brianna May**
- **Alaina McBournie**
- **Michelle Cardoso Mendes**
- **Rosalinda Ortega**
- **Kirsten Paulson**
- **Katherine Portnoy**
- **Chelsea Toledo**
- **LaToria Williams**

## Endnotes

- 1 The Brookings Institution, "Unique Device Identifiers (UDIs): A Roadmap for Effective Implementation" (December 2014), [http://www.brookings.edu/~media/research/files/papers/2014/12/05\\_medical\\_device\\_tracking\\_system/udi\\_final\\_12052014.pdf](http://www.brookings.edu/~media/research/files/papers/2014/12/05_medical_device_tracking_system/udi_final_12052014.pdf).
- 2 Food and Drug Administration, "Unique Device Identification System" (Sept. 24, 2013), <https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system>.
- 3 Food and Drug Administration, "UDI Issuing Agencies," last modified May 6, 2015, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm>.
- 4 Food and Drug Administration, "UDI Formats by FDA-Accredited Issuing Agency" (May 2014), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUIDatabaseGUDID/UCM396595.doc>.
- 5 Natalia Wilson, "The Value of Unique Device Identification Across Healthcare," *Infor* (2012), <http://wpcarey.asu.edu/sites/default/files/uploads/health-sector-supply-chain-research-consortium/value-unique-device-identification-across-healthcare.pdf>.
- 6 Karen Conway, "Are We Being Short-Sighted? Comparing the Costs and Benefits of UDI," *Healthcare Purchasing News* (October 2014), <http://www.hpnonline.com/inside/2014-10/1410-SP.html>.
- 7 Government Accountability Office, *Medical Devices: FDA Should Enhance Its Oversight of Recalls* (June 2011), <http://www.gao.gov/assets/320/319565.pdf>.
- 8 Karen Conway, "The State of Standards Adoption: The Data May Surprise You," *Healthcare Purchasing News* (April 2015), <http://www.hpnonline.com/inside/2015-04/1504-SP.html>.
- 9 Thomas P. Gross and Jay Crowley, "Unique Device Identification in the Service of Public Health," *New England Journal of Medicine* 367 (2012): 1583-1585, <http://www.nejm.org/doi/full/10.1056/NEJMp1113608>.
- 10 Natalia A. Wilson et al., "Revision Total Hip and Knee Arthroplasty Implant Identification: Implications for Use of Unique Device Identification 2012 AAHKS Member Survey Results," *Journal of Arthroplasty* 29, no. 2 (2013): 251-255, doi:10.1016/j.arth.2013.06.027.
- 11 Food and Drug Administration, *Regulatory Science in FDA's Center for Devices and Radiological Health: A Vital Framework for Protecting and Promoting Public Health* (2011), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm274162.pdf>.
- 12 David Arney et al., "Supporting Medical Device Adverse Event Analysis in an Interoperable Clinical Environment: Design of a Data Logging and Playback System" (2011), [http://icbo.buffalo.edu/2011/workshop/adverse-events/docs/papers/ArneyAEICBO2011\\_submission.pdf](http://icbo.buffalo.edu/2011/workshop/adverse-events/docs/papers/ArneyAEICBO2011_submission.pdf); and Terrie Reed, "ASTER-D: Automated Adverse Event Reporting Systems," Food and Drug Administration (September 2012), <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM320557.pdf>.
- 13 Food and Drug Administration, "Strengthening Our National System for Medical Device Postmarket Surveillance" (September 2012), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301924.pdf>; Food and Drug Administration, "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>; and The 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>.
- 14 Natalia A. Wilson and Joseph Drozda, "Value of Unique Device Identification in the Digital Health Infrastructure," *The Journal of the American Medical Association* 309, no. 20 (2013): 2107-2108, <http://www.mdepinet.org/wp-content/uploads/Value-of-UDI-JAMA-05-22-13.pdf>.
- 15 The Pew Charitable Trusts, "Medical Device Registries: Recommendations for Advancing Safety and Public Health" (Sept. 2014), <http://www.pewtrusts.org/~media/Assets/2014/09/Device-Registry-Conference-Report.pdf>.
- 16 James E. Tchong et al., "Unique Device Identifiers for Coronary Stent Postmarket Surveillance and Research: A Report From the Food and Drug Administration Medical Device Epidemiology Network Unique Device Identifier Demonstration," *American Heart Journal* 168, no. 4 (2014): 405-413, e2, doi:10.1016/j.ahj.2014.07.001.
- 17 Thomas R. Campion Jr. et al., "Implementing Unique Device Identification in Electronic Health Record Systems: Organizational, Workflow and Technological Challenges," *Medical Care* 52, no. 1 (2014): 26-31, doi:10.1097/MLR.0000000000000012.
- 18 Food and Drug Administration, "Study Data Standards for Submission to CDER," last modified Dec. 18, 2014, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm248635.htm>.





THE  
**PEW**  
CHARITABLE TRUSTS

