Proposed Revised American Dental Association
Technical Report No. 1081

FDA's Unique Device Identification (UDI) Program for Dental Devices and Biologics Regulated as Medical Devices

ADA American Dental Association®

2019

REVISED AMERICAN DENTAL ASSOCIATION TECHNICAL REPORT NO. 1081 FOR FDA'S UNIQUE DEVICE IDENTIFICATION (UDI) PROGRAM FOR DENTAL DEVICES AND BIOLOGICS REGULATED AS MEDICAL DEVICES

The ADA Standards Committee on Dental Informatics (SCDI) has approved the revision of ADA Technical Report No. 1081 for FDA's Unique Device Identification (Udi) Program for Dental Devices and Biologics Regulated as Medical Devices. Working Groups of the ADA Standards Committee on Dental Informatics (SCDI) formulate this and other standards and technical reports for the application of information technology and other electronic technologies to dentistry's clinical and administrative operations. The ADA SCDI has representation from appropriate interests in the United States in the standardization of information technology and other electronic technologies used in dental practice. The ADA SCDI confirmed approval of Revised ADA Technical Report No. 1081 on February 25, 2019.

The ADA Standards Committee on Dental Informatics thanks the members of Working Group 11.8 on Track and Trace for Implantable Devices and the organizations with which they were affiliated at the time the specification was developed:

Mohamednazir Harunani (chairman), Smile Brands, Group practice, Rockford, IL;
Leslie Tompkins Steen, US FDA Center for Devices and Radiological Health, Silver Spring, MD; and
Kristy Vogt, American Dental Association, Chicago, IL.

REVISED AMERICAN DENTAL ASSOCIATION TECHNICAL REPORT NO. 1081 FOR FDA'S UNIQUE DEVICE IDENTIFICATION (UDI) PROGRAM FOR DENTAL DEVICES AND BIOLOGICS REGULATED AS MEDICAL DEVICES

FOREWORD

(This foreword does not form a part of Revised American Dental Association Technical Report No. 1081 for FDA's Unique Device Identification (UDI) Program for Dental Devices and Biologics Regulated as Medical Devices).

In 1992, there was interest in the standardization of clinical information systems related to electronic technology in the dental environment. After evaluating current informatics activities, a Task Group of the ANSI Accredited Standards Committee MD156 (ASC MD156) was created by the ADA to initiate the development of technical reports, guidelines, and standards on electronic technologies used in dental practice. In 1999, the ADA established the ADA Standards Committee on Dental Informatics (SCDI). The ADA SCDI is currently the group that reviews and approves proposed American National Standards (ANSI approved) and technical reports developed by the standards committee's working groups. The ADA became an ANSI accredited standards organization in 2000.

The scope of the ADA SCDI is:

> *"The ADA SCDI shall develop informatics standards, specifications, technical reports and guidelines and interact with other entities involved in the development of health informatics standards aimed at implementation across the dental profession."*

FDA's UDI Ruling and Guidance

The *Unique Device Identification* (UDI) project was undertaken by the ADA-SCDI, with Dr. M. Harunani being named as the chair, to address the FDA's recent UDI rule and to offer their expertise, guidance and best practices on implementing automatic identification and data capture technologies and their application in dentistry.

This technical report was prepared by SCDI Working Group 11.8. The SCDI Working Group chairman is Mohamednazir Harunani. SCDI Working Group 11.8 prepared this report at the request of SCDI Subcommittee on Clinical Informatics.

REVISED AMERICAN DENTAL ASSOCIATION TECHNICAL REPORT NO. 1081 FOR FDA'S UNIQUE DEVICE IDENTIFICATION (UDI) PROGRAM FOR DENTAL DEVICES AND BIOLOGICS REGULATED AS MEDICAL DEVICES

SUMMARY

The Food and Drug Administration (FDA) has issued a rule to establish a system to adequately identify devices through distribution. This rule requires the label of medical devices to include a unique device identifier (UDI), except where the rule provides for an exception or alternative placement. The labeler must submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID), unless subject to an exception or alternative. The system established by this rule requires the label and device package of each medical device to include a UDI and requires that each UDI be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. The UDI will be required to be directly marked on the device itself, if the device is intended to be used more than once and intended to be reprocessed before each use

SCOPE

Once it was recognized that this rule was going to take effect, practitioners needed to have an understanding of this rule and what it will entail as it is required to go into practice, from a clinician side. The manufacture chain and responsibilities have been clearly identified by the FDA, but the clinical use has not; and thus that was determined to be the main focus of this paper. This paper covers the UDI Rule (78 FR 58786) and device marking regulations in 21 CFR 801.45. It does not cover the regulations for medical device tracking found in 21 CFR 821. There is no tracking requirement within the UDI rule.

Background

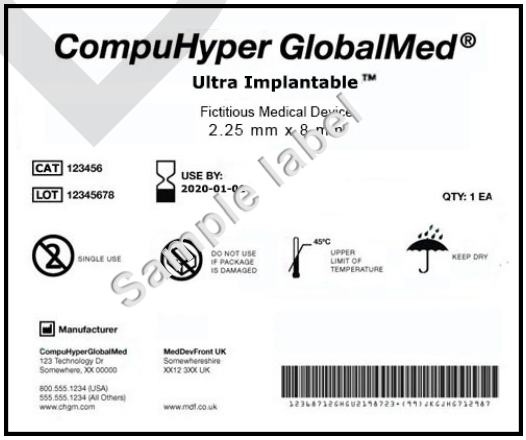
Each year, the FDA receives several hundred thousand medical device reports of suspected device-associated deaths, serious injuries and malfunctions. The ideal outcome is that we have an end to end tracking system that is transparent. Mandatory reporters (i.e., manufacturers, device user facilities, and importers) are required to submit certain types of reports for adverse events and product problems to the FDA about medical devices. In addition, the FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety. The FDA has now mandated a rule that requires labelers to affix a UDI, in plain-text and AIDC format, to the label of every medical device, unless excepted, and to submit device data to the Global Unique Device Identification Database (GUDID). There are several methods of recording the device ID. They can be:

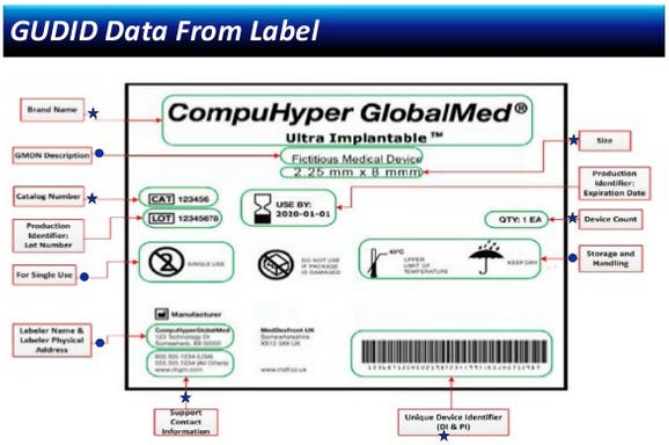
Radio-frequency identification (RFID) – the wireless use of electromagnetic fields to transfer data, for the purposes of automatically identifying and tracking tags attached to objects. The tags contain electronically stored information. Some tags are powered by electromagnetic induction from magnetic fields produced near the reader. Some types collect energy from the interrogating radio waves and act as a passive transponder. Other types have a local power source such as a battery and may operate at hundreds of meters from the reader. Unlike a barcode, the tag does not necessarily need to be within line of sight of the reader, and may be embedded in the tracked object.

Matrix (2D) barcode – a two-dimensional way to represent information similar to a linear barcode, but can represent more data.

Linear Barcodes – "one dimensional" barcode that is made up of lines and spaces of various widths. These codes can be issued by GS1, ICCBBA, or HIBBCC, who also support 2D barcodes.

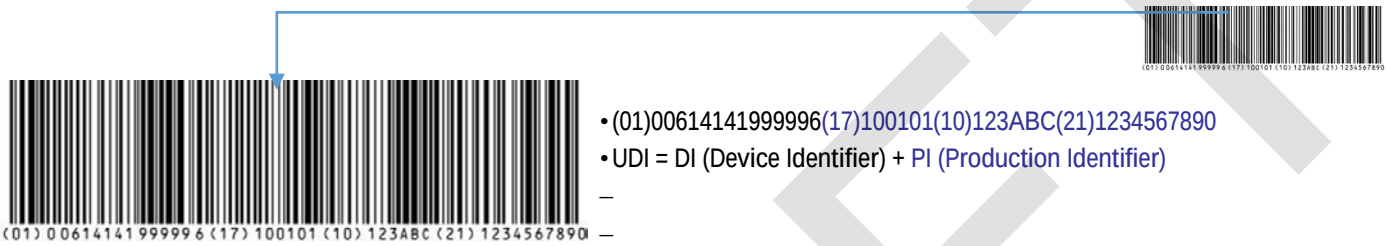
GUDID Sample:





A UDI is a unique numeric or alphanumeric code that consists of two parts:

- A device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and
- A production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
  - the lot or batch number within which a device was manufactured;
  - the serial number of a specific device;
  - the expiration date of a specific device;
  - the date a specific device was manufactured;
  - the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.



- (01)00614141999996(17)100101(10)123ABC(21)1234567890
- UDI = DI (Device Identifier) + PI (Production Identifier)

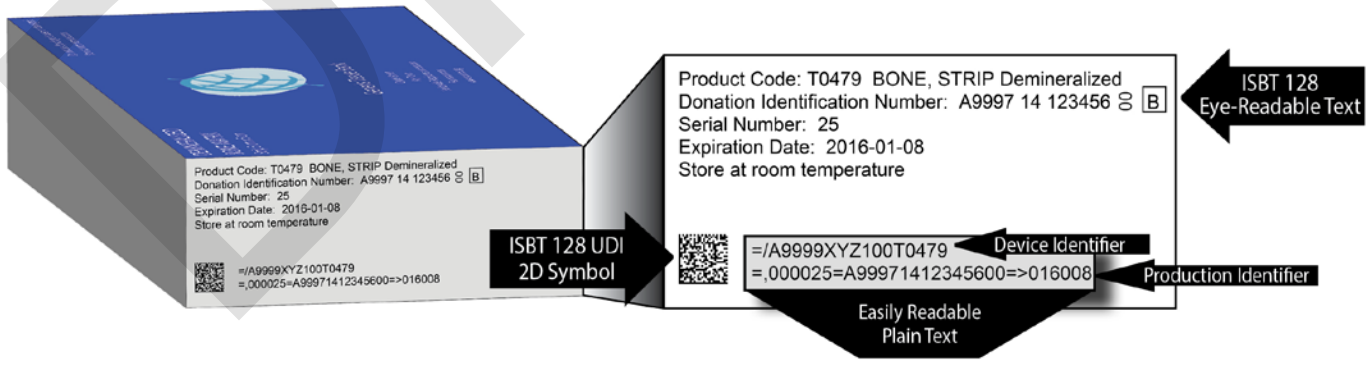
On the Device Label:

- DI is lookup key for pulling out other attributes from GUDID
- Computers can parse out lot, serial, expiration, manufacture date (if available), and distinct identification code (where applicable)

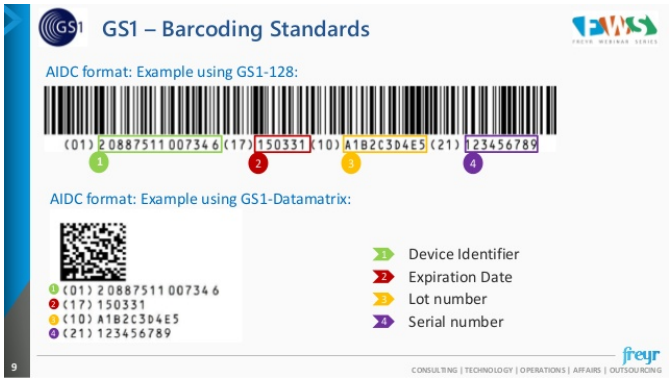
As part of the UDI system, the FDA is also creating the Global Unique Device Identification Database (GUDID) which will include a standard set of basic identifying elements for each device with a UDI. GUDID accepts input from GS1, HIBCC and ICCBBA and most of this information will be made available to the public so that users of a medical device can easily look up information about the device. The UDI does not indicate, and the database will not contain, any information about who uses a device, including personal privacy information. The original URL will no longer be supported past December 31st, 2023 and will be replaced with the new base URL for the web service, which is: https://accessgudid.nlm.nih.gov/api/v2/. All in information regarding GUDID can be found at https://accessgudid.nlm.nih.gov/resources/home. Only some tissue is regulated as a medical device so the UDI only applies to this limited range of HCT/P products and they mainly use the ICCBBA label.

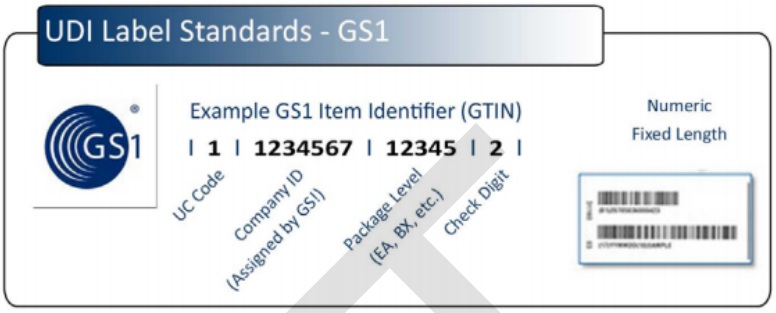
Sample ICCBBA label (mostly for human tissues)

An ISBT 128 UDI satisfies regulations and also carries critical information required for enhanced biologics traceability and biovigilance. Featuring globally unique identifiers and harmonized terminology, ISBT 128 allows for tissues from a single donor to be readily cross-referenced to support effective recall.



Sample GS1 label





GTINs may be 8, 12, 13 or 14-digits in length. Their data structures require up to 14-digit fields, and all GTIN processing software should allow for 14 digits.

Sample HIBCC label

The UDI system has been designed such that it will:

- Allow more accurate reporting, reviewing and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly. The FDA has enacted electronic Medical Device Reporting in August 2015 to more effectively collect and analyze adverse events.
- Reduce medical errors by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.
- Enhance analysis of devices on the market by providing a standard and clear way to document device use in electronic health records, clinical information systems, claim data sources and registries. A more robust post-market surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.
- Provide a standardized identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.
- Provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.
- Lead to the development of a medical device identification system that is recognized around the world.

.Compliance Dates for the UDI Final Rule

Device	Label/GUDID/Date Format	Direct Mark (When Required)[3]
Class III (including class III LS/LS)[1] Devices licensed under the PHS Act	September 24, 2014	Class III LS/LS devices must bear a permanent UDI by September 24, 2015 All other class III devices must bear a permanent UDI by September 24, 2016
Implantable (class II, class I & unclassified)	September 24, 2015	N/A
LS/LS[1] (class II, class I & unclassified)	September 24, 2015	September 24, 2015
Class II (other than I/LS/LS[2])	September 24, 2016	September 24, 2018
Class I or unclassified (other than I/LS/LS[2])	September 24, 2020*	September 24, 2022*

[1]LS/LS = life-supporting or life-sustaining
[2]I/LS/LS = implantable, life-supporting, or life-sustaining
[3]Direct Mark requirements apply to products that are intended to be used more than once and intended to be reprocessed before each use. Direct mark compliance dates are in addition to label/GUDID/date format compliance dates.

*The FDA Granted a two year extension in June 2017 for the Class I or Unclassified devices in response to concerns on implementation readiness by manufacturers.

For more details, please follow this link:
https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/udi-compliance-policies-and-udi-rule-compliance-dates
https://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM561575.pdf

Timeline for dentistry, where to start

Class III devices, classified as the highest risk devices, were to be labeled with UDI by September 14, 2014, unless the labeler was granted a one-year extension. This group of devices includes bone grafting material (approved under product codes NQA and NPZ), and other devices.

Dental implants regardless of regulatory Class assignment, bone-grafting material (cleared under product codes NPL, NPK and NPM) and other life-supporting or life-sustaining devices have a UDI compliance date of September 24, 2015. Implantable devices are not required to be directly marked. Reusable devices – If your device is intended to be used more than once and intended to be reprocessed before each use, your device must have the UDI permanently marked on the device itself. This permanent UDI may be identical to the UDI that appears on the device label or it may be a different UDI to distinguish the device itself from its packaging. The permanent UDI must be in either or both: (1) Easily readable plain-text; and (2) AIDC form or alternative technology that will provide the UDI of the device on demand. The permanent UDI requirement does not apply if your device that is intended to be used more than once and intended to be reprocessed before each use meets any of the following criteria: (1) Any type of direct marking would interfere with the safety and effectiveness of the device; (2) It is not technologically feasible to directly mark the device; (3) The device is cleared/approved as a single use device; or (4) The device already has a permanent UDI directly marked on the device. If you decide to make use of one of these exceptions, the basis of your decision must be documented in the design history file required by 21 CFR 820.30(j).

Class II devices have a UDI compliance date of September 24, 2016 and Class I devices have a UDI compliance date of September 24, 2018. Please see the summary below from the FDA to help clarify.

A three-year extension for existing inventory is available to labelers. If labelers have finished devices that are packaged and labeled prior to the device's UDI compliance date, they have 3 years to use that stock before all packaged and labeled devices must be UDI compliant.

Device	**Regulatory Classification**	**UDI compliance**
Implants		
Implants: This includes Min-implants, Removable implants, Abutments, splints/guides for implant placement	Class II; implants	All Implants (Class I & II, per FDASIA regulation) September 24, 2015 (unless implant is classified under FDA Product Code listed in extension letter published in November 2014) **If an extended implant, labeling requirements for UDI are delayed until September 24, 2016 but GUDID reporting requirement are NOT delayed.
Software to design implant/abutment	--not an implant	Class II September 24, 2016 (see 21 CFR 801.50 for specific requirements for stand alone software)
Bone grafting material		
Human	Not a device; regulated as a biologic or tissue*	N/A *Some biologics, such as demineralized bone matrix, are regulated as medical devices
Bovine or synthetic	Class III or Class II, based on composition; implant	All Class III September 24, 2014; some Class III labelers were given an extension (up to 1 year) to meet UDI labeling and reporting requirements All Implants (Class I & II, per FDASIA regulation) September 24, 2015 (unless implant is classified under FDA Product Code listed in extension letter published in November 2014) **If an extended implant, labeling requirements for UDI are delayed until September 24, 2016 but GUDID reporting requirement are NOT delayed.

Sutures		
Sutures, including silk, Chromic, Gut, Gortex, etc	All Class II; implant	All Implants (Class I & II, per FDASIA regulation) September 24, 2015 (unless implant is classified under FDA Product Code listed in extension letter published in November 2014) **If an extended implant, labeling requirements for UDI are delayed until September 24, 2016 but GUDID reporting requirement are NOT delayed.
Membranes		
Membranes, removable and non-removable	Class II; implant	All Implants (Class I & II, per FDASIA regulation) September 24, 2015 (unless implant is classified under FDA Product Code listed in extension letter published in November 2014) **If an extended implant, labeling requirements for UDI are delayed until September 24, 2016 but GUDID reporting requirement are NOT delayed.
Hormones/growth factors		
Hormones/growth factors	Class III; if regulated as a device. May be regulated as drug or biologic	All Class III September 24, 2014; some Class III labelers were given an extension (up to 1 year) to meet UDI labeling and reporting requirements
Gel foam/surgicell		
Gel foam/surgicell	Class III	All Class III September 24, 2014; some Class III labelers were given an extension (up to 1 year) to meet UDI labeling and reporting requirements
Endo filling materials		
Gutta-percha	Class I exempt	Class I September 24, 2020; ONLY Class I (GMP exempt) devices are fully exempt from all UDI requirements.
Endo filling materials	Class I or Class II	Class II September 24, 2016 Class I September 24, 2020; ONLY Class I (GMP exempt) devices are fully exempt from all UDI requirements.
Crowns	Only materials are regulated	
Porcelain	Class II	Class II September 24, 2016
Gold	Class II exempt	Class II September 24, 2016
Composite	Class II	Class II September 24, 2016

Fillings/Restorations	Only materials are regulated	
Composite	Class II	Class II September 24, 2016
Amalgam	Class II	Class II September 24, 2016
Gold	Class I exempt	Class I September 24, 2020; ONLY Class I (GMP exempt) devices are fully exempt from all UDI requirements.

Cost of Implementation to the provider

Although the goal of the unique identifier rule was to reduce medical device-related patient injuries and deaths by having a standardized, reliable and unique code for each device to identify any device from manufacture, through distribution and use, no efforts were made to either calculate or quantify the effects of this rule on the providers. It was noted that the decisions to invest in health information systems that would use a UDI would be made independently of the this rule and that having a standardized UDI system might advance the development of analytic tools and other information technology dependent on device identifiers in health information systems.

Clinical Implications

The goal of the unique identifier rule was to enable a reduction in medical device-related patient injuries and deaths by having a standardized, reliable and unique code for each device to identify any device from manufacture, through distribution and use. This would help the FDA improve post-market surveillance of medical devices and detect problem devices more rapidly, leading to a reduction in incidence of adverse events; recalls and/or public health safety alerts, for example, could be more accurate, timely and specific. In addition, a standardized UDI will contribute to future potential public health benefits from initiatives associated with the increased use of automated systems in healthcare.

Organizational challenges for UDI system implementation include coordinating multiple stakeholders to define UDI attributes and characteristics for use in EHRs, guiding organizational change within individual institutions for integrating UDI with EHRs, and guiding organizational change for reusing UDI data captured in EHRs. Workflow challenges include capturing UDI data in EHRs using keyboard entry, barcode scanning and other technologies. Technological challenges involve interfacing UDI data between EHRs and surgical information systems, transforming UDI and related patient data from EHRs for research, and applying data standards to UDI within and beyond EHRs.

Information technology infrastructure

These goals can only be achieved if there is appropriate information technology infrastructure in place throughout the medical device lifecycle. In particular, the role of health information technology has the potential to enable efficient capture, storage, and exchange of patient health information, and association of this information with UDIs.

Once fields are created for UDIs in EHRs and other systems, providers and other health system staff will need a mechanism for efficiently capturing UDIs as devices are used in patient care. As mentioned above, the Rule specifies that the UDI shall be provided in both plain text and AIDC formats on the medical device label. Automatic identification and data capture formats, such as bar coding and radio frequency identification technology, can facilitate the rapid capture of UDIs (e.g., by enabling UDIs to be read electronically through a network connection), potentially saving a great deal of time, expense and avoiding error introduced by human data entry. There are scanners available today capable of reading both linear and 2D barcodes that are UDI compliant.

The Rule is technologically neutral, leaving the decision about what form of AIDC is most appropriate to manufacturers. If health systems and providers do not already have readers for these AIDC formats, purchasing such readers could translate into an additional financial burden. This

could be particularly problematic if there is not harmonization among manufacturers in terms of the AIDC format used for UDIs, necessitating the purchase of multiple reader types by health systems and providers.

Once UDIs are captured and the information technology infrastructure has been enabled, then only can the patient information be leveraged to achieve the goals of this rule. Among other capabilities, this will require interoperability among systems and data sources, both within and outside of the health system.

Most systems will parse the UDI into its DI and PIs and display these separately (this is a requirement of the 2015 ONC HIT Certification Criteria (45CFR170.315). They will be able to:

Parse the following identifiers from a Unique Device Identifier:

(A) Device Identifier;

(B) The following identifiers that compose the Production Identifier:

- The lot or batch within which a device was manufactured;
- The serial number of a specific device;
- The expiration date of a specific device;
- The date a specific device was manufactured; and
- For an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c).

(C) For each Unique Device Identifier recorded for a patient, enable a user to access:

- The Unique Device Identifier;
- The description of the implantable device
- The identifiers associated with the Unique Device Identifier.
- The attributes associated with the Unique Device Identifier.

UDI incorporation into claims

Electronic claims data are increasingly being used for a range of activities, including active medical product safety surveillance, effectiveness research, and evaluation of patterns of care. Enriching claims data with UDIs could be very helpful, especially the UDI-DI (Device identifier). However, making changes to claim forms and claims processing systems is not trivial. Rather, such changes are typically costly and burdensome to enact, and as such, it may be challenging to gain the support of payers. For example the HIPAA X12 standard for the 837 dental clam would need to support the addition of UDIs. It has been suggested that if the Centers for Medicare & Medicaid Services(CMS) were to adopt the policy that UDIs must be reported on claim forms and made corresponding changes to its claims forms and processes, this would likely encourage other payers to follow suit. However, enacting such changes to CMS's system would be a lengthy process, requiring numerous amendments to an already complex claims processing infrastructure.

Requiring UDIs on submitted claims should also be associated with reimbursement policy changes as facilities are typically reimbursed using a global average rate per case system rather than being specific to the exact device used in many surgical procedures. These and other challenges would need to be resolved in order for UDIs to become integrated into claims data and available for use in surveillance and research activities. Other technical challenges include data protection (e.g., ensuring patient privacy) and device security, lack of information about existing data sources and their ability to contribute to our understanding of devices, and appropriate attribute development for building the GUDID.

Challenges with the UDI adoption

Lack of stakeholder knowledge, understanding, and support for the UDI system and its potential impact or benefits along with the cost of implementation will be formidable and could delay its implementation.

Successful UDI implementation will be hampered by reluctance to capture UDI information as part of the routine delivery of care or record such information in EHRs and other systems; and payers may not understand or agree with the potential benefits and uses of UDI and thus may be unwilling to invest in redesigning claims transaction systems and data warehouses to accommodate the inclusion of a new field for UDIs.

UDI implementation also is a concern relative to specific devices. In the future, clinicians may need to address, using a risk based approach, how UDI records will enhance patient care for:

- Dental instruments and handpieces that are direct marked;
- Products from dental labs; (clarify patient specific devices)
- Devices with software.
- Those biologics regulated as medical devices, such as demineralized bone matrix.

There is concern that UDI implementation could disrupt care delivery and as such may not be embraced by health systems and providers due to concerns regarding potential disruption to the clinical workflow or the sequence of processes involved in initiating and completing a procedure. Currently, providers often document a procedure or a patient visit afterward so as not to interrupt the delivery of care. However, this can lead to significant gaps in recorded information and delays in documentation.

The potential financial burden for all the stakeholders, with a potentially greater burden for smaller companies, and a desire for rapid UDI implementation should be balanced against a need to ensure that UDI implementation achieves longer-term objectives.

To assist with this, the ADA has created the ADA Dental Implant Card, which is a standard form to assist dentists and patients by consolidating information regarding implant restorations in one place. Dentists can keep one copy of the form for the patient's dental record as well as provide a copy to the patient. It is available at https://store.ada.org/catalog/ada-dental-implant-form-102799

Future Capabilities

While there are companies that are developing programs and systems that will incorporate UDIs into the EHR, there also are systems being developed that will manage UDIs at this point and will help translate or transport it to the proprietary practice management system.

There are multiple ways that the UDIs can and will be used; thus the ideal system/s will be able to:

- Capture the UDI in order to trace back from patient chart to manufacturer, distributor, procedure, patient and product placed, and vice versa (product to manufacture, distributor, provider, procedure, patient)- as per the requirements of 45CFR170.315.
- Trace use and utilization for ordering and inventory control including expiration dates.
- Scan patient info from practice management system using a bar code QR code, or other system identifier or manually enter patient information and scan the UDI using IR scanners, automatic scanners, manual scanners, mobile devices, i-pads, camera devices, or other electronic devices or manually input the UDI information to tie them together using software.
- Make it possible to be able to search the patient data from just having the UDI #, while maintaining secure storage and access to ePHI (electronic protected health information).
- Tie each UDI to a procedure note automatically via any one of the scanners or manually. This would allow one to tie every item or material used to the tooth level and be searched forward (search each patient record and know every UDI used on that patient or procedure note) and reverse (search by UDI # and know where and how it was used).
- Review UDI #s and generate a use report at the office/provider level, management group, patient, distributor and/or manufacturer level.
- Identify an item with a negative outcome or concern and generate a report to the manufacturer, distributor, dentist, office group and/or patient.
- Identify a Non-current and/or corrupt UDI and alert the FDA, manufacturer and/or distributor.
- Identify counterfeit, grey market and/or an item illegally based in the UDI and report it to the FDA, manufacturer, distributor and/or practitioner.
- Identify and track patients based continuously on the information that has been previously linked to any given patient, based on the patient specific data – this will provide the ability to identify and then contact the patient directly to warn them of any negative outcomes or concerns with the items used in their bodies based on the UDI records specially in cases where the patients have moved or the place where they received services has dissolved; providing the capability for long term data retention.
- Take the info from the item with the UDI that has had a negative outcome through the supply chain and inform all along that chain, the manufacturer, the distributer, the provider and the patient, even in cases where one of the businesses in the supply chain has been dissolved.
- Track and trace the items with those UDI's, whose manufacturer and/or distributer goes out of business.

- Provide a search function for patients, manufacturers, distributors, and end users to be able to check if a product has been recalled that they have concerns about.
- Enable auto-email function by category for manufacturers, distributors and end users (physician, dentist, healthcare providers), to be automatically informed of recalls, even for items that they did not manufacture, distribute or place.
- Provide manufacturers, distributors and end users a “certification” or authentication if no recall has been called for a specific product line, or product.
- Store and distribute details of recalls based on date of use by the clinician.
- Establish (if not already established) and maintain protocols for information disbursement on UDI problematic devices (how, when and to whom to notify).

ADA American Dental Association®
America's leading advocate for oral health

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