



**LEARNING UDI
COMMUNITY**



AHRMM
Advancing Health Care through
Supply Chain Excellence

Device Categorization Work Group Summary of Findings and Recommendations

WWW.AHRMM.ORG/LUC

DEVICE CATEGORIZATION WORK GROUP REPORT

LUC CHARGE TO WORK GROUP

WORK GROUP TOPIC

Device category is a data element that allows for analysis of device behavior at a higher level than that provided by a device identifier, Company name or Brand name. It provides the ability to search across a device type or category (containing like devices) to see trends or signals you couldn't otherwise see.

CHARTER

This work group should review the pros and cons of the Global Medical Device Nomenclature (GMDN) and Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) terminologies and review findings of preliminary pilot exercises, e.g., the Registry Assessment of Peripheral Interventional Devices (RAPID) initiative, while also recognizing that additional vocabularies for medical devices, such as the Universal Medical Devices Nomenclature System (UMDNS), United Nations Standard Products and Services Code (UNSPSC), may provide value to Global Unique Device Identification Database (GUDID) device data and National Evaluation System for Health Technology (NEST) priorities.

WORK GROUP MEMBERSHIP AND PROCESS

Work group membership includes medical device manufacturer and United States Food and Drug Administration (FDA) representatives as well as health policy consultants and the co-chairs who represented GMDN, health systems and SNOMED. The work group began meeting monthly by phone and webinar in February 2017. Additionally, the co-chairs held separate calls between meetings as needed, including calls with data users.

Approximately 30 people have participated in the work group which was co-led by:

- Joseph Drozda, MD, Director Outcomes Research, Mercy
- Kin-Wah Fung, MD, Staff Scientist, National Library of Medicine
- Barry Daniels, Technical Lead, GMDN Agency

FINDINGS

THE GUDID AND AccessGUDID

In establishing the GUDID, the FDA not only created a repository of unique device identifiers (UDI-DI) and associated device nomenclature but also a robust database that contains essential information on all Class III, II, and implantable/life-supporting/life-sustaining devices approved for use in the United States and will be able to link to the same model/version of a device in globally harmonized databases.

It is the agency's expressed desire that this information be used by manufacturers and

DEVICE CATEGORIZATION WORK GROUP REPORT

clinicians to promote device innovation and safety rather than merely to meet regulatory requirements. GUDID users are anticipated to be researchers, clinicians, insurers, hospitals and manufacturers. Both FDA and GUDID users would find benefit in the creation of clinically meaningful device categories based on use cases.

AccessGUDID is the publicly available website that enables users to interrogate GUDID device data. It enables the clear identification of a device through distribution and use. Beyond this primary goal, data from AccessGUDID will be linked to other data sources through the UDI-DI captured in every relevant patient, clinical, maintenance, outcomes or registry data source. The links permit users to benefit from capabilities such as:

1. Creating a list of all stents that are clinically used in peripheral vascular diseases or a list of high-risk implants.
2. Obtaining more granular information about device use—an example is the research on effectiveness of vascular stents based on stent size, model and other characteristics.

GMDN is used to classify devices within the GUDID for regulatory purposes, and manufacturers are required to select the most appropriate GMDN term for each of their devices entered into GUDID. GMDN terms are visible to AccessGUDID users, although the GMDN codes are not currently displayed. Through an arrangement with the GMDN Agency, SNOMED CT terms have been linked to GMDN terms. FDA has signaled that users should be able to employ the GMDN and SNOMED CT tools to create device categories that will be useful for non-regulatory purposes. The Work group has explored the utility of these tools for creating such categories. The remainder of this document summarizes its findings and recommendations.

THE GMDN—GLOBAL MEDICAL DEVICE NOMENCLATURE

INTRODUCTION

The GMDN is a list of generic names used to identify medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans. The main purpose of creating the GMDN was to provide health authorities and regulators, health care providers, manufacturers and others with a naming system that can be used to exchange medical device information and support patient safety. It was created from an amalgamation of six existing national nomenclatures.

Currently, the GMDN is used for:

- Data exchange between manufacturers and regulators, e.g., FDA UDI
- Supporting post-market vigilance and research, e.g., MHRA
- Health care authorities – Clinical engineering, e.g., MTPReg Sweden
- Supply chain management – British DoH pre-acquisition form

The GMDN is recommended by the International Medical Device Regulators Forum (IMDRF)

DEVICE CATEGORIZATION WORK GROUP REPORT

and managed by the GMDN Agency, a registered charity, governed by a Board of Trustees and a Policy Advisory Group, both of which represent regulators and industry.

The GMDN information is available to registered users via a website (gmdnagency.org) which provides help, search, account management and other functions. The data displayed on the website are current and can be downloaded from the site or an sFTP site. The dataset is translated in full or in part into around 20 languages. The GMDN Agency has ISO 9001:2015 certification for quality management systems.

To ensure continuing sustainability of the GMDN, revenues are generated through the registration/licensing of certain types of users, namely manufacturers and consultants, and the fee is graduated on the basis of the company revenue (the higher the revenue, the higher the fee). The license allows access and use of the data, and terms and conditions apply which limit the redistribution of the data. All other types of users have free-of-charge registered access, and it is likely that in the future there will be a basic-functionality, no-charge registration option for manufacturers.

The GMDN uses information about the manufacturer's intended use of the device, and GMDN assignment is not automatically tied to regulatory approved use. However, manufacturers will usually feel obliged to assign terms based on the approved use in a particular regulatory jurisdiction, and so GMDN assignment for the same physical device may differ across jurisdictions. Assignment of GMDN terms to products is the responsibility of the manufacturer, although help from the Agency is available if required. Advice on GMDN term assignment (including such issues as assigning a single GMDN term to a product and assigning system component terms for component products) is provided in many forms throughout the GMDN website including narrative, video and presentation. Registered users are able to link individual GMDN terms to their accounts, thereby making the GMDN codes available for their use. Additionally, such linkage enables GMDN to notify users regarding changes to the terms. As of June 2018, there are approximately 90 national regulators registered (50 with data download facility, i.e., using an up-to-date record set) and 4,500 manufacturers registered.

US FDA UDI IMPLEMENTATION

The US FDA UDI implementation, which was the first UDI implementation internationally, has the GMDN term/code as a mandatory requirement as part of each product record submission. Manufacturers who do not wish to register with the GMDN Agency can use a search tool to select a GMDN term that is linked to a FDA-generated code, thereby hiding the GMDN code. The assignment of GMDN terms/codes to products is not currently monitored for accuracy and multiple GMDN terms per product are permitted. GMDN data is sent regularly to the FDA for incorporation into the search tool and for code validation (active term) on record submission.

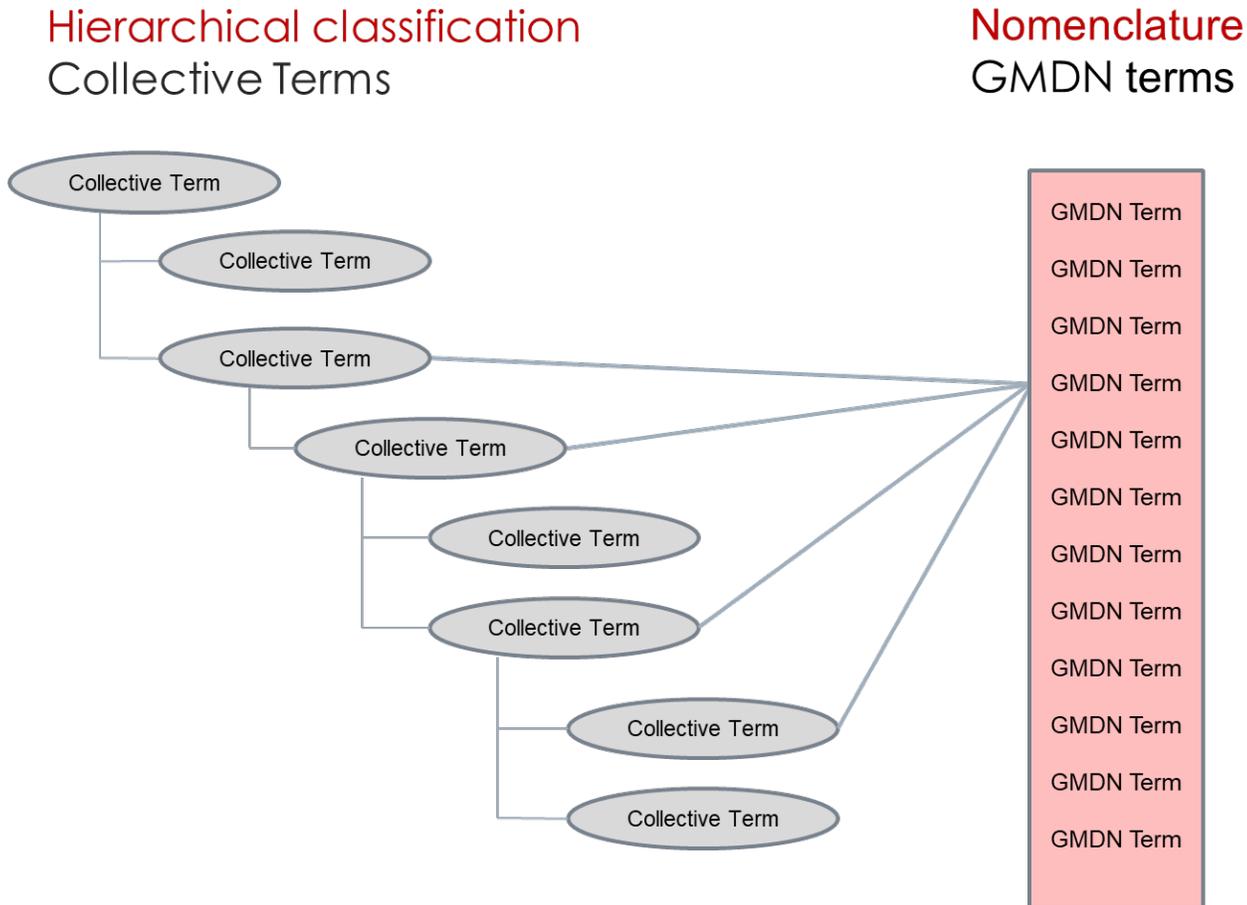
The GMDN codes are not displayed on the AccessGUDID website and cannot be used to query the AccessGUDID because these codes were originally not allowed to be publicly displayed by the GMDN Agency. Users have indicated that public access to GMDN codes would greatly improve the value of GMDN as a categorization tool. In addition, linking the GMDN CTs (higher-level grouping, see later) to records in AccessGUDID may also further increase the usefulness of the categorization tool.

DEVICE CATEGORIZATION WORK GROUP REPORT

GMDN DATA STRUCTURE

The GMDN is structured as a flat listing of “GMDN terms,” linked to a hierarchical categorization called the Collective Terms (CTs). As of June 2018, there are approximately 27,000 GMDN terms and 2,500 Collective Terms:

Figure 1.



GMDN terms consist of a name, definition and code which define the concept of a “generic device group.” For example:

GMDN Term Name: Scalpel, single-use

GMDN Term Definition: A sterile, handheld, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless steel alloy or carbon steel and the handle is often made of plastic. This is a single-use device

GMDN Term Code: 47569

TERM MANAGEMENT

To keep up-to-date with the dynamic nature of the medical device industry the GMDN dataset is updated by the GMDN Term Development Team to represent the current market with input and collaboration from manufacturers. Often input is requested from regulators and other

DEVICE CATEGORIZATION WORK GROUP REPORT

interested parties regarding requirements for term granularity.

Term changes are typically initiated by industry, whereby a manufacturer unable to find an appropriate term in the existing dataset to cover their device submits an inquiry to the Agency, and includes:

1. **New terms:** developed to cover devices that are new inventions or simply have not been presented to the GMDN previously for term development—at present, approximately 2–3 per day.
2. **Amends:** existing terms are frequently modified to broaden the scope of the device group it covers. This is to cover devices that are variations of current devices not thought to be sufficiently distinct to warrant a new GMDN term. The term name may change to reflect the new scope or may remain the same, with the widened scope described in the term definition. Notifications are sent to all users of that term and a comparison of the new and old version of the term wording is available on the website within the users account. The reason that terms are amended while retaining the same code is to avoid the large number of obsoletions that would otherwise be necessary to maintain a dynamic dataset—at present, approximately 3–4 per day.
3. **Obsoletions:** terms may be obsoleted when found to overlap with other terms or to be ambiguous. This causes disruption to industry as the manufacturer will need to assign a new term to their devices previously covered by the term. Term obsoletion is always a considered process, often with prior consultation with the users of that term, and notifications are sent to all users of that term with guidance on finding an alternative term. Currently, approximately averages at 2–3 per week.

Terms are continuously created or changed and published to meet the requirement of having new and amended terms available for regulatory submission. Therefore, the dataset version control is at the term level with each term having creation, publication and modification dates, and these are apparent in the downloadable listings along with the nature of the change. The history of all term changes is recorded in the dataset, along with annotation by the authoring team as to the rationale for the change. Therefore, the full history of every term is available for review by request.

The level of granularity for GMDN terms is the main issue in term management, i.e., how specific/narrow to make the scope of the term. This is a considered process and the GMDN Term Development Team uses a quality control process to ensure that maximum possible experience is used in making decisions. The GMDN has received feedback in the past about the relevance of term granularity, but the US FDA UDI implementation and the related projects are providing the best quality feedback to date. The GMDN is able and willing to change processes and rationale should the necessity be apparent. The GMDN Agency also has the infrastructure to host user-defined and maintained categories and to develop the means by which these are made publicly available.

DEVICE CATEGORIZATION WORK GROUP REPORT

SNOMED CT – SYSTEMATIZED NOMENCLATURE OF MEDICINE – CLINICAL TERMS

BACKGROUND AND USE

The origin of SNOMED CT can be traced back to the Systematized Nomenclature of Pathology (SNOP) created by the College of American Pathologists (CAP) in 1965, initially for morphology and anatomy. The scope of SNOP was later expanded to cover all of medicine and the name was changed accordingly. The first version of SNOMED CT was created by the merging of SNOMED RT (the first logic-based version of SNOMED) with the Clinical Terms Version 3 (also known as Read Codes) from the UK in 2002.

SNOMED CT is the most comprehensive, multilingual clinical health care terminology in the world. SNOMED CT contains over 340,000 active concepts. Each concept represents a unit of meaning, which is identified by a unique code. Each concept is associated with a fully specified name and one or more descriptions (preferred name and synonyms). SNOMED CT is a logic-based, computable terminology with a logical structure using Description Logics. Concepts are defined by other concepts through attributes and relations. The hierarchical relationship between concepts is computationally generated by a Description Logics classifier. The principal use of SNOMED CT is to encode clinical information (e.g., diseases, findings, procedures), but it also has comprehensive coverage of other domains including drugs, devices, organisms and anatomy. SNOMED CT has well-defined file formats (called refsets) for sharing code lists and any accompanying data (e.g., UDI-DIs), which are currently used in public platforms, such as the Value Set Authority Center.

In 2007, the intellectual property of SNOMED CT was transferred from the College of American Pathologists to an international governing body called the International Health Terminology Standards Development Organization (IHTSDO), which later acquired the name SNOMED International. Starting with 9 member countries, the membership of SNOMED International has grown to 34, including the US, Canada, Australia, New Zealand and many European countries. The use of SNOMED CT is free in all member countries, in low-income countries (as defined by the World Bank), and for qualified research, humanitarian and charitable projects in any country.

In the US, SNOMED CT is a designated terminology for the problem list, procedures and some other data fields in the electronic health record (EHR) according to the Meaningful Use of EHR incentive program. After the Meaningful Use program ended, the requirements for SNOMED CT use persist in the Merit-based Incentive Payment System (MIPS) and Promoting Interoperability programs.

GMDN AGENCY AND SNOMED INTERNATIONAL COLLABORATION

The GMDN Agency and SNOMED International commenced a cooperation agreement in 2012 to allow the use of GMDN as the basis for the medical device component of SNOMED CT. The agreement also allows SNOMED CT concepts to be used in the GMDN, although that is impossible as there are no definitions in SNOMED CT terms. The initial duration of the agreement was for five years and is currently legally in place until formally terminated by one of the parties. Currently, GMDN content is being regularly integrated into SNOMED CT under the agreement, for the agreed license fee, and there are regular monthly meetings between the parties to discuss content issues. The goal is to minimize duplication, support harmonization and provide greater utility and access to both terminologies.

DEVICE CATEGORIZATION WORK GROUP REPORT

GMDN AND SNOMED CT COMPARISON

OVERVIEW

The primary purpose and emphasis of the two terminologies are different. While GMDN is not restricted to regulatory use as it is not based on regulatory approved use, currently its main uses are in post-market surveillance by regulators and as a link to the UDI-DI in AccessGUDID. SNOMED CT's primary focus is clinical documentation and clinical care. There are more than 50 GMDN implementations by national regulator and clinical engineering departments. SNOMED CT is being used in over 50 countries for representation of clinical content in electronic health records. Finally, there is little restriction to the use of either SNOMED CT or GMDN code lists apart from acknowledgement of the intellectual property and agreeing to the terms of use.

DATA

Because SNOMED CT is a clinical terminology, its focus is on clinically significant devices (e.g., implants) that are expected to be documented in a patient's medical record. Out of the 27,000 GMDN terms, 9,000 clinically important terms (e.g., implants) are incorporated into SNOMED CT, raising the number of SNOMED CT device concepts from 5,000 to 14,000. To maintain the linkage between the two terminologies, a table mapping one SNOMED CT code to exactly one GMDN code (one-to-one map) was created. Due to the restriction in the distribution of GMDN codes, the mapping table is not included in the SNOMED CT release files. The mapping table is used in the backend of the AccessGUDID website to link device identifiers to SNOMED CT concepts, and it is available to license holders on agreement of both SNOMED CT and the GMDN Agency.

Although GMDN data are imported into SNOMED CT there is a fundamental difference in the data structure. GMDN terms have a name and a definition; SNOMED CT uses only the name. The GMDN definition defines the scope of the name, as it is essential for a categorization entity (the GMDN term) to define boundaries, inclusions, exclusions and other attributes that cannot be included in a relatively short name, to allow accurate assignment. In SNOMED CT, the meaning of a concept is anchored in the fully specified name. For example, "Cardiac pacemaker device (physical object)" is the fully specified name of the device. The semantic tag "physical object" distinguishes this concept from the procedure of insertion of the cardiac pacemaker.

MAINTENANCE

There are different editorial considerations in the maintenance of GMDN and SNOMED CT.

As the GMDN has a large user base with approximately 4,500 manufacturers assigning GMDN terms to their devices, it is preferable to modify the definition and/or name of a GMDN term, maintaining the same code, rather than obsoleting the term, which would require manufacturers to reassign GMDN codes, a process that can be costly and disruptive. Therefore, GMDN terms are constantly updated to keep up to date with industry innovation by broadening the scope to include slight variations of devices while maintaining the same code.

In SNOMED CT, the primary concern is consistency in meaning of its codes and concepts. This

DEVICE CATEGORIZATION WORK GROUP REPORT

is called concept permanence, one of the main principles for controlled medical vocabularies¹. It is important to maintain longitudinal comparability of data captured at different times while keeping up with the advance in medical knowledge and practice. Reuse of a code for a different meaning is not allowed. Once a concept is created, its meaning—as expressed by the fully specified name—must remain the same. Any change in the fully specified name that significantly affects the meaning of the concept will require the creation of a new concept.

Here are some examples for clarity:

1. GMDN term changed from “Knee arthroplasty force sensor” to “Arthroplasty force sensor” (a broader term). SNOMED CT cannot simply change the name of the concept but must create a new one.
2. GMDN term name changed from “ENT Foreign body extractor” to “ENT Foreign body inflatable extractor” (a narrower term), to include an attribute previously in the definition but brought into the name to make a distinction with a newly created term. SNOMED CT needs to create a new concept because the meaning has changed.

This difference in editorial policies creates two problems. In cases where SNOMED CT decides not to incorporate the new GMDN terms with amended names the one-to-one map between the two nomenclatures cannot be maintained. In cases where SNOMED CT creates new concepts to match the new GMDN terms, the GMDN-SNOMED CT map needs to be updated accordingly. Since some GMDN terms will have different SNOMED CT mappings at different points in time, clear versioning is essential to avoid user confusion and potential problems in longitudinal comparability of data.

ADVANTAGES/LIMITATIONS

In general, the GMDN is more suitable for regulatory use because:

1. There are clear definitions to assist assignment and analysis.
2. The editorial policy, previously described, limits industry disruption while keeping up with innovation.

There are some limitations with the GMDN for clinical use:

1. Term name changes may cause problems for longitudinal analysis of data.
2. Currently licensing restrictions prevent full access to GMDN data in public systems, although that is being addressed by the GMDN Agency.
3. Assignment of the GMDN term to a device is the responsibility of the manufacturer, is not currently being authenticated, and therefore can be inaccurate.

In general, SNOMED CT is useful for facilitating clinically oriented use cases because:

1. It encompasses other clinical data elements in the EHR (e.g., diagnosis,

¹ Cimino JJ. Desiderata for Controlled Medical Vocabularies in the Twenty-First Century. *Methods of information in medicine*. 1998;37(4-5):394–403.

DEVICE CATEGORIZATION WORK GROUP REPORT

- procedures, adverse events), which can provide linkages for activities such as clinical decision support, workflow management and clinical quality measurement,
2. Concept permanence—tight versioning with archiving of obsolete content—ensures longitudinal comparability of EHR data.
 3. The ability to share SNOMED CT codes facilitates collaborative work. For example, device registries can share a common set of SNOMED CT codes to identify devices of concern.

There are some limitations with SNOMED CT. Currently, SNOMED CT codes are not directly linked to devices but, instead, achieve the linkage through the one-to-one map between SNOMED CT and GMDN. Due to the difference in editorial policy mentioned previously, it is difficult to maintain the map in some cases. It is also possible that SNOMED CT will add new device concepts outside of GMDN to satisfy clinical requirements. In such cases, there is no way to link those new concepts to devices at present. One possible solution is to allow manufacturers to submit SNOMED CT terms to GUDID. Alternatively, FDA or other stakeholders (e.g., professional societies, registry owners) can take up the slack and provide maps from those SNOMED CT concepts to device identifiers. Another limitation of SNOMED CT is that it is sometimes difficult for users to assign SNOMED CT codes to devices because of the lack of textual definitions.

TOOLS FOR CREATING CATEGORIES

Currently, devices are categorized at three levels: groupers, terms and device identifiers (Figure 2).

1. Groupers are higher-level concepts in device terminologies such as SNOMED CT and GMDN. They group device terms according to broad characteristics (e.g., by clinical specialty). One device term can be grouped under multiple groupers (e.g., saline-filled breast implant is grouped under both Prostheses and associated devices and Plastic surgery and cosmetic devices). There can be multiple levels of groupers, from general to specific (e.g., prostheses and associated devices > prostheses > implantable prostheses > breast implants)
2. Device terms are the most specific (granular) level of categorization in a terminology. One device term encompasses multiple devices of the same type, as defined by the definition of the term. Device terms are generally considered mutually exclusive. In principle, a device should only have one associated device term, but in practice, there are exceptions (see following).
3. Device identifiers are the mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device. One device term generally encompasses multiple device identifiers.

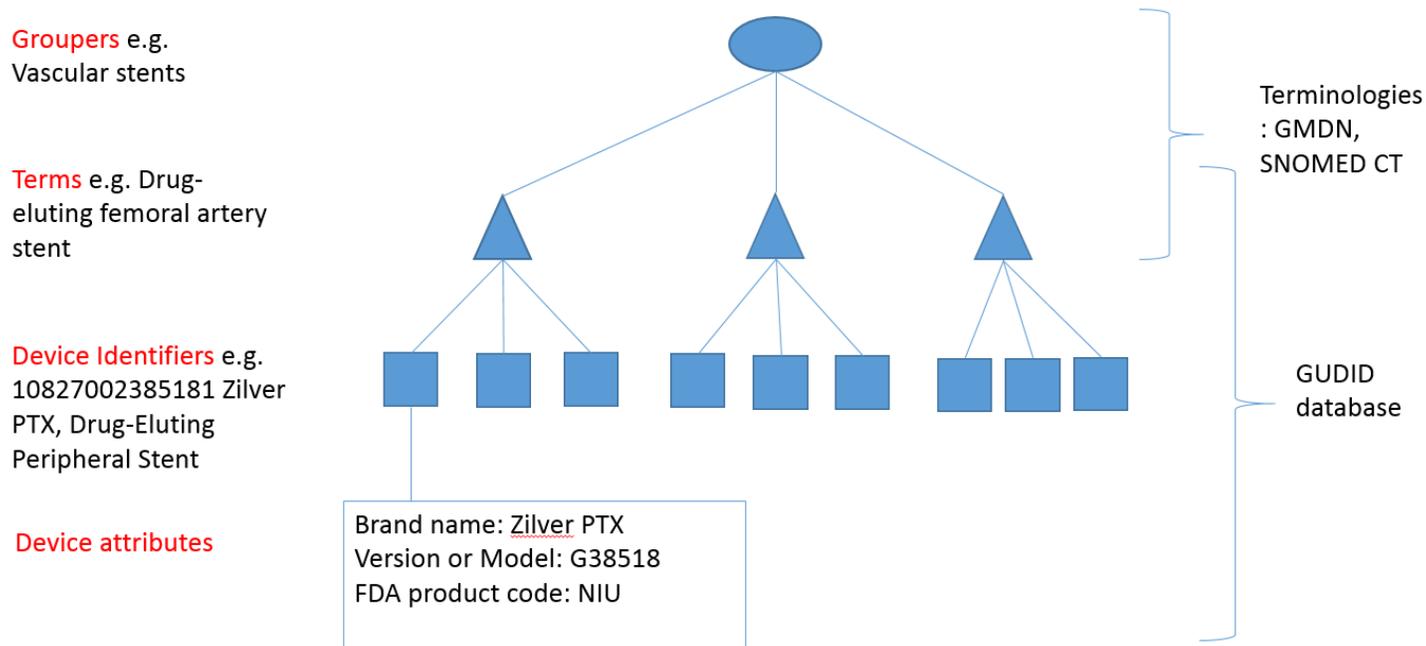
In AccessGUDID, each device is linked to a GMDN term, which can be mapped to a unique SNOMED CT term. GUDID also contains information about some common characteristics (attributes) of a device. Identifying devices using terminologies can be done efficiently by a top-down approach—using one or more groupers to retrieve the associated terms and through the terms to device identifiers. One advantage of this approach (as compared to a static list

DEVICE CATEGORIZATION WORK GROUP REPORT

of device identifiers) is that the list is easier to maintain. When new devices are introduced or old devices retired, the changes will be reflected in the device terminologies and GUDID. Information and characteristics of a specific device can be found in both the terminologies (e.g., metal stent) and in GUDID (e.g., size).

Figure 2. Device categorization: How things are organized

(For simplicity, only one level of grouper is shown, and one device term is assigned to only one grouper.)



GUDID MEDICAL DEVICE DATA CLINICAL USE CASES

The following use cases were presented to the work group by AccessGUDID users.

1. **RAPID/VQI – Carrie Bosela, James Tcheng**

The Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) currently supports 12 different registries, Peripheral Vascular Intervention (PVI) being the largest with over 160,000 cases. The PVI Registry is currently participating in the Medical Device Epidemiology Network (MDEpiNet) RAPID initiative in which GUDID data will be used. In August 2016, VQI successfully integrated a subset of GUDID device information into the PVI registry based on GMDN terms to download data quarterly and as needed between regular downloads. The terms were selected by the first selection criterion of “stent” and the second selection criterion of clinical indication for lower extremity PVI cases. After a year of collecting data, we discovered that coronary arterial stents were also being utilized in the peripheral arterial space and realized our scope of GMDN terms was too narrow. We, therefore, began adding coronary stents to our GUDID data pulls in early 2018. We also identified an issue with Canadian stents not being included in GUDID. Wendy Watson, who is the champion for UDI at the University Health Network in Toronto, is an advocate for UDI adoption and wrote an excellent case study available at <http://www.ahrmm.org/knowledge-center/resources/case-study/university-health-network-udi-capture-work-group-case-study-2017>. Wendy discovered that some Canadian products are found in GUDID, however, not all such items are represented there. If a Canadian approved

DEVICE CATEGORIZATION WORK GROUP REPORT

device is not also marketed in the United States, its DI and associated data are not submitted to the GUDID and information on the device is, therefore, not available from that source. (This is also true of any device regulated by jurisdictions outside of the United States.) In the future, as jurisdictions build local UDIDs, this will become less of an issue.

We encountered some challenges with the data in GUDID early on, as well. The DI, Manufacturer Name, Device Name, length and diameter of the device are required data elements for users to submit to the VQI PVI registry. We provide DI associated device dimensions in dropdown lists to facilitate reporting these elements. Manufacturers who submit data to GUDID have the option to populate clinically relevant size either from a dropdown list or via batch submissions using HL7 SPL format requirements. If an applicable Size Type is not available, the only option for the manufacturer is to not populate the field and submit the dimension as text. The Size Types (dimensions) currently available in GUDID are listed in Table 1. When text is used for clinically relevant size field in GUDID, VQI cannot pull dimensions from GUDID and therefore cannot make these data available in our dropdown lists. This means that end users need to enter the diameter and length manually.

Table 1. Current Definitions for Length and Diameter in GUDID (All Device Types)

Size Type (Dimension)	Definition
Length	The linear extent in space from one end of something to the other end, or the extent of something from beginning to end.
Outer Diameter	The greatest possible length of a straight line passing through the center of a circular or spheroid object that connects two points on the circumference.

Table 2. Clinically Relevant Size Work group Recommended Clinically Relevant Peripheral Arterial Stent Size Types

Proposed Size Type	Proposed Definition
Nominal stent diameter	Deployed stent diameter, as marked on packaging.
Tapered Stent Smallest Diameter	Tapered stent - second (smaller) deployed stent diameter, as marked on packaging
Nominal stent length	Deployed stent length, as marked on the packaging
Maximum stent diameter	Maximum diameter to which a stent can be distended
Catheter working length	Length of the device delivery catheter that can be inserted into a guide catheter

Changing the Size Types in the VQI to meet the requirements in Table 2, determined by the Clinically Relevant Size work group, would have to be prioritized by VQI leadership to implement. We do feel this will be a challenge for our end users if the data do not auto-populate from our GMDN query of GUDID device specific data, as these data elements are not

DEVICE CATEGORIZATION WORK GROUP REPORT

readily accessible to most clinical data abstractors for our registry.

Another challenge going forward is knowing when GMDN terms change so we can update our code to pull those devices associated with the new GMDN terms and remove the codes that have been retired.

RAPID deals specifically with devices used in the superficial femoral and popliteal beds. An assessment of the clinical utility of GMDN codes for these devices was, therefore, performed. Results of the analysis are shown in Table 3.

The analysis was performed using a clinical categorization and subcategorization of devices commonly used in peripheral artery intervention:

- Atherectomy
 - a. Excisional (cutting)
 - b. Rotational (abrasion / pulverizing)
 - c. Ablative (vaporizing)
- Stents
 - a. Balloon-expandable
 - b. Self-expanding
 - c. Covered
- Balloons
 - 1 Plain
 - 1 Atherotomy (scoring / cutting)
 - 1 Drug-coated (medication transfer)
 - 1 Temperature modulating (cryo)

The first column lists the manufacturer and brand name of devices (available in the US) that belong in each category and subcategory. The second column lists the GMDN CTTerm that seemed to be the terminal CT code for the subcategory. The third column lists the GMDN Final Term that seemed to be the most appropriate Final Term for the subcategory.

The “lens” applied in this analysis was to identify device categories and subcategories where device parameters / attributes could logically be identified that would be common (or mostly common) to all members of the category and subcategories therein.

DEVICE CATEGORIZATION WORK GROUP REPORT

Table 3. GMDN Terms and Clinician Defined Peripheral Arterial Device Categories

Clinical Device Categories & Devices	GMDN Tree – CT Term	GMDN Final Term Candidate(s)
ATHERECTOMY DEVICES		
<p>a. Excisional (cutting)</p> <ul style="list-style-type: none"> • HawkOne, SilverHawk, TurboHawk (scrape / shear / capture) – Medtronic • Pantheris (scrape / shear / capture, with ultrasound guidance) – Avinger • Jetstream – (front cutting with flush/aspiration) – Boston Scientific • Phoenix (Archimedes screw with aspiration) – Philips 	<p>CT130: Catheters and associated devices →</p> <p>CT1581: Catheters →</p> <p>CT477: Cardiovascular catheters →</p> <p>CT1025: Angioplasty / atherectomy catheters →</p> <p>CT1588: Peripheral angioplasty/atherectomy catheters</p>	<ul style="list-style-type: none"> • Mechanical atherectomy system catheter, coronary/peripheral • Mechanical atherectomy system catheter, peripheral <p>[No directly matching, single / unique, clinical category specific term]</p>
<p>b. Rotational (abrasion / pulverizing)</p> <ul style="list-style-type: none"> • Diamondback (orbital atherectomy) – Cardiovascular Systems • Rotalink (rotational atherectomy) – Boston Scientific 	<p>CT130: Catheters and associated devices →</p> <p>CT1581: Catheters →</p> <p>CT477: Cardiovascular catheters →</p> <p>CT1025: Angioplasty / atherectomy catheters →</p> <p>CT1588: Peripheral angioplasty/atherectomy catheters</p> <p>[Same tree as excisional atherectomy]</p>	<ul style="list-style-type: none"> • Mechanical atherectomy system catheter, coronary/peripheral • Mechanical atherectomy system catheter, peripheral <p>[Same as excisional atherectomy]</p> <p>[No directly matching, single / unique, clinical category specific term]</p>

DEVICE CATEGORIZATION WORK GROUP REPORT

<p>c. Ablative (vaporizing)</p> <ul style="list-style-type: none"> • Laser (laser atherectomy) - Spectranetics 	<p>CT130: Catheters and associated devices →</p> <p>CT1581: Catheters →</p> <p>CT477: Cardiovascular catheters →</p> <p>CT1025: Angioplasty / atherectomy catheters →</p> <p>CT1588: Peripheral angioplasty/atherectomy catheters</p> <p>[Same tree as excisional atherectomy]</p>	<ul style="list-style-type: none"> • Atherectomy laser system beam guide-catheter, peripheral <p>[Explicit match]</p>
<p>STENTS</p>		
<p>a. Balloon-expandable</p> <ul style="list-style-type: none"> • Omnilink, Herculink – Abbott Vascular • Express – Boston Scientific • Formula – Cook Medical • Palmaz – Cordis • Assurant, IntraStent, Paramount, Visi-Pro – Medtronic 	<p>CT244: Prostheses and associated devices →</p> <p>CT1370: Prostheses →</p> <p>CT446: Implantable prostheses →</p> <p>CT1374: Cardiovascular prostheses →</p> <p>CT485: Vascular stents →</p> <p>CT2067: Peripheral artery stents</p>	<ul style="list-style-type: none"> • Bare-metal renal artery stent • Iliac artery stent, bare-metal • Multiple peripheral artery stent, bare-metal <p>[No directly matching, single / unique, clinical category specific term]</p>
<p>b. Self-expanding</p> <ul style="list-style-type: none"> • Absolute, Supera – Abbott Vascular • Luminexx, LifeStar, LifeStent – BD Interventional • Astron, Pulsar – Biotronik • Epic, Innova, WallFlex – Boston Scientific 	<p>CT244: Prostheses and associated devices →</p> <p>CT1370: Prostheses →</p> <p>CT446: Implantable prostheses →</p> <p>CT1374: Cardiovascular prostheses →</p> <p>CT485: Vascular stents →</p>	<ul style="list-style-type: none"> • Bare-metal renal artery stent • Iliac artery stent, bare-metal • Multiple peripheral artery stent, bare-metal • Drug-eluting renal artery stent

DEVICE CATEGORIZATION WORK GROUP REPORT

<ul style="list-style-type: none"> • Zilver, Zilver PTX (drug-eluting) – Cook Medical • Smart – Cordis • Complete, EverFlex, Protégé – Medtronic • Alimaxx – Merit Medical • Misago – Terumo Interventional 	<p>CT2067: Peripheral artery stents</p> <p>[Same tree as balloon-expandable stents]</p>	<ul style="list-style-type: none"> • Drug-eluting femoral artery stent • Drug-eluting infrapopliteal artery stent, non-bioabsorbable <p>[Adds drug-eluting stent to stent concepts]</p> <p>[No directly matching, single / unique, clinical category specific term]</p>
<p>c. Covered</p> <ul style="list-style-type: none"> • CP – B. Braun • LifeStream – BD Interventional • Atrium – Getinge • Viabahn, Tigris – Gore 	<p>CT244: Prostheses and associated devices →</p> <p>CT1370: Prostheses →</p> <p>CT446: Implantable prostheses →</p> <p>CT1374: Cardiovascular prostheses →</p> <p>CT485: Vascular stents →</p> <p>CT2067: Peripheral artery stents</p> <p>[Same tree as balloon-expandable stents]</p>	<ul style="list-style-type: none"> • [No final candidate term identified] <p>[No directly matching, single / unique, clinical category specific term]</p>
<p>BALLOONS</p>		
<p>a. Plain</p> <ul style="list-style-type: none"> • Chameleon (injection port) – AV Medical • Armada, Fox, Viatrac – Abbott Vascular • Impact, Ghost, Mullins-x, Tyshack – B. Braun • Atlas, Conquest, Dorado, Ultraverse, VasuTrak – BD Interventional • Passeo – Biotronik 	<p>CT130: Catheters and associated devices →</p> <p>CT1581: Catheters →</p> <p>CT477: Cardiovascular catheters →</p> <p>CT1025: Angioplasty / atherectomy catheters →</p> <p>CT1588: Peripheral angioplasty/atherectomy catheters</p> <p>[Same tree as excisional atherectomy]</p>	<ul style="list-style-type: none"> • Peripheral angioplasty balloon catheter, basic <p>[Explicit match]</p>

DEVICE CATEGORIZATION WORK GROUP REPORT

<ul style="list-style-type: none"> • Charger, Coyote, Mustang, Sterling, Symmetry, XXL – Boston • Advance – Cook Medical • Aviator, Maxi, Opta, Powerflex, Saber, Savvy, Slalom, Sleek – Cordis • FirstChoice – DirectAccess Medical • Admiral, Amphirion, Chocolate, EverCross, Fortrex, NanoCross, Pacific, PowerCross, RapidCross, Reef – Medtronic • Ebony – Natec Medical • Cronus – Nipro • Gateway – Stryker • Crosperio Metacross – Terumo • GliderfleX – TriReme • Achilles, Castor, Hermes, Minerva, Polux, USE – US Endovascular 		
<p>b. Atherotomy (scoring / cutting)</p> <ul style="list-style-type: none"> • UltraScore – BD Interventional • Peripheral Cutting – Boston Scientific • Splitwire – Rex Medical • Angiosculpt – Spectranetics 	<p>CT130: Catheters and associated devices →</p> <p>CT130: Catheters and associated devices →</p> <p>CT1581: Catheters →</p> <p>CT477: Cardiovascular catheters →</p> <p>CT1025: Angioplasty / atherectomy catheters →</p>	<ul style="list-style-type: none"> • [No final candidate term identified]

DEVICE CATEGORIZATION WORK GROUP REPORT

	<p>CT1588: Peripheral angioplasty/atherectomy catheters</p> <p>[Same tree as excisional atherectomy]</p>	<p>[No directly matching, single / unique, clinical category specific term]</p>
<p>c. Drug-coated (medication transfer)</p> <ul style="list-style-type: none"> • Lutonix – BD Interventional • Admiral – Medtronic • Stellarex - Spectranetics 	<p>CT130: Catheters and associated devices →</p> <p>CT1581: Catheters →</p> <p>CT477: Cardiovascular catheters →</p> <p>CT1025: Angioplasty / atherectomy catheters →</p> <p>CT1588: Peripheral angioplasty/atherectomy catheters</p> <p>[Same tree as excisional atherectomy]</p>	<ul style="list-style-type: none"> • Peripheral angioplasty balloon catheter, drug-eluting <p>[Explicit match – but terminology could be improved, these are “drug-coated” balloons, not “drug-eluting” devices]</p>
<p>d. Temperature modulating (cryo)</p> <ul style="list-style-type: none"> • PolarCath – NyCryo Vascular 	<p>CT130: Catheters and associated devices →</p> <p>CT1581: Catheters →</p> <p>CT477: Cardiovascular catheters →</p> <p>CT1025: Angioplasty / atherectomy catheters →</p> <p>CT1588: Peripheral angioplasty/atherectomy catheters</p> <p>[Same tree as excisional atherectomy]</p>	<ul style="list-style-type: none"> • [No final candidate term identified] <p>[No directly matching, single / unique, clinical category specific term]</p>

DEVICE CATEGORIZATION WORK GROUP REPORT

FINDINGS

1. The GMDN ontology did not discriminate among primary clinical device categories (i.e., atherectomy, stent, and balloon devices) at the CTTerm level. The best match for the CT Term for both atherectomy catheters and balloon catheters was the same: CT1588 – Peripheral Angioplasty / Atherectomy Catheters, while the best match for the CTTerm for stents was CT2067 – Peripheral Artery Stents. See **yellow** notes in Table 3 for details.
2. Out of the 10 device subcategories, there were 3 explicit matches at the FinalTerm level (noted in **purple** in Table 3). Of note, the nomenclature of one of these explicit matches should be adjusted—specifically, instead of “drug-eluting” balloons, this category should have the label “drug-coated” (the balloons do not “elute” drug; “elute” means to remove by use of a solvent).
The 3 device categories with explicit FinalTerm matches are:
 - ablative atherectomy (laser)
 - plain balloons
 - drug-coated balloons
3. Out of the 10 device subcategories, there were 7 where no directly matching, single / unique, clinical category specific term was identified for the subcategory. Four of the 7 had multiple potential final terms applicable to the members of the device subcategory (denoted by multiple bulleted terms in the third column), while in 3 of the 7 no FinalTerm could be identified (noted in **grey** in Table 3). The 3 latter device subcategories are:
 - covered stents
 - atherotomy balloons
 - temperature-modulating balloons

A similar analysis was done separately in SNOMED CT:

Atherectomy

1. No excisional (cutting) atherectomy devices, but has cutting/scoring balloons (see following)
2. SNOMED CT has Atherectomy/thrombectomy rotational catheter (Cardiovascular catheter → Embolectomy/thrombectomy catheter → **Atherectomy/thrombectomy rotational catheter**)
3. SNOMED CT has Peripheral angioplasty laser catheter (Vascular catheter → Angioplasty catheter → Peripheral angioplasty catheter → **Peripheral angioplasty laser catheter**)

Stents

1. SNOMED CT has Balloon expanded biliary stent (Stent, device → Non-vascular stent → Biliary stent → **Balloon expanded biliary stent**)
2. Has Self-expanding stent (Stent, device → **Self-expanding stent**)

DEVICE CATEGORIZATION WORK GROUP REPORT

3. No covered stent, but has some vascular stent-graft

- a. Vascular stent → Peripheral artery stent → Aortic stent → **Aortic arch endovascular stent-graft; Aortic endovascular stent-graft extender**
- b. Vascular stent → Arterial stent → Carotid stent → **Aortic arch branch vessel endovascular stent-graft**
- c. Vascular stent → **Arteriovenous fistula endovascular stent-graft**
- d. Vascular stent → Venous stent → **Peripheral venous endovascular stent-graft**

Balloons

1. Plain: SNOMED CT has Peripheral angioplasty balloon catheter (Vascular catheter → Angioplasty catheter → Peripheral angioplasty catheter → **Peripheral angioplasty balloon catheter**)
2. Atherotomy (scoring / cutting)
 - a. Angioplasty catheter → Angioplasty balloon catheter, device → **Cutting balloon angioplasty device**
 - b. Cardiac catheter → Cardiac balloon catheter → Coronary angioplasty balloon catheter → **Cutting/scoring coronary angioplasty balloon catheter**
3. Drug-eluting devices
 - a. Has **Peripheral angioplasty balloon catheter, drug-eluting** which is a subtype of Peripheral angioplasty balloon catheter
 - b. Has Vascular stent → **drug-eluting vascular stent** which has 9 subtypes

2. Augmented UDI Data (AUDI) – James Tcheng

USE CASE DESCRIPTION

Device attributes, parameters and specifications (e.g., size, composition) are key criteria used by clinicians to select and customize specific devices to individual patients. In the Mercy Health Coronary Stent UDI Demonstration Project, almost 20 separate contexts spanning clinical, research, administrative and supply chain use cases were identified where device attribute data are needed (Tcheng et al., Am Heart J). The solution developed for the Mercy Demonstration to manage device attribute data was the Supplemental Unique Device Identifier Database (SUDID). Derived from SUDID (which was specific to only coronary stents), the AUDI system is envisioned as the reference source of device attribute data across all categories of devices. In other words, AUDI will complement GUDID by providing reference device attribute data not categorically captured as data in the GUDID system. These data are to be provided by the manufacturer to AUDI in a manner analogous to GUDID data submission and maintenance. Data will be available to consumers of the data through electronic query as reference data, replicating as much as possible the methods of AccessGUDID.

DEVICE CATEGORIZATION WORK GROUP REPORT

CATEGORIZATION REQUIREMENTS

The intention of AUDI is to electronically capture clinically relevant device attribute data as printed by the manufacturer on the package label and/or the instructions for use. The device attribute data in AUDI are to be organized by device category. In other words, all members of a given device category are to have the same set of attributes, with devices from a second device category having a different set of attributes specific to the second category. Of note, there is the potential for overlap of attributes between device categories. For example, balloon angioplasty catheters and implantable stents could have the following clinically relevant attributes listed in AUDI:

Balloon	Stent
Nominal length	Nominal length
Nominal diameter	Nominal diameter
Rated burst pressure	Maximum distension diameter
OTW vs. RX	OTW vs. RX
Guidewire compatibility	Guidewire compatibility
Working catheter length	Working catheter length
Compliance	Minimum delivery catheter Fr
Not coated vs. drug-coated	Self-expanding vs. balloon-deployed
Drug released	Bare metal vs. drug-eluting
	Drug eluted
	Not tapered vs. tapered

USER RECOMMENDATIONS

Device categorization is central to the AUDI concept. The key recommendation of AUDI is that device categories be defined wherein all devices belonging to a category share a common set of clinically relevant attributes.

3. Breast Implant Surface Type

USE CASE DESCRIPTION

Background: Breast implant associated anaplastic large cell lymphoma (BIA-ALCL), a rare type of non-Hodgkin's lymphoma, has become a serious safety concern for breast implants patients since 2011. In 2016, the [World Health Organization recognized](#) BIA-ALCL as a rare T-cell lymphoma that can develop following breast implants. FDA has issued two major updates to reflect recent progress in our understanding of the BIA-ALCL issue in 2011 and 2017.

In order to find out the relationship between breast implant's features and the occurrences of BIA-ALCL, the Division of Epidemiology, Office of Surveillance and Biometrics at the Center for Device and Radiologic Health (CDRH) in FDA leads an effort of integrating multiple data sources received at FDA, such as medical device adverse event reports (MDRs), pre-market approval (PMA) reports, post-approval study (PAS) reports and published literature. Every year, FDA will update the MDRs analysis of breast implant associated ALCL information to

DEVICE CATEGORIZATION WORK GROUP REPORT

inform the public. On the [FDA BIA-ALCL page](#), the reported ALCL cases and related breast implant information, such as surface type (e.g., textured or smooth), fill type (e.g., silicone or saline), etc. were provided. It is noted that due to the limitations of MDR data (e.g., incomplete, inaccurate, untimely, unverified or biased data) and the lack of the epidemiological cohort data, a statistically significant association between textured breast implants and BIA-ALCL cannot be established. Besides the MDR data, a significant body of medical literature has been published since the FDA 2011 report, including additional case histories and comprehensive reviews of the natural history and long-term outcomes of the disease. Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE Registry) has also been collecting BIA-ALCL cases by the American Society of Plastic Surgeons (ASPS) and the Plastic Surgery Foundation (PSF). Most of the cases reported in the literature and PROFILE registry describe a history of the use of textured implants. In all these reported cases, identifying and organizing breast implant data by its surface types (textured or smooth) or filling types (silicone or saline) is crucial.

Challenges: The FDA product code names for breast implant are FTR for “prosthesis, breast, non-inflatable, internal, silicone gel-filled” and FWM for “prosthesis, breast, inflatable, internal, saline,” which only describe the filling of breast implants. Also, the GMDN only provided “Saline-filled breast implant” and “Silicone gel-filled breast implant” to represent different types of breast implant. As no terminology is available to classify the breast implant surface type, the curation of the MDR data has been challenging. In the MDR report, multiple fields were designed to report the product, such as the brand name, product code, model number, style information and catalog number. However, these fields are not always populated. To determine the surface type of a reported breast implant, the curators often use either brand name, style, catalog number or model number to search the internet or to search FDA submissions and find relevant information. Most of the time, the curators will combine all the search results and sift through the compiled data to find or infer the surface type of a breast implant. This process is manual, thus labor-intensive, time-consuming, inconsistent and error-prone. FDA currently only performed such detailed curation with the 600 MDR reports that mentioned ALCL as of September 30, 2018. However, the whole MDR database, as of September 30, 2018, contains 44,899 reports for breast implant-related issues. Without an automated solution to classify the breast implant surface type, it is impossible to manually obtain the breast implant surface type for all of these MDR records, which makes advanced statistical data analysis impossible. We are currently working on a breast implant ontology-based text mining solution to solve this problem.

If we had a terminology describing the surface type as smooth or textured, this issue would be less of a problem. As the association between BIA-ALCL and breast implant is being continuously investigated by all the stakeholders, such as academia, professional societies and patient advocate groups, as well as FDA, the terminology that differentiates the surface type of a breast implant, and a catalog collecting all the current breast implants and their surface types, would be very useful for future post-market surveillance, research, and other data analytics tasks.

USER RECOMMENDATIONS

The CDRH breast implant surveillance team proposes to add the following terms in an appropriate formal terminology system: Saline-filled breast implant, smooth; Saline-filled

DEVICE CATEGORIZATION WORK GROUP REPORT

breast implant, textured; Silicone gel-filled breast implant, smooth; Silicone gel-filled breast implant, textured.

4. High Risk Implantable Devices – Kathleen Blake, Mary Gray, Michael Schiller

UDI adoption efforts are aimed at linking the UDI of implantable devices to the patients who have received those devices at the point of implant, and to document the UDI-DI and the UDI-PI. These efforts support the collection of real-world data as health care moves toward greater reliance on real-world evidence to monitor and evaluate performance as it impacts patient outcomes across the total product life cycle. The High Risk Implant work group is charged with the approach to be used by FDA and NLM to develop an application program interface (API) that users would run against AccessGUDID to return a report that correctly identifies implantable medical devices. This report could be used by health care organizations in multiple ways to support documentation of implants in health IT applications including enterprise resource planning (ERP) systems and EHRs as well as insurance claims (as proposed by Accredited Standards Committee X12 efforts).

USER RECOMMENDATIONS

The members of the High-Risk Implant work group have concluded that any report produced for users of the API will unavoidably include more items than just implants, i.e., implants and accessories. The designation of whether an implant is “High Risk” has proven to be very challenging as this is a new designation that does not fit neatly into a single existing classification system. However, in the interim the work group recommends utilizing the FDA’s Class II and Class III designations and definitions of moderate to high risk implants. The work group also recognizes that UDI-DI capture on insurance claims will be dependent upon contractual agreements between willing trading partners—health care organizations and their payors.

The work group further recommends that the report be developed now with the mindset that the GUDID data and API data sets will be iteratively cleansed as the community gains experience using the report output from the API. That this is the approach preferred by the work group, rather than delaying report development pending GUDID data cleansing initiatives, is the result of careful examination of multiple device categories and recognition that no standard exists (currently) that would generate a machine-generated list of all, and only, high risk implantable devices.

Lastly, ongoing maintenance of the API, its data sets and subsequent report output, while necessary, will need to be discussed as a potential LUC Phase II effort as this element is outside the scope and charter of the initial work group.

DEVICE CATEGORIZATION WORK GROUP REPORT

SUMMARY FINDINGS FROM THE USE CASES

The following characteristics are common among all of the use case examples. First, the categories being requested are to be defined by the users for specific purposes related to clinical use and are based on actual device use and not on “FDA approved” uses. Second, all devices in a category share relevant attributes that affect clinical performance. Finally, the requested categories, when viewed across use cases, are not mutually exclusive. For instance, a coronary stent could appear in VQI peripheral arterial stent, AUDI coronary stent, and high risk implantable device categories. Each of these categories has utility based on the individual use case.

The use cases also exemplify the two underlying purposes for which GUDID users wish to create device categories. RAPID/VQI and breast implant use cases are examples of ad hoc data extraction by a single researcher or collaboration to create categories for analysis that can be used as well by other investigators. AUDI and high risk implant use cases are examples of stakeholder governance groups creating categories that will be maintained over time for research, device surveillance or administrative purposes.

Further, in our analysis of the use cases, we have found that some device categorization needs are not met by GMDN and SNOMED CT due to gaps in the device terminologies and GUDID. These gaps include:

- Missing groupers, e.g., vascular devices as clinically deployed and high risk implants
- Missing terms, e.g., textured breast implants
- Missing attributes, e.g., specific drug eluted by a vascular stent
- Misalignment of a device to a term
- Multiple terms assigned to a device
- Outdated information
- Lack of history and versioning information in device terminologies
- Devices not available from GUDID, e.g., devices used in Canada

RECOMMENDATIONS

To overcome some of the challenges faced by AccessGUDID users, this work group recommends the development of supplementary categorization resources that are use case dependent (“supplementary resources”). These supplementary resources should be created with the following principles:

- Developed outside and independent of terminologies and GUDID
 - Allows for rapid, flexible and responsive development to support a specific use case
 - Overcomes the restriction of GMDN terms (and by association SNOMED CT) to intended use of devices permitting inclusion of all devices as used in clinical

DEVICE CATEGORIZATION WORK GROUP REPORT

practice

- Owned and maintained by a committed user group, e.g., professional society, expert group, stakeholder panel
- Close liaison between the supplementary resources, terminologies and GUDID
 - The purpose of the supplementary resources is to supplement but not replace the terminologies and GUDID
 - To ensure interoperability, the resources should maintain links and references to the terminologies and GUDID wherever possible
 - Contents that are useful for more general purposes should be suggested for incorporation into the existing terminologies and GUDID, e.g., new terms, new groupers, new attributes. Similarly, potential errors found in the terminologies and GUDID should be communicated to their owners
- Supplementary resources should be free and accessible to all users
 - Sharing and reuse of the resources should be encouraged
 - The resources should be downloadable through publicly available channels, e.g., AccessGUDID, NLM Value Set Authority Center, national registry websites, professional society websites

USE CASE SPECIFIC APPROACHES TO DEVICE CATEGORIZATION

The following are examples of device categorization approaches that are use case specific.

1. *VQI use case*

Through the PVI Registry, the VQI user group identified stents and other devices used in the peripheral arteries and attempted to pull associated device attributes from GUDID using GMDN/SNOMED CT groupers but has run into difficulty related to dyssynchrony between the usual clinical grouping of such devices and that used in GMDN. The user group has also encountered difficulties related to GMDN/GUDID device data being organized based on intended use in the United States and excluding devices used only in Canada.

- a. The user group worked with GMDN to refine their methods of GUDID data capture and cleaned up the list by manual review.
- b. The group has made their work available as a supplementary resource, which comprises the list of GMDN/SNOMED CT groupers, terms and the validated list of device identifiers. They created a new grouper for their use case called “clinically-deployed vascular devices,” which groups together the terms they have identified.
- c. The group communicated the problems they have found (e.g., potential misassignment of GMDN/SNOMED CT term to devices, outdated information) to the owners of the terminologies and GUDID for consideration.

DEVICE CATEGORIZATION WORK GROUP REPORT

2. *AUDI use case*

The creators of AUDI databases require the creation of categories of devices that share attributes which are not found in GUDID as discrete data. Further such categories include devices as used in clinical practice and are not based on intended use, which is the criterion for manufacturer created terms.

- a. To accomplish the goals of this use case, the user group must first identify those devices to be included in the AUDI database, e.g., stents used in the coronary arteries. This information would reside in clinical data sets, e.g., the NCDR's CathPCI Registry.
- b. A new AUDI database is set up to capture the additional attributes of the identified devices. The AUDI devices' GMDN/SNOMED CT terms and device identifiers are selected so they can be linked back to the terminologies and GUDID. This link is useful to ensure interoperability of data and will also make AUDI easier to maintain. Through GUDID, obsolete devices can be easily identified and so are new devices that are in scope for AUDI.

3. *Breast implant use case*

The user group at CDRH has identified the need for breast implant attributes that are not currently available as discrete data in the GUDID and that would support analyses of device performance. This situation could be addressed by including such attributes in an AUDI database. Alternatively, the attributes could be assigned GMDN/SNOMED CT terms and used to create breast implant categories within the GUDID. The user group has chosen the latter approach.

- a. To create categories based on different surface characteristics of breast implants, the user group identified the need to have 4 new terms:
 - i. Saline-filled breast implant, smooth
 - ii. Saline-filled breast implant, textured
 - iii. Silicone gel-filled breast implant, smooth
 - iv. Silicone gel-filled breast implant, textured

The new terms should be identified as children to the existing GMDN/SNOMED CT terms: Saline-filled breast implant and Silicone gel-filled breast implant respectively.

- b. The request for new terms was submitted through the U.S. SNOMED CT Content Request System <https://uscrr.nlm.nih.gov/>. The requested terms were approved and appeared in the July 2018 release of SNOMED CT.
- c. Through their review, the group has identified the devices belonging to the 4 types and plans to publish a table linking the device identifiers to the newly added terms as a supplementary categorization resource. The GMDN terms for the identified devices were then be obtained in order to link to GUDID information.
- d. New terms for these surface characteristics have since been added to GMDN.

DEVICE CATEGORIZATION WORK GROUP REPORT

Because of FDA guidance that new terms should be assigned when old terms become obsolete manufacturers will be assigning the new terms to their implants, effectively creating the user defined categories in GUDID². Until the new GMDN terms were in place, the SNOMED CT terms were available to enable the user maintained categories.

SUMMARY AND CONCLUSIONS

The LUC Device Categorization Work group focused its work on user defined device categories. Users include clinicians and researchers, as well as FDA work groups. These users share the need to create categories of devices as currently used in clinical practice for purposes of performance evaluation. These categories need to be linked to the GUDID in order to extract key device information to support these assessments. We have presented specific use cases to describe how GMDN and SNOMED CT could be used to support these efforts. Ultimately, the devices included in user defined categories must often be identified by the users in clinical data sets since the categories include devices as used clinically and not by intended use. Once the devices have been identified, their GMDN/SNOMED CT terms can be ascertained and used to link to GUDID and to facilitate maintenance of the categories over time.

User defined device categories should be based on, and developed as extensions of, the existing categorizations available, i.e., GMDN and SNOMED CT. Although GMDN data are used to create the SNOMED CT device listing, there are some differences between the two terminologies in editorial, maintenance and distribution policies which will influence the choice of which to use as a basis:

1. Data link to products—GMDN terms are linked to products in the GUDID. SNOMED CT is currently linked through the GMDN map.
2. Timeliness—the GMDN is available in real time with versioning at the term level, while SNOMED CT is released at six-month intervals with versioning at the dataset level.
3. Term definitions—GMDN terms have definitions of the scope of term names; SNOMED CT term names are expected to be self-explanatory.
4. Longitudinal permanence—SNOMED CT does not change the meaning of terms over time; GMDN expands the scope of terms to include new technology.
5. Scope of terminology—SNOMED CT is a multifaceted terminology including clinically relevant devices with many other aspects of medical informatics; GMDN covers all medical devices.

In order to maintain harmonization, and a link between both categorization systems and real devices, it is desirable that GMDN and SNOMED CT continue to work closely together to minimize the divergence of the data.

² Global Unique Device Identification Database (GUDID): Guidance for Industry and FDA Staff, June 27, 2014. <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf>

DEVICE CATEGORIZATION WORK GROUP REPORT
