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High-Risk Implants Work Group Report

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HIGH-RISK IMPLANTS WORK GROUP REPORT

VISION:

One of the goals when the Unique Device Identifier (UDI) was created was that information linked to the UDI and available from the public portal, AccessGUDID[1], would support medical device-related analytics and that Application Programing Interfaces (APIs) would be created to enable efficient user access to data. The Food and Drug Administration (FDA) envisioned working with stakeholders to identify data elements that should be included in the APIs available at AccessGUDID.

BACKGROUND:

The FDA has received feedback that the current implantable device list posted at the AccessGUDID does not currently meet the needs of health care providers. The current list is based upon an FDA product classification code (procode) query of the GUDID database. A procode is assigned to each record in AccessGUDID and each procode is associated with an implant flag valued as 'yes' or 'no'. The query currently returns a list of all devices that are cleared or approved with a procode where the implant flag value is 'yes'. Since the implant flag value is set during the regulatory approval process and does not necessarily mirror clinical use, the query returns a list that includes not only implants but, in some cases, may also include other medical devices (e.g. instruments) that are associated with the approved device.

FDA has considerable interest in adding the Device Identifier (UDI-DI) to billing claims as a component of its strategy for improving the post-market surveillance of medical devices and increasing the use of real-world data to improve regulatory decision-making. The X12 committee that is responsible for determining what information is included on medical claims forms is planning to recommend that the UDI-DI for high risk implants be included on those forms. Although the X12 claims update process has not yet been completed, the potential need of willing trading partners (claims submitter and claims payer) to exchange UDI-DI for high-risk implants signaled the need to develop an algorithm that could be used to generate lists of high-risk implants for users of AccessGUDID.

These considerations resulted in formation of a High-Risk Implants Work Group under the auspices of the AHRMM Learning UDI Community (LUC). The work group's charter states that it is to create a set of criteria for inclusion in an application program interface (API) for AccessGUDID queries that returns to the user a high-risk implantable device list.

PROCESS:

The High-Risk Implant LUC Work Group was comprised of representatives from manufacturers, health care providers, software application providers, consultants and the FDA. Approximately 40 people have participated in the work group which was co-led by Kathleen Blake, MD, MPH from the American Medical Association (AMA) and Mary E. Gray, RAC from Johnson & Johnson. The group began its work by defining an "implant" from a health care provider and payer perspective and tested various approaches to excluding instruments and non-implantable accessories from the implants themselves. This process included a query that

[1] The National Library of Medicine (NLM), in collaboration with the FDA, has created the AccessGUDID portal to make device identification information in the FDA's Global Unique Device Identification Database (GUDID) available for everyone, including patients, caregivers, health care providers, hospitals and the field. See http://accessgudid.nlm.nih.gov

started by pulling FDA procodes with an implant flag value of 'yes' and then applying two filters: the Global Medical Device Nomenclature (GMDN) term codes used by manufacturers to identify devices by their cleared/approved or intended use where the GMDN code was associated with the GMDN 'Implantable' Collective Term, and the designation for single use (as implants cannot be reused). The work group reviewed devices across multiple categories (general surgical, neurosurgical, cardiac) and compared the results from the automated filtering process to their knowledge of and clinical experience with the devices and their actual use. The group concluded that an algorithm that (1) identified devices with an FDA Procode for which the implant flag had been assigned a value of "yes" and (2) had a GMDN code associated with the GMDN "Implantable" Collective Term and (3) had a single use designation did not produce the desired results. This combination erroneously included and excluded too many devices.

The work group next partnered with a third-party data cleansing company with extensive experience using the AccessGUDID and other data sources, such as 510K filings and recall data, to create their version of an implantable device list. The third party volunteered to validate the outcomes of potential GUDID APIs against their cleansed data. See Appendix A for the details.

KEY FINDINGS:

- Currently there is no standard definition of "high-risk implant". Existing FDA risk classifications (Class I, Class II and Class III) apply to all medical devices and there is not a way to use the categories to identify implants. Work group participants discussed at length a potential definition for "high risk implant" and could not develop an algorithm that would adequately differentiate high- and low-risk devices, in part because a majority of work group members were of the opinion that all implants had the potential to be high-risk in the event of a recall or adverse event.
- The definition and use of the FDA's procodes are intended for regulatory use in the device approval process and do not differentiate between implants, implants packaged with accessories, accessories without implants and non-implants. Manufacturers have very little discretion over procode assignment. Therefore, work group participants are of the opinion that it would not be feasible to build an algorithm based on FDA procodes.
- The GMDN code is assigned by manufacturers and can be based on the product's actual use versus approved use. Additionally, this code can be changed by the manufacturer without regulatory implications. An initial concern with the use of the GMDN code as an indicator of an implant was the assignment of multiple GMDNs to an individual device. However, the team found that manufacturers assigned more than one GMDN code to only 0.9 percent of the devices in the GUDID. While there were some instances when the assigned GMDN code was not accurate and other instances where the work group members thought a different code would be more appropriate, most of the time, when the first GMDN code assigned indicated an implant, the designation was accurate.
- None of the alternatives tested produced a perfect implant list. Some minimized the inclusion of instruments and accessories at the expense of excluding some legitimate implants. Others captured more implants but also included more non-implantable devices.

RECOMMENDATIONS:

- The definition of "high risk implant" for the purposes of determining what implants should be included in medical claims data should be that which is mutually agreed upon by willing trading partners (e.g. health care providers and insurance companies). Currently available data from AccessGUDID is not sufficient to create a list of "high risk implants" that meets the needs of health care use.
- The implantable device API should be based on the GMDN Term Code assigned to a UDI-DI record. This approach identified more implants than when the GMDN was combined with the FDA procodes and a smaller number of implants were missed. This approach does, however, include more instruments and accessories but comes closest to fulfilling the work group's goal of capturing as many implants as possible.
- The combined active and inactive GMDN Term Codes, Term Names and Collective Terms should be easy for the public to access through inclusion in AccessGUDID. The GMDN Term Code is a numeric unique identifier for GMDN Term Names and Term Definitions. Both Term Names and Term Definitions are currently available in AccessGUDID, however, to look up their corresponding GMDN Term Codes and Collective Terms requires access to the GMDN Agency. Please see Appendix A for details.
- Health care providers and manufacturers should collaborate to improve GMDN code assignment to meet health care requirements and ensure that the first code assigned is the most accurate reflection of the actual and most frequent use of the product.
- Health care providers and manufacturers should collaborate with the FDA and the standards organizations to make the data available from AccessGUDID as accurate and usable as possible.

APPENDIX A

Analysis Introduction:

The following analysis tests and compares the accuracy of three algorithmic approaches to identify implantable devices in GUDID. The work group finds that the third algorithm below, utilizing the GMDN codes/terms assigned to UDI-DI, is shown to not only be the most accurate, but also allows for a process for correcting data submission mistakes without impacting FDA workflows.

To accurately apply a Boolean value or flag indicating whether a device is implantable programmatically relates significantly to the problem of accurately categorizing devices. Device categorization is a data element that allows for analysis and grouping of device behavior at a higher level than that provided by a device identifier, Company name or Brand name. As of this writing, procodes, a coding system used by the FDA to describe a product or a group of products for purposes of approval and administration workflows, is being used to identify implants in GUDID. One of the attributes associated to the procodes data element is an implantable flag. Thus, additional categorization data elements and their accompanying attributes were used in the initial analysis, which included:

- GMDN (Global Medical Device Nomenclature), a system of internationally agreed terms used to identify medical devices of the same type (device types) used by regulators and manufacturers to group like devices. GMDN has been selected by the US FDA to categorize medical devices in their Unique Device Identification (UDI) Rule.
- SNOMED CT (Systematized Nomenclature of Medicine Clinical Terminology), a terminology for clinical documentation and reporting endorsed by the Office of the National Coordinator (ONC) for Health IT as the clinical terminology to be used in certified electronic health record (EHR) technology.

Benchmark Accuracy:

To understand which approach is the most accurate, it's necessary to know with significant certainty whether each device represented as a UDI-DI record in AccessGUDID is implantable. By first mapping several outside data sets associated against each UDI-DI, including approval information, and combining with the descriptions submitted by manufacturers to GUDID, a text block describing a device was built. Applying a mixture of rules-based text analysis, natural language processing and supervised machine learning, the UDI-DI submitted is broken out into discrete fields with one such data element being a noun describing the device (i.e. rongeur). From this, devices that were categorized incorrectly during submission, including instruments and accessories, and were therefore associated with the wrong category data element, were removed.

Three Approaches to Implant Identification:

1. **FDA Procodes:** The current algorithm used by the FDA API and Implant Download list is located here. There are more than 6,500 procodes in total, of which 4,000 are used in GUDID as of this writing. One of the attributes associated with this code is an

implantable Boolean flag. This code is initially assigned by the FDA during the device approval process. This often results in the grouping of instruments and accessories associated with an implant into a single group. It's important to note that 16percent of devices in AccessGUDID today have more than one procode assigned. Additionally, 70 percent of procodes assigned to UDI-DIs in AccessGUDID today have at least one matching code to those assigned by the FDA during premarket approval.

2. **FDA Procodes + GMDN Terms:** The Global Medical Device Nomenclature (GMDN) term is assigned to device identifiers during submission. There are more than 23,000 active categorical GMDN terms, of which 9,700 are used in GUDID as of this writing. It's important to note that 0.9 percent of devices in GUDID today have more than one GMDN term assigned. One of the attributes associated to GMDN terms, called collective terms, is "Implantable" collective code (CT2406). This algorithm simply analyzed the accuracy of identifying implants by including only those that were both flagged implantable by the procodes AND the GMDN terms' implantable collective term.

3. **GMDN Terms:** This last algorithm finally compares the accuracy of only using the GMDN terms' implantable collective code to identify implants.

***Data and Analysis as of April 1, 2019**

1. FDA Procodes Implant Accuracy

FDA Product Code Implant List Accuracy					
FDA Implant List:	**781,895**	**% Total**	***Missing Implant:**	**6,774**	**% Total Missing SHS**
Class 1:	815	0.10%	Class 1:	2,397	0.31%
Class 2:	732,462	93.83%	Class 2:	4,222	0.54%
Class 3:	38,116	4.73%	Class 3:	126	0.02%
Unclassified:	9,861	1.25%	Unclassified:	21	0.00%
HDE:	500	0.06%	HDE:	6	0.00%
Not in Current FOI:	141	0.02%	Not in Current FOI:	2	0.00%
Instrument (only)/Accessories:	103,793				
Missing Implant:	6,774				
Accuracy:	86%				

2. FDA Procodes AND GMDN Term Code:

FDA Product Code (Implant True) + GMDN (Concept Code Implantable)					
FDA+GMDN Implant List:	**690,786**	**% Total**	***Missing Implant:**	**7,209**	**% Total Missing SHS**
Class 1:	473	0.07%	Class 1:	2,397	0.35%
Class 2:	648,787	93.92%	Class 2:	4,401	0.64%
Class 3:	33,433	4.84%	Class 3:	382	0.06%
Unclassified:	7,700	1.11%	Unclassified:	21	0.00%
HDE:	334	0.05%	HDE:	6	0.00%
Not in Current FOI:	59	0.01%	Not in Current FOI:	2	0.00%
Instrument (only)/Accessories:	13,119				
Missing Implant:	7,209				
Accuracy:	97%				

3. GMDN Term Code:

GMDN (Concept Code Implantable)					
GMDN Implant List:	**706,881**	**% Total**	***Missing Implant:**	**441**	**% Total Missing SHS**
Class 1:	10,340	1.46%	Class 1:	-	0.00%
Class 2:	654,859	92.64%	Class 2:	185	0.03%
Class 3:	33,559	4.75%	Class 3:	256	0.04%
Unclassified:	7,627	1.08%	Unclassified:	-	0.00%
HDE:	334	0.05%	HDE:	-	0.00%
Not in Current FOI:	162	0.02%	Not in Current FOI:	-	0.00%
Instrument (only)/Accessories:	22,446				
Missing Implant:	441				
Accuracy:	97%				

Summary:

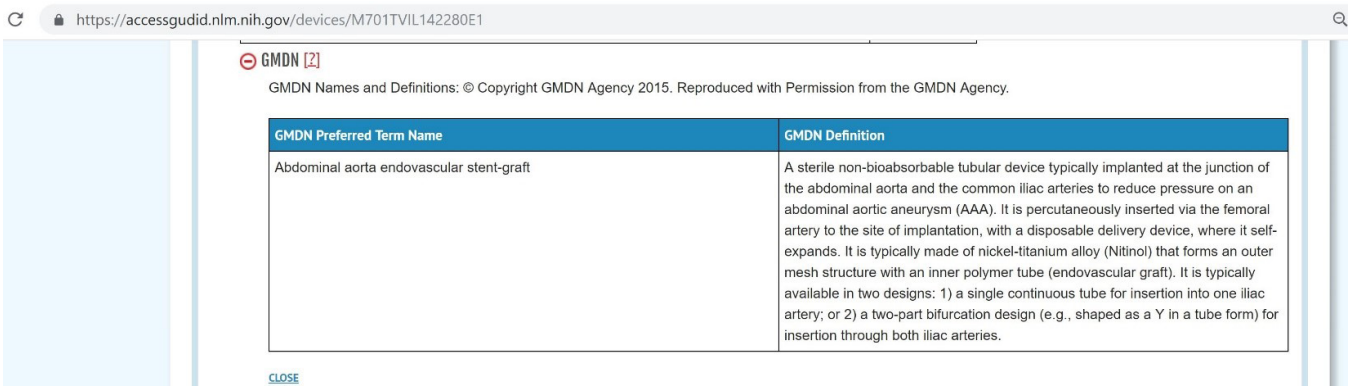
Use of the GMDN term assigned to UDI-DIs and their associated implantable collective codes supports the most accurate programmable approach to identifying implantable devices. By utilizing this algorithm for the API end point and Implant device download list, a process is created to support the correction of implant flag inaccuracies submitted by manufacturers to GUDID, by either having the manufacturer submit a more relevant term code or contacting the GMDN Agency if an implantable collective term is missing from the GMDN term. This approach does not impact the existing FDA approval workflows that use the procodes. The GMDN may be accessed and explored free of charge here.

Special Notes:

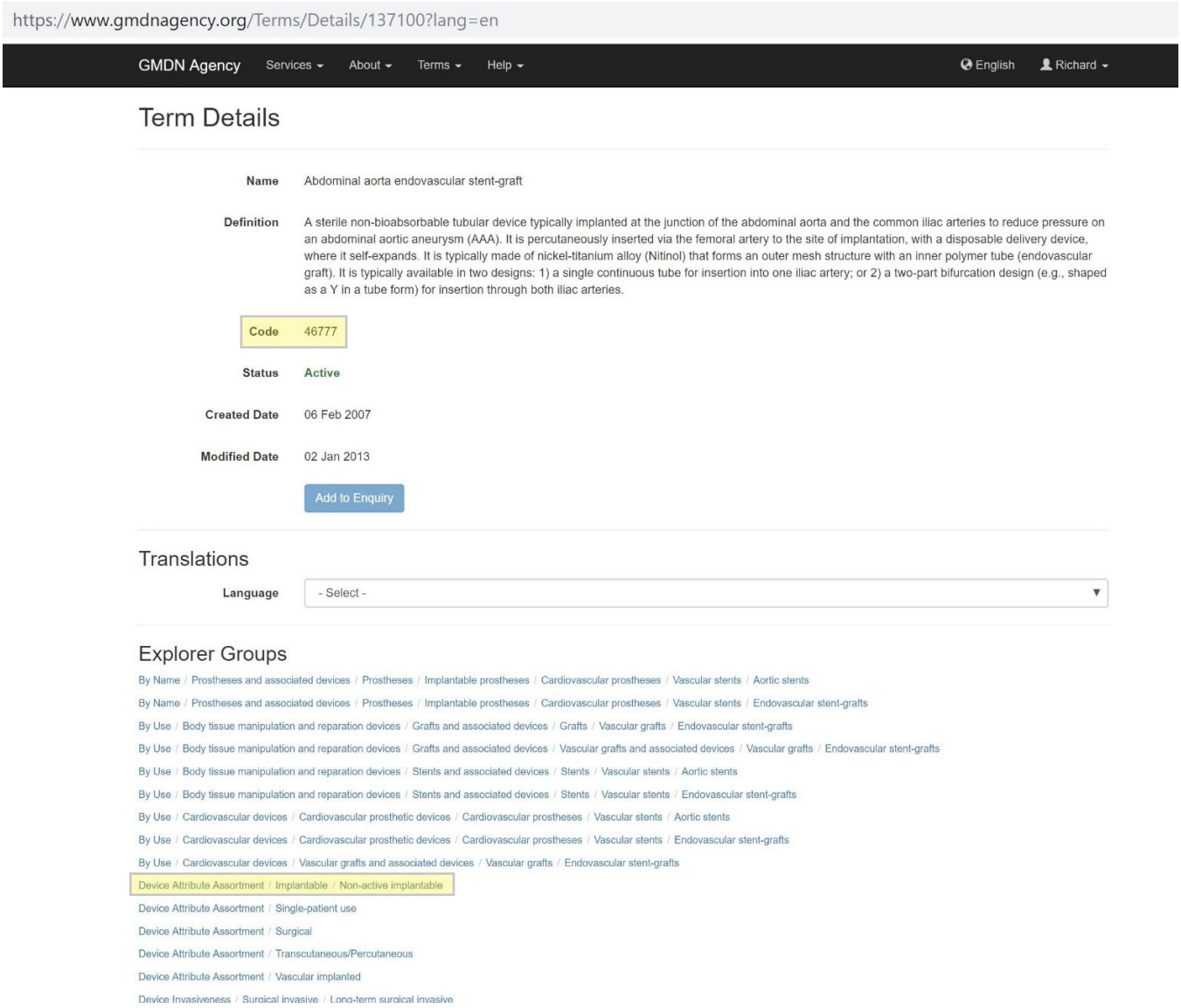
1. Both GMDN terms and FDA procodes had missing implant flags that were shared during this analysis. Additionally, both labeler organizations that were given feedback to update their GMDN term assignment promptly reviewed and updated their data sets.
2. Two percent of devices in GUDID have an inactive GMDN term code assigned. Inactive term codes as well as all GMDN information can be accessed by contacting the GMDN agency.

GMDN Background:

AccessGUDID GMDN Preferred Term Name and GMDN Term Definition associated to DI.



GMDN Term details associated with GMDN Term Name including GMDN Term Code and dates of creation and modification, and the 'Explorer Groups' (higher level groupings aka 'Collective Terms') linked to the term, including the Collective Term for 'Implantable'.



Finally, below is a screen shot of exploring GMDN Terms by their Collective Term, in this case showing all Terms linked to the 'Implantable' Collective Term.