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Advancing the Healthcare Supply Chain
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American Hospital Association

Report of the GUDID Clinically Relevant Size (CRS) Work Group

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GUDID CRS WORK GROUP REPORT

PREAMBLE

The Clinically Relevant Size Work Group was convened to examine the utility of device size data in the FDA GUDID system, to provide a framework to facilitate correction of existing device size data in the GUDID, and to standardize the accurate capture of device size data for new entries into the GUDID. It is hoped that the recommendations of the CRS Work Group can also be used to inform other national and international device reference databases.

A. PROBLEM STATEMENT

Many medical devices are produced in multiple sizes, with device dimensions frequently being among the parameters used by clinicians to select a specific device for a specific patient. This is particularly relevant for implantable devices. Reflecting the relevance of device dimensions to clinicians, size parameters are often prominently featured on package labeling. The accurate recording of device dimensions is critical in medical documentation. Clinical outcomes of some devices vary by absolute device size as well as size relative to patient parameters.

The **desired state** is for a UDI-specific query of the GUDID to return a consistent, semantically interoperable data payload (by device class) of clinically relevant size (CRS) data, as per the Office of the National Coordinator: "[…] the ability of system[s] to exchange electronic health information with and use electronic health information from other systems without special effort on the part of the user" (Office of the National Coordinator, 2015). The payload would consist of ALL CRS parameters (for that device class) and would be provided in a predictable structure. That structure would be inclusive of the dimension of the measurement, the numeric measurement itself, and the unit of measurement. The data would be terms from a formal controlled vocabulary (LOINC unit of measurement), subject matter expert-determined vocabulary (dimension of measurement), and numeric data (the actual measurement). The GUDID CRS data payload would be consumable without parsing or normalization by recipient HIT systems (other than processes for the translation of the payload data into formats for the data to be used by the recipient HIT systems). The RESTful Web services and FHIR models are frameworks that are consistent with this desired state.

There are several key **use cases** of CRS data. A primary use case is for GUDID CRS data to be available and suitable for use at the point of care (e.g., device implantation). The data payload returned from the GUDID could be presented to the clinician to verify device CRS parameters immediately prior to implantation and / or captured automatically in clinical documentation. Another use case is for reference CRS data to be available to registries such as the National Cardiovascular Data Registry (NCDR). Currently, device parameters for the 6,000 plus devices in the NCDR family of registries (CathPCI, CathPVI, ICD, IMPACT, TAVR, LAAO) are curated manually; ideally, the only device parameter that would need to be captured in a device registry would be the device UDI itself, with other parameters available by reference from the GUDID. The supply chain (inventory management) use case is another touchpoint of potentially high utility for reference CRS data, particularly from the perspective of tighter inventory management and concomitant cost savings. CRS data is critical for analytics related to device performance and clinical outcomes. For other examples, a list of 18 different use cases can be found in the report of the Mercy Health System UDI Demonstration Project (Tcheng JE et al., American Heart J).

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Given the plethora of medical devices, size measurements will not be the same from one class of device to another. It is therefore a suggested **best practice** that CRS parameters be identified by device categorization through work groups comprised of clinician subject matter experts, manufacturers (and labelers), and FDA. A demonstration of this approach was accomplished in the Mercy Health System UDI Demonstration Project (Tcheng JE et al.). Furthermore, the MDEpiNet Augmented UDI (AUDI) Work Group recommends a similar approach for all clinically relevant device attributes not included in the GUDID. A Learning UDI Community (LUC) Device Categorization Work Group has already been convened to advance concepts related to device categorization, and the CRS Work Group proposes that identification of CRS and AUDI parameters be a responsibility of these individual device categorization work groups. As an example, data currently in the GUDID regarding coronary stents includes length and nominal stent deployment diameter, but does NOT include maximum distensible stent diameter or catheter working length anywhere in the GUDID, even though these latter data are published in the IFU and are clinically relevant.

In the **GUDID today**, a set of 4 fields captures the components of device size. The set of size fields can be repeated as many times as necessary per UDI.

- sizeType – a constrained list, intended to be the measurement type (length, width, height, etc.)
- unit – a constrained subset list of the LOINC codes for Unified Code of Unit Measurement (UCUM), intended to be the unit of measurement (cm, mm, inches, etc.)
- value – the numeric value of the size measurement
- sizeText – analog text, intended to capture information not represented in the above sizeType, unit, and value fields

Of note, size information can also be placed as text in the device description (non-size-related) field.

Inspection of data in the GUDID shows that size data has been entered inconsistently and incompletely (see **Appendix**). What is illustrated in the Appendix is that each of the three manufacturers of coronary stents available in the U.S. entered stent size data (nominal length and nominal diameter) differently. There appear to be several reasons for the CRS data quality issues:

1. GUDID field names for CRS parameters that are not completely intuitive
2. Incomplete or otherwise inadequate instructions for the completion of the CRS data fields
3. Value set selection lists that are incomplete or do not have a term to represent a dimension of measurement
4. Hesitation by manufacturers (and labelers) to use said fields.

In addition, none of the coronary stent manufacturers (and labelers) elected to enter maximum distensible stent diameter or working catheter length as CRS parameters. This is despite these latter size parameters being clearly printed on the respective device packaging and IFU documents

Finally, CRS is only one of the clinically relevant parameters with GUDID data quality issues. Other parameters are the subject of additional work groups of the LUC (e.g., catalog number, unit of use, device categorization) and the AUDI Work Group of MDEpiNet. It is anticipated that a coordinated approach

by device category will be the optimal approach to address all of the data quality issues identified in the GUDID (i.e., for any given device type, **all** clinically relevant data – including size parameters - would be addressed as a unified effort).

B. ASSUMPTIONS AND GUIDING PRINCIPLES

The CRS Work Group identified the following assumptions and guiding principles.

- Preferred state is for all CRS data to be in the GUDID; failing that, CRS data can be housed in an AUDI database
- The source of CRS data is the device manufacturer; the device manufacturer is responsible for the accuracy of the data (and FDA cannot change the data)
- FDA is responsible for the GUDID system, including the facilitation of data entry into the GUDID by the device manufacturer
- Query (by device identifier) should return a consistent, predictable, structured, syntactically, and semantically interoperable CRS data payload
- The data payload should be consumable by recipient HIT systems without parsing or normalization
- The data payload should be consistent with other data exports from the GUDID, including coordinated data sources, such as the proposed AUDI database
- GUDID data field names should be intuitive and explicit
- CRS data (dimension, measurement, and unit) should be entered in the GUDID (or AUDI database) as an "all or none" set of data (and not split across non-CRS fields)
- Consistent and explicit instructions regarding data entry into the GUDID, along with education, to manufacturers (and labelers) should be provided – including examples
- Constrained lists (allowed values) for the dimension of measurement field will be best specified by clinical subject matter experts in conjunction with industry, by class of device (cf. Device Categorization Work Group of the LUC)
- Update/correction of CRS data in the GUDID will need to be accomplished by device category – and device category prioritization will therefore need to be considered
- Update/correction of CRS data in the GUDID will not trigger generation of new GTINs or derivatives (UDIs, etc.)
- FDA can assist the process of addressing CRS data quality by identifying and prioritizing items that need to be updated

C. REQUEST OF THE CRS WORK GROUP

Per the above assumptions and principles, the request of the CRS Work Group is to

a) Ensure that a UDI-specific query of the GUDID will return a consist payload of CRS data inclusive of dimension of the measurement, the numeric measurement itself, the unit of measurement, and either an implicit or explicit indicator of conformity to a standardized, well-formed CRS payload structure.

b) Have manufacturers (and labelers) update the GUDID CRS data, one device categorization at a time, in conjunction with other activities to improve data quality in the GUDID database.

1. A **collaborative work group** of stakeholders should be convened with FDA to identify and specify a technically suitable, usable, scalable, and sustainable solution that addresses the issues articulated above. It is suggest that this work group include expertise in informatics, information technology solutions, manufacturers (and labelers), and potential consumers of CRS data payloads.
2. It may be necessary to capture clinically relevant dimensional data reported as a numeric **range**.
3. A **value set authority** should be established to manage the allowed values in the Dimension (sizeType) data field that better reflects clinically relevant concepts of dimension (e.g., for coronary stents: nominal deployment diameter, maximal distension diameter, working catheter length) that conveys the information needed by clinicians to select and use devices. It is suggested that work groups identified by device categorization and comprised of clinical subject matter experts, in conjunction with manufacturers (and labelers) and FDA, be responsible for identifying and specifying the allowed values, as there is presently no SDO-specified nomenclature for same.
4. A value set authority should be established to manage the allowed values list for the Unit of Measure (unit) data field that better reflects clinically relevant units of measure (e.g., eliminate femtometer, picometer, kilometer). It is anticipated that the LOINC UCUM can be used as the basis of this work. It is suggested that the same work groups described above contribute primarily to creating a parsimonious list of the UCUM unit allowed values.
5. The FDA GUDID Data Elements Reference Table should be improved for clarity and consistency, including brief prompts to explain what information is to be captured in what data fields. In each field description, examples should also be provided. Specific instructions for manufacturers (and labelers) and for data users will be helpful. This could be the focus of a future LUC Work Group.
6. It is proposed that an LUC Work Group comprised of clinical, supply chain, manufacturing, and informatics experts be convened to identify candidate device classes to demonstrate and accomplish an update of existing GUDID CRS data fields.
    - Plan to approach by device category (not by manufacturer)
    - Develop query tools to export existing data from the GUDID CRS sub-table to manufacturers (and labelers) to identify data that needs to be updated
    - Coordinate the CRS initiative across other data quality initiatives of the LUC7
7. Create a series of work groups comprised of clinical subject matter experts, manufacturers, and FDA to test the processes and establish paradigms and precedents for update of CRS data, targeting the following implantable medical devices. These work groups can be the subject matter expert panels being proposed by the AUDI Work Group to oversee the selection of AUDI attributes, recognizing that, if CRS recommendations cannot be immediately accommodated in GUDID, they can be housed at least temporarily in an AUDI database. At such time as the CRS specifications are adopted by GUDID, they can be dropped from AUDI. Finally, demonstration of the CRS concepts articulated in this report would logically be accomplished in the already extant RAPID and BUILD projects.

- Coronary stent
- Devices used in peripheral vascular intervention
- Implantable cardioverter defibrillator
- Pacemaker/ICD lead

D. NEXT STEPS

The imperative is for stakeholders (manufacturers and labelers, providers, data consumers, patients, health care systems, registries, etc.) to provide feedback to FDA about how to improve the utility of the GUDID system. The LUC is a broad-based coalition of professionals from across the healthcare spectrum and has nine active work groups focused on various aspects of device data, data quality, and data use. The LUCs focus is to identify issues impacting UDI adoption across the healthcare field, develop solutions made publically available through a shared solutions knowledge base, and increase the likelihood of success in accelerating UDI adoption practices.

Five of these work groups have come together to focus their efforts around the quality and use of data within the GUDID, with the goal of ensuring the usefulness and accuracy of this data to all end-user groups including patients, clinicians, and supply chain professionals.

The LUC will convene workshops over the course of the next several months, utilizing face to face and webinar modalities, to build upon the existing work group efforts as well as ensure broader stakeholder representation across the manufacturer and provider communities. During these workshop sessions, we'll learn about the data quality work of the LUC work groups and discuss their best recommended practices as we seek to provide a neutral platform for open dialogue to further assess and revise these recommended practices.

Conference Workshop Schedule:

- GHX Conference — April 24
- Healthcare Manufacturers Management Council (HMMC) — May 3
- UDI Conference — June 7
- AHRMM17 Conference — July 25

Collaborating with AHRMM, organizations such as Advamed, HMMC, HIRA, and others will review the information gathered across the various workshops, distill, and publish the data as a white paper report with the goal of influencing and increasing adoption compliance of the data quality practices.

References:

Office of the National Coordinator for Health Information Technology. (2015). Connecting health and care for the nation: a 10-year vision to achieve an interoperable health IT infrastructure.

Tcheng JE, Crowley J, Tomes M, et al. Unique device identifiers for coronary stent post-market surveillance and research: A report from the Food and Drug Administration Medical Device Epidemiology Network Unique Device Identifier demonstration. Am Heart J. 2014 Oct; 168:405-413.

APPENDIX – EXAMPLE OF INCONSISTENT GUDID CRS SIZE INFORMATION

The following are the sets of information returned for 1 drug-eluting stent each from the three different manufacturers* of coronary stents available in the U.S. Clinically, the relevant sizes are length and nominal diameter values printed on the respective package labels, along with maximum diameter values printed on the IFU.

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1. [Company #1] (CRS information only in DeviceDescription field; no CRS information/data in the any of the DeviceSize fields; no record of maximum diameter):

deviceDescription: [Product] Eluting Coronary Stent System 3.50 mm x 28 mm/Over-The-Wire

deviceSizes: null

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2. [Company #2] (CRS information only as text – not data – in the SizeText field; no record of maximum diameter)

deviceDescription: [Product] Eluting Platinum Chromium Coronary Stent System

deviceSizes:

sizeType: Device Size Text, specify
sizeUnit: *[blank]*
sizeValue: *[blank]*
sizeText: 16 mm Stent Length

sizeType: Device Size Text, specify
sizeUnit: *[blank]*
sizeValue: *[blank]*
sizeText: 3.00 mm Stent Diameter

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3. [Company #3] (one dimension of CRS information as text in the SizeText field, one dimension of CRS information as data in the DeviceSizes fields, with CRS information also in the DeviceDescription field but without units of measure; no record of maximum diameter)

deviceDescription: [Product] 2.50X18OTW

**The sets of GUDID CRS Size Information are intended for illustration purposes only. Company names have been removed to protect their anonymity.*

deviceSizes:

sizeType: Device Size Text, specify
sizeUnit: *[blank]*
sizeValue: *[blank]*
sizeText: Stent Inner Diameter 2.5 MM
sizeType: Length
sizeUnit: Millimeter
sizeValue: 18.0
sizeText: null

Methodology

The GUDID provides a device lookup API (application programming interface) that returns a single device record in either the original .xml format or a .json version of that record. The API URL to return a single device record is:

https://accessgudid.nlm.nih.gov/api/v1/devices/lookup.json?di=xxxxx

where xxxxx is the device DI. A device lookup by UDI can be performed by replacing the "di" with "udi" in the URL. Of note, the "di" (or "udi") in the URL must be lower case. Also, the information can be returned in .xml format by changing the URL from …/lookup.json? to …/lookup.xml?.)

E.g.: For [Company #1] 3.5x28mm over the wire (OTW) drug-eluting stent (DES), where DI=08717648200274:

https://accessgudid.nlm.nih.gov/api/v1/devices/lookup.json?di=08717648200274

E.g. For [Company #2] 3.0x16mm monorail (RX) drug-eluting stent (DES), where DI=08714729807957:

https://accessgudid.nlm.nih.gov/api/v1/devices/lookup.json?di=08714729807957

E.g.: For the [Company #3] 2.5x18mm over the wire (OTW) drug-eluting stent (DES), where DI=00613994793300:

https://accessgudid.nlm.nih.gov/api/v1/devices/lookup.json?di=00613994793300

For the above three devices, the information returned via the device lookup API included the following. Size information is highlighted in yellow. Note that the information has been parsed and reformatted from the original .json download to make it easier to read.

For [Company #1] stent:

deviceDescription: "[Product] Eluting Coronary Stent System 3.50 mm x 28 mm/Over-The-Wire"

deviceSizes:null

For [Company #2] stent:

deviceDescription: "[Product] 2.50X18OTW"

deviceSizes:

sizeType: "Device Size Text, specify";

unit:"";

value:"";

sizeText: "Stent Inner Diameter 2.5 MM"

sizeType: "Length"

unit: "Millimeter"

value: "18.0"

sizeText: null

For [Company #3] stent:

deviceDescription: "[Product] Eluting Platinum Chromium Coronary Stent System"

deviceSizes:

sizeType: "Device Size Text, specify";

unit:"";

value:"";

sizeText: "16 mm Stent Length"

sizeType: "Device Size Text, specify";

unit:"";

value:"";

sizeText: "3.00 mm Stent Diameter"