Briefing Note for the Editorial Advisory Group
23 October 2023

Modeling of Mechanical Complication of Device

Purpose

This is an update to the previous briefing note on mechanical complication of device concepts. The intent is to support further discussion by the Editorial Advisory Group on how these concepts should be represented in the terminology.

Background

Mechanical complications of devices currently use a disorder semantic tag.There are 217 subtypes of 111746009 |Mechanical complication of device (disorder). Of these, 49 are groupers for mechanical complication of <x device> e.g., 473041004 |Mechanical complication of implant (disorder)| and the others are types of mechanical complications such as leakage, loosening, displacement and breakage. 126 concepts are currently primitive.

In addition, there are currently just under 70 requests on hold for content in this area. These are predominantly related to CMT.

The initial questions raised in the first briefing note focused on the correct semantic tag to use as well as development of a concept model. The status of these plus additional questions that have since been raised will be covered in this briefing note.

Semantic Tag

The semantic tag issue related to the use of (finding) or (disorder) as it was initially felt unclear as to whether the mechanical complication of the device could be assumed to cause an adverse impact on the patient. The EAG decision on this topic at the April 2023 meeting was that where a device is implanted it can be assumed there is a negative impact. Further investigation by the EAG supported this decision with the results showing these concepts are ICD derived and represent a disorder in the patient due to some issue with the device.

To support this work it was determined that the meaning of an implantable device needed to be understood.

What is an implantable device?

The definition of what is an implantable device has had initial discussion by the EAG but no decision has been finalized. Information on the meaning of this term from Australia, UK and US has been included in Appendix A of this document.

Draft definition to start discussions:

A medical device that is either

a) inserted partially or fully into the body via an orifice and/or surgical intervention which is intended to remain in situ post procedure; or
b) intended to replace an epithelial surface of the body or corneal surface of the eye and remain in situ post procedure.

Note: This definition does not take into account the time frame mentioned in the definitions for partially introduced medical devices. That timeframe would exclude devices such as drains and catheters which would be important to include for this area from a clinical perspective.

Modeling Considerations:

A decision on the model is yet to be finalized. Current content is inconsistently modeled and as noted above, nearly 60% of the current content is primitive. There is the potential for missing subtypes and incorrect subtypes.

Supertype

111746009 |Mechanical complication of device (disorder)|- primitive

Current attribute usage

85% of the inferred attributes are also stated. The inferred count has been provided.

Attribute	Examples	Number	Comments
After	134288007 |Blocked central line (disorder)| 213112009 |Mechanical complication of breast prosthesis (disorder)|	59	All current values are drawn from the Procedure hierarchy and concepts using this attribute would be a subtype of 312087002 |Disorder following clinical procedure (disorder)|. Given the definition of this attribute and the decision that where an implanted device has a mechanical complication it is assumed there is some form of negative impact, it isn't incorrect to apply the After attribute. In noting that, looking at current content the procedure that was performed is not explicitly included in the concept meaning, rather has been determined by the author. In addition a patient must have had a procedure to have an implant so the value of using this attribute without the explicit procedure being present in the meaning is questionable. Recommend: Only use if the procedure the mechanical

			complication follows a procedure that is explicit in the meaning.
Associated morphology	230808006 |Brain ventricular shunt obstruction (disorder)| 237473006 |Rupture of breast implant (disorder)|	40	The Associated morphology attribute specifies the morphologic changes seen at the tissue or cellular level that are characteristic of a disease. Recommend: Only where the morphologic change caused by the mechanical complication is known should this attribute be used.
Associated with	430905008 |Breakage of shoulder joint prosthesis (disorder)| 473147002 |Malfunction of peritoneal dialysis catheter (disorder)|	213	Editorial guidance already states that this attribute may be used for device finding/disorder concepts. Recommend: Modeling using this attribute unless a more specific subtype applies.
Causative agent	236734004 |Displacement of penile prosthesis (disorder)| 312723007 |Silicone oil droplets on intraocular lens (disorder)|	10	The current content predominantly uses a device concept as value. Recommend: This attribute should only be used when this disorder is known and was caused by the mechanical complication of the device. In that scenario the Associated with attribute would not be used.
Due to	230807001 |Brain ventricular shunt displacement (disorder)| 473154008 |Retained fragment of ureteric catheter (disorder)|	10	The current content uses procedure concepts as values. Recommend: This attribute should only be used when this disorder is known and was caused by the device. In that scenario the Associated with attribute would not be used.
Finding site	281450006 |Loosening of total knee	105	The Finding site attribute specifies the body part affected by

	replacement (disorder)| 285961000119107 |Mechanical breakdown of prosthetic heart valve (disorder)|		the condition. The site of the device may or may not be known. For example: • A cardiac pacemaker is not placed within the heart structure and may even be external to the body. Unless the location of the cardiac pacemaker is represented in the meaning, a Finding site relationship should not be used. • A bone screw would be placed in the bone. In this case, a Finding site relationship would be used.
Interprets/Has interpretation	1162663008 |Obstruction of Tenckhoff catheter (disorder)|	3 (1)	Only one concept uses these attributes to represent a device observable - see example. Interprets: The observable hierarchy has device observables << 408699006 |Device observable (observable entity)| including the concept 724061007 |Device status (observable entity)|. At present this is used with a Has interpretation value of 52101004 |Present (qualifier value)|. Could an observable concept or concepts be added to represent the device position, device integrity? Suitable values for use with the Has interpretation attribute would need to be considered if taking this approach. See also thoughts in relation to a new device abnormality attribute as noted below. Recommend: Discuss the potential for this approach.

Information drawn from: AttributeDetails 111746009 |Mechanical complication of device|_MAIN 20231017_030155_prod_crichardson

A new attribute to represent the device abnormality?

A question has been raised for EAG discussion on the possibility of a new attribute to represent the device abnormality.

Some initial thoughts to assist discussion:

- Need to consider the extent of use e.g. value of adding an attribute for this many concepts vs the effort?
- The issue with the device will vary. For example, the issue could relate to the integrity of the device, the position of the device in relation to expected position etc. How could this be managed by a single attribute?
- The values for this attribute would be drawn from the Qualifier value hierarchy. Which concepts would be used, need creation and what hierarchical structure is required?
    - The subhierarchy << 260245000 |Finding value (qualifier value)| currently has a small number of values such as 1156075003 |Broken (qualifier value)|, 263821009 |Obstructed (qualifier value)| but there is insufficient content at present to represent all types of mechanical complications, even looking at current content.
    - How would concepts such as ‘leakage’ be managed? Leakage from urinary catheter (disorder) could be caused by a different reason to leakage from a breast implant.
    - 22% of the current concepts use the term mechanical complication - how would the term ‘mechanical’ be represented?

Summary of Decisions:

- Where a device is implanted it can be assumed there is a negative impact on the patient.
- The semantic tag (disorder) should be used for concepts representing a mechanical complication of an implantable device.
    - Whilst it can be assumed there is a negative impact on the patient the FSN should not be updated to explicitly represent Disorder due to mechanical breakdown of <x>.

Outstanding Questions:

- Where should concepts that represent mechanical complications of medical devices which aren't implanted be placed?
    - For example, mechanical complication of an insulin pump? Note, example only, concept does not exist.
- What is the definition of an implantable device from a SNOMED CT perspective?
- What concept model should be used for mechanical complications of device concepts?

Appendix A: Implantable Medical Device Definitions

Australia:

"implantable medical device means a medical device (other than an active implantable medical device) that is intended by the manufacturer:

(a) to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure; or

(b) to replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being, and to remain in place after the procedure; or

(c) to be, by surgical intervention, partially introduced into the body of a human being, and to remain in place for at least 30 days after the procedure."

"active implantable medical device means an active medical device, other than an implantable medical device, that is intended by the manufacturer:

(a) either:

(i) to be, by surgical or medical intervention, introduced wholly, or partially, into the body of a human being; or

(ii) to be, by medical intervention, introduced into a natural orifice in the body of a human being; and

(b) to remain in place after the procedure."

Note: The definition of 'active medical device' can be found in the source document.

Source: Therapeutic Goods (Medical Devices) Regulations 2002 https://www.legislation.gov.au/Details/F2023C00565 See dictionary at end of document.

UK:

"Implantable device

Any device which is intended:

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device."

Source: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices https://www.legislation.gov.uk/eudr/1993/42/annex/IX - see section 1.2 (still current) Referenced here: The Medical Devices Regulations 2002: https://www.legislation.gov.uk/uksi/2002/618/regulation/7#commentary-key-aa504f8f26add175b5320922e2dbb0b4

USA:

“Implant means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise to protect human health”.

Source: CFR - Code of Federal Regulations Title 21: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=860.3

Cathy Richardson, 2023-10-17