Discussion Paper - Extension Modifications to the International Release

Australian Digital Health Agency - Matt Cordell October 10, 2016 Live version available at :

https://docs.google.com/document/d/18inQurHU7rcsttNgde18TwBQfMEJ5DFti4wzXsazh7M/edit?usp=sharing

1 Audience

- Extension builders including National Release Centres and other affiliates.
- IHTSDO representatives responsible to determining license restrictions.

2 Glossary

A number of terms are used within this document to help with readability.

Member in this document primarily means Member countries (who create local extensions), but Affiliates who also produce extensions may be considered. For the ease of discussion Member and Extension builder are considered synonymous in this document.

Components is used as the umbrella term for Concepts, Descriptions and Relationships. A component is has a 1:1 relationship with Identifiers. A different/new identifier equals a new component.

Core components refers to those *components* published by the IHTSDO in the international release. These are usually (though not necessarily) published on the 900000000000207008|SNOMED CT core module (core metadata concept)| module.

Primitive leaf concepts or *Terminal primitive* is a concept that is marked as primitive (not sufficiently defined) and has no "child" concepts (not the destination for an **IS A** relationship).

3 Background and Purpose

However, there is disagreement, or at least confusion, between Members as to if modifying core components by creating new versions of is allowed. The SNOMED CT® AFFILIATE LICENSE AGREEMENT states:

Clause 4.1

"Subject to clause 2.1.4, the Licensee may not modify any part of the SNOMED CT Core distributed as part of the International Release or as part of a Member's National Release."

Clause 2.1.4

"(The Licensor grants the Licensee, license to) modify the manner of formatting of the copy of the SNOMED CT Core distributed to the Licensee as part of the International Release or as part of a Member's National Release" There are a two of long standing issues associated with this:

- 1. This restriction on modifications has been interpreted generally in two ways.
 - **A.** The RF2 distribution must not be modified, beyond appending additional rows. **Overwriting** data in the distribution files such that an extension violates the append only model. Additionally, the full history provided by the international release must provided, i.e. extensions may not omit anything;
 - B. Core components must not be modified.
 <u>Overriding</u> the international content through the addition of extension components and new versions for core components.
- 2. Such restrictions as **B** may be impractical or prohibit proper quality terminology authoring.

There is no contention that that RF2 distribution should not be altered by Members (point **1.A**), beyond appending additional content. That is, deleting rows or modifying values from the international release is prohibited.

The aim of this paper is to clarify what is meant by point **1.B** and why such modifications might be considered necessary (point **2**).

This issue was discussed within the Member Forum early 2015 and there was agreement that license should not prohibit Members from adding or retiring relationships to core concepts or changing the definition status, no decision or changes were formally documented or actioned.

The expected outcomes from this paper are:

- Inform CMAG members of the issue and solicit views and advice;
- Present these views as the desires of members:
- Receive confirmation from IHTSDO regarding the nature of the restriction either through revision of license, supplementary statement.

Whether or not a change to the license is required to clarify the clause, specifically what is meant by "modify", is unknown. However, documented confirmation from IHTSDO to the community of practice would provide assurance to license holders. Formal communication through the Member Form and perhaps Technical Implementation Guide may be sufficient.

4 Release Format 2

It is suspected that the clause is a legacy artefact from the original SNOMED CT release format. This format did not support the kind of changes that are under discussion, and was one of the reasons for developing Release Format 2 (RF2). Perhaps it is not intended to be current restriction?

Changes to core components through extensions are supported within RF2, provided they are published on an extension module (and compliant with RF2). Possible changes include:

- Inactivation of core components;
- Changing the logical definition of core components (add/retire attributes);
- Addressing mistakes in terms;
- Changing the IS A relationships.

Of course such changes should:

- Not introduce conflicts with the Fully Specified Name;
- Intend to improve the machine definition and overall quality of SNOMED CT-AU:
- Be promoted to the international release if request as per the SNOMED CT license (clause 3.5).

Clause 3.5

"The Licensee shall, if requested by the Licensor, transfer to the Licensor or a Member nominated by the Licensor all of its Intellectual Property Rights in such Standards-Based Extensions (or parts thereof) as the Licensor may specify."

5 The Problem

The restriction on modifying content places limitations on the type of content that an extension may actually create that may be considered unfair, or at least impractical. At the moment, it is unclear if Members are allowed to create anything more than "primitive leaf concepts". Because doing otherwise requires modifying core relationships. Although problem is mostly with relationships, the principal may apply to all core components. The type of actions an Extension owner might need to perform include:

- 1. Create new concepts.
- 2. Fully define concepts they create.
- 3. Classify terminology extensions.
- 4. State additional IS A relationships against core (international) concepts.
- 5. Retire (redundant) IS A relationships (not necessarily stated).
- 6. Add additional defining (non-IS A) relationships to primitive core concepts.
- 7. Retire content considered "inappropriate" concepts, descriptions or relationships

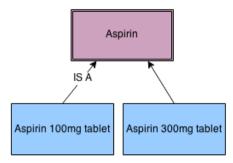
There is not expected to be any issues about the first three points, and all members and IHTSDO are believed to be in agreement that such actions are acceptable. The subsequent actions appear to be more contentious; even though they are unavoidable (if members attempt to create new concepts); ie. necessary consequences of creating fully defined concepts and classifying.

5.1 More than just primitive leaf concepts

If Members are to create quality concepts, that aren't just primitive leaf concepts, it is necessary to allow the "modification" of core relationships.

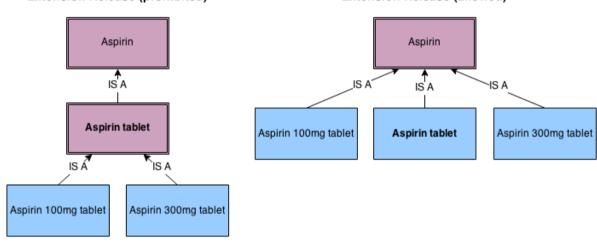
Due the history of how SNOMED CT has evolved, content has generally not been systematically created and semantic steps in a given hierarchy are unpredictable and inconsistent. The concern with being limited to only creating terminal or 'leaf' concepts is that that extension builders can only create content that is more specific than that which already exists. However, extension builders may have requirements for concepts that are less specific than existing ones. Below is an example of where an extension might want to create a concept that represents a |Pharmaceutical / biologic product (product)| with just Ingredient and Form was required. It would be correct for this new concept to subsume the existing specific concepts (left), however as the above restriction is understood, this is prohibited. The concept should be a leaf node (right).

International Release (hypothetical)



Extension Release (prohibited)

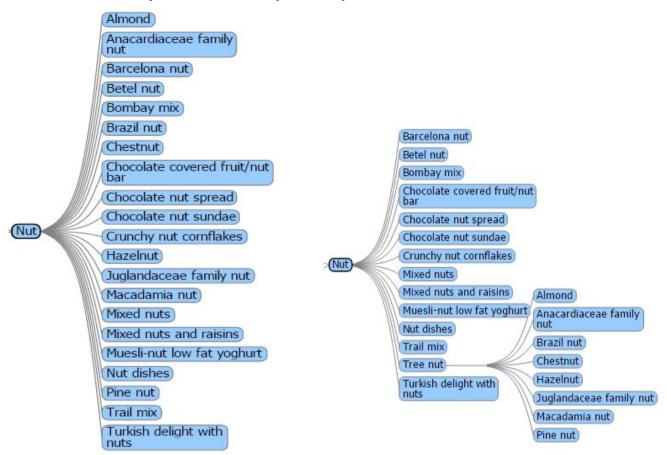
Extension Release (allowed)



- 5.2 Creation of the appropriate (yet prohibited) hierarchy on the left, requires allowance of actions 4,5,6:
 - 4 State additional IS A relationships against core.
 - The existing core concept |Aspirin 100 mg tablet| is a logical child of the new extension concept.
 - 5 Retire (redundant) IS A relationships (not necessarily stated).
 - The core relationship between |Aspirin 100 mg tablet| and |Aspirin| become redundant upon the introduction of the new Extension concept.
 - 6 Add additional defining (non-IS A) relationships to primitive core concepts.
 - Depending on the modelling of the core concepts, they may inherit (has ingredient) relationship from the new parent.

Such scenarios exist wherever Extensions wish to add concepts "in the middle of the hierarchy, whether they be primitive or defined.

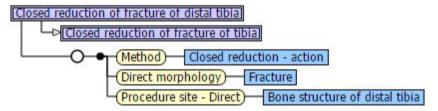
5.3 Intermediate primitive concept example



Example of Nut hierarchy <u>before</u> (left) and <u>after</u> the introduction of a new (extension) concept |**Tree nut**|. Although the concept is primitive, 8 core concepts were expected to be subtypes of this class, so additional stated IS A relationships were required. Furthermore, the existing core relationships, e.g. "Almond IS A Nut" are now redundant and should be retired. (Although the diagrams (from Shrimp) above do not show them).

5.4 Intermediate Defined concept example

An extension concept |Closed reduction of fracture of distal tibia (procedure)| is created and given a definition status of Defined with the following attributes



At this stage the Member hasn't modified any core components, however, upon classification three core concepts become children of this concept

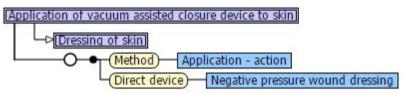
440437003 | Closed reduction of fracture of medial malleolus |

439938007 | Closed reduction of fracture of plafond of tibia |

439364008 | Closed reduction of fracture of posterior malleolus |

5.5 Defining attributes (non-IS A) and core components

An extension concept 799391000168105|Application of vacuum assisted closure device to skin (procedure)| has been created.



The following three core concepts were stated as being children of this new concept
450631000|Application of vacuum assisted closure device to skin of head (procedure)|
450632007|Application of vacuum assisted closure device to burnt skin (procedure)|
450633002|Application of vacuum assisted closure device to skin of neck (procedure)|

Upon classification, these core concepts all inherit attributes from their new parent. E.g. Direct device = Negative pressure wound dressing

5.6 Fixing defects and issues

It would be naive to believe that SNOMED CT is without defects and issues (most of which are likely the result of it's evolution from legacy code systems) as these have been widely reported. Whilst the IHTSDO may have ambitions to resolve these, with over 900 tracker items (of various complexity and scale) - many issues have and will remain unactioned for many years. Members who publish extensions may receive feedback from stakeholders identifying issues. Under ideal circumstances the member can forward the issue to IHTSDO, who would then action it in time for the next release. Alternatively, the issue may be acknowledged and linked to an existing tracker item, for resolution at an unspecified date.

Even under the ideal circumstances - the stakeholder may have to wait almost a year to see the issue resolved (given release schedules). Depending on the issue, and stakeholder involved, this can have reputational impacts such as, as well as a burden of having to mitigate the known issue and track its eventual resolution.

5.6.1 Retiring concepts

Feedback was received that the concept 384613002 | pT4b: Tumour penetrates visceral peritoneum (colon/rectum) | was erroneous, and replaced it with a new concept 813711000168104 | pT4b: Tumour directly invades other organs or structures (colon/rectum) |.

See Handling changes in RF2 (6. below) for more details.

5.6.2 Remodelling concepts

The concept 253973006 [Endemic polyarthritis (disorder)] was reported as being incorrectly modelled. It is a primitive concept with just a single stated IS A, but inherits attributes from its parent.

The concept was incorrectly stated as '**Is a**' *Polyarteritis* which Australia has revised to be '**Is a**' *Arthritis*. This process involved retiring the stated IS A, and creating a new IS A.

Upon classification, the inferred relationships were also revised.

Two relationship groups comprising four attributes were retired:

- 'Associated morphology' Inflammation
 'Finding site' Arterial structure
- 'Associated morphology' Inflammation
 'Finding site' Systemic vascular structure

New relationship group with correct Finding site create.

'Associated morphology' Inflammation
 'Finding site' Joint structure

6 Handling changes in RF2

The combination of RF2s *Append Only* history mechanism and Modulelds provides a mechanism for Members to make the edits as discussed above, without corrupting the international release. Consider the example of retiring the concept 384613002 | pT4b: Tumour penetrates visceral peritoneum (colon/rectum) | (5.6.1).

Moduleld Reference:

```
90000000000207008 |SNOMED CT core module (core metadata concept)| 32506021000036107 |SNOMED Clinical Terms Australian extension (core metadata concept)|
```

In the International January 2016 Full Concept file, the entry looks as such:

```
384613002 20030131 1 90000000000207008 9000000000074008
```

Upon retirement in the Australian Extension, the Australian Concept file (July 2016)looks as:

```
384613002 20030131 1 90000000000207008 9000000000074008 384613002 20160731 0 32506021000036107 90000000000074008
```

Presuming the international release follows suit, the International January 2017 Full Concept file would look like:

```
384613002 20030131 1 90000000000207008 9000000000074008 384613002 20170131 0 900000000000207008 9000000000074008
```

When the Australian release updates to International January 2017 - it's Concept File will look like:

```
384613002 20030131 1 90000000000207008 9000000000074008 384613002 20160731 0 32506021000036107 90000000000074008 384613002 20170131 0 90000000000000008 90000000000074008
```

This process is identical for all component files and reference sets (notably those used for historical associations). Note the middle entry never appears in the international release.

6.1 Collaborative Editing

RF2 also provides an opportunity for members and IHTSDO to collaboratively develop the terminology, without the need for everyone to be using the same tooling. Members can be responsive to their stakeholders and

action issues locally (on their Member module) and then promote the changes for consideration by the IHTSDO. If the IHTSDO accept the edit, the change can be included in the core release on the core module.

Continuing with the example above from 5.6.1 - A replacement concept 813711000168104 | pT4b: Tumour directly invades other organs or structures (colon/rectum) | was also created. This concept can be promoted to core through the same process: Such that the Australian release in January 2017 will look like:

```
384613002 20030131 1 90000000000207008 9000000000074008

384613002 20160731 0 32506021000036107 9000000000074008

384613002 20170131 0 90000000000207008 9000000000074008

813711000168104 20160731 1 32506021000036107 9000000000074008

813711000168104 20170131 1 900000000000207008 9000000000074008
```

The first three lines are the retirement of the core concept (also shown in previous section), and the final two lines are the promotion of the new concept 813711000168104 from Australia to International release.

Such a process reduces the burden on Members who contribute to the terminology in the manner, and the IHTSDO also has the option to partially accept concept, for example:

- Just the ConceptID and revise descriptions to comply with editorial policy
- Just The ConceptID and descriptions and revise the modelling
- Everything, but also improve the modelling.

An obstacle to this at the moment, is the inability of the IHTSDO tooling to accept RF2 format and honour the extension identifiers (beyond the concept Id). Thus making promotion, and compliance with License clause 3.5 a burden for Members who maintain extensions. Some coordination between collaborating organisations is also required. [Note: this has since been confirmed to not quite be the case Sept 2016]

In RF2 Namespaces function only as a mechanism for Members to generate unique identifiers (with respect to other Members and core). Ownership or responsibility of a component is indicated by the Module Id. Whilst in RF1 namespaces may have indicated the owner of a component, in RF2 it is only a "likely origin".

7 Unavoidable violations

7.1 Classification

Even if an extension builder does comply with the restriction to only create terminal concepts, this also means concepts must only be primitive. Given the previous examples (particular 5.4), even if such a concept was *stated* as a terminal concept, classification (which is required to produce the Distributed Normal Form) - results in the extension concept subsuming core concepts. Furthermore Distribution Normal Form rules require the addition of non-redundant inherited relationships, and removal of non-proximal (redundant) parents - both of which potentially require additions and retirements of relationships on international concepts.

Limiting members to only creating primitive concepts, eliminates any benefit or advantages that may be realised with the SNOMED CT Description Logic, including quality benefits such as detecting equivalents and strange modelling. As well as impacting the presentation of the extension product, as implementers are not going to encounter relationships they would expect to have.

7.2 New international Content

Finally, if a Member did create a sufficiently defined concept that resulted in being a terminal concept after classification. There may still be a situation where the international release later publishes a release that

includes a concept more specific than the extension concept. As a result, during the update and classification - the (pre-existing) extension concept, now subsumes the new international concept.

8 Conclusion and Recommendation

It is requested that the IHTSDO clarify the intent of the restriction described in clause 4.1 of the license. And in doing so, such clarification should confirm that the kinds of extension concepts described above are allowed - and that the spirit of the clause is aimed to preventing the creation of extensions that show conflicting representations of international content - through the overwriting process. Preferably, endorsement of RF2 compliant edits.

With the introduction of RF2, it is required that extensions are created on a module different to the core. As a result, an unadulterated International Release may be extracted or identified from any FULL Extension release, despite any modifications that may have been introduced.

9 Feedback and response

9.1 Content Managers Advisory Group (CMAG)

Between the August and September 2016 CMAG meetings, feedback was sought to the above proposal. The feedback provided (<u>available here</u>) can be summarised as follows:

- There was consensus that the allowances and limitations imposed by the license are ambiguous and require clarification (the initial motive of this paper).
- There was mixed support for the specific types of edits being proposed.
 Most agreed that:
 - New concepts should be allowed to be created

There is resistance to modifying any international components specifically:

- Changing the definition status and attributes
- Inactivating components

Beyond that, the feedback is somewhat conflicting, both between and within reviews. For example:

- it is not possible both prohibit changes to the international relationships AND allow intermediate
 concepts (either defined or primitive). An intermediate by definition adds an IS A relationship to an
 international concept.
- Allowing only changes to IS A relationships (such that transitive recovery is possible), potentially
 prohibits the use of adding attributes to intermediate concepts (as these become inferred, if not
 already).

The reasons for not supporting many of the edits described were fairly consistent across the reviewers.

- Reputational Such edits in extensions could degrade the perceived quality of SNOMED CT beyond just the extension.
- Interoperability 3rd party knowledge products relying on core taxonomy.

Reputational considerations are important, and part of the motivation for addressing discovered issues promptly. The quality of SNOMED CT is already challenged from various communities, and any efforts to improve it should be encouraged. Simply allowing extensions to exist at all, already carries a risk of reputational damage, especially in the absence of any standard quality/validation process for NRC's. However,

equally extensions can improve the reputation - both within their local user community and international (see content promotion).

Interoperability is important, however even edits to the international edition can "break" knowledge providers algorithms. Maintenance of such systems is unavoidable, as SNOMED CT is maintained on a 6 monthly basis. Ideally, changes in the terminology should always progressively improve the effectiveness of such (decision support) systems. It may render some parts redundant. Whilst it is a valid concern, it is not unique to extensions, but is perhaps more obvious in extensions.

Navigational concept solutions. One reviewer suggested that a navigational hierarchy be used, or some other 'side' approach. The problem with this is that it is another potential barrier to implementation (no clear guidance available) and makes the fixes 'on the side'. If such a solution was effective and transparent, such that the desired outcome is the same - all the issues raised would still be applicable. Ie. Navigational concepts appear to be just another way of creating extension content.

Content promotion & Collaborative editing

A side topic to the issue of allowing extensions to modify (or even just create) content, is content promotion. This is briefly described in section 6. Technically, everything described is generally supported by the current distribution format (RF2) and IHTSDO tooling. The main obstacles are defining the necessary processes. The simplest process is that where the IHTSDO promotes content without any change. However, some of the potential issues (and suggested solutions) to consider are:

For new content:

- IHTSDO disagrees with the extension FSN
 - In which case, the IHTSDO should notifying the extension, and advise of proposed FSN
 - If the extension disagrees because the new FSN has a different meaning, the concept should not be promoted (IHTSDO rejected).
 - IHTSDO can elect to create a new concept in core with the new FSN.
- IHTSDO disagrees with the modelling of a concept
 - IHTSDO should notify the extension of revised modeling.
 - o If the extension disagrees with the revised modelling, the concept should not be promoted.
 - o IHTSDO can elect to create a new concept still.
- IHTSDO outright rejects the concept
 - Extension considers the feedback, and either actions accordingly or ignores.

Ultimately the goals are:

- The meaning of a concept does not change during the promotion process.
- Any changes are communicated before promotion occurs.
- Extensions should be given an opportunity to contest changes and provide a rationale.
- IHTSDO is not obligated to promote any content. (Though the license states extensions are obligated to promote if requested by IHTSDO).
- Minimise the "forking" from core that occurs with extensions.

This process of collaborative/distributed editing does not rely on a single/specific authoring environment or tool. Additionally, it is expected that extensions would have either discussed with IHTSDO the intention to engage in this promotion process, particularly where extensions may be performing authoring activity that has significant impacts/changes. Such issues as described above can be minimised by the extension engaging in continuous discussion with IHTSDO around editorial choices where guidance is not clear.

Content promotion appears to be compatible with License

Clause 4.3

The Licensee may, by written notice, request the Licensor to modify the SNOMED CT Core.

Those who manage extensions are already obligated to promote content at the request of the IHTSDO as per <u>Clause 3.5</u>

The Licensee shall, if requested by the Licensor, transfer to the Licensor or a Member nominated by the Licensor all of its Intellectual Property Rights in such Standards-Based Extensions (or parts thereof) as the Licensor may specify.

Extension creators are also obligated to adhere to any IHTSDO standards, presumably to include concept model and Editorial rules <u>Clause 3.3</u>

The Licensee shall ensure that all Standards-Based Extensions and Standards Based Derivatives that the Licensee creates under this License Agreement are created in accordance with, and comply with, all applicable Standards (including, without limitation, as to the use of Namespace Identifiers).