IHTSDO approach to Quality Assurance
In the beginning . . . Brisbane 2007
In the beginning . . . Brisbane 2007

- First meeting of the quality assurance committee
- Discussion on the approach the IHTSDO should take to ensure quality and to provide assurance
- Decision to adopt a quality framework approach
- Quality Assurance framework - structured inventory of roles, rules, procedures and supporting infrastructure (the ‘components’) that the Quality Assurance committee would wish to see in place, along with quality criteria for each.
9.8.1 There will be a Quality Assurance Committee, with members who meet the Association standard for an acceptable level of expertise and experience in the risk management area.

9.8.2 With a view towards managing and lowering the risks of the Association, the Quality Assurance Committee shall have responsibility for the development and quality assurance of SNOMED CT and its related standards and the Association's other Terminology Products in harmony with proper respect to external standards.
IHTSDO Purposes and Objectives

(a) acquire, own and administer the rights to SNOMED CT, other health terminologies and/or related standards, and other relevant assets (collectively, the “Terminology Products”);
(b) develop, maintain, promote and enable the uptake and correct use of its Terminology Products in health systems, services and products around the world; and
(c) undertake any or all activities incidental and conducive to achieving the Purpose of the Association.

(b) contribute to improved delivery of care by clinical and social care professions;
(c) facilitate the accurate sharing of clinical and related health information, and the semantic interoperability of health records;
(d) encourage global collaboration and cooperation with respect to the ongoing improvement of the Terminology Products; and
(e) provide for the foregoing on a globally co-ordinated basis, thereby enabling the Members and other related organisations within their Territorial boundaries to pool resources and share benefits relating to the development and maintenance of, and their utilisation of and reliance upon, the Terminology Products.

Support IHTSDO Governance and Advisory Structures
- Support IHTSDO Governance bodies
- Support IHTSDO. Working Groups

Corporate Management
- Human Resource Management
- Strategic Planning

Tooling and Technology
- Architecture and Roadmap
- Distributed Editing Platform

Standards Development Program
- IHTSDO Standards: Definition and guidelines for Development
- Content inclusion/exclusion algorithms

Policy/Regulation Development
- Implement and Evaluate Request Submission Policy
- Allocation of Namespace Policy

Improving SNOMED CT Quality
- Quality framework
- Quality metrics

Develop, Maintain and Distribute SNOMED CT
- Manage SNOMED CT Licensing
  - Promote new licensing model
  - Collection of licensing charges
- Develop New SNOMED CT Content
  - Content development policies
  - Error prevention processes

Dimensions/characteristics
- Usability
  - Description: % policy clauses conforming to agreed presentation format at end of 6 month period
- Reliability
  - Description: % change requests not covered by explicit guidelines
- Accuracy
  - Description: % guidance-conformant change requests acceptable by requester

Harmonisation
- Laboratory tests...
- ICD...

Communications
- Content strategy
- Public website...

and Special Interest Groups
- Concept model PG
- Nursing SIG...
Why the quality framework?

- To embed quality and assurance in all activities undertaken on behalf of the IHTSDO
- To enable a structured approach to be taken when considering quality matters
- To provide assurance by the production of metrics when activities are undertaken
- To use metrics to provide evidence and assurance of quality improvement
DETAIL OF THE QUALITY ASSURANCE FRAMEWORK
Quality assurance framework

- IHTSDO Quality Assurance Framework
  - Version 1.2
  - Date: December 12, 2008
  - Editor: Ed Cheetham

Discussion document for quality assurance framework

Date 20081209
Version 1.2
General quality assurance framework for integration into IHTSDO activities
Call center services to manage customer inquiries

Activity

Component 1

Number of call center staff

Define and set targets

Quality
• Metrics
• Targets

Component 2

How licensing inquiries are processed

Standardization

Characteristics

Structure

Process
Quality assurance framework at a glance
Origins of the quality framework

- IEEE software definitions
- ISO terminology definitions

ISO/IEC 9126 software quality characteristics
(A few) Definitions

- **IHTSDO Quality**
  - *The degree to which the IHTSDO meets its specified objectives, in terms of its organisational and product development processes, as well as the services and products it provides.*

- **IHTSDO Quality Assurance**
  - *A planned and systematic pattern of actions necessary to provide adequate confidence that the IHTSDO meets its specified objectives, in terms of its organisational and product development processes, as well as the services and products it provides.*
Definitions (cont.)

- **Quality Metrics**
  - *Agreed methods and means for measuring the Quality Characteristics of Components*

- **Quality Targets**
  - *Agreed levels of achievement, performance or conformance of a Component for any given Quality Characteristic*
Scope of the quality framework

- All (any) identifiable aspects of IHTSDO activity
- Standing committees, Special Interest Groups (SIG’s), Project Groups, Central functions
  - Organisational processes and support
  - Data products (terminology reference data, mappings, translations, subsets)
  - Documentation
  - IHTSDO-responsible services and tooling provision
Framework overview

- IHTSDO stated objectives and purposes are the motivating principles for IHTSDO activities *(Why we are here)*

- IHTSDO activities act as the organising principle for quality framework components *(Gives structure to being here)*

- IHTSDO activities should be shown to be effective to support openness and transparency *(What we do when we are here, and how we can show we are being effective)*
Introduction to implementation of the framework

- Where is the framework applied
  - Anywhere where you are undertaking a project or specific work item, particularly where you will be required to show the outcome of that piece of work
- How is the framework applied
  - Quality Assurance Framework, Framework Toolkit, Framework template
- Results of implementation
  - Quality Assurance Committee
Applying the quality framework

- General quality assurance requirement
  - Set targets and demonstrate quality standards for all IHTSDO projects and services

- The IHTSDO quality framework
  - Does not say what these standards are . . .
  - . . . but . . .
    - Provides a consistent mechanism and framework for identifying project or service components
    - Specifies the quality characteristics/attributes of each component
    - Sets standards or targets for each characteristic
    - Identifies a realistic mechanism for measuring (and demonstrating) whether such standards are achieved
Framework  Detailed example

- Tooling and Technology
  - Request Submission Technical Solution

<table>
<thead>
<tr>
<th>Component</th>
<th>Characteristic and Description</th>
<th>Example target</th>
<th>Metric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical solution function/structure</td>
<td>Char: Reliability</td>
<td>99.99%</td>
<td>Request submission availability using standard system availability measures</td>
</tr>
<tr>
<td></td>
<td>Descr: Request submission system availability time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technical solution process</td>
<td>Char: Efficient</td>
<td>*</td>
<td>Probably a simple ‘does/doesn’t’ against stated requirement, but may be possible to identify the proportion of requests that cannot be coerced into standard workflow.</td>
</tr>
<tr>
<td></td>
<td>Descr: System able to support editor workflow practices</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Metrics

- Agreed methods and means for measuring the agreed levels of achievement, performance or conformance of a component-characteristic

  - **Description**: What is to be measured and how this is believed to demonstrate the quality of the associated component-characteristic
  - **Target**: Agreed levels of achievement, performance or conformance of a component-characteristic that would be felt to demonstrate adequate quality
  - **Plan**: Description of how measurement is to be carried out
  - **Level achieved**: Agreed reporting format for the metric once measured (units, timescale)
  - **Response**: Agreed response steps to follow when this metric is reported (in particular if targets are not achieved) or when a target is revised
Example of metrics

- Data production and publication
  - Schema and relational integrity conformance tests
    - Conformance metrics
- Change request management
  - Infrastructure and procedure for responding to change request
    - Change request response time metrics
- Editorial rule adherence
  - Editorial rules and their implementation
    - Degree of compliance with the editorial rules
Framework application 3 stages

- Design and development stages
- Conduct stages - measurement
- Post-measurement stages
Framework application **Design**

- Design and development stages
  - What needs to be done?
  - Who needs to do it?
  - How is it to be done?
    - Specific
    - Meaningful
    - Achievable
    - Realistic
    - Timely
Framework application  Measurement

- Conduct stages - measurement
  - What needs to be done
    - How do we measure success
    - What measurements are proof of success
  - Who needs to do it?
    - Central / local
  - How is it to be done?
    - manual / automated
Framework application  After

- Post-measurement stages
  - What needs to be done
    - Existing measures
      - Archive (if targets met)
      - Modify (if targets not met)
    - New measures identified in the course of the investigation
  - Who needs to do it?
  - How is it to be done?
    - Modify structure/process as necessary
    - Develop new measures if necessary
Component/Characteristic - Metric template

- Project, product or service name – this will allow cross-referencing to identify
- Responsible owner – this is the name of the project, product or service lead
- Component name – this may be the whole name of the project, product or service, or may be a component/part of the
  - Component type – structure, process or outcome
- Quality characteristic name – short working name for the thing being measured (probably most easily framed as “characteristic of ‘component’” (such as “accuracy of SCT-ICD-10 cross maps”)
  - Quality characteristic type – the characteristic category from the Quality Framework
  - Quality characteristic description – a description and justification for the characteristic
- Quality metric name – short working name for the metric (there may be several metrics for each quality characteristic, so these will need to be distinguished)
  - Date of agreement
  - Description – a description and justification for the metric
  - Target – the target to be achieved.
  - Measurement plan – a description of
    - how the metric will be generated and collected
    - by whom
    - timing in relation to project/service
    - publication schedule
    - review timetable
  - Planned response if target not achieved
- Outcomes would not routinely form part of a metric register, but fields to collect would be:
  - Outcome
    - Date of measure
    - Level achieved – the measure achieved
    - Remedial/additional steps taken - if required
APPLICATIONS OF QUALITY ACROSS THE IHTSDO
Examples of applications of quality

- SNOMED CT content
- Survey of request submission users
- Application of quality to translation
- Corporate metrics
A review and options appraisal for the development of Quality Improvement Metrics related to SNOMED CT

- Commissioned in Autumn of 2009
- Work overseen and advised by a joint group of Quality Assurance and Content Committees
- Data obtained by:
  - Series of expert interviews – 20, from 7 countries
  - Literature review – 68 + publications of relevance
- Identifies metrics that can be used to assess SNOMED CT’s ‘fitness for purpose’ - 78

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A review and options appraisal for the development of Quality Improvement Metrics related to SNOMED CT

- Clarity of purpose metrics:
  - Statements of purpose (4)
  - Statements of scope (4)
  - Statements of quality (1)

- Completeness:
  - Concepts
    - Domain coverage (10)
  - Descriptions:
    - Fully specified name (2)
    - Descriptions (5)
    - Cross maps and translations (3)

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A review and options appraisal for the development of Quality Improvement Metrics related to SNOMED CT

- Cross maps and translations
  - Cross maps and translations completeness (3)
- Internal consistency and uniformity
- Concepts
  - Concept consistency (5)
  - Concept stability (3)
- Descriptions
  - Description consistency (6)
  - Description stability (1)
- Cross maps and translations
  - Cross maps and translations consistency (3)

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A review and options appraisal for the development of Quality Improvement Metrics related to SNOMED CT

- Correctness
  - Concept correctness (3)
- Clarity and usability
  - Discoverability (3)
  - Consistency of use (3)
- Implementability
  - Implementability (8)
  - Issue tracking (1)
- Interoperability (4)
- Interoperability (4)
  - Documentation – presence, content consistency, internal consistency, discoverability, change management (9)
Request Submission Process Survey

- 55 surveys sent out using Survey Monkey
- 17 responses received
- 1 response was unusable
- 29% response rate
Tell us about your usage of the request submission process in the last 12 months.

How many requests have you submitted?

- 1--10: 50%
- 10--20: 14%
- 40-1000: 36%

How many of your requests were approved?

- 99--100% approved: 38%
- 90% approved: 31%
- don't know: 31%
- 1--10 approved: 50%
- 10--20 approved: 14%

There is a 0-10% rejection of submissions.
Rate your overall experience with the request submission services provided by IHTSDO
Please indicate whether or not E-mail message notification regarding your request was received.

E-mail message notification that your request has been received was provided within 24 hours of submission:
- Yes: 6%
- No: 7%
- Don't Know: 87%

E-mail message notification of the request status (completed or declined) was received:
- Yes: 0%
- No: 20%
- Don't Know: 80%
What three suggestions would you make to help us improve the SNOMED CT Request Submission Process?

- Better communication links with the support organization to aid clarification
- Provide detailed rationale for all refused or rejected submissions and a running tally of requests submitted, how many were accepted and added and how many were rejected as publicly
- Content guidelines that are understandable so we know better what is a good submission
- Integration/collaboration with other clinical record representation standards; some content requests better met by non-SNOMED solutions
- More available help to understand the concept models and content direction where it is confusing or not well documented
Translation quality toolkit

- A toolkit to assist in the measurement of the quality of a translation project
  - Background methodology document
    - Review process, bibliography
    - Implementation of IHTSDO Quality Framework
  - Methodology and tools document
    - Components and Quality Metrics
    - Questionnaires
    - Report Sheet
<table>
<thead>
<tr>
<th>Component</th>
<th>Group as indicated by Gilreath*</th>
<th>Characteristics</th>
<th>Description of characteristics/indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structure</td>
<td></td>
<td>Translation process participants’ competences and knowledge</td>
<td>Educational background and professional experience of translators; skills within translation and/or medical areas. Knowledge of SNOMED CT and of the translation process</td>
</tr>
<tr>
<td>Structure</td>
<td></td>
<td>Access to translation software</td>
<td>Tool dedicated to concept based translation Explicit specifications and tested software</td>
</tr>
<tr>
<td>Structure</td>
<td></td>
<td>Content of target language specific linguistic guidelines</td>
<td>Existence of style guides in target language and relevant content</td>
</tr>
<tr>
<td>Component</td>
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<td>Characteristics</td>
<td>Description of characteristics/indicators</td>
</tr>
<tr>
<td>-----------</td>
<td>---------------------------------</td>
<td>-----------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Process</td>
<td>Semantic adequacy</td>
<td>Concept based translation</td>
<td>Check if all translation process participants are well aware of the importance of this principle</td>
</tr>
<tr>
<td>Process</td>
<td>Continuous co-operation between TPO and TSP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process</td>
<td>Translation reviews</td>
<td>Two-level review process necessary</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-----</td>
<td>----</td>
<td></td>
</tr>
<tr>
<td>1. Have you set up a system to ensure that any translated concepts could be readily reviewed by an SME or an HCP?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Have you made sure that your SMEs/HCPs are well aware that their main task is to verify if the translations comply with the principles of clinical usability and psychological acceptability?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Have you made sure that your SMEs/HCPs are aware of the importance of terminology consistency, and have they been instructed also to take local guidelines and principles into consideration?</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Comments to the above questions:
Development of corporate metrics

- **Quality**
  - Product
  - Tools
  - Processes

- **Customer Satisfaction**
  - Customer Survey
  - Requests for Change
  - Communications

- **HR/Stakeholders**
  - Employees Performance
  - Conferences Participation
  - Committee Effectiveness

- **Finance**
  - GA to determine
  - GA to determine
  - GA to determine
2012 QAC work plan items

- **External clinical quality reviews of SNOMED CT x 2**
  - Building on previous work commissioned by QAC. Based on use cases developed by I&I and programme areas in content using methodology previously developed by QAC

- **Implementation of IHTSDO quality framework**
  - Continued driving forward application of quality across IHTSDO directly and indirectly

- **Development of quality metrics x 2**
  - In order to help community apply quality framework, development of metrics in 2 agreed categories in support of IHTSDO key areas e.g. Mapping, Tooling, Content Development Process etc

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2012 QAC work plan items

- Risk management
  - On going implementation of risk management approach
- Development of IHTSDO glossary
  - Taking recommendations and design from Glossary Steering Group and developing the actual IHTSDO glossary
- Content development process implementation
  - Implementation, review, training etc on content development process
- Technical reports, Guidelines and Standards
  - Management of development, review, maintenance etc
- Mapping validations

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Available documentation

- IHTSDO Quality Assurance Framework v2.0 (20100517)
  - Introduction and description of IHTSDO quality assurance framework
- IHTSDO Quality Framework Toolkit v2.0 (20100517)
  - Framework description and example/prototype application
- Annual Quality Report 2011
- www.ihtsdo.org for sharing and reporting, including public dashboard
The long-view for the framework.

- Quality and assurance is central to all IHTSDO activities
- Similarities across projects in terms of Quality Assurance
- Sharing and reuse of metrics across IHTSDO projects
- Consistent set of metrics across activities
- Collect and share instantiated templates
- Results used to create a broader picture of quality in the IHTSDO
The long-view for quality and quality assurance

“SNOMED CT is a proven quality product, produced by the IHTSDO, which is an organisation with quality at its core”

... And we have the evidence prove it ...