Terms of Reference:

Review of

WHO’s Revision Process

for the International Classification of Diseases (ICD)

Request for Expressions of Interest
# Table of Contents

1. INTRODUCTION ............................................................................................................................. 3  
   1.1 Objective of the Request ......................................................................................................... 3  
   1.2 Deadline for Expressions of Interest ....................................................................................... 3  
   1.3 WHO's Revision Process of the International Classification of Diseases (ICD) ..................... 4  

2. DESCRIPTION OF THE ASSESSMENT REQUEST ...................................................................... 5  
   2.1 Overarching Approach ............................................................................................................ 5  
   2.2 Assistance from WHO ............................................................................................................. 5  
   2.3 Expert Advisory Group .......................................................................................................... 5  
   2.2 Requirements .......................................................................................................................... 6  
   2.3 Characteristics of the provider ............................................................................................... 7  
   2.4 Methodology .......................................................................................................................... 8  
   2.5 Deliverables ............................................................................................................................ 9  

3. TIMELINE and INSTRUCTIONS ..................................................................................................... 9  
   3.1 Reporting requirements ......................................................................................................... 10  
   3.2 Fees ....................................................................................................................................... 10  
   3.3 Language of the Proposal and other Documents ................................................................. 11  
   3.4 The contract .......................................................................................................................... 11
1. INTRODUCTION

1.1 Objective of the Request

WHO Office of the Assistant Director General, Health Systems and Innovation, solicits expressions of interest from a suitable Contractor(s) to carry out the following work:

1. Conduct an interim assessment of the 11th Revision for International Classification of Disease (ICD) in terms of:
   • Progress towards the goals of the Revisions
   • Process and mechanisms put in place for the ICD revision
   • Project resources (financial & human) in relation to the proposed outcomes of the revision
   • Project Plans and proposed timeline for the completion of ICD 11 for 2017
   • Organization for maintenance and updates of ICD beyond 2017

2. Analyze the relevance and effectiveness of the planned features of ICD 11 in meeting the needs of the key stakeholders in WHO Member States including its:
   a. Use in Mortality statistics – e.g. Cause of Death statistics, Verbal Autopsy, others...
   b. Use in Morbidity statistics – e.g. Discharge summaries, Case-mix groupings, others...
   c. Use in Primary Care – in low and intermediate resource settings...
   d. Use in Clinical Care – for diagnosis, guidance, quality and safety indicators
   e. Use in Scientific Research- for epidemiology, genetic studies and other

3. Compile an assessment report summarizing the findings and making recommendations for improvement.

Potential contractors are requested to state the reason why they consider themselves suitable for this work and explain how they will respond to the requirements stated in this request with (a) a proposed draft work plan; (b) timeline; (c) budget with annotation.

1.2 Deadline for Expressions of Interest

Expressions of interest must be submitted on or before July 31, 2014 in order to be considered. The description of the contracting agency and curriculum vitae of the proposed team members, and proposed methods for assessment and timeline should be attached to the expressions of interest (see also 2.3). A point of contact for inquiries should be identified. WHO may contact the parties for further clarification. WHO will inform the

All expressions of interest should be submitted to the following email address: schusterp@who.int
contracted party following the selection process by 15 August 2014.

1.3 WHO’s Revision Process of the International Classification of Diseases (ICD)

The World Health Organization (WHO) has a constitutional mandate to develop international standard classifications and terminologies for health. ICD has been maintained by WHO starting from its sixth edition with periodic revisions approximately every 10 years. It serves as the international health information standard for collection, classification, processing, and presentation of disease-related data in national and international health statistics.

11th revision of the ICD was initiated in April 2007. An Internet platform was developed that allowed participation of all interested parties in the revision process. To learn from the improvements that individual countries have already made in their ICD clinical modifications (i.e. modifications in Australia, Canada, Germany, and USA), their additions were systematically merged and sorted for the ICD revision. The organization and progress of the Revision Process is summarized in Annex 1 in more detail.

The objectives of the ICD Revision Process were stated as follows:

1. To revise the ICD classification in line with scientific advances, to serve multiple purposes including mortality and morbidity statistics as well as clinical use in primary care, specialty care and research;

2. To continue to serve as an international standard in multiple languages and settings to allow for comparable data;

3. To link with computerized health information systems (directly use standard terminologies and other health informatics applications to be “electronic health application ready”).

The ICD Beta Draft 2014 was developed aiming to address the above-mentioned goals. While the development will continue on an internet based authoring platform (iCAT) which is a structured and editorially controlled and ontology based wiki-like application additional tasks including the following will be undertaken:

1. Scientific Peer Reviews
2. Additional Proposals from different groups
3. Field Trials
4. Translations
5. Transition Preparations.

Details of these steps are also described in more detail in Annex 1.
2. DESCRIPTION OF THE INTERIM ASSESSMENT REQUEST

2.1 Overarching Approach

This request for proposal is to solicit an interim assessment of the ICD Revision Process, which is independent, impartial and objective. In carrying out the assessment, the stated original requirements will be considered, with no preconceived idea of the outcome. For example, the assessment could lead to recommendations to stop, revise, eliminate, replace, maintain, or further strengthen different aspects of WHO’s ICD Revision Process.

The Assessment will:

- look at WHO’s ICD Revision Process as a whole with various components, including the use ICD for multiple purposes; organization of the revision process and its timelines,
- consult with different groups and types of stakeholders; and
- seek recommendations towards making the future ICD:
  - fit-for-multiple purposes;
  - easier to implement tool in real life situations; and
  - serve as a solid foundation for health information systems.

These overall aims are further detailed below in the 2.2 Requirements and 2.4 Methodology. The assessment will be formative (i.e. explorative) in examining the structure and process of the ICD Revision; and is not summative as the ICD revision in ongoing. The assessment will include, where feasible and relevant, the outcome of the interim products of the revision process such as the ICD Beta Draft and the accompanying internet platform, or gather views about the potential impact of the revised ICD when delivered, in terms of utility, feasibility and process.

2.2 Assistance from WHO

WHO Secretariat for the ICD revision will assist the Contractor providing them with background information, documentation, access to ICD Web tools and potential guidance in contacting requested stakeholders.

2.3 Expert Advisory Group

The Contractor will also be assisted by an Expert Advisory Group (EAG), who would provide an oversight of the assessment in terms of its roadmap and review of the draft report. The Expert Advisory Group will /may include the representatives from the following institutions or sectors:

a. UNSTAT
b. WHO-FIC Network
The Expert Advisory Group will engage:

1. At the **beginning** of the assessment project proposal, reviewing and giving feedback.
2. At the **finalization** of the project reading the draft report and giving feedback.

The Meetings of the EAG could be arranged tentatively (1) on 15 September and (2) on 15 November 2014, as virtual meetings. If possible, the contractor will be invited already occurring meetings of the stakeholders to observe and/or conduct part of the assessments, as the WHOFIC meetings in Barcelona in October 2014.

### 2.2 Requirements:

WHO requires the prospective Contractor(s) to carry out the following tasks:

1) Analyze the **relevance** and **effectiveness** of WHO’s Revision Process for ICD as described in the Project Plan Summary (*Annex I*) and consult with **multiple stakeholders** to solicit their assessments and recommendations for improvement.

For the purpose of the Project, these terms are defined as follows:

a) **Relevance**: The extent to which Revision Process has addressed the stated goals, *(page 2 text box 1)* and whether the proposed mechanisms for: eliciting proposals, reviews and field trials are adequate to resolve the issues in the classification

b) **Effectiveness**: The extent to which the changes in the revision process and the Beta Draft of ICD has improved in comparison to those of ICD-10

The **Multiple Stakeholders** will be selected being prototypically representative of the following sectors:

a. **Mortality statistics** – e.g. UNSTAT, EUROSTAT, INDEPTH group, ...

b. **Morbidity statistics** – e.g. European Project on Patient Summary; Case mix applications from USA, Australia, Germany, Canada; ...

c. **Primary Care** – e.g. WONCA, Sweden, Thailand, South Africa, ...

d. **NGOs** – e.g. International Diabetes Foundation, International Federation of Health Information Managers Association; ...
e. **Health Care Terminology and Classification Providers:** e.g. IHTSDO, NLM, Bioportal, ...

A more detailed list of stakeholders is presented in **Annex II.**

3. **Evaluate the resources for the ICD Revision Process** (both within WHO and outside WHO; including both financial and human resources) as to how best they are utilized to achieve the best results.

4. **Evaluate the TIME projections** of the ICD Revision Process in terms of:
   a. the readiness of ICD11 submission to **WHO Governing Bodies for Adoption** (tentatively as in May 2017).
   b. the **readiness of WHO Member States and stakeholders** to adopt ICD11 and use it for their intended purposes.
   c. Compare **scenarios to use ICD11 in different countries** in terms of readiness and **required transition steps**;

5. Identification of key parameters or illustrative examples for **business case(s)** for ICD-11 in WHO Member States with a view to examine the following factors:
   i. **Potential Costs** for transition to ICD-11
   ii. **Potential Benefits** for transition to ICD-11
   iii. **Time requirements** for transition to ICD-11

6. Define the **strengths and weaknesses, opportunities and threats** (like SWOT analysis); and the potential **added value and benefits** of the ICD Revision Process and its different components

7. Future recommendations on the use of **ICD-11 as a public good without any costs** to any user; including its licensing and distribution.

8. Summarize recommendations in a succinct **report** including an **executive summary**; recommended **action items** including priorities and improvements, systematically presented and discussed with WHO and the assigned Expert Advisory Group.

### 2.3 Characteristics of the provider

The Assessment Project will be carried out by a **consulting company** or a **team of consultants** with the following characteristics:
(1) The Contractor team should include relevant expertise and experience in: (a) the health information systems (b) use of ICD in different aspects such as mortality and morbidity statistics; (c) use of ICD in electronic health applications (Health Information Technology); (d) research in assessment sciences;

(2) The Contractor team should consist of at least 2, preferably 3-6 individuals with different disciplinary backgrounds and complementary skill sets to manage the different aspects of the assessment: Interviews, focus groups, analysis and formulation of recommendations.

(3) The Contractor itself (and the members assessment team) will declare any possible Conflict of Interest with the WHO and ICD Revision Process; which will be reviewed by WHO Administration.

2.4 Methodology

The Assessment methodology will be chosen by the Contractor including the following activities and steps:

1) A site visit and background information to WHO/HQ and review of the ICD Revision Process with CTS team, Director HSI and ADG HIS;
   a. On the scope and goals of the ICD Revision
   b. What has been achieved to date (2007 – 2014)
   c. The revision process (2007-2014)
   d. Plans for future (2014 – 2017 and beyond)
   e. This visit may also include possible consultations with engaged parties in WHO (Mental Health, Reproductive Health, Traditional Medicine, ...)

2) Review and analysis of relevant background documents such as ICD Project Plan, Meeting Reports, Web site and tools; proposed internal mechanisms of review for the alpha phase, beta phase and transitions requirements; basic questions in the Field Trials.

3) Planning of the Assessment Process

   a. Proposed stakeholders - analysis of stakeholder groups and their key concerns; drafting a semi-structured interview guide for 30-45 min consultation with each representative of the multiple stakeholder group. It is expected that there should be around 50 such consultations carried out live, or with telephone/video connection.
b. Other methods (a potential Internet Survey of 20-30 Questions) to increase outreach to include more interested parties by invitation (additional 100-300 participants may express their views in this way.)

4) Agreement on the Work Plan and the Roadmap: WHO and the Contractor will agree on a draft work plan before the commencement of the work. The draft work plan will include: an outline of the work schedule; regular reports on progress at agreed dates; dates for deliverables, including a first draft of the provider’s report and final draft, incorporating comments received on the first draft as appropriate.

2.5 Deliverables

In order to attain the objectives of the Project, the Contractor will produce the following deliverables, with recommendations on specific actionable items:

1) A Report on the analysis of the overall relevance, and effectiveness of WHO ICD Revision Process as these terms are defined above:
   a. To what extent does the ICD Revision Process meet the goals stated?
   b. To what extent the project plans and stated timeline are necessary and relevant to finalize the ICD-11? (including an analysis of bottlenecks, and the timeliness of WHO’s draft productions)
   c. Project progress and process to date
   d. Project resources (financial & human) compared to goals
   e. An analysis of whether WHO’s ICD Revision Process is well communicated, the rules and process is transparent and clear, and lend themselves to easy understanding, participation and implementation.
   f. Organization for maintenance and updates of ICD beyond its first release

2) Recommendations/Solution strategies: Make recommendations for the maintenance, revision, elimination, replacement or strengthening of different aspects of WHO’s ICD Revision Process

3. TIMELINE and INSTRUCTIONS

The target date for the completed first draft of the deliverable is by 10 October 2014. The contractor will also be invited to take part in the WHO Annual Network Meeting 13-17 October 2014 in Barcelona to conduct additional consultations with the WHOFIC Network Participants. The due date for the completed final product submitted to WHO will be 15 December 2014 latest.
Tentative timeline:

15 August 2014 Finalization of Contract with the selected Contractor
18-30 August Site Visit to WHO/HQ
1 September 2014 Presentation of the Work Plan to the Expert Advisory Group WHO
15 August -30 Sept Conduct of Interviews (Wave I)
13-17 October 2014 Participation in the WHOFIC Annual Network Meeting for conduct of interviews and surveys (Wave II).
15 November 2014 Presentation of interim Report to WHO
15 December 2014 Submission of the Final Report to WHO.

3.1 Reporting requirements

The contractor(s) will and work in close collaboration with, and report to, the WHO. The contractor(s) will report back to the Organization at regular intervals to be agreed upon at the start date of the contract. The final report and its contents and the data used in producing it will be submitted to WHO and should not be shared with any other party without the written permission of the WHO. WHO keeps the right to publicize the report and its contents as a whole or in parts.

3.2 Fees

The fees to be paid for the work to be performed will be commensurate with the qualifications and experience of the selected contractor, taking into account the work to be performed, up to a maximum total of 75,000 USD. The prices payable by WHO for the work to be performed under the Contract shall be fixed for the duration of the Contract and shall be in a UN convertible currency (preferably US Dollars), based on the UN exchange rate of the date of invoice. The total amount payable by WHO under the Contract may be either a lump sum or a maximum amount. If the option for payment of a lump sum applies, that lump sum is payable in the manner provided, subject to satisfactory performance of the work.
3.3 **Language of the Proposal and other Documents**

The expression of interest prepared by the contractor, and all correspondence and documents relating to the contract exchanged by the contractor and WHO shall be written in the English language.

3.4 **The contract**

The contract between WHO and the selected contractor(s) ("the Contract") will inter alia address the following issues:

1) responsibilities of the selected contractor(s) ("the Contractor(s)") and WHO;
2) clear deliverables, timelines and acceptance procedures;
3) payment terms tied to the satisfactory performance and completion of the work;
4) notices.

In line with the recommendation of the Selection Committee the WHO is free to contract one or more of the proposals to undertake the assessment.

It is expected that the formalities will take 5 working days to issue the contract and execute the first payment.
ANNEX 1: The ICD Revision Process Summary

Section 1

ICD Revision Process:

Description of the revision process

This document summarizes the ICD Revision Process, in particular, in terms of the timelines for the **finalization date** and submission to WHO Governing Bodies. Following various consultations with the WHO Member States and relevant international stakeholders, it was decided to postpone the submission to WHA to **2017 May** in various consultations with the WHO Member States and relevant international stakeholders taking into account: the developmental stage of ICD 2013 Beta, and allowing for reasonable time to complete the remaining tasks: reviews; additional proposals; field trials; translations; and the transition preparations.

Outline:

A. **Background:** need and mandate for the ICD revision

   1. ICD revision process: General organization structure
   2. ICD revision process: Phases of Development 2007-2013

B. **Timelines for the submission of ICD to WHO Governing Bodies**

   1. ICD revision process: The Beta Phase 2014 -17
   2. ICD revision process: Maintenance of ICD after finalization
A. Background: Need and Mandate for the ICD Revision

The World Health Organization (WHO) has a constitutional mandate to develop international standard classifications and terminologies for health. ICD has been maintained by WHO starting from its sixth edition with periodic revisions approximately every 10 years. It serves as the international health information standard for collection, classification, processing, and presentation of disease-related data in national and international health statistics. In 1967, all WHO Member States accepted the first “international regulations” to use ICD for mortality and morbidity statistics.

ICD 10th Edition was produced between 1982 and 1989 by annual revision conferences and it was adopted in 1990 by the World Health Assembly. It was foreseen that 10 yearly (decennial) editions would continue as the method of revision with interim annual updates in between. When the 11th revision was due in 2000, the “ICD Revision” topic was discussed in the WHO Executive Board in 1999 and a moratorium was suggested for the Secretariat to come up with a modern revision strategy in consultation with the Member States. The reason for this suggestion was the level of ICD-10 adoption by Member States: ICD was then used by only 96 Member States out of 191; its adoption and implementation had several problems including Year2K complications in health information systems. Hence a moratorium suggested better informatics support towards implementation.

In the following years, WHO addressed the implementation issues within the WHO Family of International Classifications (WHO FIC) Network and then formulated a revision strategy between 2003 and 2007. The objectives of the ICD Revision Process are listed as below:

**The objectives of the ICD Revision Process:**

1. To revise the ICD classification in line with scientific advances, to serve multiple purposes including mortality and morbidity statistics as well as clinical use in primary care, specialty care and research;

2. To continue to serve as an international standard in multiple languages and settings to allow for comparable data;

3. To link with computerized health information systems (directly use standard terminologies and other health informatics applications to be “electronic health application ready”).

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1 the WHO Nomenclature Regulations adopted by the World Health Assembly (resolution 20.18, May 1967) [http://www.who.int/classifications/icd/docs/en/NOMREGS.pdf](http://www.who.int/classifications/icd/docs/en/NOMREGS.pdf)
To achieve these objectives, an International Revision Process Plan was developed to revise the classification content in line with advances in health sciences and to add the desired functionality using modern health informatics standards. The revision process aimed to gather input from all stakeholders in an open and documented way. This revision process was initiated by a letter from Director General of WHO to all Member States in April 2007. An Internet platform was developed that allowed participation of all interested parties in the revision process. To learn from the improvements that individual countries have already made in their ICD clinical modifications (i.e. ICD Australian Modification, Canadian Modification, German Modification, US Modification), their additions were systematically merged and sorted for the ICD revision. The organization of the Revision Process is summarized in Section 1, below.

1. ICD Revision Process: General Organization Structure

To coordinate the International Revision Process, a large project platform was developed and all Member States were invited to contribute. Key elements of this process included:

a. Public Internet Platform – where all interested parties could see the current ICD-10 and make additional proposals and comments. This platform later included a “Collaborative Authoring Tool” (iCAT), an enhanced WIKI tool, which is (i) well-structured with formal links to other classifications and standard terminologies and (ii) have an editorial control mechanism. iCAT enables all users to apply the same building blocks and procedures towards standardization. In addition to iCAT, the public Internet platform has multiple components including making proposals, comments, and participating in: translations; field trials; and the review process.

b. Topic Advisory Groups (TAGs): Several expert groups have been established to guide and review the work in the subject areas of the ICD. TAGs were formed for key uses of ICD for “Mortality” and “Morbidity” as well as particular areas such as “Quality and Safety Indicators” and “Functioning and Disability”, which cross-cut the whole classification; hence the name “horizontal TAGs”. Specific content areas have their own “vertical TAGs” which include: Internal Medicine, Pediatrics, Neoplasms, Injuries, Mental Health, Neurology, Dermatology, Ophthalmology, Genito-Urinary and Reproductive Medicine, Musculoskeletal Disorders, Oral Health, Rare Diseases, Environmental Health, Occupational Health, and others. A special group worked on the “health informatics and modeling” and another one on “software development”. There are 24 TAGs or working groups currently active since 2007 along with established guidelines and standard operating procedures to revise the ICD.

c. A Revision Steering Group (RSG) that includes the heads of the Topic Advisory Groups has been overseeing the revision work to assist the WHO Secretariat in coordinating the overall revision process. This group meets by monthly web meetings and has met face-to-face at least once per year between 2007 and 2012. As this group has now more than 34 members, a Small Executive Group (RSG-SEG) has been formed by 6 members that meets on weekly
basis since 2010 and has produced 19 Information Notes on key issues to the revision process. An additional 9 Information Notes are on their agenda to sort out the emerging issues. The RSG and RSG-SEG discuss and resolve problems reported by the TAGs and others.

d. The work of the ICD Revision Process is continuously shared with the WHO FIC Network, which includes WHO Collaborating Centers for WHOFIC, some international Non-Governmental Organizations and some Academic Research Centers. Initially formed by 7 WHO Collaborating Center Heads in 1972, this network has grown since 1998 to some 40 formal member institutions and entities. The WHO FIC Network advises WHO of the key technical issues in the area of Classifications. As this network, however, does not fully cover all WHO Member States, and as the revision process requires a larger effort than the network capacity, the Revision Process has been defined purposefully outside the WHO FIC Network's Mandate. The Revision process in the final instance will be submitted to the WHO Governing Bodies for formal approval. It is foreseen that when the Revision Process is completed, the future ICD updates and maintenance tasks will be undertaken by the WHO FIC Network’s Update and Revision Committee (URC) again. Moreover, Mortality and Morbidity Topic Advisory Groups have at least their 50% of their membership from the Network. The WHO Collaborating Centers have also actively participated in the revision process by incorporating their national modifications, reviewing the ICD drafts and making suggestions. Currently, they continue to participate in the review process and may also take part in the field trials or coordinate them in their respective countries.

e. As ICD has multiple uses and users, extensive consultations have been made with a larger constituency of stakeholders. These include several medical organizations and specialty groups, health information management organizations (e.g. IFHIMA and AHIMA), the insurance sector, the labor sector (ILO), and the informatics sector including other standards development organizations (such as IHTSDO, HL7 and ISO). WHO has developed formal links with IARC (International Agency for Research on Cancer) and other international and national groups supporting the development, review and testing of the new ICD classification. In particular, further to the discussions in the WHO Executive Board in 2005 and 2006, WHO has established a Collaborative Arrangement with the International Health Terminology Standards Development Organization (IHTSDO) to avoid redundancy and align ICD and Standardized Nomenclature of Medicine (SNOMED) by an official agreement reached in 2009. Since then, SNOMED to ICD-10 maps have been produced and more detailed binding of SNOMED to ICD-11 has been developed. When ICD and SNOMED are used jointly, it is envisaged that the coding of electronic health information into ICD will lead to wider applications that are more efficient and cost-effective.

f. In addition, the ICD Internet platform has a large outreach to networks of different groups which serves as a “social computing” organization. ICD Web Pages have currently 2.5 million visits per month with 10 million average page views. Approximately 500,000 sessions/month are estimated to be directly related to the ICD revision. The ICD Internet Platform also includes discussion forums and social media links with groups in Linked-in, Facebook and Twitter, which in the coming years will have more participation in terms of testing and reviewing the classification.
2. ICD Revision Process: Progress and Current Status

Since the start of the revision process in 2007, ICD has been significantly re-engineered to continue to serve multiple purposes as the international scientific standard to classify diseases and other related health problems. This work has been carried out in multiple phases:

a) Alpha phase: An early “alpha” draft of ICD was developed within a closed group of experts and WHO circles including WHO Collaborating Centers and invited advisors which amounted to around 1200 international experts. This was a significant planning and development phase where the architectural and modeling alternatives were discussed, implemented and agreed.

b) Beta Phase: Alpha draft evolved to a “relatively stable” yet unfinished ICD Beta draft which was presented to the “public” allowing interested parties to review, comment, make proposals and test according to the established protocols. This phase is presented with caveats that the ICD Beta Draft is not final, is not yet an approved standard by WHO, and is under continuous development. Measures to avoid potential conflicts-of-interest and to maintain the intellectual property rights of ICD are also put in place.

c) Finalization and Maintenance Phase: Once the Beta phase results in more stable ICD, it will be submitted to WHO Governing Bodies for adoption. It is envisaged that the current revision process is adopted for the continued day-to-day maintenance and updates to the ICD in the forthcoming decade after the completion of the revision process. In this direction, a transition strategy is being developed for both WHO to synchronize and harmonize the current update process of ICD-10 and the future maintenance of ICD-11. (See Section B2 Future Maintenance Strategy)

The main accomplishments of the ICD Revision Process (2007-2013) to date have been:

**ALPHA PHASE:**

a. Building on the ICD-10 content and structure, additional improvements in the ICD national modifications have been incorporated as well as changes that could not be carried out by the classical ICD-10 update process have been included.

b. Scientific advances in the health sciences have been systematically searched and incorporated under the expertise of various Topic Advisory Groups.

c. A robust computerized system for ICD has been developed using contemporary health informatics standards. This system has a “foundation component” which includes all ICD entries and allows selection of subsets as “linearizations” which are tabular lists for different purposes: such as mortality; morbidity; primary care; and specialty care. ICD informatics infrastructure also links to standard terminologies in a systematic way.
d. Internet based digital editing capability has made it possible that experts **collaboratively author** the ICD on a continuous basis in a more effective way. Similarly, this infrastructure enables conducting (i) reviews, (ii) translations, (iii) field trials and (iv) making new proposals using the same internet platform.

**BETA PHASE:**

At this point in time, **1 January 2014**, an ICD Beta 2014 Version has been produced for review purposes and field trials after 6 years of drafting phases. The current ICD 2014 Beta version has a set of relatively stable **code sets** (i.e. linearizations) for at different uses. The following table summarizes different linearization examples that are part of ICD11 production:

<table>
<thead>
<tr>
<th>Level</th>
<th>Name</th>
<th>Use Case</th>
<th>Size</th>
<th>Pre –Post Coordination</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SHORT Linearization</td>
<td>• Verbal Autopsy</td>
<td>100-200 categories</td>
<td>Pre-coordinated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• <strong>Primary Care</strong> – Low Resource</td>
<td>700-1500 categories</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Intermediate</td>
<td>• Mortality Tabulations</td>
<td>2000 Categories</td>
<td>Pre-coordinated</td>
</tr>
<tr>
<td></td>
<td>Linearization</td>
<td>• <strong>Primary Care</strong> – High Resource</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Common Linearization</td>
<td>• Joint Linearization for Mortality and Morbidity Statistics Volume I tabulation</td>
<td>15,000 Categories</td>
<td>Pre-coordinated</td>
</tr>
<tr>
<td>4</td>
<td>Extension</td>
<td>• Specialty Linearizations</td>
<td>&gt; 15,000 Categories</td>
<td>Pre + Post Coordinated</td>
</tr>
<tr>
<td></td>
<td>Linearizations</td>
<td>• National Linearizations</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The **Foundation Component** is the largest set of **ALL** categories that may then take place in any given ICD Linearization. All ICD items are catalogued in a systematic fashion in the Foundation Component using modern health information technology.

**Linearizations** are lists of selected ICD categories for a **purpose**; hence they may be of different size and granularity which are fit for that particular purpose. For example a primary care provider may need to use broad categories of illness such as “upper respiratory tract infection” whereas a specialist may need to use “tonsillitis due to a specific agent”. One of the key purposes of ICD11 architecture is to make these two categories to be linked in a meaningful way- with a proper grouping logic between different linearizations. Formerly in ICD10 such linkage was made in a limited way (by truncation of codes or creating equivalence tables). In ICD11 these corresponding concepts in different linearizations are designed to be linked (a) through the exact matching in the foundation component; (b) through the “telescoping principle”: that at each level of the granularity of the categories increases and they are represented as “children” of the same family “parents”. In this way, it is possible to link the children to their relevant parents or grandparents.

In this way it is possible to link the similar concept with additional detail between the different linearizations within certain bounds of certainty for common reporting purposes; as in the example shown below:

**LEVEL 1:** Myocardial Infarction  **(Verbal Autopsy, Primary Care – for low resource settings)**
It is essential that in a particular linearization all selected items have to be **mutually exclusive** and **jointly exhaustive** for statistical purposes to avoid double-counting. Selecting ICD categories for a given linearization conforms to this principle and generates residual categories and groupings accordingly. Given the digital nature of ICD it is possible to have one category represented in two or more places in the ICD classification – but with **one single primary code**. This feature is called “multiple parenting”. For example, Malignant Melanoma is both a neoplasm and a skin disease. It can be represented in both Neoplasms chapter and Skin Diseases but with the primary code in neoplasms.

Given the four different levels of the ICD, it is possible to organize these levels in two different ways:

1. **Unnested model**: An entity is directly drawn from the foundation component and used for the particular purpose. The correspondence between the different layers is then built through the foundation component. (figure 1)

2. **Nested model**: An entity at one level covers all the children at the lower level. In the nested model the levels have a hierarchical structure and correspondence is built through the hierarchy. (figure 2).
B. ICD Revision Beta Phase 2013-2017:

The former ICD Revision Process timeline foresaw the ICD submission to the WHA in 2015; however, following various consultations with the WHO Member States and relevant international stakeholders, it was decided to postpone the final ICD submission to WHA to 2017 May. Underlying this decision the following factors were taken into account:

a. the developmental stage of ICD 2013 Beta

b. allowing for reasonable time to complete the remaining tasks:
   1. Reviews
   2. Additional Proposals
   3. Field Trials
   4. Translations
   5. Transition Preparations.

A more detailed explanation of remaining tasks and time requirements is shown in table 1. In terms of basic tasks:

a. The Developmental stage of ICD 2013 Beta – WHO Secretariat has developed the first draft ICD 2013 Beta to be reviewed by Mortality and Morbidity TAGs and scientific peers. A consultation meeting has been set in December 9-13 2013 to identify the remaining issues with the Common Linearization for mortality and morbidity purposes. From this point on, the classification linearization is expected to be relatively stable and will be in a graceful evolution by incorporating the results of the review. Depending on the results of the review, necessary changes will be incorporated into the ICD with appropriate version control mechanisms. The ICD Beta will be then presented in the WHO Internet site incorporating several measures for continuous quality improvement such as: incorporation of new proposals, checking internal consistency, and others.

b. The remaining tasks:

1. Review process: An international scientific peer review process has been designed where certain sections and aspects of ICD will be reviewed by designated experts. WHO assigned Topic Advisory Groups will act as “Editorial Boards” to evaluate the results of the review. The review process will consist of the following steps:
   a. INITIAL REVIEW:
      i. Linearization Review for Mortality and Morbidity
      ii. Content Review for specific chapters

   b. ONGOING and FINAL REVIEW
      i. Review of incoming proposals and additional changes
      ii. Review of Final ICD before it is released for official use

It is expected that each round of review take at least 4 months to complete depending on the size of the review unit and responsiveness of the selected reviewers.
The review must be repeated when changes are made and before the final ICD product is submitted to the World Health Assembly.

The reviews are made by voluntary contribution of reviewers and they are conducted remotely through e-mail and therefore may last longer than estimated.

WHO Secretariat will bring the key parties (i.e. Mortality and Morbidity TAGs together to discuss the results of the review and agree on the final Common Linearization).

2. **Public Proposals** – WHO has made an internet platform where registered users can make proposals for adding new categories to the ICD as well as other comments and suggestions for naming, inclusions and other references. These proposals will also be evaluated through the review process above in systematic fashion. It is expected that many additional comments and proposals will be coming in from the interested parties, which are useful to indicate the problematic areas, missing elements and alternative formulations. These additional proposals will be subjected to the peer review process and may take a period of 6 months to complete and integrate into the ICD.

3. **Field Trials** – WHO has designed certain field trials to test the (i) **applicability** (ii) **reliability** (iii) **utility** of the ICD in the hands of the actual users. These standard protocols are to be carried out by a large number of users and provide feedback on the finalization process. A set of standard field trial protocols are currently being pilot tested in a number of collaborating centers. These field trial protocols proved to be applicable and in three different countries. A wider scale implementation across different countries and setting may take 24 to 36 months. By the 2015 deadline, some Field Trials such as testing the bridge-coding between ICD-10 and 11 for mortality and morbidity coding may be complete. Non-English speaking countries may, however, have a time disadvantage to fit in the timeline. It is requested to give more time to non-English speaking countries to allow for more field trial results in 2015 and 2016. Noting that the resources available for field trials to WHO is limited for the development of protocols and central data analysis, implementation of field tests in different countries would require additional funding from local participants. Consideration has to be given to make continuous incorporation of field trials results in the overall ICD revision later during the maintenance phase in line with proper quality improvement principles.

4. **Translations**: WHO has created a computerized translation platform, which makes use of the existing ICD translations of ICD to enable timely availability of the revised ICD in **multiple languages**. Priority is given to WHO official languages (Arabic, Chinese, English, French, Russian, and Spanish with German and Portuguese as WHO Regional Office languages). Countries who wish to participate in ICD translations on their own resources will be encouraged to do so. Currently, Italy, Korea, and Japan have started this process. With the Internet based ICD tools, ICD translations could benefit from the previous translations of ICD-10 and could be shared between multiple translators. It is estimated that translation of ICD-11 with definitions may take 12 months for a language depending on the dedicated translators. Additional resources may be useful to expedite this process.
5. **Finalization of ICD-11** (Linearization, Reference Guide and Index): Use of ICD requires “instructions” which are organized as a knowledgebase of rules, explanations, examples, instructions and other guidance. A Reference Guide is provided as both an online tool and a printed volume. ICD use requires an “index” which matches medical phrases to codes. An index has been produced both as a print and digital tool. Additional materials and documentation (e.g. transition tables) will be produced in course to assist training and implementation of ICD and assist countries in transition to ICD. Once field trials results are incorporated and the results of reviews are obtained, it is planned that production of combined Mortality and Morbidity Linearization with the Reference Guide and Index would require 6 months to present to the World Health Assembly for approval. Currently the ICD Revision Process includes “stability analyses” that constantly track changes to the ICD-10 categories. These will be presented as “cross-tabulations” to allow transition in mortality and morbidity statistics. Finalization of the stability analyses work will be concluded when the final instance of ICD 11 is produced to guide the transition from ICD-10 to ICD-11 including appropriate software, documentation and training materials.

In Summary these multiple streams of work will continue as parallel processes with a complex integration challenges. Co-ordination of work and communication of the issues identified will present an immense challenge in terms of carrying out the resulting edits from proposals, field trials and appropriate consultations with expert groups.

The section 2 includes the detailed steps for the completion of ICD Revision Process:

1. Generating multiple ICD Linearizations & initial review of TAGs
2. Conducting external peer reviews
3. Developing the Reference Guide (Volume 2)
4. Developing the ICD Index (Volume 3)
5. ICD Beta Proposal Mechanisms
6. ICD Beta Field Trials
7. Producing ICD in Multiple Languages
8. Transition Preparations
9. Submitting the ICD to WHO Governing Bodies
10. Maintenance and continuous update of ICD after approval
11. Computerization and Software Development Tasks
12. Communication and Information Dissemination
2. ICD Revision Process: Future Maintenance Strategy:

The ICD revision process has provided useful infrastructure, mechanisms and operating procedures for the development and maintenance of the new ICD. In view of this experience, it is proposed that the revision infrastructure is adopted for the continued day-to-day maintenance and update of the ICD in the forthcoming decade after the completion of the revision process.

The current model “one foundation – multiple compatible linearizations for different uses” enhances the comparability of ICD related codings in different settings; allows flexibility to capture more detail when needed in a disciplined structure. Similarly its implementation in the iCAT platform with universal identifiers (i) provide well-structured formal links to other classifications and terminologies; and (ii) controlled editorial system including systematic peer review. After finalization, the ICD Revision mechanisms for “new proposals” and “review” may continue to serve as the basic maintenance and continuous update process. If agreed, this will replace the current “ICD-10 Update mechanism”.

In this new maintenance scheme, it is envisaged that the update proposals may come throughout the year and will be handled immediately according to a standard operating procedure. A review will be finalized by October of each year and submitted to the WHOFIC Council and a new linearization for the next year will be approved for use in the upcoming year. In this way, ICD will be named as ICD 2015, ICD 2016, ICD 2017 and so on. This mechanism will facilitate the version control with constant updates through graceful evolution ensuring stability and backward compatibility. WHO may continue to support ICD-10 Updates in a similar way for a defined period until most Member States adopt the new style. Countries who may need more frequent update cycles (e.g. twice per year) may also use the same mechanism.
Section 2:

ICD Revision Process:

Tasks for Beta Phase and Finalization 2013-2017

TASK 1: Generating multiple ICD Linearizations & initial review of horizontal TAGs
TASK 2: Conducting external peer reviews
TASK 3: Developing the Reference Guide (Volume 2)
TASK 4: Developing the ICD Index (Volume 3)
TASK 5: ICD Beta Proposal Mechanisms
TASK 6: ICD Beta Field Trials
TASK 7: Producing ICD in Multiple Languages
TASK 8: Transition Preparations
TASK 9: Submitting the ICD to WHO Governing Bodies
TASK 10: Maintenance and continuous update of ICD after approval
TASK 11: Computerization and Software Development Tasks
TASK 12: Communication and Information Dissemination
TASK 1: Generating multiple ICD Linearizations & initial review of TAGs

1. Joint Linearization for Mortality and Morbidity Statistics (volume I)

1.1. Generation and initial TAG Reviews

1.1.1. Mortality TAG review
1.1.2. Morbidity TAG review

1.1.2.1. Review meeting (9-13 December: identify issues; ... solutions)
1.1.2.2. Phase I:
   1.1.2.2.1. Start the Stability Review
   1.1.2.2.2. Multiple Parenting
   1.1.2.2.3. Duplicates
   1.1.2.2.4. Spelling
   1.1.2.2.5.
1.1.2.3. Phase II: Continued review for emerging issues

1.1.3. Quality & Safety TAG Review

1.1.4. Functioning TAG Review

1.1.5. Vertical TAG reviews

1.1.5.1. Dermatology
1.1.5.2. < ... List all >

1.1.6. Additional Reviews

1.1.6.1. Non-TAG covered areas (Infections, ENT, R, Z)
1.1.6.2. Definitions (quality for all stem codes)
1.1.6.3. Terminology – SNOMED (link to common ontology work with IHTSDO)
1.1.6.4. Taxonomy (check all groupings; parentchild relations; residuals ...)
1.1.6.5. Content Model components (signs, lab, genomics, other...)
1.1.6.6. Other


2.1. Australian Modification
2.2. Canadian Adaptation
2.3. USA Clinical Modification
2.4. German Modification
2.5. Other National Modifications
   For each item above
2.5.1. Review by National Modification Owners
2.5.2. Possible Test for bridge-coding
2.5.3. Possible test for DRG/Case-mix simulation
2.5.4.
3. **Specialty Linearizations**
   3.1. Dermatology
   3.2. Ophthalmology
   3.3. Mental Health
   3.4. Neurology
   3.5. Oncology
   3.6. Rare Diseases
   3.7. Musculoskeletal
   3.8. Pediatrics (Children & Youth)
   3.9. .... <verify all and inquire others>
   3.10. Combined Specialty Linearization

4. **Primary Care Linearizations**
   4.1. PC - High Resource Settings
   4.2. PC - Low resource settings
      4.2.1. Generation
      4.2.2. Review (Sweden, Thailand, South Africa, WONCA ...)
      4.2.3. Grouping check

5. **Verbal Autopsy Linearization**
   5.1. Generation
   5.2. Check compatibility with Grouping with 4.1/4.2 Level grouping (aggregation)
   5.3. Review

6. **Research Linearizations**
   6.1. Identification of possible research linearizations
      6.1.1. Oncology
      6.1.2. RDoC (mental health)
      6.1.3. Other

7. **Implement changes in linearizations in iCAT and Browsers**
   7.1. Evaluate results of the TAG reviews
   7.2. Identify issues (e.g. conflicts) – discuss with RSG-SEG; propose solutions
   7.3. Implement results in iCAT and Browsers

8. **Proposals for review questions and field tests**
**TASK 2: Conducting external peer reviews**

1. **Initial Reviews**
   a. Identify reviewers
   b. Review units
   c. Additional Review Questions
   d. Guidance for peer reviewers
   e. Conduct initial reviews
   f. Compile and evaluate results in consultation with TAGs and RSG
   g. Incorporate results in the iCAT

2. **Final Reviews** (only changes – and integrity of linearizations will be reviewed)
   a. Identify reviewers
   b. Review units
   c. Key review Questions
   d. Guidance for peer reviewers
   e. Conduct final reviews
   f. Compile and evaluate results in consultation with TAGs and RSG
   g. Incorporate results in the iCAT
**TASK 3: Developing the Reference Guide (Volume 2)**

1. Reference Guide outline
2. Knowledgebase software
3. Populate the Knowledgebase
4. Print draft Reference Guide
5. Reference Guide Review
6. Further Editing, Updates and finalization of Reference Guide
TASK 4: Developing the ICD Index (Volume 3)

1. Digital Index for ICD 11 Beta
   1.1. Testing coverage against ICD10 index
   1.2. Possible off-line application

2. Print index for the ICD Beta

3. Field testing of ICD Beta index
   3.1. Comparison print versus digital index use
**TASK 5: ICD Beta Proposal Mechanisms**

1. Start public proposal mechanism in the ICD Browser
   1.1. Prepare support material including user guide & workflow diagram
   1.2. Implement public proposal mechanism

2. Link proposal mechanism with review process
   2.1. New proposals if relevant should be submitted for review
**TASK 6: ICD Beta Field Trials**

1. **Pilot Phase:**
   1.1. Finalize Field Trials Pilot Phase material for core studies
      1.1.1. Feasibility & Reliability
      1.1.2. Bridge coding
      1.1.3. Basic Questions
   1.2. Develop FT Data Entry Program
   1.3. Develop FT Analysis Plan
   1.4. Ethics Clearance
      1.4.1. WHO IRT clearance
      1.4.2. National Clearances
   1.5. Coordinate the implementation of FT Pilot Phase in main stakeholder countries
   1.6. Coordinate data compilation & analysis of FT Pilot Phase
   1.7. Review and enhance FT protocols

2. **Main Phase:**
   2.1. Identify and designate FT Centers in Member States across all WHO Regions
   2.2. Update FT material for all core (mandatory) studies
   2.3. Coordinate the FT implementation of core studies
      2.3.1. Feasibility & Reliability,
      2.3.2. Bridge coding
      2.3.3. Basic Questions
   2.4. Coordinate FT data compilation & analysis

3. Implement results from FT
TASK 7: Producing ICD in Multiple Languages

1. Implement ICD-11 Multi-lingual Platform
2. Implement Quality Assurance Protocol
3. Coordinate translation process in WHO official and other languages
**TASK 8: Transition Preparations**

1. **Eliciting Transition Requirements in WHO Member States**

2. **Completion of Stability Analysis: production of correspondence tables**

3. **Application tools for the ICD**
   a. Coding tools
   b. Conversion tools

4. **Education tools**
   a. training platform

5. **Piloting Transition requirements**
**TASK 9: Submitting the ICD to WHO Governing Bodies**

1. Preparing the submission package
   a. ICD Volume I: Common Linearization; Tabulations,
   b. ICD Volume 2: Reference Guide
   c. ICD Volume 3: Printable Index
   d. Online Tools
   e. Background Documentation & Draft Resolution

2. Availability in six official WHO languages

3. Submission to Executive Board of WHO (January 2017)

4. Submission to World Health Assembly (May 2017)

5. Official Release of ICD
**TASK 10:** Maintenance and continuous update of ICD after approval

1. Maintenance platform for ICD

2. Update mechanism
   2.1. Use of iCAT for updates
   2.2. Transition of revision role from RSG to URC
**TASK 11: Computerization and Software Development Tasks**

1. iCAT Software maintenance and update
2. Browser maintenance and update
3. Translation Tool maintenance and update
4. Field Trials platform
5. URI services
TASK 12: Communication and Information Dissemination

1. WHO Web sites
2. Information Notes
3. Active information sharing with stakeholders
4. Evaluation of the communication strategy
ANNEX II: The Detailed List of Multiple Stakeholders to be contacted

1) WHO FIC Network Collaborating Center Representatives (*around 20 countries*)
2) UNSTAT, EUROSTAT and other statistical offices that use ICD data
3) European Commission DG/SANCO; DG/INFSO representatives
4) Ministry of Health ICD Users
5) Mortality Experts
   a. Mortality TAG representatives
   b. Verbal Autopsy Experts
   c. Other
6) Morbidity Experts
   a. Morbidity TAG representatives
   b. Case-mix providers/Users (Australia, US CMS, ...)
   c. Other
7) Quality and Safety Experts
   a. Quality and Safety TAG representatives
   b. Injury and External Cause representatives
8) Functioning and Disability Representatives
   a. Functioning TAG Representatives
   b. Disability Group representatives
   c. Other
9) NGO Representatives
   a. WMA World Medical Organization
   b. WONCA World Organization of Family Doctors
   c. IDF International Diabetes Foundation
   d. IFHIMA International Federation of Health Information Managers
   e. IASP International Association for Study of Pain
   f. IEA International Epidemiology Association
   g. IUAC International Union Against Cancer
   h. Other ...
10) Health Care Terminology and Classification Providers:
    a. IHTSDO
    b. IMIA
    c. NLM
    d. Bioportal

This list may also include others that the provider and/or the Expert Advisory Group may suggest.