

Report of ICD-11 Revision Review

14 April 2015

Consultancy Interim Assessment of 11th ICD Revision

January – March 2015

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Table of Contents

1. Executive summary	<u>1</u>
2. Recommendations	2
A. Timeline for implementation between March 2015 and December 2016.....	2
B. Communication, marketing, outreach, transparency	3
C. Planning	3
D. Project management	3
E. Governance	4
F. Education	4
G. Trust	4
3. Acknowledgements	4
4. Background	4
5. Introduction.	5
a. Objectives	5
b. Specific concerns	6
c. Complexity of use of ICD	6
d. Classifications and terminologies spectrum.....	8
e. Priorities for review	9
f. Method and timeframe.	10
6. Findings from Interim assessment	11
a. Process and mechanisms in place	11
b. General results of Questionnaire Survey	12
c. Progress towards goals of the Revisions.....	14
d. Relevance and effectiveness of WHO ICD Revision Process.....	20
i. Mortality	20
ii. Morbidity	22
iii. Primary Care	24
iv. Clinical Care	26
v. Scientific Research	28
vi. Updating from ICD-10.....	30
vii. Decisions on structure, content and rules.....	31
e. Project resources, financial and human.....	32
f. Communication and contribution to ICD-11 Revision	34
g. Decision making process	37
h. Project plans and timeline for completion of ICD-11 for 2017	40
i. Fitness for field trials	41
j. Implementation	44
k. Organization for maintenance and updates	47
l. Other comments.....	48
7. Assessment report.	50
a. Solid foundation for health information systems	50
8. Conclusion.....	52
Appendix 1. Specific concerns re ICD-11 Revision.....	A1
Appendix 2. Survey Questionnaire.....	A3
Appendix 3. Financial support for ICD-11 Revision Project	A11
Appendix 4. Topic Advisory Groups (TAGs)	A12
References	A13

Table of Figures

Figure 1: (Question 4) What is your role in the current ICD revision process?	13
Figure 2: (Question 5) What is your main use of ICD (past or present)?	14
Figure 3: (Question 6) Rate your knowledge and familiarity with ICD (0 none to 10 regular use),	14
Figure 4: (Question 7) To what extent do you think these objectives have been achieved so far for ICD-11?	15
Figure 5: (Question 7) What importance would you give to each of these objectives?.....	18
Figure 6: (Question 9) How would you rate the overall need for ICD-11?	19
Figure 7: (Question 10) Is the planned form of ICD-11 likely to meet requirements for use in MORTALITY statistics?	20
Figure 7a: (Question 10a) Do you expect that ICD-11 will be an improvement over ICD-10 for use in MORTALITY statistics?	20
Figure 8: (Question 11) Is the planned form of ICD-11 likely to meet requirements for use in MORBIDITY statistics?	22
Figure 8a: (Question 11a) Do you expect that ICD-11 will be an improvement over ICD-10 for use in MORBIDITY statistics?	22
Figure 9: (Question 12) Is the planned form of ICD-11 likely to meet requirements for use in PRIMARY CARE? ..	24
Figure 9a: (Question 12a) Do you expect that ICD-11 will be an improvement over ICD-10 for use in PRIMARY CARE?	24
Figure 10: (Question 13): Is the planned form of ICD-11 likely to meet requirements for use in CLINICAL CARE? 26	
Figure 10a: (Question 13a) Do you expect that ICD-11 will be an improvement over ICD-10 for use in CLINICAL CARE?	26
Figure 11: (Question 14) Is the planned form of ICD-11 likely to meet requirements for use in SCIENTIFIC RESEARCH?	28
Figure 11a: (Question 14a) Do you expect that ICD-11 will be an improvement over ICD-10 for use in SCIENTIFIC RESEARCH?	28
Figure 12: (Question 15) Has the revision process addressed problems with ICD-10 structure, content and rules that could not be addressed in the updating process?	30
Figure 13: (Question 16) With regards to making decisions about structure, content and rules for ICD-11, how effective do you consider the current decision-making process?	31
Figure 14: (Question 17) Do you think that adequate technical and financial support and resources have been provided to WHO to develop ICD-11?.....	32
Figure 15: (Question 18) Are there specific areas where you feel additional resources are needed by:.....	33
Figure 16: (Question 19) How easy have you found it to contribute to the ICD Revision Process?	34
Figure 17: (Question 20) Within the ICD Revision Process, is it easy to communicate with:	35
Figure 18: (Question 21) How useful have you found the information about ICD-11 posted on the WHO-FIC website?.....	36
Figure 19: (Question 22) Do you agree with the timeliness of decisions made about structure, content and format of ICD-11?.....	37
Figure 20: (Question 23) Do you agree with the transparency of decisions made about structure, content and format of ICD-11?	37
Figure 21: (Question 24) Do you feel you have had adequate guidance from WHO in carrying out your role in the revision process?	39
Figure 22: (Question 25) Do you think that the current project plan for completion of ICD-11 is realistic?	40
Figure 23: (Question 26) Do you think the ICD-11 release date of 2017 is achievable?	40
Figure 24: (Question 27) What do you think is the state of readiness of the whole of ICD-11 for Field Trials?	41
Figure 25: (Question 28) Do you or your country plan to participate in Field Trials of ICD-11?.....	43
Figure 26a: (Question 29a) Do you or your country expect to implement ICD-11 for MORTALITY?	44
Figure 26b: (Question 29b) Do you or your country expect to implement ICD-11 for MORBIDITY? (.....	44
Figure 26c: (Question 29c) If yes, do you expect it to be easier to implement than ICD-10?.....	44
Figure 27: (Question 30) What effect would it have on you if it were not released in 2017?	46
Figure 28: (Question 31) Do you think the organization of work for ongoing maintenance and updates is clear?	47

1. Executive summary

This project was initiated by the Director of the Department of Health Statistics and Information Systems at the World Health Organization (WHO) in 2014. It was prompted by concerns raised by member states and interested organisations about the ICD-11 Revision Process, especially those relating to mortality classification and statistical use of the classification. A small team of experts was invited to undertake the assessment. Our charge was to address the issues raised about preparation and release of ICD-11, by reaching out to a broad range of stakeholders, and to submit a report of findings and recommendations in time to provide feedback to those expressing concern and to influence the process and final product. The team included Rosemary Roberts (team leader), Marjorie Greenberg and Helene Richardsson.

Findings from a survey of stakeholders are detailed in this report. They are obviously perceptions based on personal experiences, and represent a range of positive and negative views. They reflect the concerns expressed earlier, but provide hope as well as creative suggestions for ways to solve some of the major issues.

While the infrastructure required to enable the ICD-11 Revision project is in place, there have been some delays due to the pioneering nature of the overall endeavour and the limited resources to achieve the visionary aims of many of its component goals. However, considerable progress has been made, and ICD-11 now appears achievable with tight project management and critical personnel resources for completing the Joint Linearization and reviewing the current product. Although the assessment concluded that the whole of ICD-11 is not yet ready for broad-scale field trials, the process should not be allowed to drag on interminably. It needs clear goals for 2017-2018 which are reachable and met. It also needs a staged process for achieving other key goals, including properly created and vetted primary care linearizations and building on the relationship with SNOMED-CT as well as other planned developments of ICD-11 and its maintenance.

The main issues now are project and resource management, communication with stakeholders and rebuilding of trust from the stakeholder community. All these have suffered due to pressure of time, an unclear governance model and inadequate communication as well as the enormous number of people, countries and aspects involved and the sheer complexity of the project. The decision making process needs to be clarified as well as plans for future funding of this project and lines of financial accountability.

The main recommendation from this Review is to finalise limited ICD-11 electronic and hard copy products consisting of the JLMMS with instructions and rules, Index, and Reference Guide and to have this available for report to the World Health Assembly and full field trials by 2017. To achieve this, there needs to be disciplined project management and strict reporting lines. We have recommended that urgent action be taken to employ a project manager and an additional classification expert at WHO CTS to help manage and carry out this work. Also, there should be oversight of progress by a JLMMS Steering Group,

constituted from members and invitees of the successful JLMMS informal meeting in Geneva in March 2015 plus, at a minimum, representatives from the Nordic and German Collaborating Centres but ideally with other Collaborating Centres involved. The idea of constituting this group when so many already exist is to act as a circuit breaker and build on the positive outcomes of the March 2015 meeting. Progress should be reported regularly within WHO, to existing management groups such as RSG SEG and to the ICD community, especially to the Network of WHO-FIC Collaborating Centres.

In short, the vision that inspired many of us at the beginning of this project is gradually being realised. The investments have been enormous and the credible use of a classification icon is at stake. It should not be allowed to fall at the last hurdle.

2. Recommendations

A. Timeline for implementation between March 2015 and May 2018

- Given the major step forward at the JLMMS meeting in March 2015
- Given the importance of achieving finish date of 2017 so that:
 - ICD-11 content is not out of date by time of publication
 - Expectations of stakeholders are met
 - There is a deliverable to provide to donors who have invested in revision process
- Given that most respondents to the Review survey believe that 2017 is not achievable at present rate of progress and ICD-11 is not yet ready for release for Field Trials

There are several steps that must be taken **now** to make possible an ICD-11 in 2017.

1. **Limit goals for 2017** to JLMMS. Make clear to stakeholders what product will be released in 2017 – JLMMS with instructions and rules, Coding Tool and Index, Reference Guide.
2. **Develop a JLMMS Steering Group** based on the Informal Workshop on JLMMS (Geneva, March 2015) with the addition of representatives from, at a minimum, Nordic and German WHO-FIC Collaborating Centres. Charge this group with oversight of this timeline.
3. **Employ at least two more staff at CTS (urgent!)**
 - a. **Project Manager.** Responsible to CTS coordinator and to the Director of the Department of Health Statistics and Information Systems and reporting also to the JLMMS Steering Group on progress
 - b. **Classification Expert**
 - c. Clarify roles of CTS staff, especially communication and marketing
4. **March, April 2015.**
 - a. Make changes to classification from JLMMS March meeting and work on instructions, rules and revision of Reference Guide
 - b. Disseminate this assessment report

5. **May 2015.** Release frozen version for review across the classification by MTAG and MbTAG to feed into review and endorsement by JLMMS Steering Group.
 6. **June, July 2015.** Incorporate changes from this review
 7. **August 2015.** Release another frozen version for peer review and limited field trials for morbidity and mortality with end date of **December 2015.**
 8. Incorporate changes
 9. **October 2015.** Report to WHO-FIC Annual Meeting on status of this report and its recommendations.
 10. **May 2016.** Release frozen version for review by JLMMS Steering Group
 11. **June, July 2016.** Incorporate changes as a result of this review
 12. **August 2016.** Print and prepare electronic products – Tabular List (JLMMS), Index in hard copy and as electronic Coding Tool and Reference Guide
 13. **October 2016.** Table ICD-11 at Revision Conference to be held in conjunction with WHO-FIC Network and IFHIMA meetings in Tokyo and with strong participation from members of the RSG SEG and the RSG.
 14. **December 2016.**
 - a. Release ICD-11 to WHA Executive Board for report to WHA
 - b. In report to WHA, include recommendation for ongoing development and maintenance of ICD-11
 15. **January – June 2017** ICD-11 Field Trials.
 16. **May 2017.** Report to WHA re ICD-11.
 17. **October 2017.** Second Revision Conference in conjunction with WHO-FIC Annual Meeting and with strong participation from members of the RSG SEG and RSG.
 18. **December 2017.** Release for WHA Executive Board
 19. **May 2018** WHA for adoption of ICD-11
- B. Communication, marketing, outreach, transparency**
- i. Improve communication internally and with external stakeholders to make processes more visible
 - ii. Prepare monthly or bimonthly newsletter or bulletin to stakeholders for update on progress and to provide formal ongoing information regarding process
 - iii. Ensure greater transparency in decision making and use of resources
- C. Planning**
- i. Plan future roadmap for other linearizations and completing Foundation Component
 - ii. Plan ICD-11 updating process and communicate with stakeholders (WHOFIC and member states).
- D. Project Management**
- i. **Implement and oversee timeline for implementation**
 - ii. **Prepare business plan for ICD-11** including licence fees or other revenue development and sale of hard copy. Seek additional resources
 - iii. **Address issues with IHTSDO** (re SNOMED CT in Foundation Component and joint updating between IHTSDO and WHO)

- iv. **Address issues with WONCA** (re Primary Care Linearizations to meet their needs and role of ICPC)
- v. **Address issues with WHO-FIC Network** and the role of its members in ICD-11 release and update

E. Governance

- i. **Clarify the responsibility for decision making in the Revision process, including the JLMMS Steering Group**
- ii. **Clarify roles of RSG, CTS, WHO-FIC regarding responsibilities**
- iii. **Build on goodwill and hard work of stakeholders** around the world and the reputation of WHO and ICD

F. Education during and after Field Trials through WHO-FIC and member states

G. Trust. Work on gaining trust of ICD community internally and externally through communication and involvement as well as providing evidence that this report is being acted upon and recommendations implemented.

3. Acknowledgements

The authors wish to acknowledge the readiness of stakeholders to respond to questions and surveys fundamental to this review. Their generosity in devoting time and thought to responses is greatly appreciated. We also wish to thank Dr Bedirhan Üstün and the staff of Classification, Terminology and Standards as well as other staff at WHO Headquarters for their assistance. Dr Norman Sartorius was a team member until early March and we thank him for his most helpful contribution to this review. Special thanks are due to Dr Richard Madden, Director and Vera Dimitropoulos, Executive Manager Classification Development, of the National Centre for Classification in Health (NCCCH) at the University of Sydney, for their support and especially to Imelda Noti at NCCCH for her technical and administrative help with the electronic survey and with access to background papers.

4. Background

Revising the International Classification of Diseases is a balancing act between conservatism and innovation. While it is necessary to update the classification content to reflect clinical knowledge and practice, it is also important that there be comparability between data collected in successive revisions and an understanding of how changes in the classification affect data trends. Particularly for this 11th Revision, the environment in which it is being prepared is completely different from that of the 10th revision in the 1980s. For mortality, multiple cause of death coding software has been updated and expanded and promotes consistent application of underlying cause of death rules. For morbidity, as well as allowing data collection for reporting disease trends and hospital utilisation, the codes are being increasingly used for casemix and reimbursement purposes. Technology and data handling tools are dramatically different, as are the expectations of users to extract data from electronic health records.

A balance must also be struck between the use of hard copy and electronic versions of the classification. While there is an electronic base to the classification, WHO is bound to produce both hard copy and electronic products to serve needs of users. This means that some of the rules incorporated into coding software products must be visible in the print copy as well, affecting the content of the Tabular List, Reference Guide and Index and consistency with electronic coding tools.

The WHO vision for ICD-11 is to have at its base a Foundation Component of clinical terms which can be expressed (linearized) in different ways according to expected use. These linearizations are traditionally known as the Tabular List, which contains the codes assigned for diseases or causes of death. The dominant linearization for ICD-11 is the Joint Linearization for Mortality and Morbidity Statistics (JLMMS), but others such as those for Primary Care, Quality and Safety and special clinical groups are proposed or are already in draft form.

Components of the classification are held in authoring software called iCAT which allows electronic updating, tracks changes in the classification and justifies reasons for the change. The classification can be prepared from the iCAT and Browser together for electronic and hard copy classifications, coding rules and indexes to ensure access to the classification and reliable clinical coding from patient health records and death certificates.

Another significant environmental change is the use in several countries around the world of clinical modifications of ICD-10. Countries responsible for such modifications have contributed their classifications and expertise to the Foundation Component of ICD-11 so that it can benefit from international experience. The contract between WHO and IHTSDO has allowed SNOMED-CT to be included in the Foundation Component, along with other classifications such as other members of the International Family of Health Classifications and specialty classifications such as ICPC-2.

Understanding this context of the ICD-11 Revision is vital to this review and our attempt to explain the complexity and length of the process compared with those revisions that have gone before. Our process of assembling a list of stakeholders made us aware of the thousands of clinical and technical experts involved to make this revision fit for purpose in this digital age.

5. Introduction

a. Objectives

This project was initiated by the Director of the Department of Health Statistics and Information Systems at the World Health Organization (WHO) in 2014. It was prompted by concerns raised by member states and interested organisations about the ICD-11 Revision Process, especially those relating to mortality classification and statistical use of the classification. A small team of experts was invited to undertake the assessment. Their charge

was to address the issues raised about preparation and release of ICD-11, by reaching out to a broad range of stakeholders, and to submit a report of their findings and recommendations in time to provide feedback to those expressing concern, and to influence the process and the final product.

The scope of work required by WHO was to carry out the following tasks:

- Conduct an interim assessment of the 11th Revision for International Classification of Diseases (ICD-11) in terms of
 - Progress towards the goals of the Revision
 - Process and mechanisms put in place for the ICD revision
 - Project resources (financial and human) in relation to the proposed outcomes of the revision
 - Project plans and proposed timeline for the completion of ICD-11 for 2017 (adoption by WHO governing bodies)
 - Organization for maintenance and updates of ICD beyond 2017
- 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:
 - Use in Mortality statistics – e.g. Cause of Death statistics, Verbal Autopsy, others...
 - Use in Morbidity statistics – e.g. Discharge summaries, Case-mix groupings, others...
 - Use in Primary Care – in low and intermediate resource settings...
 - Use in Clinical Care – for diagnosis, guidance, quality and safety indicators
 - Use in Scientific Research – for epidemiology, genetic studies and other
- Compile an assessment report summarizing the findings and making recommendations for improvement. This will include recommendations towards making the future ICD:
 - Fit for multiple purposes;
 - Easier to implement in real life situations; and
 - Serve as a solid foundation for health information systems

b. Specific concerns

Specific expressions of concern provided to the Assessment Team at the beginning of the project are shown in **Appendix 1**.

c. Complexity of use of ICD classification

The objectives of the ICD Revision Process have been agreed:

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

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

These objectives reflect the complexity of the revision process and the many masters which the ICD must serve. Historically, it has been viewed as a statistical classification, but with the enhanced focus on clinical use and addition of the third objective relating to electronic health applications and the inclusion of standard terminologies, the demands on the revision process have intensified. Further complications in its usage for morbidity reporting have been introduced with the use of ICD coded data for casemix classification and reimbursement through governments and insurers.

ICD-10 was adopted in 1990 by the 43rd World Health Assembly to come into effect on 1 January 1993 (delayed until publication of the alphabetic index in 1994). It endorsed the recommendation of the International Conference for the Tenth Revision of the ICD to:

- introduce the concept and implementation of the family of disease and health-related classifications with ICD as its core and
- establish an updating process within the ten-year revision cycle

ICD-10 was released in stages, first the Tabular List (1992) and Reference Guide (1993), then the Index (1994). ICD-10 has been implemented at varying intervals from country to country since 1994, with some countries implementing at different times for mortality and morbidity reporting. Of 194 member states, 50 countries are currently using ICD-10. Clinical modifications of ICD-10 have been developed by Australia (ICD-10-AM), Canada (ICD-10-CA), Germany (ICD-10-GM), Thailand and the United States (ICD-10-CM). ICD-10-CM has not yet been introduced, although the United States has been using ICD-10 for cause of death reporting since 1999.

Automated multiple cause of death coding software using WHO decision rules and the MMDS (Mortality Medical Data System) decision tables to select underlying cause has been painstakingly developed by the National Center for Health Statistics (NCHS) in the USA incorporating ACME (Automated Classification of Medical Entities) (1968), MICAR (Mortality Medical Indexing, Classification, and Retrieval (1990)) and SuperMICAR. Iris, an interactive language independent computer based system for coding multiple causes of death, and selecting underlying cause of death, was later developed by several countries in Europe and the United States using MMDS software and integrated with the WHO ICD-10 update process. The Iris Group is now hosted by DIMDI (German Institute of Medical Documentation and Information). Many European countries are using Iris and the UK, Canada, Australia and the USA have recently implemented or are in the process of doing so. These automated systems have revolutionised the reliability of mortality coding and the comparability of mortality data at an international level.

The recommendation to update ICD-10 within the ten year revision cycle became the responsibility of the Network of Collaborating Centres for the WHO Family of International Classifications (WHO-FIC) in conjunction with WHO. The Collaborating Centres in the

WHO-FIC Network play a critical role in maintenance, updating, promotion, and implementation of ICD as well as education of clinical coders and users. The updating process was put into effect in 1996 by the WHO-FIC network at its meeting in Tokyo. The formal updating mechanism required minor updates each year and major updates every three years. Input to this process was through the WHO-FIC Update Reference (later Update and Revision) Committee which included representatives of ICD-10 creators and users of mortality and morbidity data internationally. This Committee works closely with the WHO-FIC Mortality Reference and Morbidity Reference Groups to resolve issues and release updates in a predictable and usable fashion. Ability of countries to implement updates was affected in part by whether they were using electronic systems for automatic multiple cause of death coding mentioned previously and hence holding the classification itself in an electronic environment that could be updated and disseminated to users. Another constraint was the ability to translate the updates if not used in the English version. In all cases, education systems were required to inform coders and users of the changes and to amend rules for their application. A hard copy of ICD-10 Second Edition was published in 2004 with subsequent updated editions in 2008 and 2010.

Although ICD-11 would have been due in 2000 if the decennial timetable had been followed, it was delayed for a number of reasons, including the implementation of the updating process for ICD-10 and to give more countries time to implement ICD-10 for mortality and morbidity reporting purposes. As pointed out above, plans were underway to produce second and subsequent editions of ICD-10 to maintain currency of its contents until the next revision.

Discussion regarding ICD-11 was raised at WHO-FIC meetings in Cologne in 2003ⁱ and Reykjavik in 2004ⁱⁱ and work on the 11th Revision of the ICD was launched officially in 2007 in Tokyo. Although the Update and Revision Committee was working well, some of the clinical issues raised could not be solved within the framework of ICD-10. It also had proved difficult to convene international clinical experts around topics in the absence of a formal revision process. The Morbidity and Mortality Reference Groups (MbRG and MRG) developed detailed information on the special clinical topics for revision that they had been unable to address as part of the updating process^{iii iv}. Further, following the agreement between WHO and the International Health Terminology Standards Development Organization (IHTSDO) in 2010, there was increasing pressure to formulate the next revision of ICD in conjunction with SNOMED CT. ICD-11 was initially due for release in 2015, but in 2013 this time line was extended until 2017. Some of the specific concerns and responses quoted in **Appendix 1** relate to the 2015 introduction but are also pertinent for a 2017 release.

d. Classifications and terminologies spectrum

While terminologies are regarded as input mechanisms using terms arising from the clinical care process^{v vi}, classifications are regarded as outputs, aggregating terms into meaningful classes for counting purposes.

The addition of the third objective of the revision process, that relating to linkages with computerized health information systems, terminologies and use in the electronic health

record environment, has put into sharp focus the differences and similarities between health classification systems and health terminologies. ICD has traditionally been regarded as a classification, arising as it does from the need to group, classify and report causes of death and hospitalization. But in its development over the centuries, it has acquired as a basis a rich underpinning of health terminology. These terms, whether they be part of the Tabular List and placed in a category of the classification, or part of the Index of terms, where they point to a particular class in the Tabular List, are organised in the sense of being part of the classification but not as they relate to each other in a hierarchical sense.

At the same time, there have been global advances in the development and uptake of clinical terminologies, related as they are to electronic health record applications as a common language from which a patient health record can be compiled.

WHO has recognised the need to bring together and relate these two ‘poles’ of the classification/terminology spectrum. In 2010 collaboration arrangements were negotiated between WHO and IHTSDO, which owns the intellectual property rights for the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) and that terminology has been included as a reference terminology in the Foundation Component of ICD-11. The collaboration has been designed to allow users of the terminology and classification respectively to use ICD and SNOMED CT together to derive the benefits of an input terminology and an output classification. The Collaboration Arrangement between WHO and IHTSDO is seen as the basis for an ongoing relationship and program of work^{vii}.

A new feature of the ICD-11 classification which promotes its use as a clinical tool is the addition of definitions for each rubric within the classification. According to WHO, these definitions have the potential for use as a guide to clinical decision making and diagnosis. They follow the use in previous revisions of definitions for chapters such as Mental Health and the added benefit found in the application of rules highlighting specific criteria for choice of codes in Clinical Modifications of ICD-10. This initiative in ICD-11 is highly relevant in chapters such as Mental Health, Substance Use, Dermatology, Ophthalmology and Traditional Medicine and for Quality and Safety use cases.

e. Priorities for review

One of the main priorities for the Review Team was to determine if the ICD-11 release date of 2017 is feasible. It was also important to examine the concerns expressed by stakeholders relating to the classification being ‘fit for purpose’ and sufficiently stable in comparison with ICD-10 to allow least impact on time series data especially for mortality reporting purposes. Concerns had also been expressed about the electronically derived index which was formatted without the built in rules for accessing codes which had been present in previous revisions. For the Review Team itself, our priority was to assist WHO in the development and delivery of the 11th Revision by undertaking this review according to the terms of reference and to reflect accurately the feedback from stakeholders who use ICD for clinical coding and data analysis.

High priority clinical issues had been raised by the Mortality and Morbidity Reference Groups (MRG and MbRG), many of whose members now constitute the Mortality and Morbidity TAGs (MTAG and MbTAG). Following the work of the vertical specialty TAGs and the agreement in December 2013 that there be a Joint Linearization for Mortality and Morbidity Statistics (JLMMS), an Informal Workshop on the ICD Revision Process was held in Geneva in March 2015 to examine remaining issues. This meeting reviewed 27 clinical topics that had presented problems for the clinical TAGs as well as other issues that crossed TAG boundaries such as the use of pre- and post- coordination of concepts, and invalid use of parent codes with children. Discussion between mortality and morbidity experts was positive and the result was a range of decisions to guide the further refinement of JLMMS in areas such as diabetes, anaemias, chronic kidney disease, pneumonia, dementia and post-operative complications, to name a few. Some of the principles agreed were applicable in other problematic areas of the classification.

Another significant aspect of this meeting was the presentation of an electronic Coding Tool developed by staff of CTS that would allow access to the classification from a source term via the Foundation Component. This Tool contained rules that allowed navigation from clinical terms to the codes in the Tabular List for decision on the correct code. During the meeting, the need for specific sanctioning rules in the Coding Tool as well as instructions in the JLMMS was also identified.

f. Method and time frame.

The Review project was initiated at the first meeting of the project team in Geneva from 7-9 January 2015. The required deliverables for the project were an interim report on February 27 and a final report on April 1 2015.

During that initial meeting, staff from Classification, Terminology and Standards (CTS) presented material relevant to the review and provided information in face to face meetings. Further documents were provided after the meeting as requested by team members.

The main tasks undertaken during the first meeting were:

1. Preparation of a project work plan
2. Development of a list of stakeholders
3. Drafting of a questionnaire to elicit views of stakeholders

Drafts of the stakeholder list and questionnaire were refined with CTS staff during the following week for dissemination to team members. Stakeholders came from the WHO-FIC Collaborating Centres, members of groups involved in ICD-11 development as well as NGOs and data users. Following feedback, the stakeholder list, contact emails and phone numbers and the questionnaire were finalised and redistributed to the team members. The questionnaire was trialled and with minor changes the interview process was commenced at the end of January 2015 with responsibility divided roughly according to team members' background, geographical location and proximity to the stakeholders. Some stakeholders were earmarked for face to face, Skype or telephone interview while others were asked to

complete the questionnaire. A total of 133 stakeholders were subsequently contacted for interview or for completion of the survey on line. Not all attempts were successful due to changes in contact details and committee membership. The final version of the questionnaire is at **Appendix 2**.

The National Centre for Classification in Health at the University of Sydney offered administrative assistance to the Team Leader, and reformatted the questionnaire into an eSurvey instrument to be placed on the web. The link to this site was circulated to some members of the stakeholder list who could not be interviewed to facilitate their completion of the questions. Subsequently, the face to face interview results were also entered to the eSurvey to allow analysis of results of all stakeholders together.

All those interviewed were very open and generous with their comments and time, and many expressed support for the External Review process.

The Review team leader was invited to attend the JLMMS Informal Meeting held in Geneva from 9-13 March 2015. The Review team met again for several days from 13-16 March and communicated by email and teleconference in preparation of this report.

6. Findings from interim assessment

This section contains three aspects of our findings. The first relates to the structures and processes established by the CTS team at WHO to ensure widespread participation of the most qualified personnel in the revision process. Secondly, there are the quantitative results of the survey questionnaire and thirdly the qualitative comments received from survey participants.

a. Process and mechanisms in place

Information about the following processes and tools has been assembled from meetings with Dr Üstün and the CTS team plus presentations and documents provided during the Review or obtained from the WHO website.

- **iCAT Authoring Tool.** In place and used. Its appropriateness for maintenance of the classification post release needs to be established.
- **ICD-11 Beta Browser.** In place and found extremely useful by many respondents.
- **Coding Tool.** Under construction at CTS but already useable to allow translation from clinical term to relevant code in JLMMS (110,000 index terms included as of March 2015).
- **ICD-11 Translation Platform.** Uses existing translations of ICD-10 to prepare for multilingual representation of ICD-11 content (tested with current Chinese version). Works through translation of Foundation Component so there is no need to translate linearizations separately.
- **Transition Requirement Study.** This work is in response to requests made by WHO-FIC Collaborating Centres.

- **Stability Analyses.** A crosswalk from ICD-10 to ICD-11 has been completed and identifies correspondences between ICD-10 and ICD-11 Foundation Component so that it can be used to map between linearizations and ICD-10. Work has also been done by Australia and Canada to map codes added to their clinical modifications of ICD-10.
- **Topic Advisory Groups (Appendix 4)** – vertical and horizontal. Vertical clinical TAGs have virtually completed their input to ICD-11. Horizontal TAGs, especially Morbidity and Mortality, have prepared material and worked with the informal JLMMS workshop to solve cross chapter issues. They still have important work to do in reviewing chapters across the classification for consistency of structure and depth and addition of instructions and rules. Updated information is needed on what groups are working on the revision process and who is participating in the different groups as well as the role of the participants.
- **Marketing and publicity.** CTS staff present frequently at international meetings on the progress of ICD-11 and material is posted to the WHO website. There was an early attempt to use the website as the contact for information with group participants and information notes and to have other IT tools (e.g. Redmine) to contain information. The problem was that these were not maintained or updated (often due to lack of staff) and many people were unaware that they existed. It is crucial that these problems be remedied. Information media such as the regular bulletins mentioned in the recommendations need to be intensified to reach the large audience for ICD-11 and to harness their support for the last phases of ICD-11 preparation before it is presented to the WHA. There have been some initiatives using Facebook and Twitter but these and other marketing activities should wait until accurate and up to date information is given to the different stakeholders.
- **Field Trial material.** CTS staff members have put a lot of effort into preparation for ICD-11 Field Trials. Different types of core studies and optional additional studies have been developed along with instruments and procedures to ascertain issues with ICD-11 or its implementation, to undertake bridge coding and studies of inter-coder reliability. Case summaries have been collated and a web-based data entry tool (ICD-FIT) developed in conjunction with the Italian Collaborating Centre. Preparations are ongoing.
- **Project budget.** See Appendix 3.

b. General results of Questionnaire Survey

Of the 133 stakeholders (individuals or groups) contacted, 87 responded and 81 completed questionnaires or were interviewed by members of the Review Team. The balance agreed to an informal interview or provided information to register their views but did not complete a survey. Respondents were from at least 20 countries, while many had multi-country or international responsibility. They held senior academic or practitioner positions as statisticians, clinicians, classification experts, health informaticians and managers in universities, scientific and government departments.

Figure 1 (Question 4. What is your role in the current ICD revision process?) shows the distribution of roles of respondents in the ICD-11 Revision process. Many held multiple positions, and you will see that the Topic Advisory Groups and WHO-FIC Collaborating Centres are well represented with particular emphasis on those who have a hands-on involvement in use of the ICD. The “other” category in this graph was populated mostly by educators.

Figure 1: (Question 4) What is your role in the current ICD revision process?

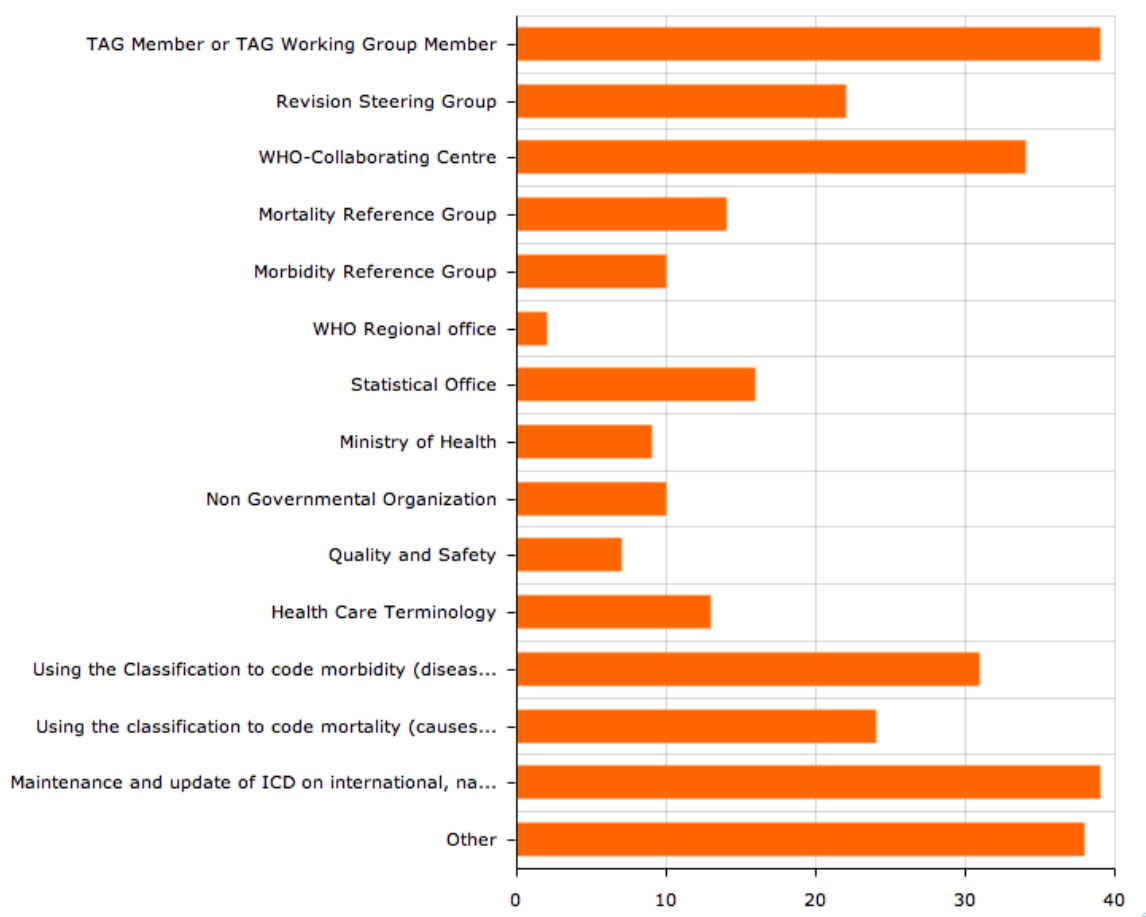
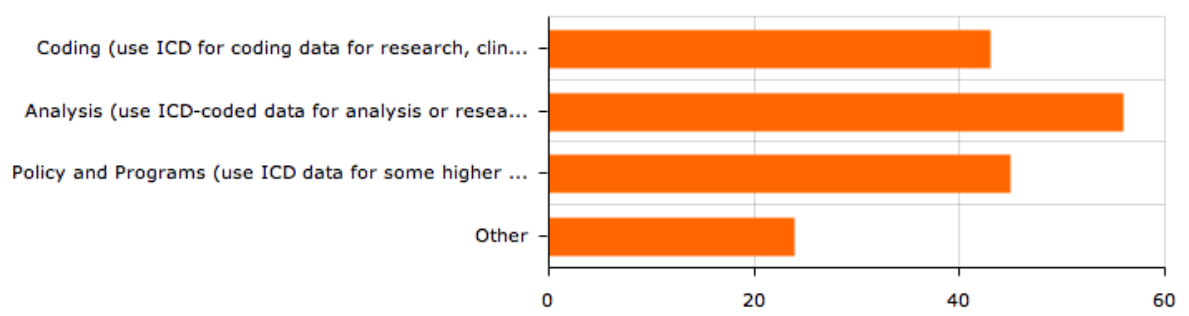


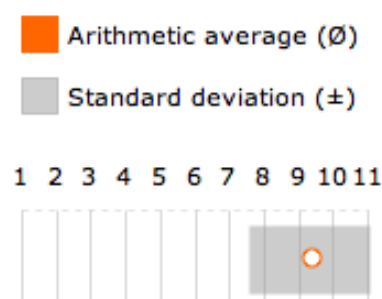
Figure 2 (Question 5. What is your main use of ICD (past or present)?) explains in more detail respondents' use of the ICD with 43 (55%) using it to match codes with clinical descriptions, 56 (72%) applying codes in analysis and research functions, 45 (58%) using codes or coded data for policy and program development and the other category again covering its use for multiple purposes, education, evaluation, mapping, data linkage, terminology and standards development.

Figure 2: (Question 5) What is your main use of ICD (past or present)?



In **Figure 3 (Question 6. Rate your knowledge and familiarity with ICD (0 none to 10 regular use))**, we see that self-rating of knowledge and familiarity with ICD scored an average of 9.4 in a scale of 0-10 (40% rated 10)!

Figure 3: (Question 6) Rate your knowledge and familiarity with ICD (0 none to 10 regular use),



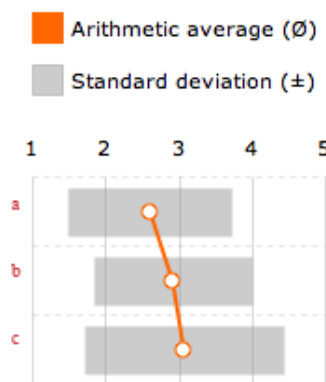
c. Progress towards goals of the Revisions.

Participants were then asked about the extent to which the three objectives of the Revision Process had been achieved so far for ICD-11. The objectives are outlined in the box below:

- 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;
- To continue to serve as an international standard in multiple languages and settings to allow for comparable data;
- To link with computerized health information systems (directly use standard terminologies and other health informatics applications to be “electronic health application ready”).

Figure 4 (Question 7a,b,c) shows the results of this question. On a scale of Very Significant to Minimal, the average for a. was 2.61 (Significant to Moderate), for b. was 2.92 (Moderate) and for c. 3.07 (Moderate). This means that 55.4% of participants saw achievement to a significant or very significant extent for Objective a., 35.1% for Objective b. and 37.8% for Objective c.

Figure 4: (Question 7) To what extent do you think these objectives have been achieved so far for ICD-11?



Summarized comments on Question 7a.

To what extent do you think Objective a. (Revision in line with scientific advances and serving multiple purposes) has been achieved so far for ICD-11?

Respondents had some difficulty answering these questions based as they were on their knowledge of ICD-11 at an incomplete stage of its development. Also, Objective a. contains two independent parts, and one comment was that the 'scientific advances' could reflect not only the current scientific views of medicine but also construction using the latest methods and techniques of IT and medical informatics.

Most comments praised the significant input from the clinical TAGs with preeminent physicians ensuring the inclusion of many new diagnoses reflecting scientific advances and with a level of detail and discrimination not available in ICD-10. There was an appreciation of the ability to translate between clinical terminology and classification and a huge gain seen in the ability to pick up quality and safety events. Generally it was felt that major steps forward have been taken in the 11th Revision, especially with issues such as rare diseases.

There were some negative views about the consistency of balance and depth across chapters and diseases and some took issue with the accuracy of definitions. There was recognition that work remains to be done by the horizontal TAGs on inter-chapter issues such as inclusion/exclusion criteria for codes especially to address boundary issues between chapters. This problem of TAG territory was raised several times resulting in inconsistency and disagreement over shared space and sometimes over current scientific thinking. Others took up the lack of clarity with rules and guidelines which are still incomplete and the need for consolidation of the content and structure across chapters. However, the provision of use cases to drive development of new content was seen as very useful although others felt that TAGs had not been given adequate guidelines on their role and on the structure of the coding

system resulting in haphazard processes and progress. There was repeated concern expressed about the structure and content of the Infectious Diseases chapter.

Regarding the overall objective, there was a query about the omission of public health in the objectives although others felt that the reflection of scientific advances in the classification would serve clinical, research and public health interests. There was some disappointment that the public system for proposals had not worked, that not enough people in the scientific community had been engaged in the revision process and fear that the JLMMS would be regarded as all that there is. However, the majority thought that the classification is shaping up to be fit for purpose, especially for mortality and morbidity reporting.

However, the main problem with this objective related to lack of involvement of primary care physicians in the development of ICD-11. Specifically, those interviewed felt that there should have been a primary care TAG with primary care physicians involved, as they have been in the primary care aspects of SNOMED CT with IHTSDO. There was uncertainty about the inclusion of ICPC-2 in the ICD-11 Foundation Component and on the input from primary care classification groups to the primary care linearization of ICD-11.

In summary, participants appreciated the need for alignment across revisions for mortality statistics, but this was tempered by ICD-11 bringing together multiple worlds – medical science, informatics, genomic, quality and safety, and policy. They recognised that this was a work in progress, but one heading in the right direction and addressing problems not dealt with in ICD-10 despite inadequacy of resources in terms of people and funds.

Summarized comments on Question 7b.

To what extent do you think Objective b (Revision developing an international standard to allow comparable data) has been achieved so far for ICD-11?

Unfortunately, most of the comments relating to this objective of achieving an international standard for comparability of data were negative. One respondent referred to the current version of ICD-11 as a 'curate's egg' (good in parts)! The objective was seen as a must for ensuring that ICD-11 is a classification and one that works. It was stated that intense review of the beta version is required to ensure the necessary solidity of the tool and that earlier attention to alignment of the TAGs might have saved the huge effort required to achieve this now, especially in terms of comparable levels of specificity across chapters and lack of cross fertilization and communication across TAGs. Cross or horizontal TAG review was seen as crucial at this point, along with translations, rules for multiple purposes (especially around main condition, stem code clustering and sequencing) and an index (with its own problems of translation). There was appreciation of the electronic translation tool being developed, as well as the computerised index, and a special mention of the need for classification expertise to ensure comparability within and between chapters. It was thought that vertical TAGs might have benefited from such expertise earlier in the revision process.

There was particular emphasis on the need to focus on international comparability of conditions most relevant to mortality. Some of the mortality interests even wondered if there was any improvement over ICD-10! There was reference to the Foundation Component as being medically sound but that work remains to be done to link with the classification for statistical reporting purposes. It was also considered that the harmonization with SNOMED CT should be a significant step toward reducing the conflict between standards.

Primary care comments were again prominent and negative, noting that primary care provides 85% of services but has 10% of data. The current Primary Care linearization is seen as inadequate and resulting in poor data quality not allowing international comparability.

Summary: Expressions such as ‘moving towards’, ‘work in progress’, ‘under construction’ and ‘on way’ were prominent amongst responses. Some were even unclear whether the JLMMS would work as a minimal standard for mortality and morbidity and between different use cases in morbidity. One comment was that “It will be a classification which will be gradually adopted” and that it would be some time before it is used as the standard for the majority of countries or for different working environments – hi and low-tech. Some even thought it was not workable as a statistical standard since the basic requirements of a statistical classification are not met. A final word was that without the publication of a robust linearization with good indexing and coding rules the data quality will suffer.

Summarized comments on Question 7c.

To what extent do you think Objective c. (Revision linking with computerized health information systems) has been achieved so far for ICD-11?

Comments here varied enormously from ‘terrific ideas’, ‘use of modern tools’, ‘one of the exciting things with ICD-11’, ‘going in a good direction’ to ‘framework there’, ‘incrementally could grow’, ‘not entirely pessimistic’ and ‘can’t be all things to all people’. This last person thought that WHO had paid attention to this objective to the detriment of the others and by so doing has alienated its base.

Most saw the need to marry the terminology with the classification, although one pointed out that there were many Foundation Component terms not in the JLMMS, especially pre-coordinated terms. On the other hand, one person thought that multiple layers of post coordination may complicate the relationship between codes and terms. It was thought that the vertical TAGs had not taken the underpinning reference terminologies into consideration. One comment was that the ICD-11 classification is not fit for purpose for direct use in computerized health information systems, but that this should be done through a clinical interface with terminologies such as SNOMED CT which can then be used to derive the appropriate ICD-11 code through mapping for mortality and morbidity statistics. Mortality interests saw a need for major investment in matching rules from ICD-10 to ICD-11 for decision tables in tools such as Iris.

Discussion in this section led to comments about ICD-11 being constrained by the need for it to remain fully compatible with the production of a paper-based version. It was argued that by the time ICD-11 is adopted, the comparative costs of producing and purchasing printed copies of ICD compared with loading ICD-11 on to an electronic platform or viewing online would mean that the poorest countries would be keenest to adopt a simple electronic solution. A further disadvantage of the print version is that updates cannot easily be undertaken. A great deal of management effort has gone into ensuring compatibility of electronic and hard copy versions which has been a distraction from considering how ICD-11 will be integrated into electronic health records. A common statement was that achieving this objective remains to be seen when ICD-11 is integrated into health information systems and its linkages with SNOMED CT can be tested. But overall, the feature of being able to move intuitively from free text to concepts to codes will represent a new environment which has high importance for the future of health information systems – ‘a good direction’!

A final comment was about an objective which is not there – not to impede or impair the existing uses and applications of ICD-10 – and that the three objectives tested are insufficient to judge whether ICD-11 meets reasonable goals.

The results for Question 7 are fairly pessimistic given that in **Figure 5 (Question 8 a,b,c)**, ratings for the importance of each objective on a scale of 1 (very high) to 5 (no opinion) are 1.75 (a), 1.41 (b) and 1.92 (c) or expressed as a percentage of those seeing these objectives as being of high or very high importance, (a) 85.5% , (b) 93.4% and (c) 77.6%.

- a = Revise in line with scientific advances & serve multiple purposes
- b = Serve as an international standard
- c = Link with computerized health information systems

Figure 5: (Question 7) What importance would you give to each of these objectives?

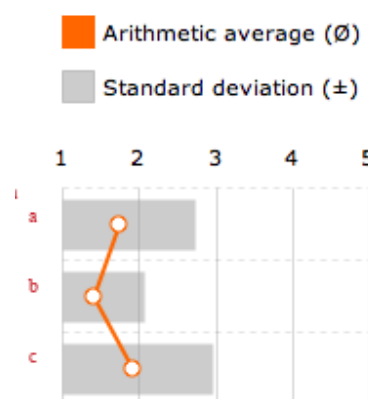
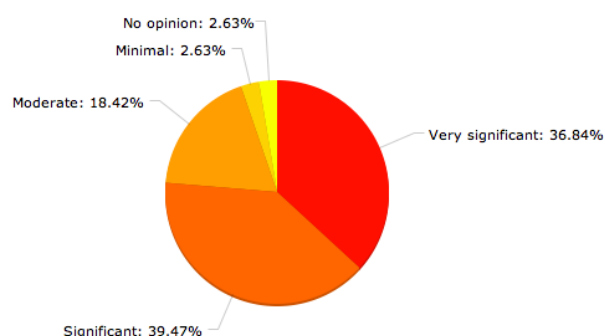


Figure 6 (Question 9) reflects the rating of the overall need for ICD-11 as 76.3% significant or very significant. Surprisingly 21% thought there was only a moderate or minimal need for ICD-11.

Figure 6: (Question 9) How would you rate the overall need for ICD-11?



Summarized comments on Question 9

How would you rate the overall need for ICD-11?

Surprisingly, there were mixed views on whether we need ICD-11 at all. However, the majority agreed that ICD-10 is outdated, has limitations in its clinical content and needs a new structure to take account of advances in scientific and medical knowledge which cannot be accommodated in ICD-10. The Morbidity Reference Group had identified many areas where the code structure or volume of updates could not be accommodated in the updating process. Although some recognised the need for change, they thought that practically the greater complexity of ICD-11 actually adds minimal value because of the lack of specificity in documentation.

On the positive side, ICD-11 was regarded as future proofing to make the classification acceptable for clinicians in an e-health environment – otherwise the classification will die! ICD-10 was seen as not sufficiently prepared for use in an electronic environment, in fact it was developed 25 years ago, before the availability of on-line authoring platforms and easy email exchange. Some parts of ICD-10 are little changed from the 6th Revision in 1948 and the enormous change in our understanding of disease since then has not allowed the collection of meaningful data. The group supporting change sees ICD-11 as representing a key strategic issue for current and future health information systems with its capability of operating in an E H R and terminology environment and its ‘telescoping feature’ of moving from granular categories to broader groupings. Other positive features noted were the enhancements in ICD-11, such as new coding rules and clustering potential from post coordination which will make the information stronger and provide new functionality in the information age.

In the middle were those who thought that the priority should have been on updating ICD-10 or a clinical modification of ICD-10 – or even using the work done on ICD-11 to update an ICD-10 classification without the need for an underpinning terminology. Some believe we need a revision rather than a revolution and that ICD is basically a statistical classification.

On a practical note, countries who have recently implemented or are about to implement ICD-10 for morbidity were reluctant to support early adoption of ICD-11 unless it has very clear and demonstrated advantages over ICD-10. Some wanted to see a business case for change, others were not clear how ready the world is for a whole new system given the significant costs of transition to a new coding system.

Primary Care groups see a high need for an appropriate primary care classification such as ICPC. However, this is not accepted as a standard in many countries, hence an appropriate Primary Care Linearization of ICD-11 would be highly appreciated.

d. Relevance and effectiveness of WHO Revision Process

i. Mortality

The first objective was then further dissected into questions about its specific aims. **Figure 7 (Question 10)** shows the results for mortality use and **Figure 7a (Question 10a)** for the improvement over ICD-10 for use in mortality statistics. In both of these, the predominant answer was “no opinion”.

Figure 7: (Question 10) Is the planned form of ICD-11 likely to meet requirements for use in MORTALITY statistics?

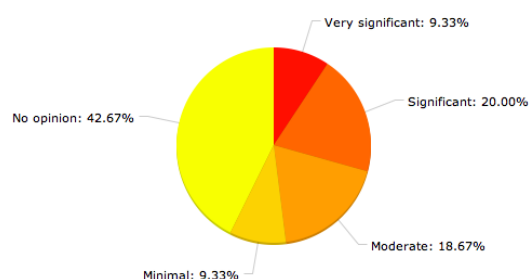
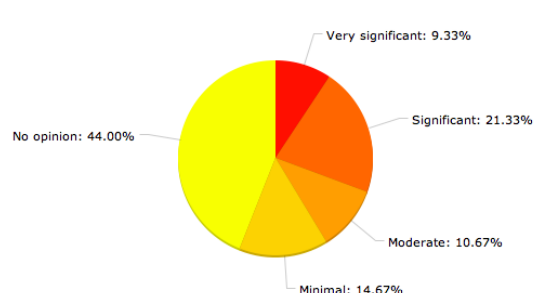


Figure 7a: (Question 10a) Do you expect that ICD-11 will be an improvement over ICD-10 for use in MORTALITY statistics?



Summarized comments on Question 10.

Is the planned form of ICD-11 likely to meet requirements for use in mortality statistics?

This is a critical aspect of the Revision and was acknowledged as such by the participants. Any outstanding issues must be solved before adoption. It was accepted that the planned form meets requirements for use in mortality statistics, but the actual form requires further work. Mortality users favour pre-coordination of codes and questioned the need for a joint linearization with morbidity. More extreme views were that “ICD-11 will bring havoc to mortality statistics” and “automated coding will come to a standstill when ICD-11 is released without decision tables”. The same respondent noted that the ICD-10 codes most used for mortality are in the .8 and .9 subgroups (other specified and unspecified) and that ICD-11 cannot handle these codes in an acceptable manner. Others wanted to wait and see how it will work with computerised systems such as Iris, while those who had looked at leading causes of death had found problems coding with ICD-11.

Others were not as critical and felt that JLMMS should meet mortality requirements, especially after decisions taken at the March 2015 Geneva meeting. More work needs to be done with the index, instructions, guidelines and rules requiring considerable resources. One non-mortality expert thought it more important to improve the quality of recording causes of death rather than ensure uninterrupted continuation of sometimes meaningless data. He also noted that the requirement for ICD-11 to support a single cause of death list limits the potential value of its overall improvements for morbidity. Another respondent thought that too little attention has been given to the basic construct of Underlying Cause of Death which has been unchanged since ICD-6 and that critical appraisal and revision is needed. It works well if you die young but not with multiple causes after a long period of decline, and there is a need now to describe the whole person with a constellation of codes.

While ICD-10 is not perfect, it works and mortality users do not want to abandon it until convinced that ICD-11 does work.

Summarized comments on Question 10a

Do you expect that ICD-11 will be an improvement over ICD-10 for use in mortality statistics?

Regarding an improvement over ICD-10 for mortality use, there were similar comments to those in question 10. One statement read “ICD-11 has lost sight of needs of Information Paradox countries” and others pointed to leading causes of death not codable in ICD-11. The functionality of the supporting database is an important factor and there were questions about whether ICD-11 algorithms had been built to use in automated coding systems such as Iris – a must if ICD-11 is to improve on ICD-10. This view was reinforced by those who thought ICD-11 would be a moderate to significant impairment to mortality statistics.

One comment expressed more hope for ICD-11 representing an improvement in quality and usefulness of mortality statistics. Examples given were changes to coding of neoplasms, diabetes, adverse reactions to medication or non-medicinal substances. There have been enormous changes to pharmacotherapy since ICD-10 was drawn up 25 years ago, and it does not represent large classes of potentially toxic and lethal drugs, while prominence is given to agents discarded decades ago. This disconnect between content of Complications of Medical and Surgical Care and current medical practice means that this section of ICD-10 is not fit for purpose. The suggested action was to have broad categories of medicinal agents in ICD-11 linked to an external terminology such as International Non-proprietary Names (INN).

The addition of textual definitions in ICD-11 was seen as providing explicit classification criteria not available in ICD-10. One respondent said that “having a content model will be extremely useful in training ...having a content model in DSM has revolutionized training in psychiatry as it contains definitions that they all learn” so that data extracted is more reliable and aligned with research literature.

Again on the positive side, there was hope that adjustment of the JLMMS would allow coding of disease that today do not have their own specific code and that design of the structure should allow for future revision needs. There was another comment that ICD-11 would represent an improvement if the quality of the data in the death certificate improved.

ii. Morbidity

However, the same questions for morbidity use (**Figures 8 and 8a**) (**Questions 11 and 11a**) gave results for Significant or Very Significant of 44% thinking that ICD-11 would meet requirements for use in morbidity statistics and half the respondents believing it would be an improvement on ICD-10.

Figure 8: (Question 11) Is the planned form of ICD-11 likely to meet requirements for use in MORBIDITY statistics?

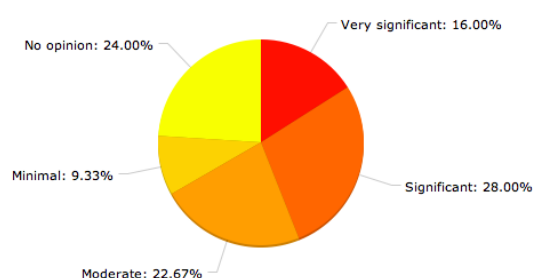
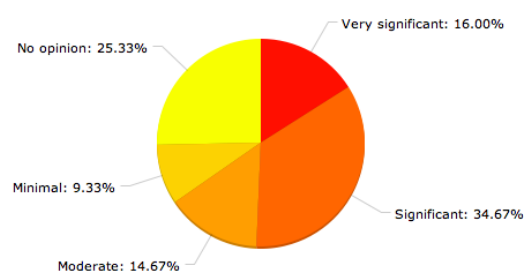


Figure 8a: (Question 11a) Do you expect that ICD-11 will be an improvement over ICD-10 for use in MORBIDITY statistics?



Summarized comments on Question 11

Is the planned form of ICD-11 likely to meet requirements for morbidity statistics?

Here again many uncertainties were expressed given the unfinished nature of ICD-11 and the many issues of structure, content and classification to be solved, making it hard to judge its eventual worth. Several liked the idea of more post coordination and clustering (although there may be a problem if a condition is in more than one cluster) and wanted to see how it would work in practice to reflect multiple causes in morbidity. There were questions of extracting accurate data in a post coordination environment and the need to have useable subsets to roll up granular concepts.

There was recognition of the advantage of having the content of the clinical modifications in the Foundation Component of ICD-11 as well as SNOMED CT link.

Some thought the advantages of ICD-11 would be felt more in developed than developing countries and in secondary and tertiary sectors rather than primary or community care.

Overall, the reactions were more positive for morbidity than mortality given the greater specificity and currency of medical knowledge in ICD-11 and use of the X chapter extension codes. As an example it was seen as “a vast improvement over ICD-10” but there were still some queries about resources for joint work on the index involving both morbidity and mortality experts. However, tying together morbidity and mortality was seen as possibly constraining the potential for morbidity with interests of the latter hijacked by mortality interests. There was still opposition to the JLMMS expressed, despite overall agreement to this linearization at the December 2013 meeting and confirmation in March 2015.

More work needs to be done by the Morbidity TAG to develop rules especially around the use of extension codes. Respondents expressed frustration in working with a ‘moving target’ and were hopeful that the JLMMS would be sufficiently stable to develop rules and sanctions especially for issues between chapters, the ‘includes’ and ‘excludes’ notes and the definition of main condition.

The cost of transition from ICD-10 to ICD-11 is seen as a challenge as ICD-10 is so widely used across health services and as the basis for products and downstream data analytics. Significant resources will be required to replace current systems. The investment by many member states in electronic health information systems which use ICD-10 may hamper implementation. The issue in the US is the forthcoming implementation of ICD-10-CM which contains many of the things that US clinicians wanted.

Summarized comments on Question 11a

Do you expect that ICD-11 will be an improvement over ICD-10 for use in morbidity statistics?

Most respondents seemed unwilling to commit given the current stage of ICD-11 development. Because it is unfinished, there is a need to sort out issues of inconsistencies within and across chapters, mutual exclusivity, clustering, extension chapter and rules. Problems with the Infectious Chapter were mentioned again. With these issues fixed, they liked the clinical focus - ‘clinical information very good and positive’. Those who were positive said ‘absolutely no doubt!’ and welcomed the increased specificity and wide range of care conditions in ICD-11, linkages with SNOMED CT and new medical knowledge represented in the classification.

It appears that some respondents are beginning to understand the vision for ICD-11 now that the pieces are coming together. They like the addition of textual definitions providing explicit classification criteria.

Some saw a real benefit over ICD-10 for use in electronic health care records and to extract computerized data and information, but noted that there is still a lot of work to be done by classification experts. Traditional medicine experts liked the inclusion of the TM chapter as well as the potential for TM practitioners to use other relevant sections of ICD-11.

iii. Primary Care

Figures 9 and 9a (Questions 12 and 12a) demonstrate the pessimism regarding the aim for meeting the needs for primary care (41.3% believing it would meet requirements moderately or minimally and 32.4% believing it would be an improvement over ICD-10). In each case, approximately 40% had no opinion.

Figure 9: (Question 12) Is the planned form of ICD-11 likely to meet requirements for use in PRIMARY CARE?

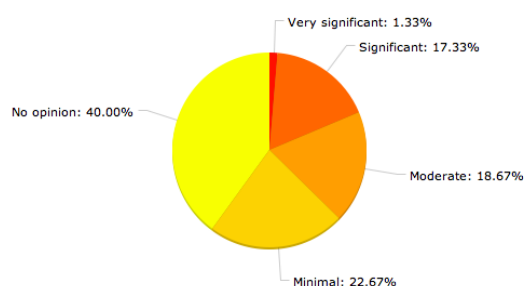
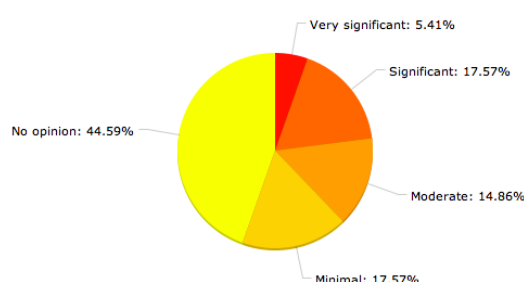


Figure 9a: (Question 12a) Do you expect that ICD-11 will be an improvement over ICD-10 for use in PRIMARY CARE?



Summarized comments on Question 12

Is the planned form of ICD-11 likely to meet requirements for primary care?

Comments in this section expressed frustration and often negativity about the use of ICD-11 in primary care. It seems that primary care physicians and organisations have sought representation on TAGs and for activities such as inclusion of ICPC2 in the Foundation Component, mapping, and development of the Primary Care Linearization.

One respondent stated: “Collaborating with the WHO Classification Unit has been extremely challenging. It indicates that it would value inputs and assistance but then fails to follow up on any approaches made. Despite numerous offers of help it has not responded, and has not initiated a TAG on primary care, so progress is minimal or none at all. Primary care classification can only be adequately developed if primary care physicians are included in the development team; this has not been the case to date. WONCA (World Organization of Family Doctors) has even volunteered its own coding system - ICPC-2 (International Classification of Primary Care; version2) - and offered to assist in modification to allow PHC linearization to ICD-11 as a workable alternative, but this offer has not been taken up. All in all VERY frustrating!”

They do want interoperability between ICPC and ICD and some even favour using ICD’s systematic nature to code reasons for encounter with facts leading to classification rather than judgement. However some of our respondents did not know the status of the two Primary Care Linearizations and are concerned at lack of funding for involvement in review or field trials.

A few countries are using ICPC, but there is limited knowledge of national use of classifications in primary care. For primary care morbidity statistics, they see ICD as

missing the meaningful higher level codes to aggregate data for primary care use cases and don't believe that ICD-11 will be any better than ICD-10 for this purpose. They say the structure of ICD-11 is impossible to use in primary care. However some see a place for a short list or higher level aggregates of ICD-11 for primary care coding. There is some use of the R chapter in ICD-10 which can be carried over to ICD-11 as well as use of the TM chapter in primary care. Others think that the granularity of ICD-11 will be welcomed by the primary care sector. There was even a comment that mapping from ICD-11 Primary Care Linearization to ICPC remains to prove helpful.

Others would rather use primary care subsets of SNOMED which are being developed with WONCA. IHTSDO (International Health Terminology Standards Development Organisation) is mapping SNOMED to ICPC. WONCA has several expert groups who have tried without success to link with CTS to help them understand primary care needs. However, they feel that CTS already knew what they wanted and sent back something that CTS had put together. This was not the experience at IHTSDO which worked with WONCA to develop a Primary Care Reference Set with crosswalks to ICPC. "IHTSDO did not have pre-conceived notions that trumped the collaboration".

They felt that a lot depends on the format in which the classification is made available. Many small countries find ICD-10 too difficult and complex for primary care and they can't see ICD-11 improving the situation – 'the twain will never meet!' They see ICD as being useful for morbidity and mortality statistics but not suited for direct use by clinicians in any care setting. Primary care has different requirements in different countries. The Asia Pacific Network has developed a Primary Care Classification from ICD-10.

One contributor thought that the format of ICD-11 needs to be downplayed as coding is something to take place behind the scenes. He thought that the emphasis should be on the ability to link information across service delivery sectors in order to improve care pathways. In the US, everyone will have to use the same version for reporting as the US government standard for acute and chronic care and hospital care. Separate versions for primary care, specialty care or research can only be used for non-reporting purposes.

Summarized comments Question 12a

Do you expect that ICD-11 will be an improvement over ICD-10 for use in primary care?

Most felt it was too early to make an informed assessment. So far, WONCA has had limited opportunities to contribute to the primary care linearizations as mentioned above. While the Swedes and Thais have developed short lists of ICD-10 for primary care, some believe that ICD is not meant for and not used in this sector and question why ICD-11 would be preferred over ICPC. However, others would like to study these short lists and compare them with both ICPC and the result of the IHTSDO PHC mapping work on a reference set which links SNOMED CT to ICPC. Some seem to want granularity and the ability to capture robust details of the encounter not available in truncated codes.

There was a strong feeling that the harmonization with SNOMED Ontology and the greater flexibility of ICD-11 would mean a smooth mechanism to map from terms and concepts used

in clinical care to ICD mortality and morbidity coding. ICD will be coarser grained than SNOMED and the JLMMS will meet the requirements of statistical reporting rather than clinical care. The new architecture of ICD-11 provides a mechanism to support alternatives designed for clinical care if this is required.

The authors of the Asia-Pacific forum ICD-10 for primary care have offered a copy for the Foundation Component of ICD-11. Also, the TM chapter is seen as a major addition to allow TM practitioners to reflect utilisation of their services.

Continuing another view from question 10, the health care continuum is a major endeavour for integrated and population based care, which will require integration of primary and secondary care. ICD-11 would bridge the gap between the two and provides a most exciting potential.

Despite the optimism expressed above, there were still strong feelings against use of ICD in primary care, many of them based on the communication difficulties between WONCA and WHO. In summary, there are real questions as to why ICD-11 is being developed for use in primary care.

iv. Clinical Care

Figures 10 and 10a (Questions 13 and 13a) demonstrate a little more optimism regarding its use for clinical care (47.3% thinking it would meet requirements significantly or very significantly and 48% thinking it would be a significant or very significant improvement over ICD-10.

Figure 10: (Question 13): Is the planned form of ICD-11 likely to meet requirements for use in CLINICAL CARE?

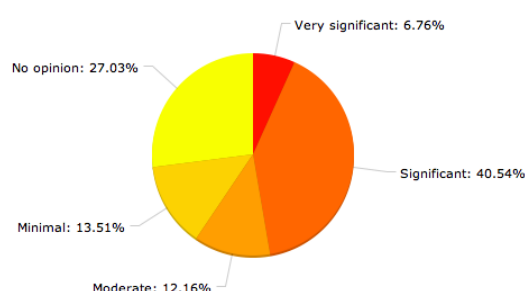
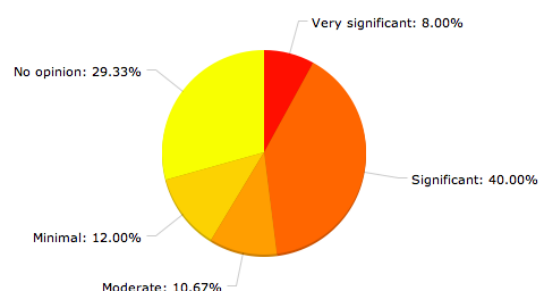


Figure 10a: (Question 13a) Do you expect that ICD-11 will be an improvement over ICD-10 for use in CLINICAL CARE?



Summarized comments Question 13

Is the planned form of ICD-11 likely to meet requirements for use in clinical care?

Responses here were equivocal. Some do not see any use in clinical care and believe that ICD is suited for morbidity and mortality statistics, but not for direct use by clinicians in any care setting where use of terminologies is more appropriate. Others see the use of terminology explorers, the detail in ICD-11 based on scientific evidence, and inclusion of definitions as being of great benefit to clinicians, especially given the clinical input to work by the TAGs. There were positive remarks about post coordination and the extension codes, as well as links between SNOMED terms and ICD-11 classes, although some thought that the amount of post coordination needed to gain robust data will be a burden on the health care provider. It was also seen as useful for clinical review and quality and safety functions by enabling easy collection of clinical data to improve care and support record linkage and better identify medical errors and quality issues. Linkages with terminology would allow tracking of individual patient morbidity and problems. Even with terminologies, there is still a need to have clear categories backup up by a content model like ICD-11.

ICD-11 remains to be tested against the clinical vignettes prepared for the field trials. One respondent felt that the field trials in mother tongue are essential for evaluation of the usefulness of ICD-11 for clinical care.

This lengthy comment is a direct quote: “The original plans for ICD-11 published in 2007 were visionary, particularly in the recognition of the importance of data capture via EHRs. Much of the vision is still there but there is a real danger of them being submerged. The ICD-11 Foundation Component is an enormous resource. I have suggested to WHO that there should be a “cleaned up version” of this available for use in hospital-based EHRs covering the wide field of hospital specialist care and thus being more akin in granularity to ICD-10-CM or ICD-10-AM. This could be regarded as a generic secondary care linearization but could be visualized using the navigational tree available for viewing concepts in the Foundation Component in the Beta Browser and thus taking advantage of the poly-hierarchies which have been developed there. Because each concept has a unique digital identifier it should be straightforward to use these to identify that concept by title in a hospital record and to link it to its representation in different linearizations (which in the case of the Joint Linearization will often be “Other specified....”) and to its Joint Linearization mapping code for the purposes of international statistical reporting. By taking advantage of existing flags for specialty linearizations it would be possible to switch on or off filters to drill down to a set of generic secondary care concepts together with a full set of specialty concepts (e.g. ophthalmology, neurology, paediatrics etc.)”.

Summarized comments Question 13a

Do you expect that ICD-11 will be an improvement over ICD-10 for use in clinical care?

Comments here ranged from ‘absolutely no doubt’ to hope because of the inclusion of a terminology, multiple parenting and scientific currency to some pluses, some minuses, to not applicable for direct use by clinicians in any care setting (classifications such as ICD-10 and ICD-11 are statistical classifications used for reporting).

The optimists believe that potentially it should remove or at least reduce the need for clinical modifications, at least in those jurisdictions that have access to SNOMED. If clinical modifications continue to be required, they should be very much easier to generate and manage. They thought that sharing of clinical data and information would be improved with the use of ICD-11 and that its ability to accommodate updates to classes with frequently seen conditions would be a bonus. Collaboration with IHTSDO and harmonization with SNOMED CT should guarantee coverage of key clinical terms in certain areas such as rare diseases.

The pessimists thought that unless there can be agreement as to appropriate terminology and code placement, ICD-11 is unlikely to be any better than ICD-10.

The TM chapter in ICD-11 was seen as a useful clinical tool for TM practitioners.

v. Scientific Research

Figures 11 and 11a (Questions 14 and 14a) for scientific research show 51.3% anticipating that requirements would be met significantly or very significantly and 54.6% thinking that it would be a significant or very significant improvement over ICD-10.

Figure 11: (Question 14) Is the planned form of ICD-11 likely to meet requirements for use in SCIENTIFIC RESEARCH?

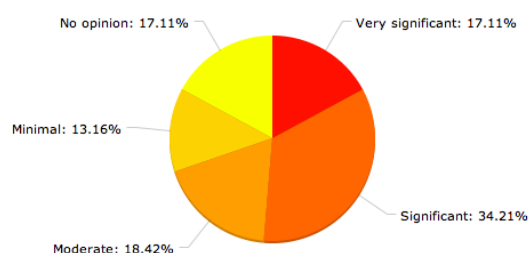
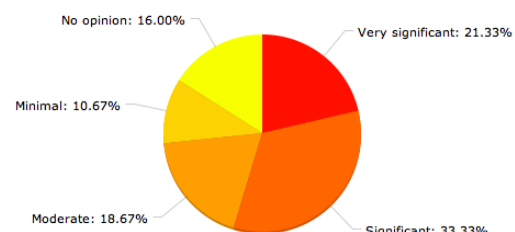


Figure 11a: (Question 14a) Do you expect that ICD-11 will be an improvement over ICD-10 for use in SCIENTIFIC RESEARCH?



Summarized comments Question 14

Is the planned form of ICD-11 likely to meet requirements for use in scientific research?

Despite the inclusion of a lot of detail in ICD-11 that could benefit research, e.g. rare diseases, a lot depends on how this information is documented in the patient record. Also, updating is crucial e.g. pressure ulcers which have not been updated from consensus statements. There need to be good business rules around updating and clinically meaningful terms, e.g. 'chronic virus' used by clinicians in preference to 'carrier status'.

Because of the wide variation in needs of scientific research there will be a wide range of classifications used. It is likely that ICD-11 may be useful for some scientific research projects if it is stable and of high quality. To give comparable results, it must be easy to use so that secondary use of clinical data is possible. Its specificity is an advantage although researchers will need help in selection of appropriate codes for their research. One comment was that "ICD-11 opens the door to a new level of integration with components of health information" although some thought it was not appropriate for population and public health except for statistical research on morbidity and mortality data. Some saw significant enhancements in interpretability of data with the ability to cluster, and use extension codes. They thought that harmonizing coding rules would help international comparability in global health research and that expanded data capture through the use of qualifiers would enhance researchers' ability to drill down into the data without having to go to multiple sources.

Other positive comments include: "Linkages with genomics is transformative"; "The Foundation Component will possibly be an important base for research"; and "serve as a more granular translation of events that happen in clinical care". There was some concern that not all chapters meet the requirements for research in terms of current terminology and reflecting current clinical thinking.

Primary care interests believe ICD is not satisfactory for primary care and that ICPC was developed because of this. However, they recognise the need for ICD-11 research on integrated care but still need a terminology related primary care classification.

Traditional Medicine respondents see the inclusion of the TM chapter as a useful basis for research.

Summarized comments Question 14a

Do you expect that ICD-11 will be an improvement over ICD-10 for use in scientific research?

For this to be supported, the specialty linearizations need to be workable, and rules such as definition of main condition need to be clear. Secondary use of clinical data for scientific research should definitely be enhanced with more detailed information being coded and use of definitions to ensure discrimination between codes. The Foundation Component and

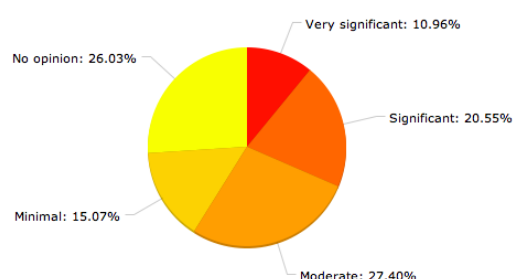
Common Ontology being poly-hierarchical will support multiple views and should make it easier to find all the required codes in any linearization, particularly the JLMMS. Introduction of post coordination is seen as a major enhancement as is greater granularity of concepts.

There is a need for evidence that coding accuracy in the hands of experienced coders can be as high in ICD-11 as it is for ICD-10, so that the correct code can be used to claim cases from patient registries or other data bases.

vi. Updating from ICD-10

Figure 12 (Question 15) highlights the mixed perceptions that ICD-11 would address problems with the ICD-10 structure, content and rules that could not be solved in the updating process.

Figure 12: (Question 15) Has the revision process addressed problems with ICD-10 structure, content and rules that could not be addressed in the updating process?



Summarized comments on Question 15

Has the revision process addressed problems with ICD-10 structure, content and rules that could not be addressed in the updating process?

Many respondents felt that many problems and decisions from URC were not transferred to ICD-11 development. Specifically, there were concerns that the list of special topics developed by the Morbidity Reference Group had not been systematically addressed. Prior to March 2015 meeting, there also was concern that specific problems raised by the MTAG and MbTAG also had not been addressed.

A minority view is that the problems have been mostly addressed. In some cases they have also been solved. At least one TAG Chair offered many examples.

Another frequent concern was that ICD-11 has addressed some problems with ICD-10 that could not be solved by the updating process, but it has created many more problems, some of which are very fundamental. Improved content in some chapters, problematic structure and content in others (Chapter 1, the new Chapters 6 and 8). Many of these problems appear to have been addressed during the March meeting.)

Another theme is that the Vertical TAGs were not given adequate instructions and guidance about problem areas in ICD-10 and about classification principles.

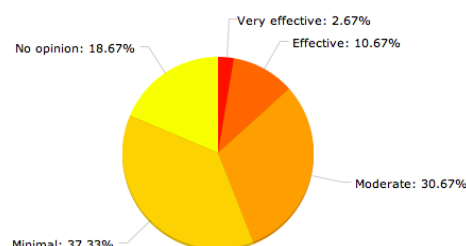
There were multiple comments about lack of input from statistical or classification experts. A common view was that a better product, that would be more useful, should have been developed with the classification concepts in mind first and then the medical aspects added (rather, the reverse has been the actual case). Stronger input to the work of the vertical TAGs from a classification perspective could have improved the consistency and robustness of the developing ICD-11 product.

A positive view shared by some was that ICD-11 is built on a foundation of ontology and linearization and therefore its use will address problems with ICD-10 content, structure and rules. Semantic linking with SNOMED CT will lead to internal consistency.

vii. Decisions on structure, content and rules

In **Figure 13 (Question 16)**, we see that 68% thought that decisions about structure, content and rules for ICD-11 were only minimally or moderately effective.

Figure 13: (Question 16) With regards to making decisions about structure, content and rules for ICD-11, how effective do you consider the current decision-making process?



Summarized comments on Question 16

With regards to making decision about structure, content and rules for ICD-11, how effective do you consider the current decision-making process?

There are some very strong comments on this question, including, “Nub of the issue. Not effective enough;” “Worst thing, terrible;” “Can’t understand when and why decisions are made;” “Not at all. WHO nods their heads and do whatever they want. Don’t address issues. Not clear why decisions were made, how they were made, who made them, no documentation, no rationale. It’s the reason why we’re where we are right now, with all the controversy and problems.” Finally, again, “Morbidity TAG has brought forward issues repeatedly and nothing seems to happen.”

A minority opinion is that “WHO staff (are) knowledgeable and inspirational;” “Agree with current decision making process;” “The early decision making process was problematic. These problems have been largely overcome, and the decision making is now quite good by comparison with other similar large collaborative developments.”

A middle-ground position is that “In a project as complex as this, it is not surprising that changes to the rules and structure have had to be made over time. Much time and effort has, however, been wasted as a result of changes in direction over the course of the project.” Also, “many principles should have been decided earlier. e.g., pre and post coordination,

format, cluster (horizontal or vertical).” Some suggest that decision-making may be “effective”, but it is not transparent.

There is a clear consensus that the process needs “a binding way to make decisions”.

Primary Care is a problem area. “Concerning primary care there has not been an appropriate decision making process. There is currently no work plan or described method according to which classes should be included or excluded in a PC-linearization.”

Many agree that “The WHO team are too few to really cope with all tasks.”

“Has worked through the decibel method, it seems - whichever TAG has talked loudest has won the battle for where a condition gets placed in the classification.”

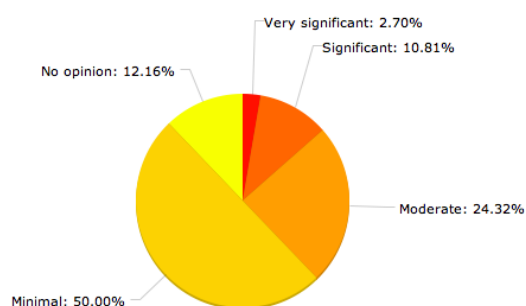
“It is not transparent and very difficult to get documentation about, even as one trying to link SNOMED CT in.”

e. Project resources, financial and human

(Appendix 3 outlines the approximate income for the Revision Project so far (Information from Dr B, Üstün 16.3.15.)).

Asked about adequacy of technical and financial support for WHO to develop ICD-11, 74.3% responded that minimal or moderate resources had been provided (50% minimal) (**Figure 14**) (**Question 17**).

Figure 14: (Question 17) Do you think that adequate technical and financial support and resources have been provided to WHO to develop ICD-11?



Summarized comments on Questions 17.

Do you think that adequate technical and financial support and resources have been provided to WHO to develop ICD-11?

The common answer to the question is No.

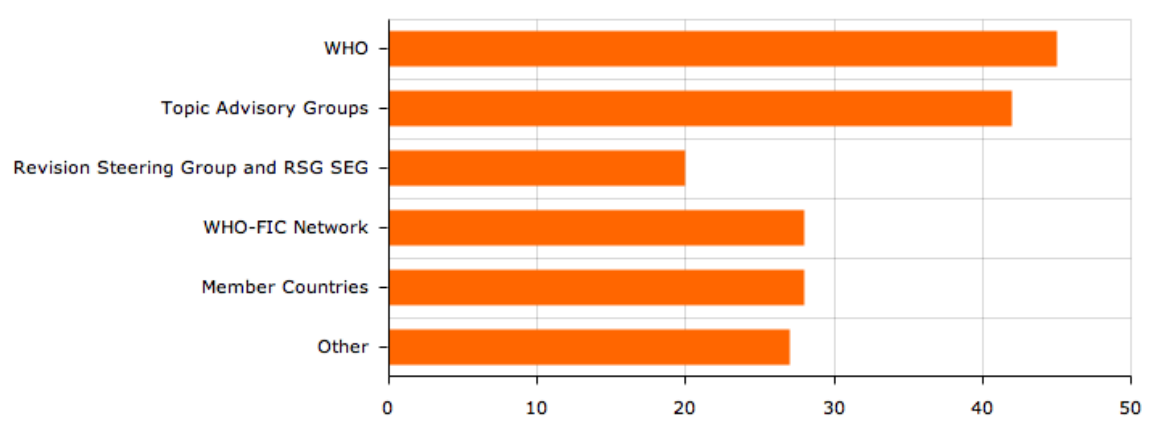
“The resources have never met the ambition of the project, or even its minimal realization. WHO staff have done as much as is reasonable and sometimes more, but the project as a whole has been over-dependent on goodwill and volunteer work.”

“So many of their responses have been driven by the lack of resources to carry out the job. This is an international resource that needs to be developed as such. It needs a new business

model. At the same time, does not think that WHO would use additional resources wisely. Should be an overarching agreement between WHO and other international professional groups (IHTSDO. WONCA etc.) with ongoing forum where work is done. Would need some governance and oversight that WHO doesn't currently have"

Figure 15 (Question 18. Are there specific areas where you feel additional resources are needed by WHO, TAGs, RSG and RSG SEG, WHO-FIC Network, Member Countries, Other) shows responses to specific areas thought to need additional resources (45 respondents (over 60%) believing that WHO itself as well as the topic advisory groups deserving of more resources).

Figure 15: (Question 18) Are there specific areas where you feel additional resources are needed by:



Summarized comments on Questions 18

Are there specific areas where you feel additional resources are needed?

There are many comments that are asking for more classifications experts as well as the need for better coordination of the project. Expertise on Primary care is also needed.

"The project is grossly underfunded and there is no redundancy in the system. If key people were to move on to other positions, the project would fail."

"The coordination of the project and the documentation should be organized in a more clear and structured way. This might save resources"

"Coordination and cooperation needs improvement"

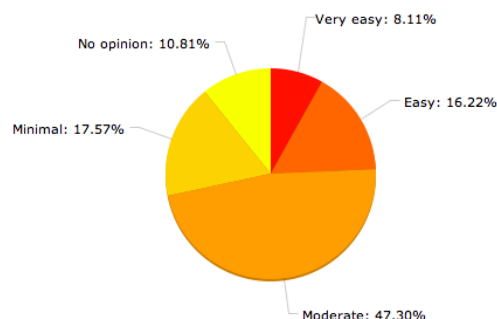
"WHO needs more skilled people in organizing and communication, so that more frequent contacts is made with member countries."

"Need for a stronger project management resources."

f. Communication and contribution to ICD-11 Revision Process

Figure 16 (Question 19) depicts the relative ease that most felt in contributing to the ICD Revision process.

Figure 16: (Question 19) How easy have you found it to contribute to the ICD Revision Process?



Summarized comments on Question 19

How easy have you found it to contribute to the ICD Revision Process?

Answers fall into at least three categories – 1) Whether it is easy to contribute because of the process and systems, 2) Whether it is easy to contribute, given a person’s “day job” and other responsibilities, and 3) Whether WHO pays attention to or acknowledges the contributions people make. All three are associated with problems.

“Not very easy at all....People not listening;” “Communication process not set in place at the beginning;” “Easy working on platform but changing all the time;” “Easy superficially but very wearing because things don’t seem to stick and vanish into the ether. No process for firm decisions nor register of decisions. No new proposals refer back to previous decisions;” “The ICAT platform has been frustrating;” language also is a problem for some. Regarding SNOMED CT, “I can only comment on trying to work through the collaboration and it has been very difficult”; “I am experienced in coding in ICD-10 and therefore was interested in contributing. In some attempts that I have made to participate, the attempts failed.”

“Easy from organizational point of view, hard to travel”; “Very difficult, ICD is on the periphery of my paid employment, any contribution is fitted into evenings and weekends”; “The combination of teleconferences and face-to-face meetings has worked reasonably well. There have been too many occasions on which necessary work was laid out but could not be achieved for lack of resources;” “WHO has been open and well-receiving of input, but day job has created time constraints;” “Difficulties have not had to do with WHO.”

“But recommendations not always followed up;” “Very difficult - almost impossible. Have to yell!” “Not at all. For years, has felt completely ignored;” “Make comments and suggestions and is ignored. When critical, told it’s not helpful to be critical;” “Can communicate but no feedback, can’t see results of their input and action;” “You never got any answers to your suggestions;” “Making a contribution is not difficult, but it is not clear what did happen with contributions”; “the EIC has supported work on volume 2 and has been asked to provide information for field trials (but little acknowledgement of what has been done/provided, not sure if it is suitable or useable.)”

“Easy to send stuff in, making sure that they pay attention is another matter. This is primarily a resource issue. Amazed that doing as much as they do.”

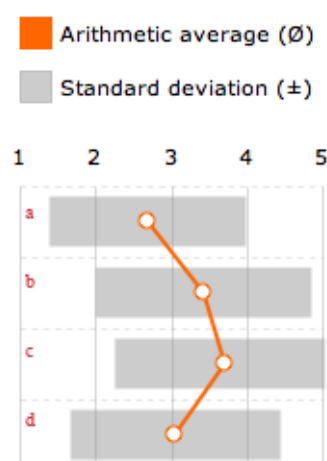
“It has been extremely time-consuming and has lasted much longer than I had anticipated. Nevertheless I feel it has been worthwhile and that there has been much very valuable consultation within my topic area and between our TAG and the majority of groups where there have been topics of mutual interest. Changes in direction and emphasis, often without notification, have been frustrating.”

Several people commented that it was difficult to communicate with the (other) Vertical TAGs (see below) but at least moderately easy to communicate within one’s own TAG. Injury TAG and its members have been very helpful to Q&S TAG. One TAG Chair stated that “I have had tremendous help from the majority of colleagues I have approached in the different “vertical” TAGS over the time I have been involved in the project.”

However in **Figure 17 (Question 20)** we see that communication was easiest with the WHO Classification Team, although even that scored midway between Somewhat agree and Somewhat disagree. Communication with the RSG and TAGs did not score well although there was a high proportion of ‘don’t know’ in these answers.

- a. = WHO Classification Team
- b. = Revision Steering Group (RSG)
- c. = RSG Small Executive Group (SEG)
- d. = Relevant Topic Advisory Group

Figure 17: (Question 20) Within the ICD Revision Process, is it easy to communicate with:



Summarized comments on Question 20

Within the ICD Revision Process, it is easy to communicate with: WHO Classification Team; Revision Steering Group; RSG Small Executive Group; Relevant TAGs

This question is similar to the previous one but focuses on communication with specific groups (some of which is covered above, as well). Frequent comments include:

Communication within a very complex and resource-constrained structure has been a challenge. Communication in the sense that you try to understand each other (even where you do not agree) was difficult.

As the majority are volunteers there does not appear to be the resources and time to apply solid management practices such as seeking input, documentation and a feedback loop.

Comments regarding communication with WHO include: “Strongly agree that it is easy to communicate with some members of the WHO Classification Team”; “Don’t feel welcome”; “WHO staff can take a long time to respond to emails and responses are not always related to the original concern.”

Comments regarding RSG were mostly negative, with a few exceptions, as follows: “Communication with the RSG and RSG SEG is possible, but it seems difficult to obtain responses to queries”; “RSG meetings too big, can’t contribute;” “RSG teleconferences useless;” “Concerned that the RSG as a body has not really functioned as a Steering Group but has merely had decisions presented to it”; “RSG only meets by phone, so there is no interaction between chairs”; “RSG too big for normal function. Not an effective communication process”; “RSG teleconferences very difficult, especially for non-English speaking participants. Too big.”

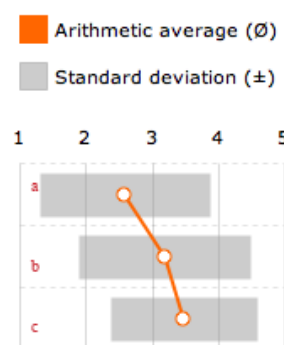
Comments regarding RSG SEG: “SEG operates on their own without regard to the TAGs;” “RSG SEG has a suitable number of people, sometimes influential and helpful but often not really. No register of decisions.”

Comments regarding communication within and between TAGs vary: “Injury TAG and its members have been very helpful to Q&S TAG”; “Communication with the vertical TAGs not possible - where do we find who to contact?”; “Most Tags and their managing editors have worked exceeding well and in a very collegial manner. A few huddle down and insulate themselves from working with others”; “Vertical TAGs – you can communicate with them, but some of them are not very receptive. It differs across TAGs. Some are quite prickly. No problems communicating with Horizontal TAGs”; “No contact with Morbidity TAG at all, Contact with the Mortality horizontal TAG has been facilitated through regular communication with MRG” (A few others did report communicating well with horizontal TAGs).

Most participants found that the browser of the beta draft of ICD-11 on the WHO-FIC website was on the whole moderately useful to useful (**Figure 18**) (**Question 21**) while the proposal system and other tools such as the FAQs and Information Notes were moderately to minimally useful.

- a. = Beta Draft (browser)
- b. = Proposal System
- c. = Other (e.g. FAQs, Information Notes)

Figure 18: (Question 21) How useful have you found the information about ICD-11 posted on the WHO-FIC website?



Summarized comments on Question 21

How useful have you found the information about ICD-11 posted on the WHO (–FIC) website?

The positive comments are around the browser and that it has improved a lot lately, but it needs instructions on how to be used. There are also comments on the need for information about the current status of ICD-11, how it's been developed and different roles.

“Absolutely useful documents, but often I felt the documents were outdated or they were only representing information on a general level.”

“Quite often out of date, or late or confusing.”

g. Decision making process

The following two **Figures (19 and 20) (Questions 22 and 23)** show general dissatisfaction with the timeliness (**Figure 19 and Question 22**) and transparency (**Figure 20 and Question 23**) of decisions made about structure and content and format of ICD-11.

Figure 19: (Question 22) Do you agree with the timeliness of decisions made about structure, content and format of ICD-11?

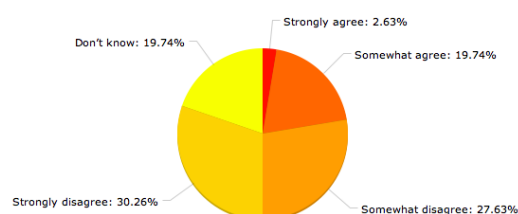
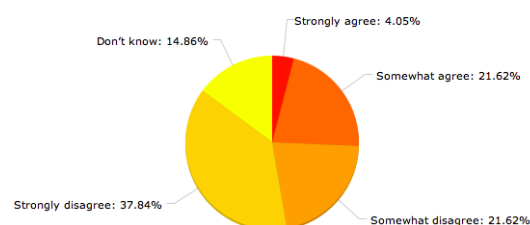


Figure 20: (Question 23) Do you agree with the transparency of decisions made about structure, content and format of ICD-11?



Summarized comments on Question 22

Do you agree with the timeliness of decisions made about structure, content and format of ICD-11?

A consensus opinion is that many key decisions were taken years too late, leaving too many options open in the first half of the revision process. Specifically, “Decisions about structure from a coding perspective were left very late.” Some things still are not decided. “It is still a moveable feast!”

“Communication has been extremely poor and some decisions about fundamental aspects of the classification came very late in the game. Structure is a fundamental building point. A lot

of disagreement about the structure, so just let everyone go along with work program without acknowledging that you couldn't do the work without structure decisions."

It was suggested by several that, "It has been rather haphazard at times and secretive at others;" "Final structure still a mystery!"; "Information not fed back. Don't know how decisions are made or who decides."

As commented above, "Timeliness has been a challenge because governance doesn't enable quick decisions. Need a better process for decisions."

"Relationship with IHTSDO is strained: "All I can say is that from perspective of linking SNOMED CT and ICD-11, there is no attempt by WHO to commit to any timelines for any joint work."

One interesting comment was that "Might have been better about timeliness with respect to other standards development."

On the positive side, there were some comments that it (decision-making) has improved since it started. Also, one commenter opined, "A little bit slow, but that isn't necessarily wrong; WHO reverses some decisions but it is an iterative process."

Summarized comments on Question 23

Do you agree with the transparency of decisions made about structure, content and format of ICD-11?

While recognizing the complexity of the project, the majority opinion is that transparency has been lacking. One commenter went so far as to suggest that there is not a "transparency tradition" at WHO. A common view is that, "There isn't a time and place and group that makes a decision.... Somehow, somewhere decisions do get made. Could be better if leaders were given a governance to work with. WHO needs to solicit input into what improved governance structure should be."

Communication is stated as a problem again and again, with some reference to limited resources at WHO. "It has been difficult to obtain information on this aspect of the classification;" "Too many people don't know what's going on;" "The general information to countries and CC could be more often, regular and informative. But this is mainly a resource matter at WHO. More staff needed"; "Information not fed back. Don't know how decisions are made or who decides"; "Major problem. Can't see why or how or by whom decisions are being made." "WHO has not explained the roles of different participants. MRG/mTAG find out about decisions a year later. No clear map for getting to 2014, then 2015 and now 2017. Still don't see clear map to 2017. Better, but not very clear."

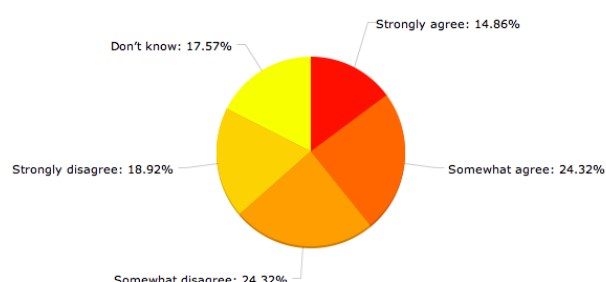
Some specific complaints are that "Driven by informatics rather than classification"; "Should meet needs of mortality first, consistent with mortality linearization. Others later - morbidity and Q&S." This reflects the different points of view and constituencies.

A minority opinion is that "Even when decisions are made behind closed doors, the rationale is available." "The most positive view and perspective is,

“These are complex issues and there are many competing interests, particularly between “traditionalists” and “reformers”. If ICD-11 is accepted it will mark a major change in the way disease is classified and should set the pattern for the remainder of the century in the same way that ICD-6 introduced major structural changes in 1948 which last to this day. I think that the voice of the would-be reformers has not been as strong as that of the traditionalists.” Even this respondent concluded, “ There has been secrecy around some aspects of the revision.”

Figure 21 (Question 24) expresses the mixed result regarding guidance received from WHO in participants’ roles in the revision process.

Figure 21: (Question 24) Do you feel you have had adequate guidance from WHO in carrying out your role in the revision process?



Summarized comments on Question 24

Do you feel you have had adequate guidance from WHO in carrying out your role in the revision process?

Many of the same themes continue in these responses. *“Expectations have not always been clear”; “Communication poor from Day 1. e.g., decisions, planning, coordination”; “lack of standard business rules etc.”; “There has been some guidance during the years but due to the fact that things are changing very quickly roles seem to change too.”*

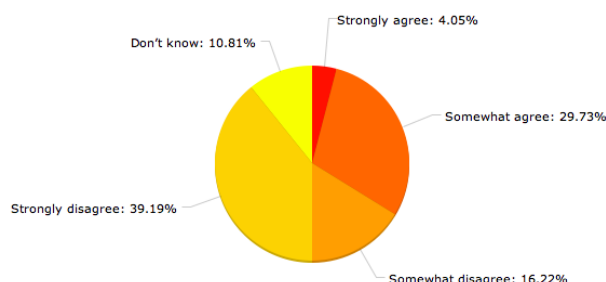
Concerns were expressed by TAGs, WHO-FIC Network, Primary care classification community and others: *“It would have been so much better if there had been a project management plan from the beginning so the Vertical TAGs knew what their rules were and what they have to work with”; “Lip service but offers not accepted and expertise from primary care not used. No role, no guidance;” “Strongly disagree regarding WONCA’s broader efforts to contribute more broadly to revision process. WONCA wanted primary care person on every TAG and could have provided it, but WHO declined the offer”; “(WHO-FIC) Education and Implementation Committee commented on Vol 2 but doesn’t know if anyone took notice - no feedback;” “WHO-FIC left out”; “From Morbidity TAG perspective, have repeatedly asked for guidance or direction and don’t get any answer or a satisfactory answer. Moving target”.*

Again, issues of WHO commitment raised by IHTSDO: *“With regard to work with IHTSDO, I have felt for some time there is no commitment to collaborative work and the common ontology form part of WHO - not a priority and maybe even an inconvenience.*

h. Project plans and timeline for completion of ICD-11 for 2017

More than 50% of respondents believe that the current project plan for ICD-11 is unrealistic (Figure 22) (Question 25).

Figure 22: (Question 25) Do you think that the current project plan for completion of ICD-11 is realistic?



Summarized comments on Questions 25

Do you think that the current project plan for completion of ICD-11 is realistic?

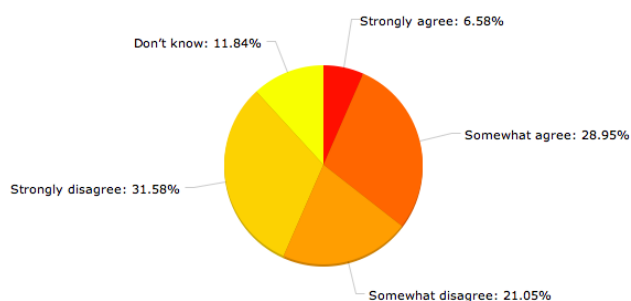
There are quite a few comments about the fact that they have not seen the project plan. The ones that have seen it believes that it is very ambitious and in need of an update. The need for better project management is mentioned again.

“Doesn’t take into account the need to take the rest of the world on the journey. Many unknown quantities.”

“It is much more important to get this project right than to rush to implement it.”

More than half did not think that the release date of 2017 is achievable (Figure 23) (Question 26). For those not considering 2017 achievable, 2018 – 2020 was the range of dates thought possible.

Figure 23: (Question 26) Do you think the ICD-11 release date of 2017 is achievable?



Summarized comments on Question 26

Do you think the ICD-11 release date of 2017 is achievable?

There was a lot of ambivalence about the release date and about the meaning of 'release'. Most believe that a fully-fledged field tested ICD-11 is not possible by 2017. However, if 2017 is a date for a modified cause of death list and Mark 1 morbidity list, then this is achievable. The tabular list even with inconsistencies is likely good enough but the index, coding rules and translations have the greatest relevance and impact and it is hard to see how all this could be finished by 2017.

There were a few who thought that 2017 might be a date by which the classification could be ready for field testing, and quoted the statement in the UNSC document E/CN.3/2015/20 dated 8 December 2014 that WHO is undertaking the revision of the ICD through a systematic process and is currently targeting a submission date in 2017 and the first international release for use in 2018.

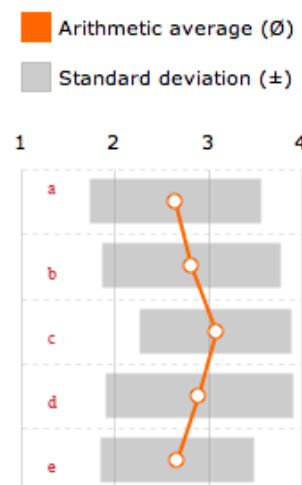
Overall there was a general reluctance to release prematurely a product that is not finished or useful. This was balanced by those who had provided support for the revision process and could not see this continuing past 2017 when a new Director General will be appointed.

i. Fitness for field trials

Figure 24 (Question 27) outlines the belief on average that all parts of ICD-11 and the transitions are partly (2) or not ready (3) for field trials.

- a = Tabular list
- b = Reference guide
- c = Index
- d = Transitions (crosswalks)
- e = Definitions

Figure 24: (Question 27) What do you think is the state of readiness of the whole of ICD-11 for Field Trials?



Summarized Comments on Question 27

What do you think is the state of readiness of the whole of ICD-11 for Field Trials?

Overall, respondents do not feel that ICD-11 is ready for field trials, although some chapters (Mental Health, Traditional Medicine, and Injuries and External Causes) already have been tested. *“The changes that need to be made cross over the tabular list, reference guide and index.”*

Comments about Tabular List: “Hard to comment because of degree of change;” “There are still so many deficiencies, inconsistencies and design errors in the current version, that Field Trials are not in order. FT should be done when the ICD-11 is almost ready for use”; “No chance to review yet”; “More changes need to be inserted before field tests”; “Infectious Diseases is in really bad shape”; “Finding problems and sorting them out will take time”;

Comments about Reference Guide: “Sporadic progress. Can't do the reference guide without a fixed classification with rules - moving deck chairs”; “The rules have to be discussed much more. The resources for all parties at present too small for that process;” “Hasn't been developed or reviewed by the RSG”; “did a major review of Volume 2, it needs more work.

Comments about Index: “The index is the key to correct coding and quality of data. Should not be underestimated”; “Need better search engine and rules to cut down need for index. Why can't we have an index electronically searchable?” (Apparently, this is being worked on); “needs reformatting as a real index with structured decision logic, not a laundry list”; “Index is not currently useable. Lack of understanding of how the classification is used (prior to March 2015 meeting)”; “It's not that Mortality experts want a paper index, they're asking for something that works”; “Could do targeted field trial to see whether terms in ICD-10 index are in current index”; “Half of physician offices in U.S. use a book for coding morbidity.” “The CTS electronic coding tool very impressive”.

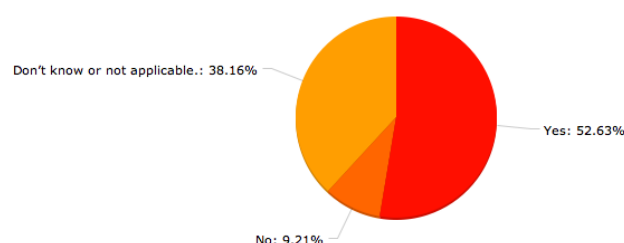
Comments about transitions: There were some positive, although tentative, comments about the crosswalks (more for mortality statistics). “Mapping very good”; “crosswalks are the item most close to being ready”; “Have made good attempt but need to test it (with real data)”; Caveats are that: “Crosswalks are only meaningful when the structure of the classification is stable, and the exclusion notes on chapter and group level are ready”; “Until they are released and validated by a group that was not involved in generating them it is hard to determine readiness”; “For morbidity analysis, we know that the concept still exists, but we don't know where.”

Comments about definitions: Definitions are a complicated topic. There are strong proponents of including definitions in the classification: “Definitions very important for clinical use”; “Big advantage over ICD-10”; “Biggest challenge for Kaiser is mapping to its Convergent Terminology on definitions.” However, even those who support including definitions in ICD-11 note problems with the current ones: “Good idea. Principle good. 50 year project”; “Good in some places, less informative in others”; “Can see advantages, but many issues, including copyright issues”; “Definitions (or descriptions = a better word) are useful, but problematic to really get good ones”; “definitions need a lot of corrections. Sources of definitions are often unclear even for TAG members”; “Perfect can't be enemy of good. They will be refined over time. Peer review of every definition will bog the process

down. Feels it's a good first step. Explaining what is meant by a concept, e.g., foreign body left during a procedure, is a good thing." Others are either against including definitions in the classification or, at best, sceptical: "Incomplete and questionably useful"; "This is the area most likely to cause adoption problems in some countries"; "Didn't want them in the first place; they will cause problems for coders"; Have a lot of concerns about putting clinical definitions in a classification. Will contribute to resistance on part of countries moving to ICD-11." Regardless of whether people support definitions, most agree that there are problems with the current ones: "Many come from Wikipedia, haven't been vetted"; "More work needed on definitions and more supervision of interns doing work"; "The way it's been curated, you can't say that they are consensus definitions"; "The 'definitions' are a complete mess for a significant number of entities." Most agree that trying to complete this component in the short-term will "bog down" the process. One problem area is that "Work on aligning the definitions with SNOMED CT has not yet commenced." SNOMED has definitions for a small percentage of terms.)

Figure 25 (Question 28) shows that 52.6% of participants believe that their country will participate in the Field Trials (although nearly 40% did not know).

Figure 25: (Question 28) Do you or your country plan to participate in Field Trials of ICD-11?



Summarized comments on Question 28

Do you or your country plan to participate in Field Trials of ICD-11?

As noted above, some groups have already done field trials and plan to do more. Others state that it depends on available resources, the maturity/quality of the classification and its translation. Several groups in the U.S. said they planned to participate in some aspect of the field trials. Australia, Canada and Japan will, Netherlands and others are not sure. One respondent, referring to the multiple frozen versions, asked "But how often are people going to do field trials?"

j. Implementation

Figures 26a and 26b (Questions 29a, 29b) show the percentage expecting that their country will introduce ICD-11 for mortality and morbidity (nearly 50% but again there was a high proportion who did not know). Over half thought it would be harder to implement than ICD-10 (**Figure 26c**) (**Question 29c**).

Figure 26a: (Question 29a) Do you or your country expect to implement ICD-11 for MORTALITY?

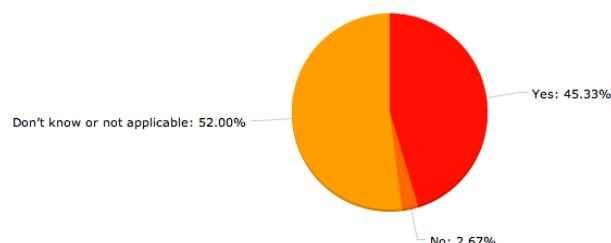


Figure 26b: (Question 29b) Do you or your country expect to implement ICD-11 for MORBIDITY?

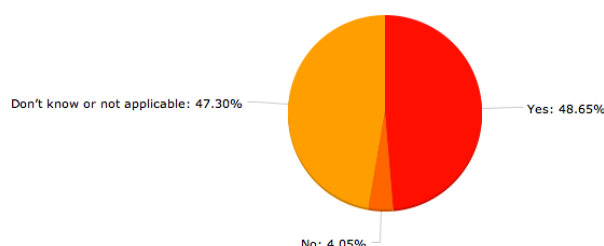
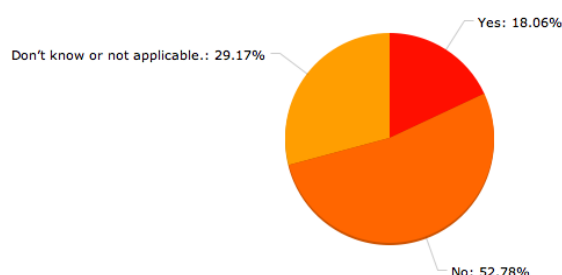


Figure 26c: (Question 29c) If yes, do you expect it to be easier to implement than ICD-10?



Summarized comments on Questions 29a, 29b, 29c.

Do you or your country expect to implement ICD-11 for a. mortality, for b. morbidity, and c. If yes, do you expect it to be easier to implement than ICD-10?

Q 29a. For those countries expecting to implement ICD-11 for **mortality**, many had no idea of time frame – for those ready to provide an estimate, the earliest was 2018 through 2020 and 5-10 years after approval. A lot depended on resource requirements and adaptability for decision tables and the automated coding system Iris. Countries have an obligation to implement for mortality, but their Ministries of Health make the decision. There is good will and intention subject to ICD-11 being fit for purpose. It was pointed out that mortality data is too important to risk being early in taking on a new version of ICD without it being fully tested and reliable.

Q 29b. For **morbidity**, results for implementation were even more uncertain from 2019 to ten years or more. Again, reluctance to commit depended on government and resources in terms of cost and education of coder workforce not to mention translation and having a workable quality product available with stability analyses bedded down and dual coding studies done to assess impact. It was also seen as a question of the system being ready for the electronic systems.

Q29c. ? easier to implement than ICD-10.

Several points were raised here including:

Optimistic:

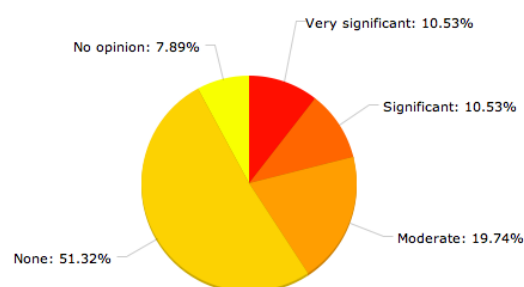
- Questionable need for national modifications and if required, feasibility of developing such modifications from Foundation Component
- Others thought that informatics and improved infrastructures in health information systems would make it easier to implement ICD-11 than ICD-10
- Optimism that ICD-11 has a more rational architecture and will produce better data
- The ontology will take the subjective nature out of mapping between ICD-10 and ICD-11. Old wine in new bottle will make transition a lot easier – industry rather than a government solution
- Basically the issues are the same: retraining of coders, adapting software, translation, bridge-coding studies

Pessimistic

- Influence of different code structure and content compared with similar concepts and structures when changing from ICD-9 to ICD-10
- Likely harder to implement given the change from manual coding for ICD-10 to coding in an electronic environment with ICD-11. Also the complexity of coding multiple lines of post coordinated codes as well as potential risks from having definitions in the system
- The increased number of use case specific procedures and systems might make implementation more difficult
- Major obstacle is that all IT and Patient Administration systems will have to be changed or updated due to a totally different code structure. Casemix systems will have to be reworked

Figure 27 (Question 30) shows the anticipated effect if ICD-11 were not released in 2017 (more than half indicating no effect).

Figure 27: (Question 30) What effect would it have on you if it were not released in 2017?



Summarized comments on Question 30

What effect would it have on you if it were not released in 2017?

Responses here ranged from a practical appreciation that ICD-10 is outdated and we need a better method of classifying to the substantial loss of confidence in international classification effort if it is not released. Some thought that a delay to 2018 would be acceptable, but there were many comments that there would be a lost opportunity if all the work is not utilised especially as ICD-11 provides for more precise and discriminatory analysis of activity, particularly in quality and effectiveness. Any release beyond 2017 would not enhance the credibility of the revision process and might make users lean towards other classifications. However the release of an unfinished ICD-11 that is less usable than ICD-10 would do much greater harm to the use of ICD.

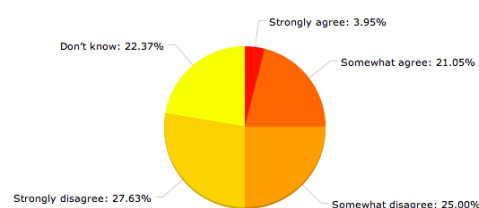
It was thought that WHO might lose face and find it harder to get additional resources for any extension of time for completion and that it would be difficult to explain the delays to donors who have invested on the basis of a 2017 release, particularly as there has already been an extension from 2015. This school of thought felt that it might not have to be a complete product in 2017 but good enough to do more refined pilot tests. In the meantime, ICD-10 could be used for a few more years.

On the whole, the replies showed a pragmatic balance between the importance of the revision and getting it right and the need to fulfil expectations and have a product by 2017. Most countries will continue to support positive progress and would hate to abandon all the good work because it was not complete by 2017. However countries are securing funds now to build implementation plans that are dependent on the release date of ICD-11 and that take into consideration its new format, content and structure so they are ready with a system that will accommodate this significant change.

k. Organization for maintenance and updates

In **Figure 28 (Question 31)** we see that more than 50% are unclear about the organization of work for updates and maintenance of ICD-11.

Figure 28: (Question 31) Do you think the organization of work for ongoing maintenance and updates is clear?



Summarized comments on Question 31

Do you think the organization of work for ongoing maintenance and updates is clear?

Many commented on the confidence developed in the operation of the existing WHO-FIC Update and Revision Committee (URC) for ICD-10 and the expectation that this group would take over the updating mechanism for ICD-11 after the Revision Steering Group has finished its work. However there is a need for wider participation and for greater clarity on business rules for updating, frequency of updates (? annual or less often as with ICD-10) and resources to manage the updates as well as a transition phase between updating of ICD-10 and ICD-11. There is some doubt whether URC will have the capacity to manage the updates in a new environment. Language is also a problem with updates and disseminating and maintaining parity between language versions and country modifications, not to mention hard copy publications.

Some respondents stated that we should think of other ways to revise apart from URC. The argument was that there will be more users than there are for ICD-10 and there will be a need to get their agreement on updates. With this wider audience there may be a need for more resources and a different approach and format – perhaps going back to the TAGs or to WHO-FIC – but it all needs rethinking. One suggestion was that WHO itself should retain responsibility for maintenance given that the data will be computerized. There is also the question about the division of labour and reconciliation procedures between WHO/ICD and SNOMED/IHTSDO and the possibility of the WHO/IHTSDO partnership to be jointly responsible for updating rather than WHO-FIC which feels ownership of the function. There appears to be a good adequate initial tool for web-based commenting and request for changes, although there have not been sufficient resources to implement the range of services originally envisaged.

It was thought that the availability of a comprehensive software tool (iCAT) to support ICD-11 could greatly facilitate the maintenance and updating process. However, IP and other ownership issues and resources for software changes to develop a maintenance rather than a

development environment could still cause challenges which need to be resolved as part of the planning for maintenance and updating of ICD-11.

There seems to be a great deal of confusion surrounding responsibility for updates and maintenance, its frequency, mappings between versions and how users will manage the updates. As this is such a major issue for member states and contributors it needs to be addressed very soon (although another respondent thought it a little too early to focus on this aspect).

I. Other comments

Summarized comments on Question 32

Do you have any other comments?

“Significant concern that there is very little succession planning happening to ensure the continued knowledge and expertise of the WHO-FIC Network members. From my vantage point, all Collaborating Centers are struggling to maintain their current involvement let alone bring along new blood to replenish the Network as the old guard retires.”

“I am very strongly supportive of ICD-11 but WHO needs to be sure that it is of the highest standard before it is released to the world, as implementing it will be a major global operation. I would hope that its release will then in future times be seen as a transforming event, enabling much better capture of information on disease across the world.”

“While all of the effort is being directed towards getting ICD-11 ready for release, there is no evidence on any effort being paid to create the processes, mechanisms and tooling for maintaining ICD-11 and releasing it after the initial release. This needs to be urgently addressed for the overall success of ICD-11.”

Many of these comments expand on specific comments to the survey questionnaire regarding the need for improved project management and communication, additional resources and attention to core uses of ICD (mortality and morbidity statistics, epidemiology and disease surveillance). There also is further detail about the lack of adequate collaboration with primary care classification experts and IHTSDO. Comments include strong words of praise for CTS and its vision, and strong frustration, as well. The marginalized role of the WHO-FIC Network is noted.

Comments not generally covered in responses to the questionnaire include:

I do not think ICD-11 as it stands is a useable product for a small or developing country, particularly those where the actual coders do not have sophisticated technological support and/or internet access. Developing countries ignored in the revision process.

The cost of the classification needs careful consideration - one of the major problems with ICD-10 is its affordability. Countries not represented by the members of the WHO-FIC Network need to be consulted about their requirements for ICD-11 and need to be involved in

the field trials. This means the field trials need to be offered manually as well as via the internet. The classification is not just for countries with highly developed information systems.

While all of the effort is being directed towards getting ICD-11 ready for release, there is no evidence on any effort being paid to create the processes, mechanisms and tooling for maintaining ICD-11 and releasing it after the initial release. This needs to be urgently addressed for the overall success of ICD-11.

If we're going to be successful in the long run, gradual updates of ICD would be the best approach for the world, rather than always trying to do something new and different. They should never have another major revision. Update on a rolling basis.

Wants to recognize the significance of the contribution that WHO has made to make an effort in aligning ICD with ICF and maintaining the integrity of the two separate classifications.

Those involved in creating ICD-11 have an exciting vision that it is stretch for many of us, but as it comes into focus, I'm impressed that this is going in an exciting direction. Would hate for status quo to rock innovation.

7. Assessment report

a. Solid foundation for health information systems

The creation of ICD-11 has brought together two formerly disparate worlds – the world of classification for statistical purposes and the world of terminologies and health informatics. WHO has done this to ensure that ICD continues to live and grow and is fit for purpose in the modern technological age. As envisioned, and it was visionary, it would be all those things, but its realisation has not been without its problems because what is being created has never been done before. Although there have been ten previous versions of the ICD, the marriage of classifications and terminologies has never been attempted. The index to ICD has always contained terms that provide the interface between either causes of death on the death certificate or the diagnoses written on the patient record. The Clinical Modifications have embellished these indexes and they have gradually acquired more and more structure as the need for accurate coding has increased. However they are not the same as a clinical terminology like SNOMED CT which is poly-hierarchical and where each concept is uniquely identified.

There are risks, of course, in attempting something so revolutionary for an audience that has grown up with the basic uses of ICD for reporting mortality and morbidity statistics and developed sophisticated ways to apply the classifications in increasingly complex environments and with new tools. This especially applies to automating rules for multiple cause of death reporting and using clinical modifications of ICD for quality and safety and casemix funding purposes. There are risks of non-acceptance, of stumbling in developing the tools required to produce and maintain the marriage of a classification and terminology envisioned for ICD-11 and of upsetting systems that have required major investment and that work. But given the technological tools available to us now and the increasing use of electronic health records in an environment of health informatics, it is difficult to see how we could *not* attempt to meld the worlds of classification and terminology to the benefit of both.

At risk also is the expenditure of scarce health resources for this endeavour. Some electronic tools are unproven, expertise is hard to come by, WHO itself is under-resourced, especially in this area, and there are conflicting demands. For example, it would be ideal to offer the classifications as a public good, but the reality is that the function needs to be self-sustaining and a business plan is essential – not only for income but to control the licensing arrangements and intellectual property of the classification and its contents.

A landmark contract has been negotiated between WHO and IHTSDO to allow the inclusion of SNOMED CT in the Foundation Component of ICD-11. Hopefully it will continue so that both ICD-11 and SNOMED CT can be updated together.

The huge size of the audience for ICD presents another risk. It is diverse in nature, there are many uses and users of ICD in developed and developing countries, each with its own environment and culture. So the classification has to be agile enough to be applied in these different milieus and responsive enough to react to their needs and recommendations. Just

looking at the objectives of the revision gives some idea of the different interests to be served and accommodated in the classification. Basing ICD-11 on a Foundation Component is a brilliant answer to this complexity as it brings together not only a clinical terminology such as SNOMED CT but the clinical modifications of ICD-10, other members of the WHO Family of International Classifications and classifications for different settings (e.g. ICPC) and specialty interests (e.g. rare diseases). Using this Foundation Component as a base to develop linearizations from a common core allows ICD to be bigger and better and more flexible. It also helps in crosswalks and transitions within and between classifications and revisions.

The risk here is that we might not be able to serve all interests at once. Some have priority and these need to be clearly spelt out. This report (and WHO itself) has nominated the JLMMS as first priority and that is what should be the aim for 2017. Early chapter specific releases in areas such as Mental Health and Traditional Medicine should be discouraged as the whole of ICD is required to reflect a patient's condition, even if presentation is to a mental health or traditional medicine practitioner. However, if these specialties wish to maintain or propose a Derived Classification in their area, for example the two existing publications for ICD-10 Mental and Behavioral Disorders, the material prepared for ICD-11 could be used to update such classifications.

Another risk is the obligation for WHO to produce both hard copy and electronic ICD products. The need for hard copy is understandable, and it is of course possible to produce hard copy from an electronically held base. But it does complicate the development process. If only an electronic product were available, it might in fact be easier for countries to adopt and disseminate the classification and to apply updates as they become available. The coding process itself using electronic tools can be more reliable than using books, and education in how to apply the classification made easier to distribute and to maintain consistency.

Translations are a major issue as well, especially in a hard copy environment. Alphabetic indexes are difficult to replicate in different languages and maintaining the classification even in the WHO official languages is a major task. Electronic translation tools are an enormous help but cannot solve all problems. Electronic coding tools based on terms in the Foundation Component and linked to linearizations provide a great leap forward in not only accessing the term from the patient record in the classification but in making inter coder ratings more reliable. Such a tool is being developed by staff at CTS. Which brings us to another risk, and that is the risk of losing staff members and expertise at CTS. They all have rare or unique combinations of skills, and in such a small team there is often only one person who knows the intricacies of a specific role. Even if they were all contented and fulfilled, there are normal reasons for attrition to be taken into account, and others should be trained to accept responsibility during absences or illness or as part of succession planning.

One of the major risks to WHO in producing ICD-11 is loss of credibility and trust. Loss if the revision is delayed again, loss if it is published in an unfinished form. Either would weaken this classification lynchpin of WHO and should be avoided at all costs – hence our recommendations to produce a basic linearization for 2017 as expected and to deliver on

investments. The knowledge that has gone into ICD-11 is not static. It should not be allowed to go stale. Resources should be used wisely to allow a staged implementation of this vital tool and to bring stakeholders along with the process and help them to implement this extraordinary revision as a solid and updatable foundation for health information systems.

8. Conclusion

Developing the 11th Revision of the ICD is a very complex process and it has been conducted so far with a somewhat limited amount of resources. There has been a lack of personnel working on the subject and therefore some of the needed work has been neglected. We believe that the work would have progressed better if more personnel resources with the right skills had been available. There have to be realistic expectations on what can be achieved given the budget available. What we have identified as lacking are:

- a. Information about the ongoing process to stakeholders on a regular basis
- b. Updated information on what groups are working on the revision process
- c. Updated information on who is participating in the different groups as well as the role of the participants
- d. Description of the governance model, where decisions are taken and by whom
- e. Adequate number of personnel in the team to do needed work
- f. Description on how different IT-tools are connected and dependent on each other to work in the most efficient and secured way
- g. Calculations on what the maintenance of the IT-Tools will cost for the future
- h. Adequate project management
- i. A plan to improve sustainability of CTS
- j. A clear roadmap with agreed deadlines on joint work with IHTSDO to link SNOMED CT with ICD-11
- k. A clear roadmap with agreed deadlines for collaboration with WONCA to create and vet the primary care linearizations
- l. Clarity about the role of the WHO-FIC Network in release of ICD-11 and its future updating

How to solve this?

- a. Start spending time on creating information at an executive level that can be communicated to the stakeholders. This can be achieved by using the personnel currently working on Facebook and Twitter. Social media is fine, but basic and correct information needs to come first. It might be published to the WHO's web site if there is a possibility for the stakeholders to receive messages when the information is updated.
- b. In order to have more transparency on ongoing work, there needs to be clear and accessible information about who is participating in what groups.

- c. It needs to be clarified if the stakeholders are representing themselves as persons with an interest in the subject or if they are representing larger organizations.
- d. In order for the stakeholders to have trust in the on-going process it needs to be clarified who has the mandate to make decisions and in what areas. The decisions should then be made public as soon as possible to all stakeholders.
- e. Create a business model for the usage of the ICD instrument. This can be done both on the gain of selling printed books on ICD as well as developing different models of licensing the usage of the classifications. If this is not done, there has to be a substantial amount of central money from WHO to support this important work.
- f. Description of connectivity of IT tools needs to be done as soon as possible in order to make it understandable for more persons than just those who have been involved in the development of the different tools.
- g. If the new ICD classification will be based on IT, there should be a plan for how to maintain it, otherwise it will fail. Resources are essential for this work.
- h. Appoint a project manager and an additional classification expert urgently.
- i. Seek resources to ensure ongoing viability of CTS in developing and maintaining ICD-11 and other members of the WHO-FIC.
- j. Address issues with IHTSDO (re SNOMED CT in Foundation Component and joint updating between IHTSDO and WHO).
- k. Address issues with WONCA (re Primary Care Linearizations to meet their needs and role of ICPC).
- l. Address issues with WHO-FIC Network and their role in ICD-11 release and updating.

- **UN Statistical Commission 2013** Report on the 44th session Page 35. The Statistical Commission expressed concern that the 11th revision of the ICD might be too complex and challenging for countries to implement, and requested WHO to give sufficient time to the revision process and to subject the revised classification to field test and assessment before adoption;
- **Eurostat 2013.** Letter to WHO expressing concerns about ICD-11. It listed a series of activities needed for the completion of ICD-11 development before adoption:
 - Completion of the Foundation Component to a sufficient standard of consistency and coherence across chapters, including resolution of between-chapter inconsistencies
 - Completion of the Linearization for Morbidity, including coding instructions (similar to Volume 2 of ICD-10) and other supporting material, and endorsement by the Morbidity Reference Group
 - Creation of the Linearization for Mortality, including coding instructions and rules for selection of underlying cause of death (similar to Volume 2 of ICD-10) and other supporting material, and endorsement by the Mortality Reference Group
 - Resolution of inconsistencies between the Morbidity and Mortality Linearizations and agreement on their relationship
 - Development of alphabetical indices covering the Foundation Component and Linearizations (similar to Volume 3 of ICD-10) with accessibility for manual users of the classification
 - Presentation of the Linearizations (operational classifications) in official WHO languages, in a form which facilitates translation into further languages, and in forms suitable for manual users
 - Scoping and conceptual design for computerised ICD-11 coding systems, based on the existing ICD-10 coding systems such as IRIS (Europe) and ACME (USA), including a realistic work plan for the adaptation of existing systems or development of replacements
 - Principles for the implementation of ICD-11 in other computerised systems such as national statistical production systems and health sector administrative systems

- **Eurostat statement 2013**
 - The EU legislation requires Member States to report causes of death (COD) following the ICD classification. The completeness of the new ICD-11 will be crucial for its proper implementation. It is a pre-condition for continuity of time series and for comparability at EU level. We would strongly oppose any consideration for adopting an ICD-11 in May 2015 with missing or incomplete guidelines, cross classifications tables or adaptation of dictionaries and field testing thereafter. Such an approach would jeopardise its success, as it would put all burden for the implementation of ICD-11 on National Statistical Authorities, which have already expressed their concerns at experts' meetings on COD statistics at EU level.
- German Collaborating Centre 2013, 2014. Issues relating to:
 - review process
 - structure of linearizations
 - national modifications
 - crosswalks
 - extension codes/Chapter X codes
 - definitions
 - exclusion notes
- mTAG 2014
 - Problems in state of classification that can't be solved by 2017
 - Problems that will have major impact on cause of death statistics
 - Index problems
- Coding of death certificates in Nordic-Baltic region using frozen version of ICD-11, August 2014
 - Found 66% agreement between coders
 - Coders newly trained, coded from index
 - Concluded that current alphabetical index not ready for use
 - Thorough review needed
 - Need for ground rules on which terms to index, standard formatting of index terms, uniform spelling, inclusion of 'unspecified', consistency of index

Survey Questionnaire

APPENDIX 2

REVIEW ICD-11 REVISION

26.1.15

Dear colleague

Consultancy Interim Assessment of the process 11th Revision of the International Classification of Diseases

We are members of a Team that has been requested by Dr. Ties Boerma, Director, Department of Health Statistics and Information Systems of the World Health Organization, to conduct an external review of the ICD-11 Revision Process. The terms of reference for the project require us to gather information from a variety of stakeholders who have been actively involved in the revision process itself or whose organisations have a strong interest in its outcome.

The scope of work is briefly as follows:

1. Conduct an interim assessment of ICD-11 in terms of:
 - Progress towards the goals of the Revisions
 - Process and mechanisms put in place for the ICD Revision
 - Project resources (financial and human) in relation to the proposed outcomes of the revision
 - Project plans and proposed timelines for the completion of ICD-11 by 2017 (adoption by WHO governing bodies)
 - Organisation for maintenance and updates of ICD beyond 2017
2. Analyse 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 use in mortality and morbidity statistics, primary care, clinical care and scientific research.
3. Compile an assessment report summarising the findings and making recommendations for improvement, including making future ICD fit for multiple purposes, easy to implement and to serve as a solid foundation for health information systems.

The following questions have been compiled to obtain information necessary to carry out the review. We would be most grateful for your cooperation in helping us by completing the questionnaire. We do not expect answers from you for all questions but you may wish to add information from others who are experts in particular areas.

In preparing our final report we do not intend to associate specific comments with individuals, and the findings, in general, will be grouped by type of use or user.

Our report is due for delivery to WHO by the end of March so we would appreciate very much your early attention to this matter and completion by March 6 2015 at the latest. Questionnaires completed on line do not have to be sent – we will access your completed form on the survey internet site.

Yours sincerely

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Brief profile of each respondent

1. Name _____
2. Affiliation/Country _____
3. Position _____
4. What is your role in the current ICD revision process? (tick one or more)
 - ☐ TAG Member or TAG Working Group Member
 - ☐ Revision Steering Group
 - ☐ WHO-Collaborating Centre
 - ☐ Mortality Reference Group
 - ☐ Morbidity Reference Group
 - ☐ WHO Regional office
 - ☐ Statistical Office
 - ☐ Ministry of Health
 - ☐ Non Governmental Organization
 - ☐ Quality and Safety
 - ☐ Health Care Terminology
 - ☐ Using the classification to code morbidity (diseases)
 - ☐ Using the classification to code mortality (causes of death)
 - ☐ Maintenance and update of ICD on international, national or local level
 - ☐ Other (*please specify* _____)
5. What is your main use of ICD (past or present)?
 - ☐ Coding (*use ICD for coding data for research, clinical or administrative purposes*)
 - ☐ Analysis (*use ICD-coded data for analysis or research*)
 - ☐ Policy and Programs (*use ICD data for some higher level purpose such as mortality and morbidity monitoring, casemix, quality and safety indicators or other*)
 - ☐ Other (*please specify*) _____
6. Rate your knowledge and familiarity with ICD (0 none to 10 regular use)

Questions

The objectives of the ICD Revision Process have been agreed:

- a. 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;
- b. To continue to serve as an international standard in multiple languages and settings to allow for comparable data;
- c. To link with computerized health information systems (directly use standard terminologies and other health informatics applications to be “*electronic health application ready*”).

7. To what extent do you think these objectives have been achieved so far for ICD-11?

- a. Revision in line with scientific advances and serving multiple purposes?

Very significant Significant Moderate Minimal No opinion

Comment _____

- b. Revision developing an international standard to allow for comparable data?

Very significant Significant Moderate Minimal No opinion

Comment _____

- c. Revision linking with computerized health information systems?

Very significant Significant Moderate Minimal No opinion

Comment _____

8. What importance would you give to each of these objectives?

- a. Revise in line with scientific advances
- b. Serve as an international standard
- c. Link with computerized health information systems

Very high High Medium Low No opinion

9. How would you rate the overall need for ICD-11?

Very significant Significant Moderate Minimal No opinion

Comment _____

10. Is the planned form of ICD-11 likely to meet requirements for use in **mortality** statistics?

Very significant Significant Moderate Minimal No opinion

Comment _____

a. Do you expect that ICD-11 will be an improvement over ICD-10 for use in **mortality** statistics?

Very significant Significant Moderate Minimal No opinion

Comment _____

11. Is the planned form of ICD-11 likely to meet requirements for use in **morbidity** statistics?

Very significant Significant Moderate Minimal No opinion

Comment _____

a. Do you expect that ICD-11 will be an improvement over ICD-10 for use in **morbidity** statistics?

Very significant Significant Moderate Minimal No opinion

Comment _____

12. Is the planned form of ICD-11 likely to meet requirements for use in **primary care**?

Very significant Significant Moderate Minimal No opinion

Comment _____

a. Do you expect that ICD-11 will be an improvement over ICD-10 for use in **primary care**?

Very significant Significant Moderate Minimal No opinion

Comment _____

13. Is the planned form of ICD-11 likely to meet requirements for use in **clinical care**?

Very significant Significant Moderate Minimal No opinion

Comment _____

a. Do you expect that ICD-11 will be an improvement over ICD-10 for use in **clinical care**?

Very significant Significant Moderate Minimal No opinion

Comment _____

14. Is the planned form of ICD-11 likely to meet requirements for use in **scientific research**?

Very significant Significant Moderate Minimal No opinion

Comment _____

a. Do you expect that ICD-11 will be an improvement over ICD-10 for use in **scientific research**?

Very significant Significant Moderate Minimal No opinion

Comment _____

15. Has the revision process addressed problems with ICD-10 structure, content and rules that could not be addressed in the updating process? Please give examples.

Very significant Significant Moderate Minimal No opinion

Comment _____

16. With regards to making decisions about structure, content and rules for ICD-11, how effective do you consider the current decision-making process?

Very effective Effective Moderate Minimal No opinion

Comment _____

17. Do you think that adequate technical and financial support and resources have been provided to WHO to develop ICD-11?

Very significant Significant Moderate Minimal No opinion

Comment _____

18. Are there specific areas where you feel additional resources are needed by: (tick as many as necessary)

☐ WHO

☐ Topic Advisory Groups

☐ Revision Steering Group and RSG SEG

☐ WHOFIC Network

☐ Member Countries

☐ Other (please specify) _____

19. How easy have you found it to contribute to the ICD Revision Process?

Very easy Easy Moderate Minimal No opinion

Comment _____

20. Within the ICD Revision Process, it is easy to communicate with:

a. WHO Classification Team

Strongly agree Somewhat agree Somewhat disagree Strongly disagree Don't know

b. Revision Steering Group (RSG)

Strongly agree Somewhat agree Somewhat disagree Strongly disagree Don't know

c. RSG Small Executive Group (SEG)

Strongly agree Somewhat agree Somewhat disagree Strongly disagree Don't know

d. Relevant Topic Advisory Groups (Vertical, Horizontal)

Strongly agree Somewhat agree Somewhat disagree Strongly disagree Don't know

21. How useful have you found the information about ICD-11 posted on the WHOFIC website?

a. Beta Draft (browser)

Very useful Useful Moderately useful Minimally useful No opinion

b. Proposal system

Very useful Useful Moderately useful Minimally useful No opinion

c. Other (e.g. FAQs, Information Notes)

Very useful Useful Moderately useful Minimally useful No opinion

22. Do you agree with the timeliness of decisions made about structure, content and format of ICD-11?

Strongly agree Somewhat agree Somewhat disagree Strongly disagree Don't know

Comment _____

23. Do you agree with the transparency of decisions made about structure, content and format of ICD-11?

Strongly agree Somewhat agree Somewhat disagree Strongly disagree Don't know

Comment _____

24. Do you feel you have had adequate guidance from WHO in carrying out your role in the revision process?

Strongly agree Somewhat agree Somewhat disagree Strongly disagree Don't know

Comment _____

25. Do you think that the current project plan for completion of ICD-11 is realistic?

Strongly agree Somewhat agree Somewhat disagree Strongly disagree Don't know

Comment _____

26. Do you think the ICD-11 release date of 2017 is achievable?

Strongly agree Somewhat agree Somewhat disagree Strongly disagree Don't know

Comment _____

If not, when do you think it will be ready? _____

27. What do you think is the state of readiness of the whole of ICD-11 for Field Trials?

a. **Tabular list** Ready Partly ready Not ready No opinion

Comment _____

b. **Reference guide (Vol 2)** Ready Partly ready Not ready No opinion

Comment _____

c. **Index** Ready Partly ready Not ready No opinion

Comment _____

d. **Transitions (Crosswalks)** Ready Partly ready Not ready No opinion

Comment _____

e. **Definitions** Ready Partly ready Not ready No opinion

Comment _____

28. Do you or your country plan to participate in Field Trials of ICD-11?

Yes No Don't know or not applicable.

Comment _____

29. Do you or your country expect to implement ICD-11?

a. For mortality

Yes

No

Don't know or not applicable

If yes, how many years after it has been approved? _____

Comment _____

b. For morbidity?:

Yes

No

Don't know or not applicable.

If yes, how many years after it has been approved? _____

Comment _____

c. If yes, do you expect it to be easier to implement than ICD-10?

Yes

No

Don't know or not applicable.

Comment _____

30. What effect would it have on you if it were not released in 2017?

Very significant

Significant

Moderate

None

No opinion

Comment _____

31. Do you think the organization of work for ongoing maintenance and updates is clear?

Strongly agree

Somewhat agree

Somewhat disagree

Strongly disagree

Don't know

Comment _____

32. Do you have any other comments?

Thank you very much for your participation.

APPENDIX 3

Financial Support for ICD-11 Revision Project

Information from Dr B Üstün, Coordinator, CTS, WHO. 16.3.15.

Approximate project income over 9 years (2007-2015)

Source	Income
WHO core funding for CTS Coordinator and 1 staff member (70%) and secretary from 2007-2015.	\$ 7,400,000
WHO departments – Mental Health, Neurology, GURM, Oncology	\$ 2,400,000
Japan Hospital Association	\$ 2,700,000
Traditional Medicine	\$ 3,600,000
European Commission – Mental Health and Rare Diseases and Public Health Informatics	\$ 800,000
In kind support:	
Stanford	\$ 320,000
Australia NCCH	\$ 600,000
World Federation of Chiropractic, Italian CC	\$ 400,000
Meeting Grant	\$ 50,000
TOTAL	\$18,270,000

Topic Advisory Groups (TAGs)^{viii}

Vertical TAGs:

Dermatology
External Causes and Injuries
Genito-urinary, Reproductive & Maternal Health
Internal Medicine
Mental Health
Musculoskeletal
Neoplasms
Neurology
Nutrition
Ophthalmology
Oral Health
Pediatrics
Rare Diseases
Traditional Medicine

Horizontal TAGs:

Functioning
Morbidity
Mortality
Quality and Safety

Working Groups for Internal Medicine

Cardiovascular
Endocrinology
Gastroenterology
Haematology
Hepatology & Pancreatobiliary
Nephrology
Respiratory
Rheumatology

References

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- ⁱ Roberts R, Rust J. The role of the Update Reference Committee and the development of ICD-11. (WHO/HFS/CAS/C/03.49). Paper presented at WHOFIC Cologne 19-25 October 2003.
- ⁱⁱ Ustun TB. ICD Revision Process: towards ICD-11. PowerPoint presentation at WHOFIC Reykjavik 24-30 October 2004.
- ⁱⁱⁱ Morbidity Reference Group – Discussion paper. Revision topics for topic advisory groups (TAGs). April 3, 2009. Contributors include: North American (US and Canada), Australian, Nordic, Japanese Collaborating Centers).
- ^{iv} Morbidity Reference Group and Mortality Reference Group. ICD-11 rules, conventions and structure. Paper updated following the Delhi meeting. January 3, 2009.
- ^v Roberts R, Innes K, Walker S, Scott P (2004) Avoiding a war of words (and numbers). The uncertain future of terminologies and classifications, *Journal of AHIMA*, 75(9): 27-32
- ^{vi} Bowman S (2005) Coordination of SNOMED-CT and ICD-10 – Getting the most out of E H R systems. *Perspectives in HIM*. Spring
- ^{vii} <http://www.who.int/classifications/whoihtsdo>
- ^{viii} <http://www.who.int/classifications/icd/TAGs/en/>