3. ICD-11 beta draft: will be the field trial version for testing for its feasibility, reliability, utility and other predefined objectives. It will be simultaneously presented in 6 WHO official languages and tools for translations to other languages will be provided. The beta draft will be structured (linearization) similarly to the ICD-10 fourth edition with possible field test options to test the conversion from 10th to 11th version. This convergence will allow users to switch from ICD-10 to ICD-11 in a seamless fashion, and preserve statistical continuity.

2 Structure of ICD-11

The ICD-11 will be a set of dynamic relationships that are constantly updated.

The prevalent distributed version of ICD-11, a linearized view of the core structure, will continue to be based on the structure of ICD-10 and its alpha-numeric coding. The core structure of ICD-11 will fully reflect concept relationships and logical definitions, as a dynamic representation of scientific progress and will be continuously updated. Predicable, stable disease categories will be derived from this logic core, and be manifested as the ICD-10 style linearization.

More importantly, ICD-11 will be linked to ontologies and terminologies with human readable textual definitions, which are also in a computer format, thus allowing automated reasoning, decision support and user specific linearizations.

The information model will apply to all of the categories of ICD-11. Human and computer readable definitions for every rubric of the information model (where applicable) will be provided through linkages to established terminologies and ontologies. Structured full text definitions enable human editing and usage, and enforce consistency in use and translation. (Inclusion terms of the current ICD are at a higher level of detail and will not have their own definitions, unless evidence calls for separating some into individual categories.)

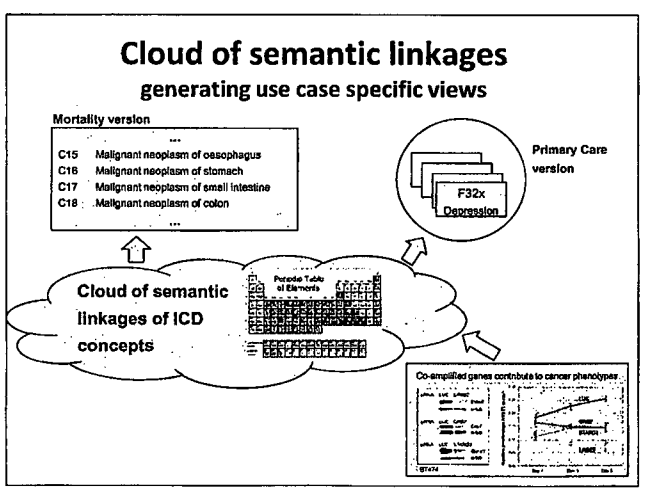

Figure 4 – A cloud of linked concepts of ICD-11 is source for usecase specific views

ICD revision starts from present ICD structure first. This sets a clear starting point to offset the risk of biasing the revision.

Definition: Depressive Disorder F32.0

A.	Low mood	{41006004}
	Loss of interest	{417523004}
	Low energy	{248274002}
B.	Appetite *(decrease, increase)*	{64379006, 72405004}
	Body weight *(decrease, increase)*	{89362005, 8943002}
	Sleep *(decrease, increase)*	{59050008, 77692006}
	Psychomotor *(decrease, increase)*	{398991009, 47295007}
	Libido loss	{8357008}
	Low self esteem	{286647002, 162220005}
	Guilt, self blame	{7571003}
	Thoughts of death ...	
	Suicide Ideation	{102911000, 6471006}

Figure 5 – Linkages between diagnostic criteria of ICD-10 category F32.0 and SNOMED

The joint proposed work with IHTSDO for the harmonization of disease classification terms will enable the building of these formalisms with standard tools. The knowledge representation underlying the constellation of clinical and laboratory findings related to the diagnostic categories in the ICD will enable better operational definitions in line with the information model. This can be described as aggregation logic or algorithmic approach.

It is essential that the ICD diagnosis can be further elaborated using clinical terminologies to formalize the diagnosis with operational algorithmic definitions. For example, F32 Depressive Disorder will be captured as SNOMED CT terms each coded and defined such as (Low mood, loss of interest, low energy, sleep problems (insomnia, early awakening,...) appetite problems (low appetite, binging...) sexual problems (libido loss); guilt ; thoughts of death and suicidal ideation or acts. In the context of ICD revision DSM and ICD will aim at aligning their mutual definitions.

Similarly Tuberculosis, A15.0, will be further detailed by primary infection, positive tuberculin test, infection site (lungs, bone, kidney etc...) symptoms (coughs, sputum, fever, sweating, weight loss...) and findings (bacillus positive, culture positive etc) (see Figure 6 below).

Definitional criteria of the information model on the example "Tuberculosis"

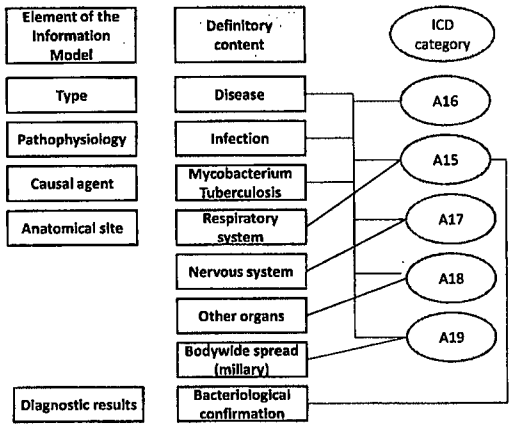

Figure 6: Diagnostic algorithm by defined dimensions and separation of ICD-10 categories – for Tuberculosis

Information Model - Example Tonsillitis (J03.0)

Name : J03.0 Acute Tonsillitis: Streptococcal tonsillitis

1. Textual definition: Inflammation of the of n tonsil, due to infection by beta-haemolytic streptococci.
2. Synonyms:
3. Index terms - Tonsillitis (acute) (follicular (cancerous) (infective) (linaval) (septic) (subacute) (ulcerative) streptococcal

Definitional characteristics

1. **Type:** disease{64572001}
2. **Pathophysiology :** infection{40733004}
3. **Anatomical site** tonsil{265787001}: part of upper respiratory tract{361381009}::respiratory tract: human body
4. **Manifestation Attributes**
   1. Symptoms: pain
   2. Signs: inflammation{23583003}
   3. Diagnostic results --
   4. Functional impact --
5. **Etiology**
   1. Causal agents: beta-haemolytic streptococci : cellular organisms; Bacteria; Firmicutes; Bacilli; Lactobacillales; Streptococcaceae
   2. Mechanism: --
   3. Genomic characteristics: --
6. **Temporal Relations**
   1. Chronicity: NOT chronic (acute)
   2. Episodicity. --
7. **Severity and/or Extent**
8. **Treatment/Prevention**
9. **Hierarchical relationships :**
   Is child of J03: has no children

Maintenance attributes

A. **Subset, adaptation, and special view flag**
   Primary Care, Clinical Care, Research, Public Health
B. **Unique identifier :**
   {lxm40kzmoasdégj¯¨1^395ièkäc$mt03}
C. **Mapping relationships**
   (Linkages to other systems like SNOMED etc.)
D. **Sanctioning rules**

Figure 7: All attributes of the Information Model are filled in for the example of category J03.0, Acute streptococcal tonsillitis. Integer numbers in brackets are references to SNOMED-CT.

This same process will be done for all areas of medicine under the WHO classification guidelines together with international experts in the related fields. WHO's previous work on specialty adaptations (such as classification of tumours and ICD-O, mental health etc) and joint work with CIOMS on International Nomenclature of Diseases (IND) will enable us to populate this model as it is fit for the template. Other work already existing in knowledge bases in rare diseases (i.e. Orphanet) and others will be incorporated in a similar fashion.

Section II- The Management Plan

The management plan provides an overview the budget, describes tasks and progress, and analyses risks of the project.

This section describes the individual tasks in sequence, and includes the milestones. Tasks are divided into up to four levels. All tasks are briefly described. Tasks include stage of progress and make reference to working instructions that are detailed in appendices, as necessary and available. All tasks include descriptions on who does the work. Resources and consequences of failure are always specified down to the second level, and in critical cases below. Tasks contain cross references to relevant precursor tasks. Incompletely specified tasks are tagged "< detail under development>". For details, a Gantt chart is available under Annex 5. Milestones are highlighted with grey background and contain criteria for achievement, as necessary. Summary costs for achievement of the milestones are listed in a separate section, as is a summary assessment of risks.

1 Organization of revision entities & design of processes

Goals and generic process of the revision of ICD are specified. A project team is formed. Tasks and workflows are formulated. Communication mechanisms between the teams are specified. Progress is tracked and reported.

Revision entities share work for specific parts of the revision work. A Revision steering group oversees and coordinates the overall work. Topic advisory groups (TAG) coordinate work for specific domains of ICD. One or more Workgroup review, summarize and work out change proposals for such domains. In addition, everybody contributes with suggestions and comments on the web based revision platform.

Coordination of workflows and roles in the revision process is specified in Annex 4 . Detailed workflows exist for the WHO Update and Revision platform. Workflows for the HiKi (Wikipedia like platform) are currently being designed, and will depend on the progress of revision, stage of availability of HiKi, and tooling suggestions by the Health Informatics and Modelling Group.

Workflows are elaborated by WHO CTS team, in collaboration with the RSG and the TAG HIM. Resources exist.

1.1 Forming Revision Steering Group (RSG)

The Revision Steering Group (RSG) acts as an organism that assists WHO in the oversight and coordination of the revision process. Membership includes traditional stakeholders, and chairs of the TAGs. Membership should not exceed 12 persons to prevent inefficiencies in the work process. For the traditional stakeholders, coordination with the WHO-FIC Network is ensured by membership of one chair of the Network's council. Specific guidance on past and present ICD maintenance needs in mortality and morbidity uses of ICD is provided by the chair of the WHO-FIC Update and Revision Committee (URC). Input on developments, and alignment of the other classifications members of the WHO FIC is carried out by the chair of the WHO-FIC Family Development Committee (FDC). A liaison between WHO-FIC and development of Primary care classification ICPC by WICC/WONCA) ensures close collaboration in this sensitive topic.

Terms of reference of the RSG are detailed in Annex 1.

Resources ensure regular face to face meetings of the RSG.

Expansion of membership of the RSG is carried out by TAG chairs while TAGs are formed. An initial RSG is already operational.

1.2 Formulating user guide for Topic Advisory Group (TAG) work processes

The user guide describes the tasks (ToR), procedures, informs about criteria for selection of members, and contains also the necessary legal framework, as on conflict of interest, and intellectual property. Find current version under Annex 3.

Edits by WHO are ongoing, in collaboration with chairs of existing TAGs, and the RSG. Edits concern mainly further specification of workflows and deliverables.

Resources for the production are ensured.

1.3 Forming of TAGs

TAGs organize the work for the revision of ICD in a specified domain based on procedural, terminological and taxonomical guidelines of the revision process. Equitable geographic distribution, expertise, and active leadership are guiding principles for membership. Further details about membership and tasks are specified in the manual for TAG and Workgroups (see also Annex 3 and par. 1.2).

WHO in collaboration with RSG, NGOs, and the WHO-FIC Network advocate for participation in the revision of the ICD. Press releases, internet sites, presentations at world summits of relevant disciplines, and information from NGOs will allow the mobilization of contributions in human and financial resources. TAG chairs are selected by WHO with advice from NGOs and the RSG. TAG chairs identify relevant experts following the rules of the manual. TAG chairs will seek WHO's agreement for the membership.

Resources come from the TAG's members donating their time and donors supporting the work. WHO will acknowledge TAG members with a formal letter, after signature of Declaration of conflict of interest and Intellectual property agreements.

Formation of TAGs is critical in adhering to the ICD-11 timeline up to the point of completion of the revision. Main input to the revision should come before the formulation of the Alpha draft. Some TAGs will provide input later. Structural changes, as well as creating new and changing cluster categories, can be taken into account until formulation of the Beta version in 2011. Minor edits and changes to individual categories at the terminology level, are possible until the end of the field tests (mid 2012).

1.4 Forming Work Groups within each TAG

Workgroups carry out the reviewing process by, searching for evidence, incorporating comments and proposals into one consolidated proposal for ICD-11 in their specified domain. Formation of Workgroups is at the discretion of the relevant TAG. Members are appointed in agreement with WHO. Members and other contributors are acknowledged by WHO with a formal letter as Contributing Experts after signature of Declaration of conflict of Interest and Intellectual property agreements.

Revision team is formed.

This milestone is achieved as soon as TAGs have been formed covering all domains currently contained in ICD-10. Where gaps in coverage persist at the time of formulation of the beta version, revision is informed only by existing clinical modifications, and proposals. Summary proposals in such case will be elaborated by MRG/MbRG.

2 Needs analysis and concepts of core Usecases

2.1 Assessing of ICD users' needs

Information on use and obstacles to implementation of ICD are compiled in an implementation database. Public health informatics needs are assessed in an online survey. Workgroups specify the usecases for ICD. A summary report is produced.

WHO has implemented the implementation database. Content comes from member states and from previous surveys.

WHO is conducting the Public Health informatics survey in collaboration with Michigan University.

Usecases are formulated by working groups (see 7).

2.2 Assessing of resource specific needs

This task is covered by user and country needs assessment and is not described separately.

2.3 Assessing of countries needs

Implementation Database and analysis of shortlists of diagnoses inform this task.

Work is carried out by WHO in collaboration with ICD experts from Collaborating Centres.

Resources are ensured by WHO and its Collaborating Centres.

Needs analysis achieved.

2.4 Formulating usecases

Public health surveillance corresponds to the most widespread use of ICD-10. Two variants do exist: mortality and morbidity data. Explicit definition of categories of ICD, incorporation of implicit coding rules of the index and of current Volume 1 of ICD, and incorporation of selection rules of volume 2 in descriptive logic will ease and standardize use of ICD.

Additional uses that are relevant to the revision are casemix, quality and patient safety, and primary care settings.

A scheme for description of usecases has been developed. It is based on an IT modelling technique. A prototype of a mortality usecase description guides groups that work on other usecases.

The relevant usecases are identified with the aid of the WHO-FIC Network, and research groups. Specification of the usecases is ongoing.

The same groups will review or guide review of ICD-11 against these usecases.

Resources are assured for definitions. Resources for testing have to be identified.

3 Formulating Information Model (IM), software and revision tools

The elements of the revision platform are designed and programmed in collaboration between WHO, Mayo, and Stanford University under guidance by the TAG HIM.

3.1 Formulating IM

The meaning of "information model" includes definition of structure and systematized content (value sets), in the context of the revision of ICD.

The information model specifies the rubrics relevant to a category of ICD. It contains definitional elements, and meta-information, as use of the category, structural context in the classification, and versioning including time relationships. The information model allows explicit machine readable definition of a category, linkage to terminologies and ontologies, and application of reasoning software in revision and maintenance of the classifications.

The information model is critical to the revision of ICD. It has to be stable by begin of the formulation of the alpha draft in mid 2009. Failure will result in need to large scale editing at a later stage, living with a dysfunctional model, delays in definitions of the categories.

Resources are ensured by current funds and donations in time by RSG, and TAG HIM members.

3.1.1 Drafting information model templates

Drafting of model templates starts from the implicit model that is the basis of ICD-10. WHO drafts first models on this basis. Criteria for use of descriptors of the information model have to be defined. Attributes of the information model have to be reviewed, and their use clarified.

3.1.2 Consulting with RSG and TAG HIM

Edits and usability of a prototype of the IM are assessed in collaboration with the RSG. Detailed design will be elaborated by the TAG HIM. Membership of the TAG HIM ensures that existing information models for disease is taken into account.

3.1.3 Selecting value sets for each IM rubric

The task includes definition on how a specified attribute should be applied to a particular disease, and the selection of relevant existing value sets for such an attribute of the Information Model.

Problems in the definitions of relevant value sets arise from:

- Non existing value sets for a specific attribute
- Intellectual property issues

For most of the attributes, the HIM TAG will consider short-term and long-term solutions to the modelling problems. Value sets for several attributes will come from SNOMED. IP and terms of collaboration have to be specified.

Resources are ensured by WHO and Stanford University. Additional resources may come from collaboration with NLM and IHTSDO.

3.1.4 Creating a web-based template

Based on the model structure and the relevant value sets the information model will become available for input and editing definitions of ICD.

Tasks depend on availability of the information model and decision of tooling environment. At present, both existing frontends of the revision platform (WHO ICD-10-PLUS, and LexWiki at Mayo) have the capacity to handle template. Tooling decision will depend upon recommendation by TAG HIM and availability of the relevant frontend.

3.1.5 Formulating information model recommendations for TAGs

TAGs will provide the definitions based on scientific evidence and international consensus. Guidance will make sure the IM is applied by all TAGs in the same way.

The TAG-HIM will formulate the recommendations. Reviewing and piloting by sample TAGs will result in edits before the recommendations are shared with all TAGs.

3.2 Producing ICD-10+ platform

The ICD-10-PLUS platform serves to collect all proposals and existing modifications to ICD. Its content informs the work of the TAGs. The TAGs will discuss and post their summary proposals onto the platform. Functionality follows the one of the current updating process. Additional elements for definitions and changes in the workflow are necessary. Way of implementation of definitional input elements will depend on progress in the other frontends and the availability of the information model.

Resourcing is ensured for ICD-10-PLUS and HiKi. Need for resources for explicit knowledge representation will depend on progress and recommendations by the TAG HIM, and additional research outcome from the US NCBO.

3.2.1 Producing platform tool with ICD-10+ information

Production involves adding workflow for revision, and incorporating the information model template to the existing update platform.

WHO carries out the necessary work. Resources are ensured.

Production of the platform is critical to the revision. The work will be achieved by late 2008. Implementation of features for definition of categories depends on decisions and availability of value sets.

3.2.2 Identifying access paths for different users

Users of the platform are heterogeneous. Options for collaboration are dependent on the user's role in the revision, and the type of contribution.

Main access paths have been identified by RSG and WHO. Additional ones may result from the work of the TAG HIM.

Work is achieved. Additional steps may be necessary pending input by the TAG HIM.

3.2.3 Identifying workflows

Workflows of the platform will allow routing proposals for editing and discussion between different groups and layers of the platform resulting in different degrees of access to the proposal.

Proposals are routed by a moderator, or editing rights depend on layer and role. Comments are possible everywhere to everybody or comments are possible depending on role and layer.

Layers are switched by the group editor or by overall platform moderators on request by the owner of a proposal.

Workflows have to be detailed out by the time TAGs start working and discuss summaries on the platform. This will be the case late 2008.

3.2.4 Programming commenting feature

Comments will be possible by proposal, by category, and by attribute of a category. Relevant functionality has to be programmed.

Work is carried out by WHO.

Work for commenting proposals is achieved. Functionality for commenting attributes exists. It will come into practice pending progress in the information model.

3.3 Creating HiKi tools

The HiKi tool will allow editing a category, linearizations and definitions. Multiple edits may occur. In fixed cycles, a TAG will review the edits and decide about changes to the authoritative version of ICD.

3.3.1 Designing HiKi tool

Design includes features, technical approaches, frontends, and transition from or fusion with existing platform. Potential migration to, or incorporation of ontology tooling has to be planned.

Based on existing semantic wiki tools, and informed by present update platform and maintenance tool of ICD a prototype is being designed at Mayo, the LexWiki. Multiple edits to linearizations (to proposed structure) of ICD must be presented by the tool in a humanly understandable format. This point has been identified as a particular challenge. Frontends need to be shaped facilitating the input from the crowd.

The HiKi tool should become latest with the beta version. Earlier publication may facilitate completion of definitions.

Resources come currently from Mayo. Future resources have to be identified.

3.3.2 Programming Wiki frontend

The frontend is the face of the tool. Simple, slightly different frontends will facilitate input by the crowd. Detailed functional descriptions, migration strategies, and assessment of LexWiki will result in recommendations by the TAG HIM.

3.3.3 Programming terminology-ontology link feature

The feature allows viewing hierarchies of the relevant terminologies and ontologies while selecting the most appropriate concept for definition of an attribute of a concept of ICD.

Technologies for viewing and linking exist, e.g. at the NCBO Bioportal. Start of work depends on progress of the HiKi and on decisions regarding the Information Model.

3.3.4 Programming revision specific workflow

Same technical aspects apply as for 3.2.3, Identifying workflows.

A type workflow has been implemented at the LexWiki. Edits may be the result of recommendations by the TAG HIM and the RSG.

3.3.5 Programming commenting feature

For technical description see 3.2.4.

Feature is essentially implemented. Additional work will follow consolidation of the information model.

3.3.6 Programming structure editing feature

This feature allows making recommendations for structural changes of ICD in traditional linearization allowing the contributor to carry out the relevant change.

Programming a prototype has been carried out by Mayo.

The work is achieved. Next steps depend on the recommendations of the TAG HIM.

3.3.7 Programming linearization frontend

The linearization frontend will allow generating versions of ICD that differ in sets and arrangement of concepts.

Appropriate description logic and language exists (OWL). Detailed specifications largely depend on type and linkages to other ontologies, on the developments in the ontology tool and on recommendations by the TAG HIM.

Resources have to be identified.

3.4 Producing ontology tools for formal representation of disease knowledge

The ontology tooling is the prerequisite to description of all relationships between ICD concepts and between their attributes. Software (reasoners) can then identify logical conflicts with principles of classification, thus improving consistency and facilitating maintenance of ICD-11. Multiple conceptually consistent presentations (linearizations) that accommodate the uses of ICD in different settings can be produced that are based on structural definitions and external ontologies.

Work will be carried out by experts that need to be identified, in conjunction with Stanford/NCBO experts.

Funding is uncertain. Partial funding can come from a grant of the NIH.

This part of the project is relevant to accessibility of ICD in electronic environments and to facilitation of implementation. Non-achievement does not endanger the revision but will very much reduce functionality to the traditional level.

3.4.1 Developing protégé distributed web editing

Editing and formalization of the knowledge will at first rely on a small set of experts. Maybe a broader audience will join. Migration of existing content of ICD needs further discussion.

3.4.2 Programming revision specific workflow

Principles are the same as in the relevant paragraphs above. Progress will depend on funding and technical decisions.

3.4.3 Programming RDF export/master import

This interface is relevant to communication with existing standards in terminology and classifications (LexGrid for maintenance, ClaML for maintenance and specific output).

Already, from current HiKi, and with additional features, from present ICD-10+, output in ClaML could be generated. Achievement of this task is crucial to generation of customized versions of ICD, as soon as the whole ICD is described in OWL.

3.5 Assembling Revision Platform

ICD-10-PLUS is shaped for proposal based work. HiKi allows editing of structure and content in a Wiki Style, the ontology tool allows formal representation of ICD structure and content. All three platforms have functionality that will be necessary for the revision, and continuous maintenance of ICD.

Assembly means these tools communicate with the same database, or migration to one or another technical base preserves the functionality above.

Approaches to that task depend on development of HiKi and of the Ontology tooling. Feasibility of migration or merger of present reification of HiKi with ICD-10+ has to be assessed.

Funding has to be identified.

Effectors have to be identified.

Impact of failure depends on achievements in HiKi, and Ontology tooling. Guidance by TAG HIM can prevent technical obstacles. Failure while all tools are developed, will result in lacking functionality for output, or for input, and of the ICD-11 itself.

Revision Platform is ready for inputs.

The milestone is achieved, as soon as all components of the platform are ready. Achievement depends largely on funding, and on timely progress of the work of the TAG HIM. Partial achievements do not endanger the revision of ICD for traditional uses.

Funding gap is an estimate 1 Mill USD, for HIKi, Ontology tooling and Assemblage.

4 Populating the revision platform

Existing edits to ICD, existing definitions and known problems with ICD will inform the revision and accelerate the revision process thus providing or proposing solutions.

Population with proposals depends on participation on the platform. Several points have been identified by present stakeholders already.

For progress in other subtasks, see below.

Resourcing is assured, pending amount of work for routing and organizing proposals.

Broad participation in this task is one core goal of the revision. Failure will result in parts of ICD that are not updated despite urgent need, in impaired acceptance of ICD-11, reduced evidence base, and reduced features that are related to the definitions, but will not endanger the uses of ICD-11.

Clinical modifications, reviews from TAG and input from stakeholders are necessary to the revision of ICD. Failure will make revision impossible. Input to the definitions is critical to features and linkage to ontologies and terminologies. Failure will result in lacking embedding of ICD in Health IT environment, and lacking consistency in data quality (status quo).

4.1 Adding clinical modifications (ICD-XM)

Countries have adapted ICD to better serve need in morbidity context. Usually more detail has been added.

Owners of such modifications have to be asked for permission to use information on type and site of such modifications to inform the revision. Permissions have to include presentation of the changed elements on the revision platform.

Modifications in languages other than English may require translation. Modifications may be present in different technical formats that need to be aligned for import on the platform.

Some modifications have been parsed and are on the revision platform. Copyright and confidentiality limit progress in importing others.

Conceptual additions have mainly been made in English, French, German, and Swedish. With respect to similarity of medical terminology there was seen no need for translations of these versions.

Resources come from WHO and Mayo.

4.2 Adding specialty adaptations

Medical specialties have expanded ICD for more detail in parts relevant to them. Most adaptations date back 10 years, or more.

Access to the adaptations is limited, as electronic files are not accessible, or do not exist, except for the ICD for Oncology (current ICD-O-3), and the International Classification for External Causes of Injury (ICECI).

ICECI has been imported to the platform. Due to structure of ICD-O-3 such import will be of questionable advantage to the revision. For other specialty adaptations exploration for files is ongoing.

Present work has been achieved by Mayo and WHO.

Necessary additional resources depend on the source formats.

4.3 Adding existing definitions (IND, etc)

WHO and NGO own several sets of internationally agreed definitions. They are identified approaching systematically the relevant entities and solving potential copyright. Import of existing definitions requires conversion of formats from text into a format suitable to input to a database. Second step involves transformation into explicit machine readable definitions of the attributes of the Information model.

The International Nomenclature of Diseases was the terminological basis of ICD-10. It is co-owned by WHO and CIOMS. Majority of its definitions are available as electronic source files. Previous to import on the platform parsing and manual editing will be necessary. Work will amount to 10 person days.

At WHO's, definitions of the manual for communicable diseases are accessible, TBC and Malaria programmes have definitions as well. Edits and parsing will be necessary. Some definitions are available from the Manual for reporting adverse drug reactions.

IARC owns definitions of Neoplasias ('Blue Books'). Collaboration with WHO for the revision of ICD has been agreed.

Orphanet, platform for rare diseases and TAG Rare Diseases has well formed definitions of over 2000 rare diseases. 112 rare diseases have their own category in ICD.

Such work is resource intensive. For import of IND about 10 person days are necessary. Assumptions go for similar dimensions for the other sets of definitions, proportional to their size. Copyright has to be arranged with FIGO, and other NGO. Definitions of Orphanet were shaped for direct import. This part of the work has been achieved.

Necessary resources for format conversion and import are available at Mayo and WHO. Resources for transformation into machine readable definitions have to be identified. Part of it may come from TAGs' work.

4.4 Searching for other definitions (NCBO etc)

Sets of machine readable definitions exist. They have to be identified, and prerequisites for inclusion in ICD have to be assessed. Among others, the NCBO is a typical portal that contains already a set of biomedical ontologies, with and without definitions.

The TAG HIM will identify other definitional systems, and assess quality and prerequisites to their inclusion.

Resources exist for assessment. Resources to a limited extent exist for inclusion in ICD, pending size of necessary legal arrangements, technical prerequisites.

4.5 Engaging input from all stakeholders

Categories with imported definitions and without definitions are presented on the HiKi online platform. Users of the platform edit the definitions and add missing ones. Users also make the explicit definitions of the attributes.

Prerequisites include availability of HiKi functionality, availability of the Information Model, and availability of TAG that verify, edit and agree on definitions.

Resources for HiKi exist, at WHO and Mayo. Pending recommendations by the TAG HIM additional resources may be necessary. TAGs are starting their work in several fields. Specific editorial staff that work on the definitions has to be identified and funded.

4.6 Engaging inputs from NGOs

Broad input on the web based platform is one improvement of this revision of ICD. WHO advocates continuous for participation through media, attendance and organization of meetings.

Resources exist for individual trips. They have to be identified for organization of meetings.

4.7 Encouraging developing countries expert inputs through WHO disease specific programs

WHO's disease programmes communicate with a large number of experts in the field in all regions. Such expertise is an asset to the revision, because it makes sure categories and definitions meet the needs in the field. Disease programmes ideally have one or more staff that coordinates input by these experts to the revision. Programmes include ICD work in their work programmes.

Resources for organization come from WHO. Resources for working time or travel of the abovementioned experts have to be identified.

4.8 Engaging input from Health Systems specialists

ICD is the basis for management of several health systems. Input consists of suggestion of categories' suitability to health system information.

Relevant experts are available at WHO Department for Health systems. Other groups have to be identified.

Resources have to be identified.

4.9 Encouraging usecase related inputs

Usecases guide the development of ICD. Groups specify the usecases and verify existing and new categories for their suitability to the relevant use. Groups that carry out these activities are formed from relevant stakeholders. Advocacy and identification of stakeholders establishes contacts to such experts.

A set of usecases for purposes and relevant uses of ICD have been specified (work ongoing). Relevant groups are existing reference groups for mortality, morbidity, case mix experts, and initiatives and institutions for Quality Management and Patient Safety. For Primary Care, relevant contact is WONCA, and collaboration has been agreed.

Resources exist inform of voluntary contribution to Mortality and Morbidity. Limited resources exist for Quality and Primary Care.

4.10 Organizing all relevant proposals

Proposals for changes or non changes to ICD are generated and put on the revision platform. TAGs have to synthesize summary proposals for their domains. This task consists of routing the proposals to the relevant TAGs, and rerouting according to issues of overlap between two TAG, as identified by RSG or TAG.

One full time assistant with knowledge of ICD per 400 proposals will be necessary to carry out that work. To a limited extent, with low traffic (up to 200 proposals) this work can be handled by the URC secretariat together with WHO.

This subtask is critical to the revision. Failure will result in incapacity to carry out the revision.

Resources are made available by WHO.

4.11 Reviewing all inputs by TAGs and Workgroups

TAGs receive all proposals that relate to their domain. They receive summary proposals from their different workgroups. They review the relevant proposals and create summaries following their work instructions (see Annex 3) for the relevant domain. Work includes organization of teleconferences, routing email and organizing and attendance of face to face meetings.

Resources are needed for 3 meetings for a TAG (kick-off, alpha version, beta version, teleconferences, at least 1 face to face meeting of every single workgroup). Linking such meetings to international meetings of relevant NGO, or scientific societies reduces necessary budget. Working time is donated by the members of TAG and Workgroup, in addition to financial and organizational support by NGO and member states. Recompensation by WHO consists in acknowledging contribution in an official letter and naming the contributor in the context of the work.

Work is assured for External causes and injuries, Internal Medicine, Maternal Health, Neoplasms, Ophthalmology, Psychiatry and Rare Diseases. Under exploration are Dermatology, Dentistry, Orthopaedics, Neurology, and reasons for encounter. Groups for infectious diseases and urogenital diseases have to be identified by WHO.

The task is critical to the evidence base and up to date definitions. Failure will result in very limited review of ICD, and uncertain bias of revised parts of ICD-11 by interest groups (advocacy, political, or scientific).

All information relevant to revision is compiled.

The milestone is achieved as soon as all tasks under 4,'Populating the revision platform' are achieved.

5 Formulating ICD-11 Alpha-draft

5.1 Drafting segments of ICD-11

Clusters of concepts of ICD that are closely related due to similarities in their definitions, based on present ICD structure at block level are reviewed as segments. Resulting reshaped concepts are labelled and defined according to the specifications (information model).

Work will be carried out in different ways pending stage of the tooling environment.

Present tooling: WHO editors in collaboration with TAGs carry out the work.

Full functional HiKi: Proposal technology allows redrafting parts of ICD directly by users. Proposed changes are summarized by the tool. Decisions for adoption are made by TAGs, and WHO editors, after review for conflicts and evidence.

Ontology tooling: Reasoners identify constructs that conflict with existing other parts of the classification. TAG and WHO editors verify feasibility and evidence.

Resources come from TAGs, collaborating centres, and WHO. Resources for 2 and 3 are being identified.

Stage 1 is critical to the revision. Failure results in failure of delivery of ICD-11. Step 2 and 3 are critical to improved consistency of ICD and reduction of resources for maintenance of ICD.

5.2 Reviewing by TAGs and WHO editors

Drafted segments are reviewed for conflicts between areas of overlap, and usefulness and feasibility for the purposes of the classification is verified with the aid of the usecases.

Work is carried out by TAG chairs, RSG and WHO-editors.

Resources are ensured by WHO.

5.3 Harmonization with FIC & ontologies

The classifications of the WHO FIC overlap for specific areas. The same will applies to linked ontologies and terminologies. Pending specific shaping of concepts for specific uses, such shared conceptual domains should share the same concepts. Only some Members of the WHO-FIC are owned by WHO.

Work will consist of the set of tasks below.

Resources come from all involved parties. Travel costs are not ensured.

5.3.1 Solving copyrights and other legal issues

Copyright and legal issues are relevant where sources are outside WHO.. Issues are solved by agreements with relevant entities. Such entities are WICC/WONCA for primary care, IHTSDO for clinical terminology, WHO collaborating centre for Drug Use (ATC/DDD) in Oslo, and the WHO collaborating centre for drug monitoring in Uppsala.

So far, an agreement with WICC/WONCA ensures ICPC-3 and ICD-11 will be developed ensuring matching concepts. This includes using the relevant sets of concepts on both sides.

An agreement with IHTSDO is under development; discussions with the drug centres are progressing.

Need for additional arrangements depend on the specifications of the Information Model.

WHO carries out the work.

Resources are ensured.

5.3.2 Consultation with other product owners

Consultation with other product owners relates to terms of collaboration ensuring development of aligned conceptual bases in the ICD and the 'other' system.

WHO carries out the consultations.

Resources are ensured.

5.3.3 Modifications and alignment

Editing external systems or concepts of ICD is aimed at establishing conceptual consistency. Working procedures need to be established that allow such alignment.

Steps include: identification of areas of overlap.

5.4 Commenting by RSG

Final summary proposals from TAG are reviewed by the RSG together with the TAG's report on process and arguments. Persisting conflicts in issues of overlap between two TAG will be arbitrated by RSG, and in case of failure of arbitration decided in discussion between RSG and WHO.

Amount of work will be shared between the members of the RSG. No member reviews the work of its own TAG. Results of the reviews will be reported for discussion at the Alpha draft meeting of the RSG. No additional content experts are consulted.

An estimate 2 person weeks per chapter (of traditional ICD) makes 44 person weeks of working time.

Resources include donation of working time, one meeting and communication with TAG, as necessary. Financial Resources exist with WHO.

5.5 Commenting by URC

URC will comment on drafts of the ICD-11 in the standard linearization, from a classificatory point of view. Comments will be informed by TAG summaries that have been reviewed by the RSG, and by TAG work reports. No additional external (national) experts may be consulted. Results will be reported to WHO and the RSG. TAGs edit their summary reports. WHO editors edit the drafts of ICD-11.

Amount of work will be one half person month per chapter, is a total of 11 person weeks.

Resources come from the collaborating centres.

Endorsement of Alpha-draft ICD-11 by WHO.

WHO will consider endorsement of the alpha draft, after all concerns of RSG and URC have been duly taken into account.

5.6 Incorporating comments

5.7 Checking for consistency, continuity, completeness

Consistent use of terminology and the information model is verified, and edits are mad in collaboration with the relevant TAG. Backwards compatibility is assessed. Where continuity does not exist, facts are reconfirmed with TAG, as necessary. Existence of suitable categories for all cases is verified, through comparison with ICD-10.

Work is carried out by WHO editors. The amount of work depends on the amount of proposed changes. Dimensions will be an estimate of 1 person year of ICD expert.

Resources are in part ensured by WHO.

5.8 Writing Alpha-draft ICD-11 report

5.9 Pilot testing

Pilot testing will show feasibility and utility of selected parts of ICD-11. Selection criteria include number of changes per section (more than 20%), parts that caused conflicts in overlap between two domains, or in linguistic assessment.

Pilot testing will include double coding (ICD-10 and ICD-11), and parallel coding (inter rater reliability, inter language reliability). Cases have to be identified; hospitals and other facilities have to be contacted for double coding.

RSG will consult with WHO on the parts that are piloted. RSG, Collaborating Centres and TAG ensure availability of the relevant facilities. Evaluation is done by the RSG. Results are discussed with the TAG upon solicitation by the RSG.

Resources are uncertain and depend on the availability of facilities that have to be contacted.

Failure will result in reduced evidence for choices aiming at solution of problems that arise in the revision.

5.10 Conducting expert consultations

Alpha draft of ICD-11 is presented to experts on the revision internet platform. WHO departments, members of national or international institutions that are involved with one or more use of ICD, will be invited to give their feed back.

WHO and RSG identify relevant contacts. WHO invites for comment. Results are forwarded to TAGs by WHO editors.

Resources are ensured for initiating consultations, and commenting on the revision platform. Additional face to face meetings are not planned. For several experts this can be achieved in the context of relevant meetings at WHO's. Timeline for revision is a constraint to this approach.

Failure will result in reduced evidence base and reduced acceptance of ICD-11.

6 Formulating ICD-11 Beta-draft

Beta draft is informed by expert reviews and pilot test of the alpha version. Beta draft is used for field testing.

6.1 Reviewing by TAGs of all proposals and amendments

TAGs receive comments and results of pilots of their domain. TAGs review evidence for proposed changes and edit their summary proposals. Some TAG that were formed late may still provide input to revision the same way as the early ones did for the Alpha draft.

6.2 Reviewing of all inputs by RSG

For details see 5.4,'Commenting by RSG'.

Amended summary proposals are reviewed by the RSG.

Work will be an estimate 20% of the review of the Alpha draft (pending amount of work resulting from late proposals), is 9 person weeks, to be shared among the members of the RSG, and one face to face meeting.

Resources are ensured by WHO.

6.3 Commenting by URC

For details see 5.5, 'Commenting by URC'.

Work will be an estimate 20% of the review of the alpha draft, is about 3 person weeks.

Resources come from the collaborating centres.

6.4 Incorporating comments

WHO and WHO editors review comments and edits, and arrange for edits to the alpha draft, as necessary.

Resources are ensured by WHO.

Beta - draft released

This work is achieved with the milestone publication of the beta draft of ICD-11. It is independent from production of manuals or print products that are prerequisites for field testing.

6.5 Establishing the field trial protocols & tools

Field trial protocols will identify suitability to usecases, inter rater reliability, feasibility, and IT integration. Trials and protocols will be informed by testing of ICF and by bridge coding protocols that were used in transition from ICD-9 to ICD-10. Existing protocols have to be reviewed, and rewritten for ICD, with additional sections that are specific to the usecases.

7 Field trials focused on usecases

A set of generic usecases reflects the needs for ICD-11 based on experiences with ICD-10. Usecases are formulated by current stakeholders.

Agreement on disease concepts, phenotypes, is relevant to all usecases.

Clinical phenotype and public health phenotype are put under one hood, as most public health relevant diagnostic data are output from clinical context. Delineation to terminologies will depend on use.

7.1 Mortality

Field tests consist of double coding of existing electronic full text certificates of death will ease understanding of statistical impact of changes implemented in ICD-11, and indicate achievability of current categories. Data exist at the US NCHS, and with reduced level of detail at French INSERM. Other sources may follow by the time of presentation of the beta version due to efforts of introduction of electronic certificates of death. Limitations way result from confidentiality and related national legislation. Work is carried out by the national entities that handle the data. Several of the abovementioned are collaborating centres.

Additional field tests depend on the explicit description of the rule base in Ontology Web Language (OWL), and linkages to terminologies. They include automated derivation of cause of death from patient records and logic software that applies selection and coding rules.

Resources come from centres and relevant institutions. Funding for evaluation of the outcome has to be identified.

< Further detail under development>

7.2 Morbidity

Relevant group of the WHO-FIC Network specifies the usecase.

Effectors and resources for field testing have to be identified.

< Detail under development>

7.3 Casemix

Casemix systems that are based on ICD currently guide payment systems.

< Detail under development>

7.4 Quality and patient safety management

A working group specifies the generic usecase and the specific usecases. ICD is tested against such usecases.

Input comes from Global alliance for Patient safety, JCAHO, IMECCHI, and other institutions.

< Detail under development>

7.5 Primary care scenarios for activity, quality, and financial administration

Primary care scenarios of the abovementioned generic usecases share importance in assuring health services, limited resources and direct involvement in prevention programmes. Appropriate simplification of ICD and representation of appropriate concepts in ICD has to be evaluated.

Input and work comes in collaboration with WICC/WONCA. Additional effectors have to be identified.

Resources have to be identified.

< Detail under development>

Field trials completion

The milestone is achieved as soon as all ICD-11 has been tested in all mentioned usecases, and reports are available. Failure will result in uncertain usefulness of ICD for untested usecases.

8 Final draft

Final draft incorporates outcomes of the field trials, last consultations between WHO, NGO and major other stakeholders. Preliminary comments from reviews by WHA may feed into the final draft as well.

8.1 Reviewing by TAGs of all proposals and amendments

TAGs receive comments and results of field tests of their domain. TAGs review evidence for proposed changes and edit their summary proposals. Input from late TAG work can be considered for definitions and isolated changes of categories that have no impact on other domains.

Resources come from TAGs.

8.2 Reviewing of all inputs by RSG

For details see 5.4,'Commenting by RSG'.

Amended summary proposals are reviewed by the RSG.

Work will be an estimate 20% of the review of the Beta draft (pending amount of work resulting from late proposals), is 2 person weeks, to be shared among the members of the RSG, and one face to face meeting.

Resources are ensured by WHO.

8.3 Commenting by URC

For details see 5.5, 'Commenting by URC'.

Work will be an estimate 20% of the review of the beta draft, is about 1 person week.

Resources come from the collaborating centres.

8.4 Formulating Pre-Final Draft

WHO and WHO editors review comments and edits, and arrange for edits to the beta draft, as necessary. WHO editors edit instruction manual and verify index and synonyms.

Pre-final draft released

The prefinal draft is available for public viewing online. A print version of standard linearization (alike ICD-10) is produced.

Resources are ensured by WHO.

8.5 Inviting Public consultations

Press release and a WHO press conference announce availability of the prefinal draft of ICD-11 for public commenting. A circular letter by the Director General of WHO invites Member States for comments.

Resources are ensured by WHO.

8.6 Editing, formulating the Final draft

RSG and URC consult for necessary edits. Proposals for major structural changes are forwarded to the relevant TAG for comment. Pending feedback RSG and URC make final recommendations. TAG reports are put together into the revision report.

WHO editors carry out the changes, and produce the revision report.

Resources are ensured by WHO, URC members and TAG, pending amount of necessary work.

Endorsement of ICD-11 by WHA.

WHA receives Final draft 6 months preceding the general assembly of the WHA, together with the revision report, and adopts the ICD-11.

8.7 Publishing final ICD-11

Amendments that are requested by the WHO are carried out by the WHO editors. A classic print version of ICD is produced. Electronic versions for incorporation in software and lists for statistical reporting are produced.

Work is carried out by WHO editors with assistance by the revision platform, the TAG HIM, and the Electronic Tools Committee of the WHO-FIC Network.

Resources are ensured by WHO in part. Amount of software assistance depends on success in the development of the relevant parts of the revision platform, in particular the ontology tooling.

Progress in ontology tooling will impact on necessary minimum functionality of the other parts of the revision platform in order to enable production of the ICD-11 for the different media.

9 Implementation, Dissemination & Public Health engagement

9.1 Writing ICD-11 user manual

The user manual will instructs customers of correct use of ICD and ensures consistence use of ICD.

ICD categories are specified for use in specific contexts, as mortality and morbidity. Rules for selection of a single cause are specified. Instructions for coding that is based on paper versions and for electronic versions are formulated. Rules for access to and incorporation of specific database versions of ICD are formulated. Conventions of ICD are described. Rules for statistical presentation are formulated. International legal conventions for use of ICD in Member States are added.

Use of categories is specified by TAGs in collaboration with usecase groups as soon as the relevant parts of ICD-11 are compiled.

Coding rules for the relevant versions are taken from current ICD version and adapted by usecase groups.

Effectors for instructions that relate to database versions have to be identified. The TAG HIM is recommended for this work.

Summary editing is carried out by WHO.

Resources include donation of working time by TAG members, workgroup members, collaborating centres and WHO.

Majority resources are ensured. Additional resources for editorial assistance have to be identified.

Failure will result in failure of producing ICD-11.

9.2 Producing training material

Training material for ICD-11 refers to training on structure, content, maintenance and proper use of ICD. Training material comprises lessons on structure, content, and proper use of ICD on syntax, as well as standards for metadata in context of ICD, quality assurance, principles of classification and terminology, statistical presentation and confidentiality. Information on maintenance will increase awareness of mechanisms for participation in the continuous improvement and adjustment of the ICD.

Training material is currently compiled for ICD-10. Content follows the elements above that are founded on 15 and more years of training experience with ICD-10 and precursors (core curricula elaborated by the WHO-FIC Network). Present production allows easy adaption to ICD-11, and expansion for additional lessons, e.g. on relationship between different linearizations, scope of definitions, linkages, use in conjunction with linked terminologies and ontologies.

The majority of necessary changes and additional will become apparent with the Alpha version of ICD-11. The timeline allows having the training materials ready for the field tests.

Editors, authors, and financial resources for adaptation to ICD-11 have to be identified. Collaborating centres may act as editors or reviewers, pending funding.

Sustainable mechanisms and resources for updating in line with updates to ICD-11 have to be identified.

Failure results in delayed implementation and inconsistent use of ICD-11.

9.3 Crafting tools and strategies for transition from ICD-10 to ICD-11

This set of instruments includes transition tables, algorithms for assessment of statistical impact of transition, and procedural descriptions for implementation of transition.

Transition will be easier than the one from ICD-9 to ICD-10. ICD-11 is built starting from ICD-10. Electronic explicit tracking of conceptual changes will allow automated creation of transition tables for the major part of the classification. Human review is necessary for thoroughly changed parts of ICD. The electronic tracking of changes (e.g. of source concept in ICD-10 and target concept in ICD-11) allows also identification of areas of potential statistical continuity. Existing full text electronic death certificate data allows double coding of the same source data.

This task is critical to adoption of ICD-11. Failure results in delayed implementation or non implementation of ICD-11.

Resources have to be identified.

9.4 Designing mechanisms for updates and their dissemination

The HiKi allows continuous commenting and proposing of changes to ICD. This input is reviewed on an annual basis. Reviews inform amendments to ICD-11. Changes are published online for automated and manual incorporation in electronic systems. Files of updates for print are available online. Publication of updates is announced in the WHO Bulletin. Paper based versions are produced every 6 years.

The public makes proposals and provides some evidence. TAGs continue to exist after revision and review these comments as for the interim versions of ICD-11 (Alpha version and Beta version). WHO disseminates the updates.

RSG and URC review proposed edits. WHO editors carry out the edits.

Sustainable resources have to be identified.

Failure results in irregular or missing updates and/or their dissemination. In consequence compilation of international statistics is limited by incompatibilities between different versions of ICD-11.

9.5 Assembling user tool package

The user tool package includes training tools, sample implementation strategies, and translation tool.

WHO editors pull together the tools on a single CD or other portable format.

Resources have to be identified. Collaborating centres can assist WHO in this task.

Failure results maybe in delayed implementation.

ICD-11 implementation package ready.

All tools under 7.4-7.8 are available. Assembly (7.9) is an asset.

9.6 Implementing in selected pilot countries (developed and developing)

Implementation in pilot countries will allow assessment of routine data collection and technical incorporation of ICD in countries' health information systems.

Selected translations are made by collaborating centres of Alpha, Beta and Final Version of ICD-11.

Selected countries implement full ICD in selected coherent parts of their health information system, as in one administrative region for all applicable usecases.

Volunteers are invited by WHO.

Resources come from some countries. For low resourced countries, sustainable funding has to be identified. Pilots can be part of a donor project for implementation of a specific component of health information, as mortality.

Failure will result in lacking information for implementation obstacles at level of concepts, produced formats, language and cultural aspects.

Pilot countries implemented ICD-11.

Selected countries have implemented full ICD in selected coherent parts of their health information system, as in one administrative region for all applicable usecases.

10 Producing multilingual versions

10.1 Assessing linguistic aspects

Languages have different sets of preferred terms and synonyms that may or may not correspond to the ones expressed in the English master version. Conceptualization of diseases may defer depending on language and culture.

Linguistic assessment comprises:

- Summary of translation problems with previous versions of ICD, and other classifications
- Reporting translation problems in early language versions at Alpha stage
- Translation and back translation of core concepts and category titles on a multilingual online system by users:
  - English texts are presented for translation proposals. The translation proposals are commented/edited by the crowd. Intensity and duration of changes will indicate a potential problem.
  - Texts of translations of the Alpha version will be presented in conjunction with the English source. Comments and proposed edits are made by the crowd. Intensity and duration will indicate problems.

Detected problematic parts of ICD will be reviewed and edited by the relevant translator together with the relevant TAG.

10.2 Assessing cultural aspects

Health and perception of health is a continuum between 'modern' and 'traditional' medicine. Some health related concepts are perceptions of illness from culturally dependent angle.

Cultural aspects were relevant topics already in formulation and maintenance of ICD-10, as for complications of traditional medicine interventions, lifestyle interventions, or some mental diseases.

Effectors and resources have to be identified.

Failure will result in concepts missing or not suitable to specific cultural settings.

10.3 Programming multilingual transition software

Translation software eases translation presenting English version and allowing parallel view on translations. Output will consist in standardized file format suitable to construction of multilingual ICD-11 and incorporation in the HIKI. Translations will become more consistent and can be reviewed online. The translation tool incorporates the translation guidelines (see 10.5, 'Formulating guidelines').

Effectors for design and programming have to be identified.

Resources have to be identified.

Failure results in non comparable and inconsistent translations hampering comparability of data between language regions.

10.4 Pilot test translations

Pilot translations are translations of the alpha and beta version of ICD core concepts at three character category level. A pilot translation would include titles of categories, only. In selected parts that reflect the full range of structural elements (corresponding to present chapters V, IV and XX) all conceptual levels will be translated. Pilot translations will be guided by the definitions that are part of ICD-11. Pilot translations will be used for linguistic and cultural assessment, and for field testing.

Revision process has to ensure all definitions are available for the selected sections that are translated fully. Failure will result in reduced evidence in assessment of translation errors.

Categories of ICD-10 that remain unchanged in ICD-11, no new translation is necessary. Linguistic and cultural assessment will apply to old and new concepts of ICD, as there has been no such procedure in the past.

Pilots in the six official languages are envisaged. In addition there will be pilots for Portuguese, German and Japanese. Pilots in additional languages are welcome and depend on the availability of appropriate centres and resources.

Pilot translations are carried out by the relevant collaborating centres. Resources for pilots in French, Spanish, German and Portuguese are available. Resources for Arabic, Russian and Chinese have to be identified.

Failure results in missing input of linguistic problems to ICD and resulting possible inconsistent translations.

10.5 Formulating guidelines of language versions

Translation guidelines will inform translators about extent, quality and tooling of translation. They will contain instructions on standard formats to be used. The guidelines are aimed at improving consistency between the different language versions of ICD, as well as ensuring completeness of translations. Standardized formats will facilitate linguistic assessment.

Core points include:

- Solutions to the orphans
- Differing preferred terms and literal translations
- Quality assurance (see also 10.1)
- Compilation of lists of synonyms (formerly index)
- Use of ICD maintenance tool and ClaML
- Maintaining consistency between translated ICD and linked terminologies, as SNOMED.

They are based on the ones that were formulated for ICF, on experiences by collaborating centres and on internal recommendations of WHO.

The translation guidelines are formulated by WHO in collaboration with its collaborating centres during the planning phase of the revision, and will be ready before the alpha version.

Tools for development of synonym lists and production of indices have to be developed. Joint work with NLM, IHTSDO, WHO-FIC ETC, and others can facilitate development.

Resources have to be identified.

Failure will compromise creation of the translation tool.

10.6 First draft versions in languages other than English

First translations are full translations of all elements of ICD-11. They contain the definitions at least at the "public health level" of ICD-11. This would correspond to a 300 definitions. Explicit definitions that are linked to multilingual terminologies will facilitate translations.

First translations will include the piloted ones. They will become available shortly after the beta version and enable field testing in different languages, and cultures.

Resources for full translations in some official languages have to be identified (see also 10.3).

Failure will result in delayed implementation, and reduced linguistic adjustment of ICD-11.

ICD-11 in six official languages.

10.7 Final translations

Final translations will be based on the draft translations and include all elements of the final English master version. Potential limitations in feasibility and need of translating definitions at all levels are under discussion. Achievement of the milestone includes electronic and printable versions of ICD-11. A multilingual online version will announce completion. Resources have to be identified. To a large extent resources will come from the collaborating centres. Additional resources have to be identified.

11 Project coordination & management

Organization of process, editing and maintenance of the workplan, keep up communication, monitoring of progress, financial administration.

WHO has formulated the goals and created a project team that consists of WHO staff, and the Chair of the Revision Steering group. The RSG consults the project team.

WHO has established communication mechanisms have been established in form of annual meetings and monthly teleconferences of the RSG. WHO and RSG share project documents on a WHO SharePoint site. The chairs of Topic advisory groups are members of the RSG and liaise with their TAGs via teleconferences, email, and biennial face to face meetings. The TAGs liaise with their working groups via email, and, as necessary, at face to face meetings. Work results are presented on the Revision Platform. Input, as proposals and all comments is made on the revision platform.

Detailed information on roles and responsibilities is described in Annex 6 Roles and responsibilities'.

Additional resources for WHO assistants and a project manager have to be identified.

Failure will result in incomplete achievement of the goals of the revision up to total failure of the revision.

I. Budget Summary

This section provides summaries of costs per task and per milestone.

MILESTONE	ACHIEVED BY	COST	CUMMULATIVE COST
Needs analysis executed	Sep 2008	$190,000	$190,000
Revision team is formed	Oct 2009	$994,000	$1,184,000
Revision Platform ready for all types of inputs and outputs	Dec 2012*	$1,500,000	$2,684,000
All information relevant to revision is compiled	Mar 2011**	$4,738,000	$7,422,000
Alpha-draft released	Feb 2010	$2,115,000	$9,537,000
Beta- draft released	Nov 2011	$1,405,000	$10,942,000
Field trials completed	July 2012	$1,590,000	$12,532,000
Pre-final draft released	Mar 2013	$725,000	$13,257,000
ICD-11 endorsed by WHA	May 2013	$255,000	$13,512,000
ICD-11 implementation package ready	July 2013	$2,850,000	$16,362,000
ICD-11 published in six official languages	Mar 2014	$6,000,000	$22,362,000
Pilot countries implemented ICD-11	Mar 2014	$13,338,000	$35,700,000

*functionality for relevant revision work will be available by 2010. Advanced output functionality will be available for preparation of the pre-final draft

** major input will be ready for the alpha draft. The process allows additional input until beta version for field testing.

Total budget of USD 42,600,000 includes USD 6,900,000 project coordination cost fully supported by the WHO.

II. Risks

Risks include lack of funding for field testing and Ontology/Terminology aspects of the revision. Failure will result in production of ICD-11 in traditional formats. Evidence base will be reduced. Incorporation in electronic health information systems will be subject to limitations.

Risks include lack of participation in providing contributions for specific fields (e.g. formation of appropriate TAG) or in commenting. Failure will result in no update to relevant parts of ICD.

Risks include lack of appropriate legal arrangements. Failure will result in non distributable definitions, missing linkages to relevant terminologies and ontologies.

Risks include lack of organization. Failure will result in uncoordinated activities, duplication of efforts and delays.

Risks include change of political directions of WHO. Results are not predictable.

Annexes

Annex 1 Terms of Reference of the Revision Steering Group

The Revision Steering Group will serve as the planning and steering authority in the ICD revision process. Its terms of reference are as follows:

1. *Oversee the revision process and give advice for coordination of workgroups:*
   RSG will
   - determine the content of the revision process
   - review and make suggestions about the overall progress of the revision process
   - ensure adequate coverage of all chapters and codes to ascertain the input from existing clinical modifications of the ICD and other WHO-FIC members
   - maintain continuity between 10th and 11th editions
   - see to whether the full scope of health care diseases and related health conditions are congruent with the overall structure.
   - synthesize different inputs including field trials, ensuring participation from various regions, countries, languages and multiple stakeholders including NGOs.

2. *Identify uses of the classification and ensure that the revision process addresses the needs of users:*
   RSG will
   - ensure that the main uses of ICD for mortality and morbidity are maintained, and oversee proposals for other uses the classification; and
   - preserve coherence and consistency of the description of entities between the interlinked versions of ICD for Primary Care, Clinical care and Research.

3. *Identify basic taxonomic and ontological principles:*
   RSG will observe the consistency and coherence of basic taxonomic and ontological principles across the overall revision process, including:
   a. Key definitions: examples include disease, disorder, syndrome, sign, symptom, reason for encounter, trauma, and external cause
   b. Separation of disability and joint use with ICF
   c. Attributes, as mentioned in the information model ...
   d. Linkages to other WHO-FIC classifications and ontologies
   e. Be guided by input by the TAG HIM

   RSG will arrange for the development of clear taxonomic rules for the development of ICD-11.

4 *Generate suggestions to resolve problems and ways to field test options as necessary:*
   RSG will make suggestions to solve problems or conflicts arising across different proposals, and may make suggestions for field trials to gather empirical data for their solution. This area of function may include comorbidity coding, inference of causality in coding rules, and indexing.

5 *Develop plans and tools for transition from ICD-10 to ICD-11:*
   Identify requirements for users to adopt ICD-11 including coding guidelines, versions fit for various purposes, cross walks, electronic tools, and educational materials.

Annex 2 Terms of Reference of the Advisory Group HIM

Terms of reference for a TAG
for
Health Informatics and Modelling (HIM)

The revision plan for ICD-11 incorporates intricate linkages between the classification scheme and terminologies. ICD-11 will have explicit operational linkages to underpinning ontologies built-in during the revision process which will result in both human-readable and machine-readable definitions. Depending on the purpose of the use of the classification, the semantic network around the ICD-11 concepts may allow different extractions for the classification (i.e. mortality, morbidity, case-mix grouping, primary care use etc).

To enable this objective of creating an ICD-11 with multiple semantic linkages to ontologies, a specific Technical Advisory Group is constituted to advise WHO and the Revision Steering Group on the following issues:

To identify a cogent "information model" (a.k.a. context model) to express the several dimensions that relate to ICD-11 classes *(such as the classification entity as a disease, disorder, injury, sign, symptom etc; Site; Manifestations; Cause; Temporal Relations; Extent/severity; Impact/disability; use and other possible attributes)* and evaluate existing disease models for their suitability to ICD-11;

To identify the logical operators that relate to knowledge representation in ICD such as the *description logic* to define, to diagnose, and to group diseases and other ICD categories;

To evaluate and link the experiences of other taxonomy, terminology and ontology projects to contribute to the ICD-11 development (e.g. NCBO, ...)

To design the specifications and requirements of a tooling environment that accommodates the use case needs for the revision process: A **web based tool** that allows editing the semantic structure of the classification through controlled distributed development by multiple groups. Design and production will start from the current ICD structure and enable use of available tools such as Collaborative Protégé, OWL and LexGrid structures.

Annex 3 Topic Advisory Groups' and Workgroups' user guide

ICD Revision Manual for TAG and Workgroups

Please find information on the overall revision process and access to the revision platform on the Internet at www.who.int/classifications/icd/ICDRevision .

Contents