Executive summary

Introduction

The International Classification of Diseases (ICD) is a key instrument of the World Health Organization. Upon the formation of WHO in 1948, ICD was adopted and has been maintained ever since, representing the basis for national and internationally comparable and up-to-date consistent collection, classification, processing, and presentation of disease-related data. ICD was initially developed for coding causes of death. However, continuous evolution now renders ICD useful for coding morbidity, as well as recording specific diseases, injuries, signs, symptoms, complaints, social circumstances, reasons for presentation and external causes of both injury and disease.

ICD informs public health bodies, clinicians and researchers alike in the evolving environment of increasingly complex health systems, ensuring the provision of language and system-independent definitions that are applied for:

- National and international health statistics (mortality and morbidity);
- Epidemiology, surveillance, and monitoring;
- Individual patient records and electronic health records;
- Reimbursement and health system financing;
- Reference for treatment guidelines, scientific literature and research;
- Quality assessment at the level of individual cases up to assessment of health system outcomes and monitoring.

WHO leadership in health information, and the role of ICD was reemphasized in the WHO Nomenclature Regulations[i] that stipulate ICD in its most up to date version is to be used for mortality and morbidity reporting in all Member States.

The success of ICD-10 is unequivocal:

- 70% of the world's health expenditures (3,500 Billion USD)[ii] are allocated using ICD directly for reimbursement and resource allocation;
- 110 countries that collectively account for 60% of the world's population use cause of death data coded with ICD for health planning and monitoring in a systematic fashion.
- ICD-10 is cited in more than 20,000 scientific articles.

Developing countries bear a large burden of disease with many of their health systems lacking resources in the face of an overwhelming tide of urgent and life threatening demands. Consequently, planning of interventions may be less than optimal and their effectiveness limited accordingly and once established, such vicious circles are an obstacle to achieving the best possible health for a population from an already limited amount of resources.[iii] Effective deployment of ICD-derived tools would facilitate the use and collection of health information under such challenging circumstances and therefore facilitate quantitatively informed decisions.

ICD is a core member of the WHO Family of International Classifications. These core classifications form the basis for numerous additional derived & related modifications. WHO owns all rights and processes that relate to ICD and its other core classifications and has the responsibility to ensure conceptual consistency in all the changes that are introduced accordingly.

Historically, ICD has been revised at an interval of approximately every 10 years, with the exception of the 20-year period between the last two revisions, ICD-9 and the most recent version, ICD-10. ICD-10, was completed in 1990 and the WHA requested that it should be revised as necessary, with such revision being organized and coordinated by the WHO Secretariat in order to provide support for the eventual transition from ICD-10 to ICD-11. Below we present the goals, the organizational structure and the plan of the revision process.

Goals for the current ICD revision: ICD-10 to ICD-11

1. **Update ICD to accommodate new scientific, clinical and public health knowledge**

   Since ICD-10 was issued, health-related knowledge and related applications have expanded dramatically. For example, progress in biotechnology and genome sequencing and disease gene mapping, novel disease and epidemiology and intervention effectiveness modelling (e.g. GBD, cost-effectiveness), as well as web-driven information sharing and computer-based analysis have widely impacted many aspects of our current understanding and interpretation of health.

2. **Integration of broad consultations and new, internet-based technologies for information gathering, integration and sharing**

   The revision has two facets: firstly, building from a backbone of expert reviews and stakeholders' consultations and secondly, expanding to embrace internet-based technologies enabling knowledge capture from a broader, multi-discipline global community and ensuring effective facilitation of integration with a broad spectrum of health systems.

3. **Integration and cross-referencing with health-related terminology systems**

   The current revision links ICD-11 to modern terminology systems that form reference bases for medical definitions and accordingly ensure seamless integration with electronic health information systems.

4. **Harmonize with ICD-related and derived classifications as well as other members of the WHO Family of International Classifications**

   Revision towards ICD-11 establishes procedures and mechanisms that enable ICD-11 to co-evolve and capture the valuable synergies offered by complementing health information systems, keeping up with fast development of knowledge, and the associated evolution of computer applications and classifications.

5. **Build in needs-driven adaptations to the revision process around priority ICD Use Cases**, including public health mortality and morbidity surveillance, phenotype stability, quality and patient care, financial management applications.

6. **Accelerate global implementation plans with particular focus on developing countries**

   ICD-11 implementation success will depend on ease of integration with current applications and other health system technologies and methodologies. Developing countries will not only participate early in the revision process, but also will be able to articulate their specific needs for

information presentation and tools that can build capacity for accelerated introduction, implementation, and transition from ICD-10 to ICD-11.

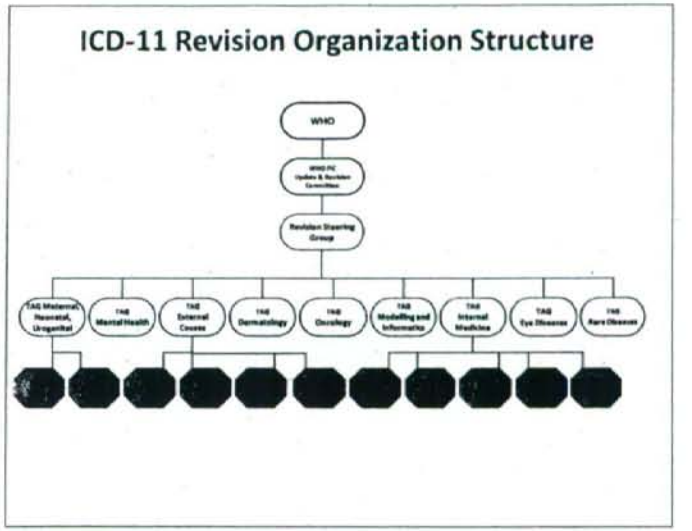
Project milestones and budget, and organizational overview

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
ICD11 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 ICD11	Mar 2014	$13,338,000	$35,700,000

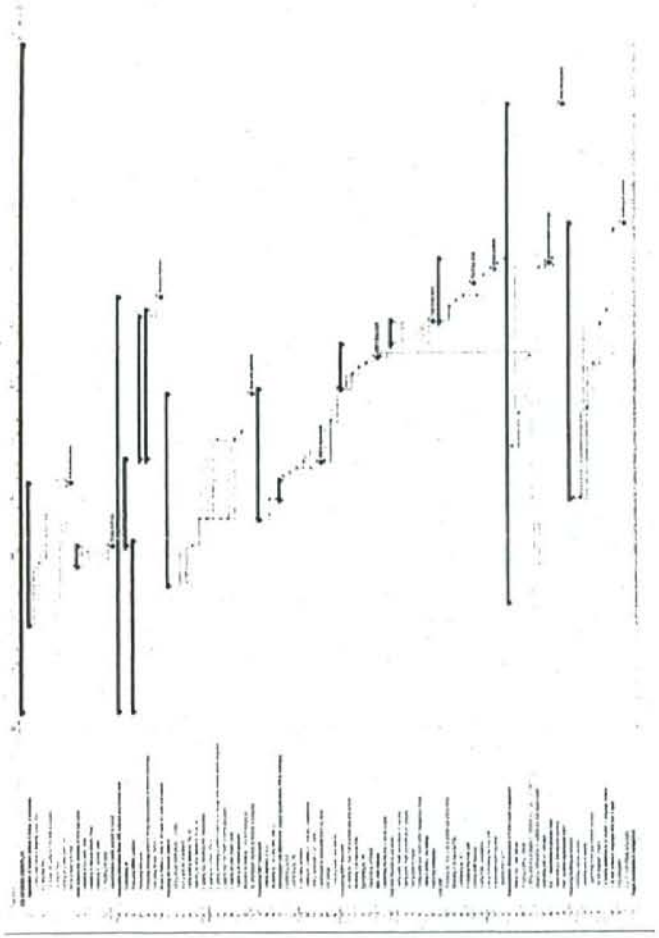
*functionality for relevant revision work will be available by 2010. Advanced output functionality will be available for preparation of the pre-final draft

** 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.



ICD-11 Revision plan chart



Version History

Date	Version	Modifications
12 February 2008	0.1	Robert Jakob, Susan Fenton
21 February 2008	1.0	Bedirhan Ustun
26 February 2008	1.01	Robert Jakob
2 March 2008	1.03	Bedirhan Ustun
3 March 2008	1.04	Robert Jakob
5 March 2008	1.05	Group work in DC
9 September 2008	1.09	Robert Jakob
23 October 2008	1.10	Robert Jakob
13 November 2008	1.11	Robert Jakob
9 December 2008	1.12	Robert Jakob, Sara Cottler

Version 1 describes all aspects of ICD Revision project plan, in terms of processes, activities, products and various usecases. Version 2 includes solutions. The Revision Steering Group (RSG) will decide together with WHO about the major version changes. Intermediate versions will document the progress of the document and will be assigned by the project management group consisting of WHO, chair of the RSG, and project manager.

Scope of the document

This document describes the ICD revision process as an overall **project plan**, in terms of key streams of work, activities, products, and key participants. It informs all contributors of the environment, decisions, architecture, procedures, risks, and open questions. This is a dynamic document which will evolve during the revision process and changes are documented in the revision history with version control.

Organization of the document

The document consists of 3 sections. The first describes goals and refines expected outcome of the Revision. The second section contains the management plan, as budget and tasks. Part 3 contains annexes that provide detail for roles, tasks, workflows, and the budget.

List of Acronyms

ATC/DDD	Anatomical Therapeutic Chemical Classification/Daily Drug Doses System
caBIG	cancer Biomedical Informatics Grid
CEN	European Committee for Standardization
CIOMS	Council for International Organizations of Medical Sciences
DSM	Diagnostic and Statistical Manual of Mental Disorders
FMA	Foundational Model of Anatomy ontology
G8	Group of Eight leading industrialized nations
GIS	Geographical Information System
HIM	Health Informatics and Modelling
ICD	International Classification of Diseases
ICD-O	International Classification of Diseases for Oncology
ICECI	International Classification of External Causes of Injuries
ICF	International Classification of Functioning Disability and Health
ICPC	International Classification of Primary Care
IHTSDO	International Health Terminology Standards Development Organization
IND	International Nomenclature of Diseases
ISO	International Standards Organization
KMS	Knowledge Management System
MbRG	Morbidity Reference Group
MeSH	Medical Subject Headings
MRG	Mortality Reference Group
NLM	National Library of Medicine
OECD	Organization for Economic Co-operation and Development
OMIM	Online Mendelian Inheritance in Man
OWL	Web Ontology Language
RDF	Resource Description Framework
RSG	Revision Steering Group
SNOMED	Systematized Nomenclature of Medicine
SNOMED CT	Systematized Nomenclature of Medicine—Clinical Terms
SQL	Structured Query Language
TAG	Topic Advisory Group
UMLS	Unified Medical Language System
URC	Update and Revision Committee
WHO	World Health Organization

Glossary

Aggregation logic	Forming sets of elements that share one or more attributes, e.g. a category contains a group of diseases
Definition logic	Clustering of symptoms, signs and other attributes towards definition of a concept, e.g diagnosis
Generic Usecase	Description and logical sequence of a set of usecases for a specific use of ICD
Linearization	Listing of elements of ICD according to a specified order that is shown as a tree that clusters elements of such list (alike any classification).
Purpose	Uses that ICD is designed for
Use	How ICD is used
Usecase	Single individual process where actors uses ICD achieving a specific output, and can rely on other usecases or be based on sub-usecases

Section I Goals and structures

1 Goals of the ICD Revision Process

The revision of ICD will be guided by a set of goals, and use new technologies in a stepwise approach. The following paragraphs will provide an overview:

- Establish ICD-11 as a user-friendly and scientifically credible classification that is continuously updated with the use of modern knowledge management and sharing methods.
- Provide evidence-based linking of each decision and category to the relevant scientific literature available as a dynamic classification system that will be regularly updated online through predefined processes overseen by expert advisory groups using a collaborative online platform.
- Link the classification to underpinning terminologies and ontologies (e.g. SNOMED-CT, GeneOntology and others) through human and machine readable formal descriptions (e.g. categories are defined by logical operational rules on their associations and details).
- ICD-11 linkage to terminologies and ontologies will be based on standard knowledge representation methods (description logic, aggregation logic, algorithms etc) to link the underpinning diagnostic constructs within a coherent information model.
- Ensure that ICD-11 will seamlessly function in an electronic health records environment.
- Serve as an international and multilingual reference standard for scientific comparability and communication purposes.

1.1 National Modifications

ICD is an international classification system; however, several countries may modify the ICD to meet their needs in practice. This limits comparability of data, development of guidelines, and linkage to knowledgebases and terminologies. WHO is working on ICD-10-XM, a cross-country version, which incorporates all of the national clinical modifications. The clinical modifications will be shown in the ICD-10-Plus structure. While ICD-11 cannot capture all of the varied needs of individual countries, substantial input to the revision process is anticipated regarding where the users need improvements to the ICD-10. In addition there may be a better structure for accommodating further national modification and their compilations (i.e. ICD XM as necessary, in the future).

1.2 Multilingual versions of ICD-11 drafts

It is a specific goal to make ICD multilingual in 6 WHO official languages with further guidelines and tools to make it available in other languages as it is an important international public good. Currently ICD-10 exists in 40 different languages and it is expected that the ICD-11 will also be available in as master working version during the revision process with near-simultaneous production of 6 official languages. This means that master English version will be generated as a representation of language independent constructs and it will be represented with the best possible term in other languages. Planned linkages to terminology systems and other knowledgebases could improve adequate linguistic representation in other languages.

1.3 Linkage to terminologies and ontologies

Linking ICD (and all WHO Classifications) with standard terminologies is one of the main aims of the revision process. ICD-11 categories will be linked to sound terminology systems based on logical, understandable and internally consistent knowledge representation, and established ontologies.

Classification means clustering information according to logical rules. The way of grouping is driven by a specific purpose. Terminology contains information bits at higher granularity, e.g. body parts, findings, or other elements that e.g. constitute a disease. In a terminology, a disease can be defined e.g. establishing linkages between terminologies' elements, such as anatomy or findings. Specific aggregation rules may allow grouping similar elements of a terminology (e.g. diseases) for specific purposes, thus creating a classification. It does not matter whether aggregates are incorporated in a terminology, or displayed separately as a classification. A classification system implicitly refers to terminologies and conversely a terminology system does the same. Terminologies and classifications should be considered as complementary and the implicit referencing should be made explicit. In the case of the revision, ICD represents the internationally agreed standard for aggregation and is developed in collaboration with the relevant stakeholders. SNOMED-CT is the largest clinical terminology compilation. Independent aggregation of disease concepts in ICD and SNOMED leads to incompatible data and duplication of efforts. ICD and the leading terminology fit well together, being complementary elements of a health information system (see Figure 3).

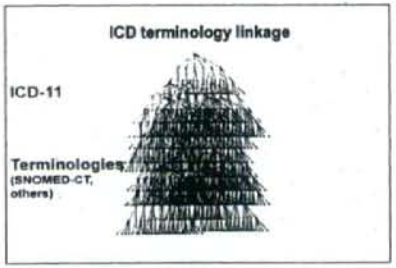


Figure 1 - Relation of ICD and SNOMED CT in terms of aggregation levels

Linkage to SNOMED will apply to all definitions, inclusion terms (*including relevant historical links, and index terms)* and exclusion terms within ICD. Extent of definitions will evolve in stages following the development of ICD-11.

ICD-Terminology-linkage will require ontological definition of a category of ICD that includes taxonomic status for one specific linearization, i.e. in what chapter, section in the classification tree the concept would be presented. Such taxonomic description includes information on whether the category represents a group of diseases, a single disease, disorder, injury, syndrome, sign, symptom, other.; its possible level of use such as in Primary care, Clinical Care, Research; and other characteristics such as periodicity, severity, chronicity, ...). The definition logic aggregates symptoms and findings to a new dimension: a disease concept of ICD, whereas the aggregation logic defines grouping of diseases in ICD.

All this information will be structured within an information model that consists of the dimensions that are used as split criteria ICD-10, already (current draft):

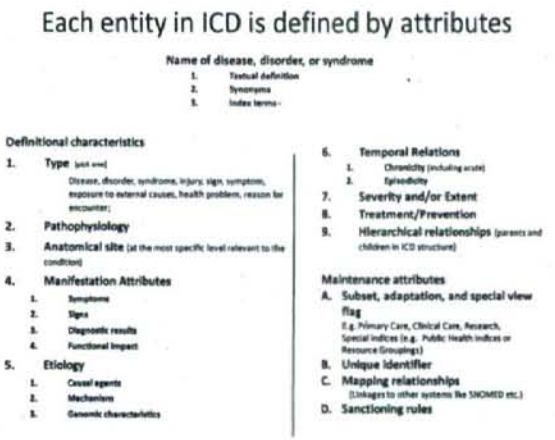


Figure 2 – Draft information model. Each entity in ICD will be defined with known ontological properties

Working Groups will be given the mandate of formalizing core constructs and concepts of ICD-11 using terminology/ontology tools to formalize the concepts, as Protégé, and constructs using SNOMED and/or any other terminology. This formalization will be useful in creating knowledge linkages (also known as mappings) and algorithms for assessment tools or Clinical Interface (e.g. Map of Medicine).

However, relevant dimensions may differ among settings, as clinical medicine, pathology, or knowledgebases, as shown in disease models of SNOMED, or ICD-10 Classification of Mental and Behavioural Disorders. A special group will aim at defining a disease model that accommodates the needs of the users of ICD, after assessment of existing models. (Annex: Health Informatics and Modelling Group TOR).

1.4 Usecases - Meeting the users needs

The ICD revision process aims to:

- Develop a coherent , internally consistent, and reliable international classification system that will serve multiple purposes:
    - Coding Mortality (causes of death)
    - Coding Morbidity (diseases and related health problems)

    - Could be used at different settings (e.g. primary care, clinical care) and for different purposes (research, public health, quality ...)
    - Scientific consensus as high-level clinical phenotypes
    - Bearing consistency across these different uses so that data could be exchanged meaningfully

1.5 Change history

The ICD-11 follows software development practice in terminology, supporting a change history, and keeping compatibility with previous editions. While new diseases are certainly introduced as they emerge, outdated concepts of e.g. diseases, symptoms or syndromes will not be deleted, but inactivated. Additionally, any changes in aggregation or other characteristics will be tracked to allow for longitudinal data use.

1.6 Web based distributed development

Former ICD revisions were conducted through week long revision conferences and multiple editorial groups communicating through conventional means (see introduction to Vol. 1 of ICD-10). Given the opportunities presented to us by technological advancements, the ICD -11 drafting environment is planned as a Wiki–like structured Joint-Authoring Tool based on a semantic wiki application that incorporates a structured information model and identified terminology system (see figure 1). This tool is called HiKi. Selected groups of experts will be given the mandate of drafting portions of ICD-11. Each working group will place their draft into the WHO web portal using a web based joint authoring tool. The ICD-11 draft will include the following rubrics wherever applicable: (1) name of each category, relevant inclusion and exclusion terms, and a structured description including clinical and/or research rules for diagnosis. Each rubric will be posted in the Wiki application, following a taxonomic review and clarification by WHO experts, as needed. WHO will also commission a structured scientific peer review to assure the quality of the submitted drafts such as completeness, adequacy, clinical utility, relevance for information systems and other aspects. This work is carried out by expert groups for disease domains in collaboration with user groups for usecases of ICD.

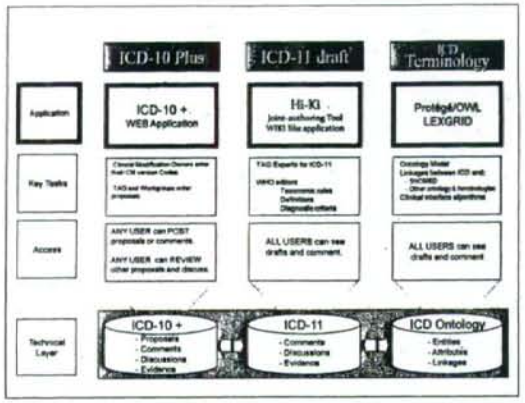


Figure 3 - ICD Development Phases - A web platform will allow developing ICD-11 and field tests

The revision process will be open to many experts from all over the world. In order to facilitate better **communication** and **collaboration** the revision process will be open for comment to public. The Revision portal will be the *single point of access* for the update and revision process with different user interfaces, levels of access and editing rights.

1.7 ICD Development Process Phases:

Towards an ICD-11, three major phases are planned:

1. ICD-10-Plus: This phase aims to compile all suggestions and user needs. A web-based platform called ICD-10-Plus brings together three main sources:

I. Combination of all additional codes from national modifications of ICD (e.g. USA, Canada, Australia, Germany, Thailand, Korea and others), primary care versions, and specialty adaptations (Oncology, Mental Health, Neurology, Headache, Sleep Disorders, Dentistry & Stomatology, Paediatrics and others).

II. Suggestions from different users and user groups: any interested person or group could make a structured proposal for a possible change in the ICD system.

III. Definitions of disease entities, as of IND, DSM, Orphanet, WHO, WHO Classification of Tumours, SNOMED...

2. ICD-11 alpha draft: **will be compiled by the WHO assigned editors and Topic Advisory Groups (TAGs)** for review by the internal users (e.g. involved experts, core users as WHO FIC network,) It will contain reviewed conceptual structure and definitions at the level of detail that corresponds to blocks and three character categories of ICD-10.

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, while preserving 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 will also be in a computer format, thus allowing automated reasoning, decision support and user specific linearizations.

The information model will apply to 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.)

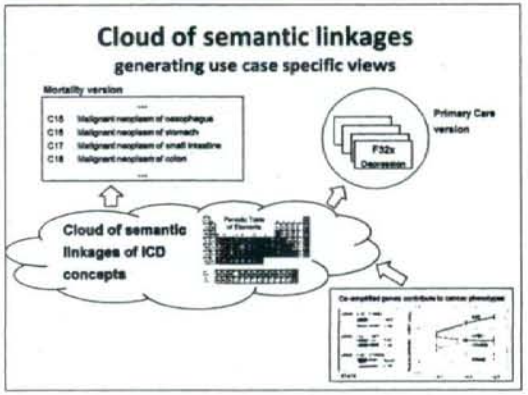


Figure 4 – A cloud of linked concepts of ICD-11 is source for usecase specific views

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

Definition: Depressive Disorder F32.0

A.	Low mood	(41006004)
	Loss of interest	(11752004)
	Low energy	(248274002)
B.	Appetite *(decrease, increase)*	(64379006, 72405004)
	Body weight *(decrease, increase)*	(89362005, 8943002)
	Sleep *(decrease, increase)*	(59050008, 7769200 6)
	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 formal descriptions 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 should 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"

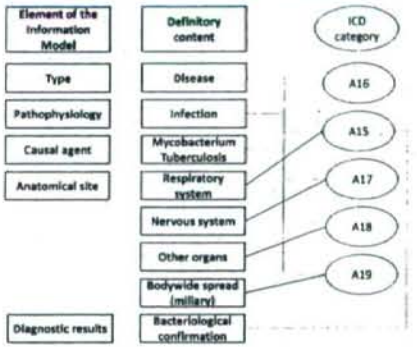


Figure 6: Diagnostic algorithm by defined dimensions and separation of ICD-10 categories – for Tuberculosis

Information Model - Example Tonsillitis (J03.0)

Name : J03.0 Acute Tonsillitis; Streptococcal tonsillitis

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

Definitional characteristics

1. Type: disease(64572001)
2. Pathophysiology : infection(40733004)
3. Anatomical site tonsil(91578001); part of upper respiratory tract(81101009); 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. Mechanisms: –
   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 : (kxm40kzmoasdég] ~1^395ièkàc5mt03)
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. Interger 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-Management Plan

I. Introduction

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

II. Tasks

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. 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 workgroups will review, summarize and work out change proposals for such domains. In addition, everyone will contribute 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 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 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. Size should not exceed 12 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 from 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 being 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 (e.g. conflict of interest, 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 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 site, presentations at world summits of relevant disciplines, 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 its timeline up to the point of completion of the revision of ICD-11. 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 reviewing process by searching for evidence, incorporating comments and proposals which will be consolidated into one 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, 'Field trials focused on usecases').

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.

Implementation 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 yet 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. Review 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 ICD10+ 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 pilot 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 in the HiKi 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 ICD10+, 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 ICD10+ 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.

Information Platform 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, reduces the evidence base, reduces 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, 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 coordinate input by this 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.

6.5 Beta - draft release

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.

6.6 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 ICD11 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