- In addition it will see to whether the full scope of health care diseases and related health conditions (such as traditional medicine entries) are congruent with the overall structure. RSG will also make suggestions about the overall progress of the revision process, and synthesis of different inputs including field trials as well as participation from various regions, countries, languages and multiple stakeholders including NGOs.

- *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

- *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:
  - Key definitions: disease, disorder, syndrome, sign, symptom, trauma, external cause...
  - Separation of disability and joint use with ICF
  - Attributes: etiology, pathophysiology, intervention response, genetic base ...
  - Linkages to other classifications and ontologies

- *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.

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

The Revision Steering Group will communicate on an ongoing basis by email, have monthly telephone conference calls, and will convene at least twice annually for an in-person meeting. The composition of the Revision Steering Group will be as follows:

1. the chairs of the Topic Advisory Groups in the Revision Process
2. Representatives of the WHO-FIC Network (chairs of the Update and Revision; Family Development Committee, and Planning Committees)
3. Other invited terminology, classification and public health experts
4. responsible WHO officers

The Revision Steering Group may invite consultants and other members of the Topic Advisory Groups and related workgroups as necessary to take part in their meetings.

B. Topic Advisory Groups (TAG)

Topic Advisory Groups will serve as the planning and coordinating advisory body for specific issues which are key topics in the update and revision process, namely Oncology, Mental Health, External Causes of Injury, Communicable Diseases, Non-communicable Diseases, Rare Diseases and others to be established.

The primary charge of each group will be to advise WHO in all steps leading to the revision of topic sections of ICD in line with the overall revision process. In particular:

- *Advise on particular topic revision steps and establish workgroups and partners to involve* - The TAGs will advise WHO on constitution of working groups to undertake generation of necessary evidence, to develop proposals for changes and to focus on specific issues as needed. Each TAG will (a) determine the number and content areas of the workgroups, (b) identify the members and chairs of the workgroups, (c) present an initial mandate to each workgroup, (d) establish procedures for the activities of the workgroups, and (e) facilitate cross-fertilization of ideas and reducing redundant efforts by making workgroups aware of one another's activities.

- *Advise in developing various drafts of topic segments in line with the overall production timeline of ICD-11* TAGs will review initial recommendations of the workgroups and consolidate those to achieve consistency in proposals across groups and areas.

- *Advise in developing protocols for and in implementing field trials* - TAGs will also assist WHO in identifying appropriate representatives of various stakeholders and in establishing effective collaboration/consultative mechanisms.

Topic Advisory Groups will consist of experts within each major domain of the classification chapters. Currently there are following:

– Mental Health:	S. Hyman
– External Causes:	J. Harrison
– Rare Diseases:	S. Ayme
– Oncology:	IARC Editor(s)
– Internal Medicine	K. Sugano
– Others	*to be formed e.g. Child and Adolescent Health etc.*

Each TAG will function at two levels: *chairs and members*, and if necessary a *workgroup structure*. TAGs will maintain regular communication among members and workgroups using the ICD revision and update platform as the main information management and sharing portal as well as phone and e-mail.

C. Workgroups

Work Groups will serve as the key functioning unit for the review of evidence and generation of main proposals at a specific topic in the classification. For example, the TAG in the Mental Health Area will be responsible for the whole of chapter V and its linkages, whereas it may generate 5-10 working groups to carry out the systematic reviews on special sections of the chapter such as schizophrenias and psychosis; mood and anxiety disorders or topics such as children and youth, common brain disorders, etc

Each workgroup will be led by preferably two co-chairs, one of whom will be a member of the relevant TAG. These individuals will be responsible for selecting the members of the workgroup and establishing the membership and focus of the subgroups. They will supervise the work of the workgroup, monitoring progress and ensuring quality control. If necessary each workgroup may include subgroups corresponding to subclasses of disorders or other areas requiring focused attention within the workgroup domain. Workgroups are expected to include approximately 10-12 members. Subgroups can include participants who are not members of the workgroup, but must be chaired by a member of the workgroup. An effort will be made to draw members of workgroups and subgroups from multiple disciplines and nations.

Co-chairs of all workgroups will have privileged access to the ICD Update and Revision Portal and will participate in a monthly telephone meeting with the TAG so that co-chairs from each workgroup can learn about the activities of other workgroups.

Tasks for the Workgroups will include:

- *Developing a preliminary position statement on each core diagnostic issue:*
The workgroups will be asked to consider core issues that they will seek to address for each diagnostic entity in their content domain, and to develop a preliminary position on each issue based on their preexisting knowledge of this domain. The initial position statement will effectively set the agenda for the workgroup and will define the range and scope of questions that the workgroup will consider. The initial set of core *diagnostic issues* to be considered by each workgroup are listed in box I - these may be taken as an example by each workgroup to expand further on the key classification issues on the topic of interest.

TEXT BOX 1: Core diagnostic issues for each workgroup to consider:

I. **Definition of the diagnostic entity as a medical disease or disorder.** Given the key taxonomic guidelines and definitions each group should draw a line around the entity of interest, identifying its critical properties. How does the workgroup fundamentally view the full spectrum of disorders/diseases in this chapter in terms of their classification? Identify key criteria and level of evidence.

II. **Clustering of signs, symptoms, and operational characteristics.** Identify the features that are necessary and sufficient to define the disease/disorder.

III. **Link to underlying pathophysiology and genetic markers.** Identify the intra-individual markers that are associated with the disease/disorder, considering their biological plausibility, their measurement properties (e.g., specificity, predictive power), and their role in treatment response.

IV. **Clinical utility of the classification entity.** Consider the usefulness of the classification entity in diagnosis, predicting treatment response, course, and outcome.

V. **Reliability of the use of the classification entity.** Consider the stability of the classification entity over time and its consistency of detection across assessors and measurement instruments.

VI. **Validity of the classification entity.** Consider the associations of theoretically relevant variables with measures of the disorder and the support they provide for the validity of the diagnostic construct.

VII. **Separation of disease and disability elements.** Identify the features that signal the presence of the disease/disorder, defining the disease/disorder without reference to the distress, impairment, or other consequences that it produces. Suggestions to link to WHO ICF and operationalize specifically the criteria on disability and distress related rubrics.

VIII. **Cultural elements that need to be attended.** Consider variability in the presentation of the disease/disorder across cultures. Identify ways to achieve cross-cultural comparability and utility of diagnostic criteria rather than listing separate culture-bound syndromes or formulations.

IX. **Threshold considerations.** Identify the number and nature of diagnostic criteria that should be required to qualify for the classification entity. Consider the nature of the boundary separating the disease/disorder from normality, including evidence for the categorical/continuous distinction. Consider the classification entity boundaries with other classes, including challenges of differential diagnosis.

X. **Other nosological issues relevant to this entity** Identify any other aspects of the classification entity that the workgroup believes to be in need of evaluation, including potentially controversial aspects of the disorder that will need to be addressed. This list of additional issues may change as the evidence related to this disorder is reviewed.

- *Review the empirical evidence - Workgroups* will survey the available evidence for each diagnostic entity to address the core diagnostic issues described in BOX I. Evidence will be reviewed using a three-tiered, iterative process that maximizes input from sources that are most readily accessible: (1) Systematic review of the published literature; (2) If necessary and possible, targeted secondary analysis of existing data, (3) If required, proposal for collection and analysis of new data collection to address unanswered questions through rapid distribution of target measures to clinicians in the revision network *{see below 4.2 field trials }* that can be completed by the clinicians themselves or administered to their patients.

- *Report results and recommendations to the TAG and global community* - Using the results of their evidence-based reviews, the disorder workgroups will formulate suggestions for updating and revising the ICD-10 diagnostic categories, operational criteria, and/or overall coding structure. Each disorder group will be asked to write and to post on the KMS portal an interim report of its progress every six months as well as a final report documenting its final results and recommendations.

- *Respond to feedback from peer review - comments* on workgroup reports will be solicited from the scientific community and other ICD stakeholders. Public comments will be continually collected and reviewed by WHO staff that will screen them for content and relevance before forwarding them to the appropriate workgroups. Workgroups will complete their proposals taking into account the reviews and annual updates of their literature reviews to ensure that the information in their final report is as comprehensive and up-to-date as possible.

- *Suggestions and evaluation of field trials:* The provisional revised diagnostic criteria recommended by the workgroups will be tested in one or more iterations of field trials *{see below 4.2}*. Field trials will be conducted in collaboration with the international network of mental health practitioners who will apply the provisional criteria in their clinical practice. Results obtained through this Global Health Practice Network (GPHN) will be used to provide additional feedback to the workgroups about aspects of the diagnostic criteria that could be further improved. Given the key questions identified in the review process workgroups will be asked to develop questionnaires. Results of the field trials will be provided to the workgroups to serve in developing the final revisions and recommendations.

- *Final revisions and recommendations* - Workgroups will prepare a final report which will be the key document annotating the key evidence as the authoritative source. These reports will be presented to the Revision Steering Committee and posted on the ICD update and revision platform. These reports should also identify unresolved and emerging questions for continuous update process. The resulting proposals will be published in one or more of several possible forums, including the ICD text itself, the ICD web page, books published by WHO on the ICD update and revision process, or a companion workbook accompanying the newly-published ICD-11.

4. 2 ICD Revision Field Trials

An international network of practitioners will be created in collaboration with the WHO-FIC Network and different NGO's in relations with WHO. This Global Health Practice Network (GHPN) will include numerous health professionals throughout the world who agree to participate in quarterly e-surveys aimed at providing diverse kinds of information about patient characteristics that can be used to inform the ICD update and revision process. Both clinician ratings of individual patients and patient self-report questionnaires collected by the participating clinicians will be used as part of these ongoing surveys. The GHPN will enable real-time collaboration to obtain direct patient assessments on crucial diagnostic questions among current patients within practices throughout the world. In addition to providing a venue for quick, large-scale data collection to inform the review of evidence and development of diagnostic criteria, the GHPN will also serve as the main process in field trials that will allow us to test the provisional revised criteria and evaluate their reliability, validity, and clinical utility in a range of clinical settings around the world

4.3 Knowledge Management and Sharing Portal for ICD Revision

To facilitate communication among the members of the workgroups, and make the expert group processes transparent to the field, we intend to create a permanent internet process, which we call the Knowledge Management and Sharing (KMS) portal.

Many experts from all over the world will participate in different aspects of the update and revision process. In order to facilitate better **communication** and **collaboration** this process will be open to public and to working groups at different levels of access. The portal will be the *single point of access* for the update and revision process. However, the communication will not be one way as in classical web sites. On the contrary most of the contents of the site will be generated by the users. The site will be composed of different components such as a calendar of activities, discussion forums, collaborative document creation process document libraries, etc.

The important elements of this *KMS Portal* will be:

a) *The ICD Revision Platform* - This platform is described in sections 3.1, 3, 2 and 3.3 as ICD-10 PLUS, ICD-11 DRAFT and ICD TERMINOLOGY. that will both facilitate communication within expert workgroups and will make the expert workgroup processes transparent to the field by requiring expert groups to post interim products of their deliberations on a regular schedule for comment through use structured notes in form of "blogs" (short for web-logs to annotate the evidence behind the decision making); and "wikis" (joint authoring tools to write in a predetermined style over internet including many participants and reviewers) for wider participation and linking evidence to proposals (e.g. participants will be asked to back their comments with publications from PUBMED and other open sources).
b) A *public forum* in which end-users can provide feedback to expert groups throughout the development process;

c) *Structured field trials* focusing on key questions, and testing of various options for their feasibility, utility and relevance.

All of these components will be grouped according to a grouping structure that will be generated by experts of the field. Each user entering the portal will see a custom page for him/her depending his/her roles in the update and revision process. This is important because the participants will have expertise on a diverse number of topics. We would like to show them the information that is relevant to their area of expertise so that they can function in a more efficient way. The level of participation of the users will be different as well. For example, some users may be only participating in the discussions where as others may be in charge of editing the documents in the light of the discussions. In summary, we should be able to define **roles** and assign users to these roles so that each user accesses the portal from a perspective specified by his/her roles.

We expect that through the KMS portal the final revision will be broadly responsive to many different aspects of health care, and provide unprecedented access to the ICD by users who were unable to access previous editions because of financial constraints or limited distribution of hard copies. This kind of transparency and constant back-and-forth exchange between the expert groups and the field represents our best hope of making the final ICD revisions useful to its wide range of likely constituents.

Each step of the ICD update and revision process will be documented in an Internet knowledgebase process. There will be open access to this system in order to allow online data sharing and unrestricted discussion among participants from any relevant discipline throughout the world as the revision process evolves. Although the ultimate goal of this system is to refine successively evidence-based conclusions, an important component of this system will be the posting of data gaps. As noted in the last paragraph, our aim in doing this is to make relevant researchers aware of these data gaps in the hope that relevant data will sometimes be available and that targeted secondary analysis can be carried out to shed some light on a number of important knowledge gaps.

The activity will thus produce *permanent internet based workspace* that will document the evidence-based systematic reviews, meta-analysis of available data and discussion forum open to international multi-disciplinary participants. We will create an Internet Platform in multiple languages (English, Spanish, French, Chinese, Russian, Arabic as UN Standard Languages and other languages that may be supported by other partners - such as in Japanese) to enable participation of all interested parties using transparent knowledge management and sharing mechanisms. We will use the same internet platform to help disseminate the products of our labors throughout the world as an international public good. This kind of transparency and constant back-and-forth exchange between the expert groups and the field represents our best hope of making the final ICD revisions broadly useful to the wide range of constituents for whom it is being devised.

The KMS portal will allow increased feedback from the global health community. In the past, draft versions of proposed revisions were reviewed only by workgroups. WHO advisers saw only the penultimate and final versions of the proposed revisions, whereas the revised criteria were not seen by anyone else prior to their publication. This arrangement will be modified in the ICD update and revision process to provide earlier feedback. Specifically, interim drafts of the proposed ICD revisions will be reviewed by the TAG as well as posted on the KMS Portal for the public for comment and debate as soon as they become available. In addition, steps will be taken to involve the

broader community in the update and revision process and to make workgroup activities open and transparent. The workgroups will review and synthesize the feedback offered by the TAG and by the members of the international research community who participate in the commentary, debate, and sequential refinements of the revisions posted on the KMS Portal. Thus the impact of annual meetings will be multiplied with the establishment of a permanent platform that enables continuous input and quality improvement.

5. Basic Taxonomic Principles and Health Information System Implications

It is imperative to address the taxonomic requirements of a key classification as ICD to represent the health knowledge in appropriate fashion to be useful in health information systems. Data coded in ICD will be useful in public health decision making as an international standard specifically addressing issues of mortality and morbidity statistics, clinical decision making and other administrative decisions.

The WHO and the participants in the revision process should address, agree and adhere to common taxonomic principles to maintain internal consistency and coherence of the ICD as well as its interoperability with other health information system elements.

A classification should be clear about what it classifies: its universe, its key dimensions, its units of classification and definitions of these units, its organization in terms of its structure and relations among its units, and its presentations in different versions. Key taxonomic principles need to include epistemological clarifications, ontological definitions and pragmatic conventions as a result of common consensus. For example, as a classification of diseases ICD has to define what a disease is. So far ICD has not officially adopted a definition of disease. We have, therefore, put up a working definition to guide the current work --which may be improved as the work progresses. The current working definition is as follows:

A disease is a set of dysfunction(s) in any of the body systems defined by:

1. *symptomatology - manifestations*: known pattern of signs, symptoms and related findings
2. *etiology*: an underlying explanatory mechanism
3. *course and outcome*: a distinct pattern of development over time
4. *treatment response*: a known pattern of response to interventions
5. *linkage to genetic factors*: e.g., genotypes, patterns of gene expression
6. *linkage to interacting environmental factors*

This definition is also intended to allow ontological analytic breakdown of each entity in ICD whether it is a disease or other entity such as a disorder, injury, sign, symptom or other entity which all have to be defined and identified. Such definitions will provide attributes which are necessary in creating an ontological system. ICD-11 will then be defined as an operational relational model of diseases and related health conditions which will have clear descriptions of each entity and their attributes such as which body system, body structure or function, causative agent or other origin, temporal relations (such as onset, course, offset), severity (such as spread, gravity) impact (such as activity limitations, participation restrictions, distress).

It is clear that ICD is used in various settings with different level of resolution ranging from a set of 100 codes to 10,000s. It therefore requires a compatible coding scheme that can zoom in and out across various levels - which is possible through a computer application that tailors a master version to generate versions for Primary Care, Clinical Care and Research. For example the ICD-11 Primary Care version should focus on most frequent conditions which are treated in primary care which are generally broad categories (e.g. depressive disorder) . Clinical version would include all clinical conditions with diagnostic guidelines (e.g. unipolar, bipolar depressive disorder mild, moderate, severe...). Research version would include detailed standardized criteria for all disorders for identifying research groups and tentative disease labels that are not yet in official classification.

It is essential that the ICD diagnosis should be further elaborated using clinical terminologies to formalize the diagnosis with operational 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. Similarly Tuberculosis 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). Same will be done as capturing all the diagnostic schemes for all areas of medicine under the WHO classification guidelines together with international experts in the related fields.

The formal representation of ICD in terminologies will allow two possible ways of processing the health information (1) declarative searches: allowing automated coding of medical records in electronic environment identifying the presence of a constellation of symptomatology and if present a probability towards the ascertainment of an official diagnosis. (2) Procedural searches: As in the case of Map of Medicine the coded information will build a template for verification of diagnostic explorations similar to a computerized diagnostic support system.

6. CONCLUSIONS

The active phase of the ICD update and revision process will begin in 2007. This work will go in two streams. ICD -10 Updates will routinely continue as annual updates. Every three years major updates and cumulated updates will be published.

Towards an ICD-11 two major drafts will be developed. An *alpha draft* for view by the internal users (e.g. WHO FIC network and experts) and a *beta draft* for the whole world for field testing. It is envisaged that a beta version could be developed by 2010. Given the interest by multiple stakeholders and use of available resources the overall revision process will enable participation from the global health community and multiple stakeholders. Ensuring web-based tools the revision process will be transparent to all users and will make use of larger synthetic capacity of empirical literature through use of work groups and topic advisory groups. The ICD 11-beta draft will be subjected to systematic field trials for feasibility, reliability, clinical utility and validity.

Given the fact that the active phase of the ICD revision process starts in 2007, a beta version of ICD-11 will be available in 2010 for systematic field trials. Field trials will focus on the feasibility, reliability, clinical utility and validity of the classification. Following the field trials, we will have a penultimate version for public viewing and response from all interested parties. A final version is intended to be submitted to the World Health Assembly for approval by 2014.

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