参考資料４

Production of ICD-11:

The overall revision process

< WORK IN PROGRESS - PLEASE DO NOT QUOTE OR CITE>

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Total 6652 words

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Summary:

This paper describes the overall process for producing the 11th revision of the International Classification of Diseases (ICD).

A coordinated series of methods will be utilized to revise the current ICD-10 to arrive at a new generation of classification. The ICD-11 revision will proceed in three stages: (1) systematic review of scientific, clinical and public health evidence relevant to classification, (2) creation of a draft ICD-11 and field-testing it (3) development of meaningful linkages to standardized health care terminologies to facilitate communication, standardized data processing and research. The traditional form and uses of the ICD for mortality and morbidity reporting will be maintained. To assist additional needs different users the revised classification will have in three interoperable formats for primary care, clinical specialty care various knowledge domains such as constellation of signs and symptoms, severity and course, and research. To represent knowledge adequately the classification will be built using ontological tools that include various domains such as constellations of signs and symptoms, severity and course, as well as genetic and other information. This ontological approach will also enable standardized information processing by computers in e-health applications. Material from other WHO classifications, notably the International Classification Functioning Disability and Health (ICF) and national modifications of ICD will be included to improve the ICD content and to improve alignment between the classifications. The revision process will make use of distributed web-based tools such as a structured open database platform to collate suggestions, discussions and evidence. Secondly, and a structured Wiki-like tool will be used to generate the successive drafts of ICD-11. Users will engage in field trials through the global web based platform. This internet based knowledge management and sharing process will allow broader participation of multiple stakeholders in the creation and review of the new classification.

A review and coordination mechanism will be built in order to evaluate the progress of the revision process to ensure that it is proceeding in desired directions. Currently a Revision Steering Group has been established as and oversight mechanism. Each main area of revision will be worked through a topic advisory group and multiple workgroups. Following this roadmap we expect to arrive at a desired product that not only serves as a classification system but also as a building block for health information systems.

Keywords: ICD, Classifications, Terminology, Health Information Systems, International Health.

1. Background

The International Classification of Diseases (ICD) {REF} provides a public global standard to organize and classify information about diseases and related health problems. ICD is a member of the World Health Organization's "Family" of International Classifications (WHO-FIC) which provide the basic building blocks for health information systems. The overall function of the WHO Classifications is to capture data at various service delivery points in a manner that is interoperable across systems and countries using a suite of integrated standard tools. In this way, meaningful communication and exchange in the health sector is possible globally across the health sector.

To keep the scientific currency and public health utility of the classifications, ICD is scheduled for 10 yearly periodic revisions and annual updates in line with the recommendations of the governing bodies of the WHO[3]. The latest revision, ICD-10, was adopted by the World Health Assembly in 1990 {REF}.

An update and revision process has been prepared by the WHO involving all stakeholders. The process is similar to "software release" in that it will maintain compatibility with previous versions, allow new functionalities and developments in modular structure, and will test the revision proposals before implementation. The main objectives of the ICD update and revision process are to create a user-friendly and scientifically credible classification utilizing modern knowledge management and sharing methods to synthesize scientific advances in the health and information fields in a continuous manner.

A common information infrastructure for the update and revision process has been created for all ICD chapters to link the supporting evidence to the classification; this infrastructure includes better knowledge and meta-data representation. Of course this infrastructure will yield a product no better than the scientific content provided within the various disciplines. Certain areas such as oncology, mental and addictive disorders, internal medicine, and external causes of injury have been identified by the WHO-FIC Network as main foci of the update and revision process. In each area of health care the health information will be systematically reviewed in three interconnected main lines: (1) a Scientific Stream, (2) a Clinical Stream, and (3) a Public Health Stream. This work will be carried out by a core team of WHO-FIC investigators along with a group of international collaborators and advisers utilizing a permanent Internet-based knowledge management and sharing portal.

[3] *The resolution can be found at hyperlink: WHA ICD Resolution (WHA 43.24).*

2. The specific aims of the Update and Revision Process:

The revision process will aim to create a platform for the ICD that will allow continuous improvement in terms of following three *streams of work*:

1. Scientific Evidence: ICD should reflect the advances in medicine and all health sciences. The scientific understanding of the underlying process should guide the classification and representation of knowledge in the classification.

2. Clinical Utility and health system utility: ICD should be easy to use, support clinical decisions and health system management and should be readily integrated into routine practice in different settings including primary care, more specialized clinical care and research. Accordingly it may have different but compatible versions that can be used interchangeably in different levels of health care.

3. Public Health Usefulness: ICD should assist in public health policy, resource allocation and monitoring outcomes by recording mortality, morbidity and other population health parameters. It should also be compatible with other classification schemes and health information system elements.

Under these streams of work the specific aims of the Revision Process can be further expanded as follows:

1. Scientific evidence: To explore the scientific basis and epidemiology of diseases so that the ICD revision is based on the best available data. To achieve this specific aim, systematic reviews of the literature will be carried out by selected expert groups. A standard protocol will be followed to identify scientific publications to be reviewed. Journals included in Index Medicus and the Science Citation Index since the publication of ICD-10 (i.e., 1990) will be systematically reviewed to explore the implications for ICD categories. Specific questions will be formulated by expert groups to guide this research. For example:

    a. Do the new discoveries of infectious agents or new understandings of their prevalence or role in disease require classification or coding changes? (E.g. Helicobacter pylori, SARS Corona virus, Ebola virus, etc...)

    b. Do new discoveries concerning treatment other interventions require specific coding changes? (e.g. coding of drug resistance, refractory treatment, similarity of treatment response in different diseases, new diagnostic procedures and therapeutic interventions?)

    c. Does the rapidly growing availability of information on disease risk genes, somatic mutations, or patterns of gene expression alter taxonomy? (e.g., patterns of gene expression in lymphoma or breast cancer; the first convincing risk alleles in common genetically complex disorders)

d. Is the taxonomy developmentally sensitive so that it is applicable across the life span? For example, same disease definitions apply equally both to children, adults and elderly?

2. To explore the clinical utility of the Clinical and health system utility: Given the use of ICD for in the daily practice of various clinicians in different settings such as primary care, hospital settings, rehabilitation and long-term care settings, the classification should match the needs of users so that an appropriate level of detail is available.

   a. The classification should reflect the relevant categories which are most frequently seen and treated in those settings without redundancy and with sufficient detail for differential diagnosis (e.g. the same classification of ICD could be presented in primary care with a single category for appendicitis, depression or diabetes mellitus. However, these diagnoses may not be sufficient for clinical care, and are less likely to be sufficient for research. One would like to know further details such as the type, treatment need and possible complications.)

   b. The update and revision process will explore the needs and practices of different users to tailor the level of detail for different users without changing the overall master standard of ICD. ICD has been used for various purposes ranging from mortality, morbidity to patient safety and quality assessment tools. To achieve this there will be internet based *international discussion forums* that are open to clinical experts from different countries.

   c. ICD should be appropriate for use in electronic health records. There may be a need to expand the level of detail of classification entities by linking them to standard description of signs, symptoms and other descriptors of illness. These are being formally developed over the world as standard terminologies. The revision process should proactively define the linkage between terminologies (e.g. SNOMED -CT {REF} and other terminologies) and the ICD-11.

   d. The basis for clinical modifications made in different countries should be investigated to inform the revision process such as ICD-10-CM in the USA, ICD-10 AM in Australia, ICD-10 CA in Canada and ICD-10 GM in Germany {REF}and many others. Would other countries follow such clinical modification examples? If so what is the best way to maintain standardization and comparability? The revision process should aim to minimize the need for further national modifications.

   e. The proposed changes will be tested involving various clinical practitioners in a field testing trial organized as a *Global Practice Network* in terms of their ease of use, relevance, utility, reliability and other properties.

3. Public Health Usefulness: The main topics of exploration will include:

   a. ICD implemented to record deaths in different countries (i.e. mortality)? What are the main codes used, who makes the coding, which tools do they use, accuracy of coding practice, suggestions for improving standardization to achieve comparability, accuracy

and reliability? What are the cultural and local implementation issues regarding is the interpretation of codes?

b. How is ICD implemented to record diseases in different countries (i.e. morbidity)? What are the main codes used, who performs the coding, which tools do they use, accuracy of coding practice, suggestions for improving standardization to achieve comparability, accuracy and reliability?

c. What is the use of ICD for health financing and reimbursement purposes? How could it provide better input to casemix groupings (e.g. variants of Diagnosis Related Groupings and others)? {REF} in many health systems. The revision process should ensure that casemix users have adequate input and joint use of WHO FIC classifications to produce casemix groupings.

d. How is ICD used for disease surveillance, clinical registries, public health reporting, disease prevention, and population based surveys ? How could data from individual level use could be aggregated for population level indicators?

e. Following the approval of the International Classification of Functioning Disability and Health (ICF) by the World Health Assembly as a WHO's international framework to describe and report health and disability, there is a need to align ICD codes and their definitions with the ICF, and review their joint use as WHO reference classifications for public health purposes.

These three streams of work will need to be woven together within an architecture that allows scaling for use in primary care, specialist clinical care domains, research and other settings. The architecture will build on the traditional ICD categories and improve each category with clear textual descriptions detailing their ontological properties and identifying relations between them.

This architecture will intend to link ICD with other health information system rubrics as a versatile information source and coding scheme and allow dynamic tailoring of the scheme for various users in e-health applications.

3. Plan of Activities

To address these specific aims we would like to create a set of activities that will bring together the above questions in a coordinated work plan and activity that we in short call an *"update and revision process for ICD"*. This process:

- will be coordinated by the WHO Headquarters with active participation of whole WHO Network inviting all interested parties to improve the classification in terms of its scientific basis, clinical and public health use.

- will create a network of users involving scientists, practitioners, administrators, policy makers and consumers to make better use of this classification for understanding, communicating, planning and administering health care.

- will make state-of-the art evidence based reviews to reflect the most updated scientific knowledge in the classification including recent advances in medical and health sciences as well as in information technology

- will include field trials which are essential for testing the applicability of the classification as well as obtaining operational characteristics such as reliability measures. In addition the field trials serve to identify linguistic and cultural applicability issues, and serve as knowledge dissemination mechanisms.

- will allow linking classifications and clinical terminologies through their proper knowledge representation i.e. the *diagnostic formulations* as formal operationalization of any diagnosis including signs, symptoms, laboratory findings etc. in standard vocabularies

- will serve to provide the necessary transformation to the 21st century health information system needs to monitor and evaluate health outcomes.

A coordinated series of methods will be utilized to systematically-review existing evidence to revise the current ICD 10th version in order to arrive at a new generation of classification that will serve the needs of multiple users. This process will take place in three stages:

(1) compilation of scientific, clinical and public health evidence for revision, which is briefly called ICD-10 Plus.

(2) creation of a draft ICD-11 and field testing,

(3) creation of a systematic linkage to standardized health care terminologies to allow information processing by computers.

<insert figure 1 here >

3.1 ICD-10 PLUS

ICD-10 Plus is a web application which allows users enter structured proposals for ICD revision. These may, for example, be changes in existing codes or insertion of new codes. Users can fill in a form in which they explain a proposal with the underlying rationale and publication references from PubMed or they can upload documents that are relevant to the proposal. The proposals are organized according to the existing ICD-10 structure so that all the users may browse through the classification and see what is proposed in various parts of the classification. The application allows searching the proposals and generating reports and works as a *workflow engine* which documents the decision process on the proposals and related annotations. This system requires moderation to avoid irrelevant entries. Any relevant entry by registered users will be displayed on the internet and will be open to discussion and commentary.

Relevant parts of national modifications that have evolved from main ICD10 will form part of ICD-10 Plus as they clearly indicate user requirements. In addition input from other WHO-FIC members will be inserted in ICD 10 Plus. ICD-11 is the first version of ICD to be developed since the Family of Classifications was put in place. Only in exceptional cases will ICD codes be deleted and the user referred to another classification. But many of the classifications can inform the development of ICD codes. Examples include use of ICF domains (especially in chapters 18 and 21), alignment between ICECI and chapter 20 and between ATC-DDD and any ICD list of drugs.

3.2 ICD-11 DRAFT

ICD -11 Draft is envisaged as a Wiki–like structured Joint-Authoring Tool. Selected Expert Groups will be given the mandate of drafting portions of ICD-11. Each Expert group will place their draft in to 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 entity, relevant inclusion and exclusion terms and a textual description (2) detailed clinical description including clinical and/or research rules for diagnosis. Each rubric will be posted in the Wiki application {REF}. Following a taxonomic review and clarification by WHO experts as needed. WHO will also commission a structured scientific peer review. The product will then be posted for public review for comments and later for field trials as explained later in this document.

3.3 ICD - Terminology links

Linking ICD (and all WHO Classifications) with terminologies is one of the main aims of the revision process. ICD-11 Draft Codes, Titles and all rubrics will be based on a sound terminology based on a coherent and internally consistent ontology system. This linkage will cover all the inclusion terms *(including relevant historical links, and index terms)* and the exclusion terms. This linkage will require ontological definition of the entity including its taxonomic status (i.e. in what chapter, section in the classification tree, whether it is a 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 episodicity, severity, chronicity, ...) Expert Drafting Groups will be

given the mandate of identifying core constructs and concepts of ICD-11 using terminology/ontology tools to formalize the concepts and constructs using SNOMED and/or any other terminology {REF} 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) {REF} and possible Decision Support Systems

These three web-base applications will be the core of the KMS portal which is described in more detail under 4.3.

4.1 Organizational Structure and Detailed Plan of Activities

WHO Headquarters will coordinate the overall ICD revision in consultation with the WHO Member States, the WHO-FIC Network, and multiple professional organizations to ensure that the final revision is broadly responsive to the many different aspects of health care. The work will be mainly carried out by the Revision Steering Group and the Workgroups as shown in figure 2 and described below:

<insert figure 2 here >

A. The Revision Steering Group (RSG)

A Revision Steering Group will serve as the planning and steering authority in the update and revision process. Its terms of reference will focus on the following issues:

- *Oversee the revision process and give advice for coordination of workgroups:* RSG will review the content of the revision process and will aim to ensure adequate coverage of all chapters and codes to ascertain the input from existing clinical modifications of the ICD and other WHO-FIC members, and maintain continuity between 10th and 11th editions. 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.