Terms of Reference of the Topic Advisory Groups

Topic Advisory Groups will serve as the planning and coordinating advisory body for specific issues which are key topics in the ICD development process.

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

- Advise on particular ***topic development 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, and to focus on specific issues as needed. Each TAG will (a) determine the number and content areas of the workgroups, (b) identify nominees for the members and chairs of the workgroups, (c) develop an initial draft mandate for 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. 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 (TAG) will lead the work in different fields of expertise. Such fields can be vertical, as the Six Stages of Disease Transformation, or horizontal, such as terminology which can be found in every area. The TAG will organize **workgroups** to deal with relevant subtopics, as necessary.

Ten rules will ensure consistent quality of work across all groups:

I.	**Definition of the diagnostic entity as a medical disease, pattern, or disorder.**
II.	**Clustering of signs, symptoms, findings, and operational characteristics.**
III.	**Link to underlying pathophysiology and genetic markers when applicable.**
IV.	**Clinical utility of the classification entity.**
V.	**Reliability of the use of the classification entity.**
VI.	**Validity of the classification entity.**
VII.	**Separation of pattern/disease and disability elements**
VIII.	**Cultural elements that need to be attended.**
IX.	**Threshold considerations.**
X.	**Other nosological issues relevant to this entity**

Terms of Reference of the Working Groups

Work Groups will serve as the key functioning unit for the review of evidence and generation of main proposals at a specific topic. For example, the TAG in the Classification of Interventions will be responsible for all interventions, whether medication or practice based, and their linkages, whereas it may generate 2-3 working groups to carry out the systematic reviews on special sections of the chapter, such as acupuncture, herbal medications, or manual interventions such as tuina, chiropractic, etc.

The workgroups are 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 pre-existing knowledge. 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 broad range of activities can be described by a set of tasks:

- TASK 1. Develop a preliminary position statement on each core diagnostic issue. Blocks of ICD may be a suitable entity.
- TASK 2. Review the empirical evidence
- TASK 3 Generate summary proposals on the development platform for comment by other groups, ICD RSG, and the global community.
- TASK 4. Revise reports
- TASK 5. Field trials
- TASK 6. Final revisions and recommendations

1.1 TASK 1 Develop a preliminary position statement on each core diagnostic issue

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.

I. **Definition of the diagnostic entity as a medical disease, pattern 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 patterns/disorders/diseases in this chapter/field 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 pattern/ disease/disorder, based on the common model of ICD.

III. **Link to underlying pathophysiology and genetic markers, when applicable.** Identify the intra-individual markers that are associated with the pattern/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 pattern/disease and disability elements.** Identify the features that signal the presence of the pattern/disease/disorder, defining the pattern/disease/disorder without reference to the distress, impairment, or other consequences that it produces. Suggestions to link to WHO ICF and specifically operationalize the criteria on disability and distress related rubrics.

VIII. **Cultural elements that need to be attended.** Consider variability in the presentation of the pattern/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 pattern/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 pattern/disorder that will need to be addressed. This list of additional issues may change as the evidence related to this pattern/disorder is reviewed.

1.2   TASK 2. Review the empirical evidence

Workgroups will survey the available evidence for each diagnostic entity to address the ten diagnostic issues described above. Evidence will be reviewed using a three-tiered, iterative process that maximizes input from sources that are most readily accessible.

Review the published literature*.* A standardized system should be chosen to guide the compilation and coding of published results. This system will be researched and suggested by the ICD Revision Steering Group and provided to co-chairs early in the development process. Participants will also receive guidelines concerning the parameters to be used in the literature reviews (e.g., inclusion criteria, exclusion criteria, review, and reporting style). Workgroup coordinators will then carry out these reviews at collaborating sites throughout the world. Study managers based at WHO Headquarters will remain in constant contact with the workgroup coordinators and the workgroup co-chairs throughout the development process.

Targeted secondary analysis of existing data. If no published studies are available to answer a particular question identified by a workgroup, workgroup members will search for existing data that would address this question but that have not yet been analyzed or published. Workgroup co-chairs will seek appropriate data by (a) directly contacting researchers in the field who may have relevant data and (b) putting out an open call for data relevant to the question at hand. When researchers with relevant data are identified, the co-chairs will, at their discretion, arrange with these researchers to share or analyze their data or to collaborate with workgroup members on analyses to address the knowledge gap. Results of these analyses will be evaluated using the same standardized rules used to evaluate published results in the literature reviews. Informative results may be published in the online Classifications Journal or in books or articles to be published by WHO on the ICD development process.

Collection and analysis of new data. When no data sets are available to address unanswered questions of the workgroups, new data need to be collected. Because time and resources for new data collection are limited, such efforts will likely be restricted to questions that are relatively circumscribed and that can be fruitfully addressed through basic descriptive studies. Workgroups will generate proposals for data collection to address unanswered questions through rapid distribution of target measures to clinicians in the Global Health Practice Network that can be completed by the clinicians themselves or administered to their patients. These data will then be analyzed and their results systematically coded and integrated with evidence gathered in the first two tiers.

1.3   TASK 3   Generate summary proposals on the development platform for comment by other groups, ICD Revision Steering Group, and the global community.

Documenting the evidence on which recommendations are based and using the results of their evidence-based reviews, the workgroups will formulate suggestions for developing ICD diagnostic and ontological categories, operational criteria, and/or overall coding structure.

Reporting interim and final results. Each working group will be asked to write and to post on the development platform an interim report of its progress every six months as well as a final report documenting its final results and recommendations. The ICD Revision Steering Group, in consultation with the TAG and workgroup co-chairs, will establish explicit guidelines for the workgroups to use in preparing these reports, including separate templates for interim and final reports. The purpose of these guidelines will be to ensure completeness of desired information and consistency across documents submitted by different workgroups. As an incentive to engage in the report-writing process, workgroup members will have the opportunity to publish interim reports in special issues of the online Classifications Journal.

In addition to their review by the ICD RSG, interim and final reports of the workgroups will be posted on the development platform. This platform will serve as a public forum in which end-users can provide feedback to the workgroups throughout the development process, increasing the likely usefulness of the ICD for the wide range of constituents for whom it is being devised. To that end, comments on reports will be solicited from the scientific community and other ICD stakeholders. In addition to general comments, workgroups may request suggestions for future directions or call for information or data on a particular topic. Public comments will be continually collected and reviewed, who will screen them for content and relevance before forwarding them to the appropriate workgroups. These comments will be considered and weighed using the same criteria as those used in the review of empirical evidence.

1.4 TASK 4. Revised reports

Workgroups are likely to complete multiple rounds of reports in an iterative process in which they report their findings, receive feedback from the ICD RSG and the world community for a health field, and revise their work in response to feedback. The ICD RSG will propose a set of criteria for evaluating workgroup reports and may bring in external consultants to assist in the evaluation process. Evaluations may be followed by requests for clarification of competed work or for additional work in particularly important, controversial, or understudied areas. In addition, workgroups will complete annual updates of their literature reviews to ensure that the information in their final report—and the evidence on which final recommendations are based—is as comprehensive and up-to-date as possible.

1.5   **TASK 5. Field trials**

The provisional revised diagnostic criteria recommended by the workgroups will be tested in one or more iterations of field trials. Field trials will be conducted in collaboration with existing global networks.

Proposing questions for the field trials. Given the key questions identified in the development process, workgroups will be asked to develop feasible questionnaires that could be applied within the global Network.

Evaluation of the feedback from the field trials. Results of the field trials will be provided to the workgroups to serve in developing the final revisions and recommendations.

1.6   **TASK 6. Final revisions and recommendations**

Preparing a final report. Based on the results of field testing, the workgroups will finalize the ICD diagnostic criteria/external causes and prepare a final report summarizing their results and recommendations. The report will be presented to the ICD-Advisory Group and posted on the Internet platform.
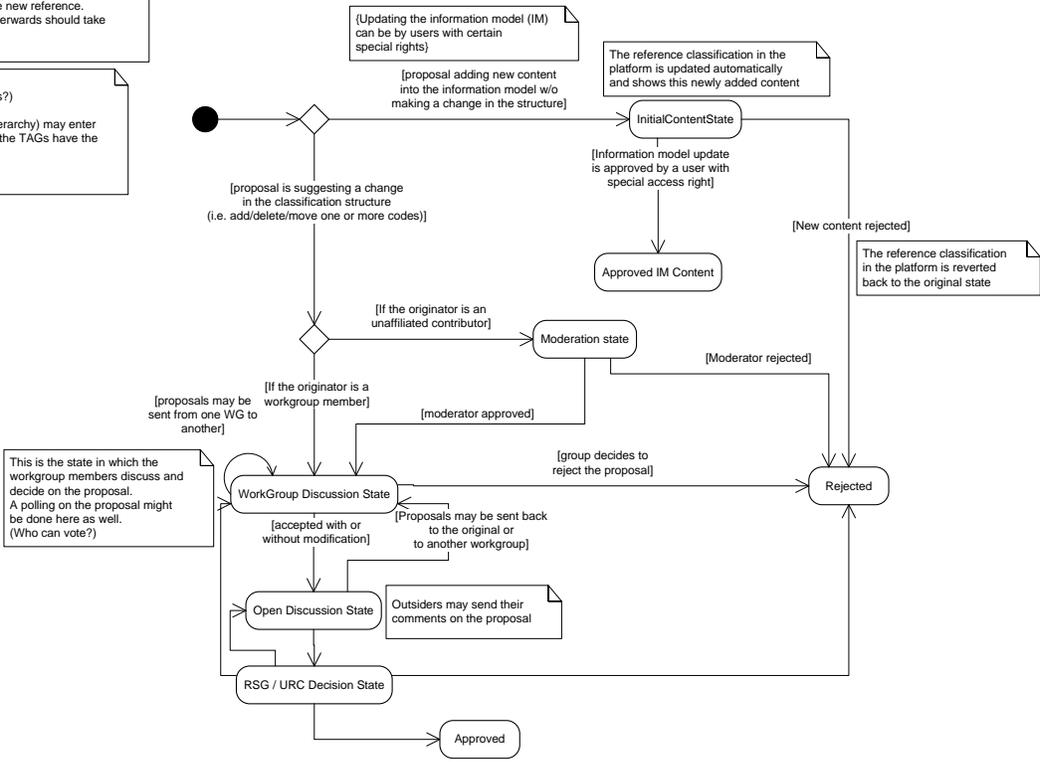
Setting an agenda for future work. While it is hoped that the comprehensive survey and synthesis of the literature will yield important advances in our understanding of patterns/disorders and their external causes, it is also expected that many questions will remain unresolved and that some new questions will become apparent as the development process draws to a close. Having just reviewed and contributed to the available literature, the workgroups will be in an ideal position to identify remaining gaps in knowledge, chart the steps needed to fill these gaps, and set an agenda for the field for future research. The resulting proposals will be published in one or more of several possible forums, including the ICD text itself, the ICD web page, the knowledge portal, books published by WHO on the ICD development process, or a companion workbook accompanying the newly-published ICD.

2   Workflow

Proposals for ICD information can be generated by Workgroups, or everybody accessing the development platform. The proposals can relate to modifications of the structure of ICD, to modification of definitional content of ICD, or to both. Any structural changes will be decided before definitional content is formulated. In some cases definitions will be present in existing internationally agreed sources, thus guiding decisions that may lead to structural changes. The graphics below depicts the flow of a proposal:

A proposal is a change request made on the
Reference version of ICD. We will start with
ICD-10 as the reference version but once we have
a sufficient number of approved proposals we will
prepare interim versions of ICD-11 and they will be
placed on the platform as the new reference.
New proposals that come afterwards should take
that version into account

Who initiates the process?
(i.e. Who adds the proposals?)

Any contributor (see user hierarchy) may enter
proposals in the system but the TAGs have the
mandate of doing ...

{Updating the information model (IM)
can be by users with certain
special rights}

The reference classification in the
platform is updated automatically
and shows this newly added content

[proposal adding new content
into the information model w/o
making a change in the structure]

InitialContentState

[Information model update
is approved by a user with
special access right]

[New content rejected]

The reference classification
in the platform is reverted
back to the original state

Approved IM Content

[proposal is suggesting a change
in the classification structure
(i.e. add/delete/move one or more codes)]

[If the originator is an
unaffiliated contributor]

Moderation state

[Moderator rejected]

[If the originator is a
workgroup member]

[proposals may be
sent from one WG to
another]

[moderator approved]

This is the state in which the
workgroup members discuss and
decide on the proposal.
A polling on the proposal might
be done here as well.
(Who can vote?)

WorkGroup Discussion State

[group decides to
reject the proposal]

Rejected

[accepted with or
without modification]

[Proposals may be sent back
to the original or
to another workgroup]

Open Discussion State

Outsiders may send their
comments on the proposal

RSG / URC Decision State

Approved

Chairing of TAGs and Workgroups

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

Chairs are liable to WHO that rules and regulations of the revision process are followed by their groups.

Chairing is a proactive undertaking, and the range of activities and responsibilities that a chairman must perform is huge. The chair of a TAG is accountable to WHO. The chair of a committee must realize that the success or failure of that committee rests squarely on his/her shoulders. The primary duty is to guide the group's discussions. He/she should encourage every member to participate in the work and keep track of the discussion focused on the matter at hand. The chair ensures there are agendas and structured reports.

In particular, the chair ensures revision procedures are applied by the TAG and its workgroups

- Creation of workgroups

- Workflows

  o Proposals

  o Comments

  o Conflict resolution

- Evidence based review guidelines

- Communication with ICD RSG/WHO

The chair is also responsible for encouraging opportunities for interactions between the members. Group should be provided the opportunity to get to know each other. Groups tend to work better if the members are familiar with one another. If members don't get along well, the leader must not allow those members to impede the flow of the meeting. A quick solution is not to allow the conflicting people to sit near each other or in the direct line of fire.

Members of workgroups should be carefully selected. These are the people who will help resolve issues for the relevant specialty. They should be knowledgeable in the area of the group's responsibility. Members should be a diverse group without being incompatible. Try to recruit people from different perspective on the committee – when these people agree on the solution, you know it's a good one.

Remind members that they should be receptive and open to new ideas and other people's opinions as work is accomplished in a committee through the give and take of an open, uninhibited discussion.

- Always lead by example
- Carefully plan your agenda; think of an agenda as a roadmap that will ensure your meeting serves its purpose
- Know where you are going; review the meeting objectives and desired outcomes in your opening remarks
- Make sure everyone participates in the discussion
- Anyone who voices a problem must also offer a potential solution… meetings should not be constructive, and not a forum for complaining about everything and everyone
- Ensure that committee members take ownership in desired outcomes by inviting them to do something to support the goals of the committee
- Delegate but have realistic expectations of the amount of work that should be asked from each members given their respective responsibilities
- Provide an agenda at least 4 days prior to the meeting date
- Indicate business items to be discussed versus decided upon
- Circulate minutes no later than 10 days following the meeting.
- Chairs can also send a quick "to do list" summary the day after the meeting by email
- Evaluate your group from time to time by asking members about their experience on the group

Committees are an integral part of every successful organization. A committee with a clear purpose, a well-informed leader and dedicated members is on its way toward success.

Workgroups are an integral part of the revision. A working group with a clear purpose, a well-informed leader and dedicated members is on its way toward success.