World Health Organization
Family of International Classifications 2021

Table of Contents

1 Acknowledgements

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2 Introduction

Health data are needed to measure performance, improve programme decisions and increase accountability, inform health system financing and resource allocation, evidence-based practice, are used in guidelines and decision support, monitoring of health outcomes and access to services, and the assessment of the health of individuals and populations. Accurate and timely data are an essential resource for Countries to document progress in the Sustainable Development Goals and Universal Health Coverage, health emergencies and healthier populations. WHO is the Steward and custodian for monitoring the health-related SDGs.

WHO's constitution mandates the Organization to establish and revise as necessary international nomenclatures of diseases, causes of death and public health practices, and requests the Member States to submit annual reports on health status and actions taken to improve health.

The WHO-Family of International Classifications provides a standardized common language for coding a wide range of information about health and wellbeing, and about interventions delivered to individuals and populations. The classifications and terminologies have been developed based on sound scientific principles, ensuring that the classifications are internationally and culturally appropriate and can convey information in an unambiguous way across languages, cultures, settings and borders.

Accordingly, WHO sets and maintains data collection standards that the Member States need, including the WHO Family of International Classifications that include the International Classification of Diseases (ICD) and the International Classification of Functioning, Disability and Health (ICF) (resolution WHA54.21) and the International Classification of Health Interventions (ICHI, under development). The world health assembly, in its recent resolution for adoption of ICD-11 (resolution WHA72.15), explicitly reiterated its request to develop further and implement the family of disease- and health-related classifications, with the International Statistical Classification of Diseases and Related Health Problems linked to other related classifications, speciality versions and terminologies. WHO terminologies complement this set for cancer registration (ICD-O, anatomy, tissue type of tumours), pharmacoactive substances (International Nonproprietary Names, devices nomenclature, dimensions of injury mechanisms (e.g. site, objects) and more.

WHO leads the maintenance and implementation of its classifications and related products as critical standards for the international community. Since 1970 WHO has worked in partnership with its Network for the Family of International Classifications (WHO-FIC), which includes Collaborating Centres, non-governmental organizations, technical linkages to member states and other partners. The work involves all levels of WHO, its technical departments and other UN and international agencies.

The WHO-FIC includes three core ("reference") classifications:

- The *International Statistical Classification of Diseases and Related Health Problems* (ICD) is used to classify diseases and related health problems, such as symptoms and injury, causes of injury and more.
- Functioning is classified separately in the *International Classification of Functioning, Disability and Health* (ICF) and environmental factors.
- The third reference classification, the *International Classification of Health Interventions* (ICHI), is in the final stages of development and classifies health interventions delivered across all health system sectors.

This document describes the WHO-FIC and its members, focussing on how the WHO-FIC is modernized to meet health information needs in the digital age. It is intended for a range of readers and does not assume prior knowledge of the WHO-FIC or technical expertise. It is of value to those interested in producing and using high-quality statistical information about health, including government officials, policy- and decision-makers, clinicians, researchers, educators, managers and administrators, and health system users.

This document describes the relationships between the reference classifications, related, and derived members of the WHO-FIC.

This work assists stakeholders in understanding the improved and practical classification tools in support of the WHO mandate of promoting and supporting the provision of universal health care internationally.

3 WHO Family of International Classifications (WHO-FIC)

The WHO-FIC is a set of integrated classification products that share similar features and can be used individually or jointly to provide information on different aspects of health and health systems. The classifications are designed to cover the core dimensions of death, disease, functioning, disability and health interventions.

The constitution of the World Health Organization states that "Each Member shall provide statistical and epidemiological reports in a manner to be determined by the Health Assembly" (Article 64). In support of the requirement of member states to provide data in a form that can be compared across countries and over time, one of the functions of WHO is to "establish and revise as necessary international nomenclatures of diseases, of causes of death and of public health practices" (WHO 1995). These international statistical classifications, endorsed by the World Health Assembly for reporting on the health of populations of member states, are the basis of the WHO-FIC and the notion of a WHO-FIC was further reinforced by the adoption of ICD-11 in 2019 (WHA 72/29) stating "….to further develop and implement the family of disease- and health-related classifications, with the International Statistical Classification of Diseases and Related Health Problems as the core classification linked to other related classifications, speciality versions and terminologies…".

World Health Organization Family of International Classifications

The WHO-FIC consists of three (3) broad groups: reference classifications, derived classifications and related classifications. The reference classifications are international reference standards, from which the derived classifications have been developed to accommodate information needs in specific areas of health. Related classifications cover health domains beyond mortality and morbidity, functioning and health interventions (e.g. medicaments).

The reference classifications within the WHO-FIC are part of the broader UN Family of Statistical Classifications (https://unstats.un.org/unsd/classifications/Family). The UN Family also includes other classifications of relevance to health service production and financing.

3.1 Purpose

The purposes of the WHO-Family of International health-related Classifications to:

- Provide a conceptual framework of information domains for which classifications are, or are likely to be, required for purposes related to health and health management.
- Ensure semantic interoperability in integrated health information systems
- Provide a set of endorsed classifications for specific purposes defined within this conceptual framework.
- Facilitate the storage, retrieval, analysis, disaggregation, interpretation and exchange of data for individuals and populations and the compilation of internationally consistent data.
- Improve health through the provision of sound health information to support decision making at all levels, including to support the financing of health systems (including case-mix classification systems and general funding of health services); and to
- Stimulate research on health and the health system.

All the uses mentioned above characterize the WHO-FIC as a set of tools for monitoring relevant targets identified within the Sustainable Development Goal number 3, "Healthy lives and wellbeing for all at all ages" (SDG3). More specifically, the WHO-FIC could be a key element in monitoring Universal Health Coverage, one of the most critical of the SDG3 targets.

Uses of the ICD, ICF and ICHI are diverse and widespread. Specific usecases include, but are not limited to:

- Cause of death monitoring
- Information on what people die of is recorded on standard forms, analyzed, and reported following ICD standards. The information reliably provides a long-term trend of the health of a population. It also can serve short-term monitoring of epidemiological information, like in an epidemic or pandemic.
- Functioning assessment

- The ability to carry out tasks by oneself and participate in daily life are means by which to describe, in summary, the overall functioning of a person. It can also track the situation in general or before and after treatment. ICD includes a set of functioning categories based on the WHO Disability Assessment Scheme (WHODAS2) to calculate a functioning score.
- Quality and Patient safety, device and medication safety
- Quality of care and patient safety uses ICD-coded information to describe the situation of the patient, substances or devices involved, the outcome of treatment and incidents or near-incidents including mechanisms and involved objects such as the failure of an infusion pump or the accidental wrong dosage of a medicament by the patient in line with the WHO recommendations for patient safety incident reporting and learning systems.
- Casemix, costing, resource allocation, Diagnosis Related Grouping (DRG)
- ICD-coded information is used for resource allocation or lumpsum payments of statistically equal groups. ICHI complements ICD with clinical, functioning and public health interventions.
- Traditional Medicine
- Traditional medicine is an enduring and important area of health care in many countries. ICD-11 includes a supplementary chapter for optional dual coding use, entitled 'Traditional medicine conditions' to better reflect this reality. ICD-11 enables, for the first time, the counting of traditional medicine services and encounters; the measurement of their form, frequency, effectiveness, safety, quality, outcomes, and cost; comparison with mainstream medicine; and research, due to standardized terms and definitions nationally and internationally.
- Cancer registration
- Cancer registration provides detailed information over time on cancer patients. Information on the type of cancer, location, spread and behaviour is coded with ICD.
- Clinical documentation in primary, secondary and tertiary care
- WHO core classifications and terminologies have been merged into a common structure that facilitates coding and provides a level of detail for the different settings in health. Due to their multilingual design and the controlled translation environment, it is a reliable tool for communication across settings, borders and languages.
- Morbidity coding and reporting
- Accurate and precise information on what people fall sick from and are treated for is recorded and reported with ICD. This includes all levels of health from primary to secondary and tertiary care. This information further serves policy design, planning and monitoring of all aspects of the health of a population.
- Research
- Comparability of coded information in multiple languages and with common diagnostic approaches allows the pooling of information from different sites, both globally and locally, for research and trials. WHO-FIC provide levels of detail required for complete clinical and research documentation across languages, borders and settings
- Rehabilitation and social medicine.

- The ICF provides the dimensions for describing the functioning of a person and thus enables comparisons and monitoring of individuals and a population.

3.2 Characteristics

To achieve these purposes, WHO-FIC classifications must:

- be based on sound scientific, taxonomic and ontological principles
- be culturally appropriate and internationally applicable
- focus on the multidimensional (bio-, psycho-, social-) aspects of health
- meet the needs of its different and varied users
- reflect current knowledge while providing relative stability over time
- enable derivation of summary health measures
- provide a platform for users and developers
- be compatible with the use of information from electronic health records and terminologies.

3.3 Statistical classifications and clinical terminologies

The development of ICD-11 and the migration of ICF and ICHI to the same ontological infrastructure in 2021 have enabled the full integration of terminology and classification in a common platform, in a way that lossless clinical documentation is possible (code all detail necessary), statistical aggregation integrated, end to end digital solutions are provided, and links to other terminologies for other uses are enabled.

According to the definition of *terminology* in ISO 1087-1:2000, WHO classifications and clinical terminologies can both be regarded as terminologies. Nevertheless, we need to distinguish between classifications and clinical terminologies in terms of their purpose.

The ISO 17115 defines classifications and clinical terminologies as follows (International Standards Organization 2007):

- Classification: ‘an exhaustive set of mutually exclusive categories to aggregate data at a pre-prescribed level of specialization for a specific purpose'.
- Clinical terminology: ‘terminology required directly or indirectly to describe health conditions and healthcare activities'.

A (statistical) classification provides a system for the ordering and hierarchical grouping of concepts in a given domain for statistical purposes. The grouping of concepts is driven by the purpose for which the classification is designed. Classifications have residual classes ('other specified') to ensure that all cases can be classified; thus, they can accommodate new or unanticipated things encountered in a domain. Classifications also include granular index terms and rules that guide users to the correct concept.

Typically, clinical terminologies are more granular than classifications to support the exchange of concepts at the level of detail required for documentation within a community

of practice. A clinical terminology does not need to have mutually exclusive and exhaustive partitioning of a parent class. In health systems, clinical terminologies are designed primarily to capture, store, retrieve, translate, and communicate health data. At the same time, statistical classifications provide a foundation for collecting, aggregating, analyzing, and comparing statistical data.

Statistical classifications and clinical terminologies play complementary roles in supporting health information needs (Fortune et al., 2017). Consistency and relatability between classifications and clinical terminologies are essential for healthcare information tools to efficiently support the functioning of the health systems they serve. With the common Foundation, an important step in integrating terminology and classification has been done. This aspect is of increasing importance given the digitalization of health information systems.

With different developers and stewards of the various information products, international agreement processes are necessary to develop and maintain linkages between standard terminologies and classifications.

4 Scope and conceptual framework of the WHO-FIC

The WHO-FIC serves to provide a classification system with the range of needs for health data as its scope. Data needs for health include:

- how healthy people are
- what people fall sick or die of
- factors that influence health
- health systems responses

All types of these data, locally, nationally and internationally, are needed to implement Universal Health Coverage and support monitoring of the UN's Sustainable Development Goals, for example.

Health for these purposes is defined using the World Health Organization's 1948 definition:

> “A state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.”

World Health Organization Family of International Classifications

The range of factors that influence health, sometimes called 'determinants', is described by the WHO as follows[1]:

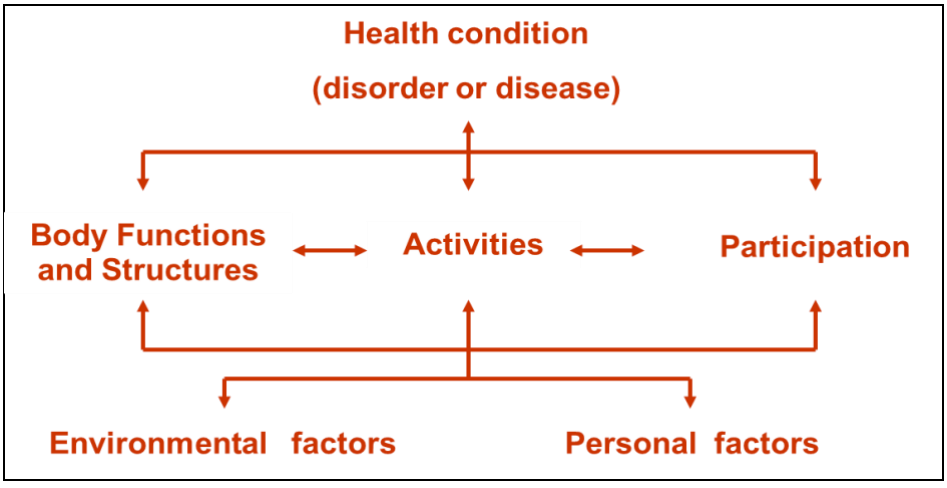
Many factors combine to affect the health of individuals and communities. Whether people are healthy or not is determined by their circumstances and environment. To a large extent, factors such as where we live, the state of our environment, genetics, our income and education level, and our relationships with friends and WHO-FIC all have considerable impacts on health, access and use of health care services add up to this. The determinants of health include:

- the social and economic environment;
- the physical environment, and
- the person's characteristics and behaviours.

The ICF provides a framework for the scoping and conceptual basis of the WHO-FIC. The ICF is the WHO's classification for describing functioning and health at both individual and population levels and is built upon the WHO biopsychosocial model of health[2]

(Figure 1). The model depicts that, in line with the WHO's definition of health, the functioning and health of a person or population is the result of the interaction of health conditions, body functions and structures, and activities and participation in life areas, all influencing each other and influenced by environmental and personal factors.

Figure 1 Relationship between the core components of the WHO biopsychosocial model of health



[1] https://www.who.int/teams/environment-climate-change-and-health/air-quality-and-health/hia-tools-and-methods/using-evidence-within-hia

[2] https://www.who.int/standards/classifications/icf/en

The members of the WHO-FIC can be related to the components of the biopsychosocial model:

- The ICD classifies health conditions (diseases or disorders as causes of morbidity or mortality). Although not its major role, it also classifies some environmental factors (for example, external causes of injury and poisoning) and some personal factors (as reasons for contact with health services).
- The ICF includes classifications of body functions and structures, activities and participation and environmental factors.
- The ICHI classifies health interventions. It incorporates classifications of body structures and functions, activities and participation, environmental factors and personal factors into its Target axis.

This common conceptual framework supports both the complementary use of members of the WHO-FIC to capture health data and the ongoing integrated development of the WHO-FIC. The framework also allows related classifications to be positioned in the WHO-FIC, helping to ensure that they play a role in filling conceptual gaps.

In addition, classifications relevant to treatment and care include the ATC/DDD, which covers medicines, and the ICNP that addresses nursing practice. A range of classifications formerly derived from ICD have been absorbed into ICD-11. This includes speciality versions like ICD for Oncology (ICD-O) and the detail added to national modifications of ICD.

5 Structure of the WHO-FIC

The classifications in the WHO-FIC and the broader United Nations family of economic and social classifications are of three major types. Figure 2 represents the types of classifications in the WHO-FIC.

Figure 2 Schematic representation of the WHO-FIC

World Health Organization Family of International Classifications

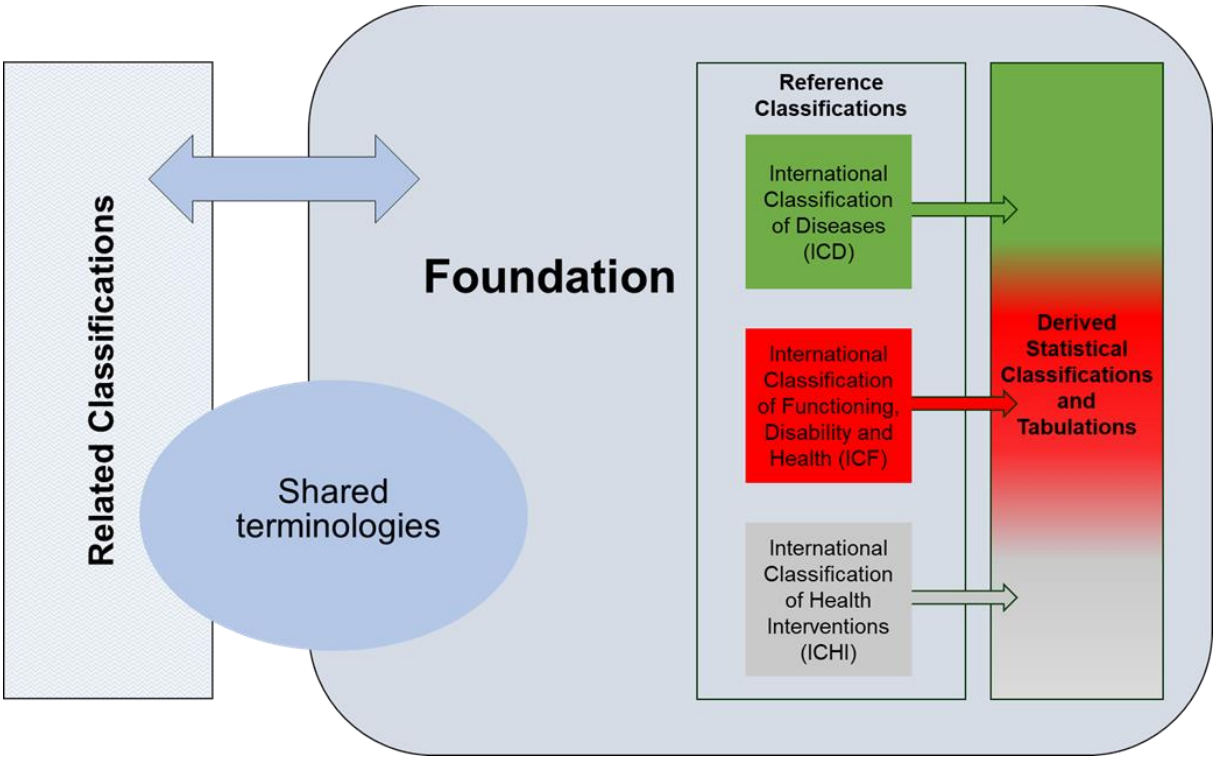


Figure 2 shows the relationships between the classifications in the Family of International Classifications, the Foundation and shared terminologies.

In its simplest form, the Foundation is a large collection of terms and their relationships (and other properties) that describe health and health-related domains. The formulation of the Foundation is evolving. ICD-11 is the first WHO-FIC classification for which a Foundation component has been implemented. The reference classifications will share components of the Foundation.

The Foundation includes a set of terminological lists that permit increased coded detail when combined with categories of the core classifications, or that could be used alone in other health contexts. Examples for such lists include anatomy, severity, infections agents, medicaments, health devices, relevant chemicals, or histopathology of tumours. A fracture of the radius could be refined by adding the extension code for the shaft of the radius. Similarly, subsets or special ways of groupings (tabulations) may be derived from the common Foundation, drawing on one (e.g. special tabulation of causes of death) or multiple (e.g. primary care coding of diagnoses and interventions) reference classifications.

Within the WHO-FIC, related classifications are regarded as complementary to the reference and derived classifications. Related classifications have their own sets of terms but share terms within the WHO-FIC. For example, the International Classification of Nursing Practice (ICNP) (International Council of Nurses, 2017), a related classification in the WHO-FIC, could draw on terms from the Foundation in the same way that the reference and derived classifications could draw on terms from the Foundation. ICNP also uses terms specific to nursing practice that may not be found in the Foundation but could be included in the future.

"Shared terminologies" refers to using terms from the same terminologies by more than one of the reference, derived or related classifications.

Figure 3 The WHO-FIC as a bridge linking health and health systems and services.

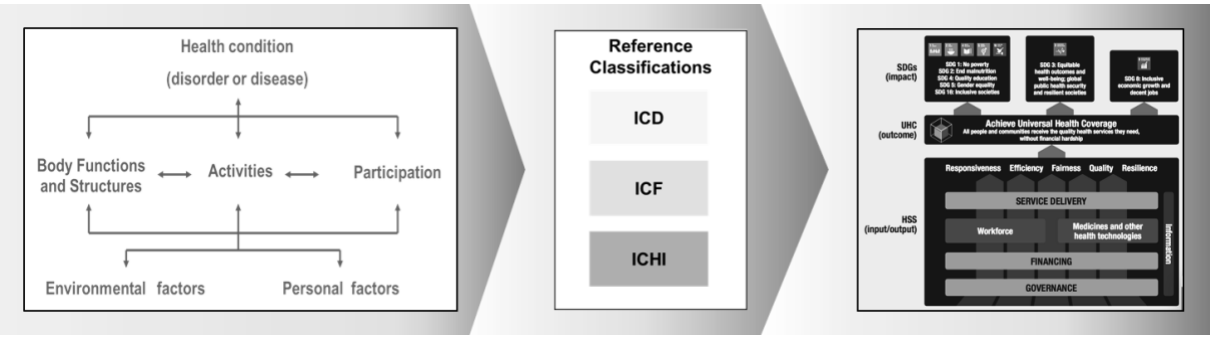


Figure 3 visually depicts the link that the WHO classifications provide, bridging health and functioning, as represented by the biopsychosocial model (both at the personal and population level), with the universe of health services as seen in the context of Universal Health Coverage and the Sustainable Development Goals (source for UHC/SDGs diagram: WHO 2017).

Reference classifications

The three reference classifications of the WHO-FIC are:

- the *International Statistical Classification of Diseases and Related Health Problems* (ICD), which is used to classify diseases and other related health problems, such as symptoms and injury.
- The *International Classification of Functioning, Disability and Health* (ICF), which classifies functioning and health, and
- the *International Classification of Health Interventions* (ICHI), which classifies health interventions.

These are the classifications that cover the main parameters of health and the health system, such as death, disease, functioning, disability, health and health interventions. They have achieved broad acceptance and official agreement for use and are approved and recommended as guidelines for international reporting on health. They may be used as models for the development or revision of other classifications with respect to the structure, character and definition of the categories.

5.1.1 International Statistical Classification of Diseases and Related Health Problems (ICD)

The structure and taxonomy of ICD are determined by a combination of history, relevance and feasibility. ICD needs to accommodate a broad range of settings and uses. All have different thresholds regarding the level of detail that is necessary and achievable. In the development of the classification, an important aspect is the balance between scientific progress and the need for statistical continuity.

ICD began life as the *International List of Causes of Death* in the closing years of the nineteenth century. By the early twentieth century, the list had been adopted by numerous countries, and in 1899, its creators initiated a process of decennial revisions to ensure that it remained current with developments in medical knowledge (Moriyama et al., 2011). At the time of writing this document, the most recent revision of the ICD in use is the Tenth (WHO 1989, version 2019). The Eleventh Revision (ICD-11) was adopted in May 2019 for use from January 2022 and represents a significant overhaul to optimize the classification for today's information technologies.

ICD has been widely adopted for this purpose in the compilation and dissemination of vital statistics around the world. From its first revision, the list was also used to derive causes of sickness (Moriyama et al., 2011, p.13). The demand for this use grew throughout the first half of the twentieth century, and the Sixth Revision (WHO 1948) incorporated a list explicitly for classifying morbidity. Today, the ICD has evolved to a comprehensive

classification system for use in mortality, morbidity, casemix, patient safety and quality[3] and is complemented by accessory lists (extension codes) that allow coding additional detail.

5.1.2 ICD-11

In developing ICD-11, a high degree of flexibility was sought to enable multiple needs to be met from a common base, the ICD-11 Foundation Component. As described in the ICD-11 Reference Guide, the ICD-11 Foundation Component is a structured collection of all 90000 ICD-11 concepts (diseases, disorders, injuries, external causes, signs and symptoms), relationships, descriptions, definitions, diagnostic criteria (see ICD-11 Reference Guide).

Each concept in the ICD-11 Foundation Component is defined in a standard way using a structured Content Model. The purpose of the Content Model is to encode the knowledge that provides the basis for the definition of each ICD-11 concept in a systematic way, that determines how more complex terms can be built from simpler terms in the ICD-11 Foundation Component, and that allows different tabular lists to be built from the ICD-11 Foundation Component. (see ICD-11 Reference Guide).

ICD-11 for Mortality and Morbidity Statistics (MMS) is the tabular list of about 17000 categories which forms the classification designed for mortality and morbidity coding. It is formed from the Foundation by aggregating concepts to statistical categories. More detail may be added using code combinations and a range of extension codes (such as laterality, severity and temporality), or coding additional detail from the Foundation using the Uniform Resource Identifier. ICD-11 can be accessed at https://icd.who.int.

This structure provides a strong base for ICD-11. Importantly, the ICD-11 Foundation Component also allows a flexible way to develop specialist derived classifications consistent with ICD-11.

ICD-11 has been built using a flexible information technology platform, facilitating coding and translation into multiple languages. A comprehensive Reference Guide accompanies ICD-11 (WHO 2018a), which includes both mortality and morbidity coding rules.

5.1.3 International Classification of Functioning, Disability and Health (ICF)

The International Classification of Functioning, Disability and Health (ICF) was first released in 1980 as the International Classification of Impairment, Disability and Handicap (WHO 1980). It was endorsed for international use by the World Health Assembly in 2001 (WHA 2001). The ICF was designed as complementary to the ICD; integrated use of both classifications has the potential to provide a comprehensive perspective on functioning and health.

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[3] https://icd.who.int/en/docs/icd11factsheet_en.pdf

World Health Organization Family of International Classifications

The ICF provides a standard language and conceptual basis for the definition and measurement of human functioning and disability (WHO 2001). It conceptualizes functioning as a "dynamic interaction between a person's health condition, environmental factors and personal factors". In reflecting the model of health embraced by the WHO, the ICF offers a shared perspective for defining and communicating data on functioning and health. Thus, ICF terminology influences the other WHO-FIC reference classifications and can be found in the definition of ICHI targets, as well as in the functioning rubric of ICD-11.

Functioning and disability are used as umbrella terms denoting the neutral and negative aspects of functioning from a biological, individual and social perspective. The ICF, in integrating major models of disability - the medical model and the social model - as a "bio-psycho-social synthesis", provides a multi-perspective, biopsychosocial person-centred understanding of health which is reflected in the multidimensional model. It recognizes the role of environmental and personal factors in the experience of functioning, as well as the role of health conditions.

The interactions between the components of the ICF are shown in Figure 1.

Definitions and categories in the ICF are worded in neutral language, wherever possible, so that the classification can be used to record both the neutral and negative aspects of functioning.

ICF is organized into two parts:

Part 1 Functioning and disability

- body functions and structures, and impairments thereof (functioning at the level of the body);
- activities of people (functioning at the level of the individual) and the activity limitations they experience;
- participation or involvement of people in all areas of life, and the participation restrictions they experience (functioning of a person as a member of society).

Part 2 Contextual factors

- environmental factors which affect these experiences (and whether these factors are facilitators or barriers) (WHO 2001);
- the importance of personal factors to the experience of functioning is recognized in the ICF model, but they are not classified or coded.

More information about the ICF is available via the online browser (http://apps.who.int/classifications/icfbrowser) and the ICF Practical Manual (WHO 2013).

5.1.4 International Classification of Health Interventions (ICHI)

WHO and the WHO-FIC Network have developed the International Classification of Health Interventions (ICHI) since 2007 (WHO 2018b). The aim is to meet many use cases, including

international comparisons, providing a classification for countries that lack one, and supplying additional content for countries that have a national classification focused on medical and surgical interventions. ICHI can support global initiatives such as the Sustainable Development Goals and Universal Health Coverage and provide an information base for work on health system performance and patient safety.

ICHI incorporates a definition of "health intervention" that encompasses interventions for health promotion, disease prevention and treatment, rehabilitation, support and palliation provided by all types of providers across the entire health system, ranging from individual clinical interventions through behavioural and educational interventions to those with broader public health objectives. ICHI covers all parts of the health system and contains a wide range of new content not found in national classifications. It describes health interventions using the three axes of Target, Action and Means. Users may choose to record a range of additional information such as quantifiers, use of equipment and relationship to other interventions using extension codes. The ICHI browser gives more information and may be accessed at https://

www.who.int/standards/classifications/international-classification-of-health-interventions.

The Target axis contains the concepts on which the action is carried out. Targets include anatomy, human function, person or client, and group or population.

Action

Action is defined as a deed that is done by an actor to a target during a health care intervention. Actions include: investigation, treating, managing and preventing.

Means

The Means axis contains the concepts describing the processes and methods by which the action is carried out. Means include approach, technique, method and sample.

5.2 Derived classifications

Derived classifications are based upon one or more reference classifications and are often tailored for use at the national or international level or use in a particular speciality or setting. Derived classifications with ICD-11 are maintained in the common ontological Foundation and focus on particular usecases, like dermatology, mental health, pain, safety or oncology. The derived classifications may include elements of more than one reference classification, like primary care.

WHO permission is required for a specialist user group to develop a derived classification, and resources need to be made available for authoring. Derived classifications must be made available to WHO for general use.

5.3 Related classifications

Related classifications are included in the WHO-FIC to describe important aspects of health and functioning or of the health system which complement reference or derived classifications or are represented and used differently. They may arise from work in other sectors of the WHO, as in the case of medicines (ATC-DDD). Some have been developed by other organizations such as the International Classification of Nursing Practice (ICNP), developed and maintained by the International Council of Nurses (International Council of Nurses 2017), and the International Classification of Primary Care (ICPC-2), developed and maintained by the World Federation of Family Care Physicians (WONCA International Classification Committee 1998).

The design of the common Foundation has enabled close linkages to the derived classifications. For example, extension codes for medicaments are based on ATC and ICHI shares concepts with the ICNP.

Related classifications should be as accessible to users as other classifications in the WHO-FIC.

Stewards of related classifications need to collaborate actively with the WHO and the WHO-FIC Network to increase alignment between their classifications and the WHO-FIC to meet evolving client needs in the most efficient form possible.

There is a range of health-relevant classifications that are not currently related classifications in the WHO-FIC. These include the classifications of health care functions and health care providers included in the System of Health Accounts (OECD/Eurostat/WHO 2011). Other health-relevant concepts are classified in more general classifications, including the International Standard Industrial Classification (United Nations 2008) and the International Standard Classification of Occupations (International Labour Organization 2008). Appropriate use of these classifications in association with the WHO-FIC is important to promote international comparability and to avoid possible duplication.

5.4 Using the classifications together

One of the challenges within the WHO-FIC is the alignment of classifications, including related classifications, to facilitate effective joint use of the classifications.

The reference classifications contain several similar concepts (such as anatomical terms). There has been an initial effort to align concepts across the three reference classifications, although this process is far from complete. However, it is a vision for the WHO-FIC to have a structure for common concepts sharing a common ontology. Ontology in this context refers to the underlying logical structure of a classification. Ontology explains how a certain domain can be described in terms of how categories relate to each other and which terms belong to a certain category. The ICD-11 Foundation Component, including all ICD-11 terms and entities, form the basis for the common Foundation for the WHO-FIC, as described in Figure 2.

The WHO-FIC aims to work with stewards of related classifications to reduce, as far as possible, inconsistencies with reference classifications, which could involve a change in either the reference classification or the related classification or both.

A way forward is through:

- involving stewards in the WHO-FIC Network to establish working relations;
- sharing ontological approaches between the member classifications;
- comparing content models to identify the describing concepts or parameters and concepts;
- proposing solutions for differences.

5.5 Alignment

An aim of the WHO-FIC is that a concept should be described only once. Concepts from one classification may be used in other classifications, and they should have the same label.

This principle has been followed in the ICF and ICHI, where associated health conditions are not included but sourced from the ICD. Many ICHI Targets are sourced from the ICF. The result is classifications of more manageable size and avoidance of the need to harmonize going forward.

5.6 Development and update cycles

A criterion for inclusion into the WHO-FIC includes rules/principles for regular revision, for example, updating schedules for reference classifications. A similar regular and transparent update process is needed for related and derived classifications to remain aligned with the relevant reference classification(s).

6 Processes and considerations for adding and deleting classifications and terminologies to and from the WHO-FIC

6.1 Introduction

This part outlines the process for adding classifications or terminologies as members of the World Health Organization Family of International Classifications. The WHO-FIC Network advises the WHO on the process. The process involves the Classifications and Terminologies Team (CAT Team) in WHO, the Family Development Committee (FDC) and the WHO-FIC Council.

A submission for classification inclusion in the WHO-FIC must demonstrate consideration of the principles in Part II. These principles are designed to guide classification Stewards and submitting organizations and should not limit information included in any submission.

The submitting organization may be an agency or program manager who has identified a classification or terminology and considers that it is suitable for inclusion in the WHO-FIC. The submitting organization need not be the Steward of the classification; however, stewards should be aware of the proposal and be included in consultations. These responsibilities are set out in the principles. Any submitting organization needs to demonstrate that the functions of the Steward are fulfilled, either by itself or another organization. If stewards are unable to fulfil the functions, ensuring maintenance and updating it is the responsibility of the submitting organization.

6.2 New classifications

During the development of a new classification, broad-based consultation and evaluation should be undertaken. The purpose of this is to ensure that the classification is acceptable to stakeholders and fit for the purpose for which the classification is being developed. Consultations will need to include the full range of possible users.

There are two phases for the endorsement of a classification in the WHO-FIC, alpha and beta. Following the development of a classification from the first principles, the submitting organization should bring a submission to the FDC for consideration. At this stage, a position in the matrix should be identified, and the state of development of the classification clarified. The FDC would provide advice about the further development of the classification to determine the status.

The alpha phase includes development to the stage where the technical qualities can be demonstrated. During the beta phase, the classification will be used in the field, and the qualities of validity, reliability and international applicability will be demonstrated. At the end of each phase, the submitting organization will present the candidate classification to the FDC and subsequently the Network meeting and, if acceptable, will be admitted to the WHO- FIC as a standard.

Alpha phase

The first round of evaluation should address at least the technical characteristics of the classification, as outlined in principles 1-3. Other principles may be addressed as appropriate to the stage of development of the classification.

The consultation must be carried out with consideration of all the stakeholders. This might include providers of information to be classified, users of the information, researchers, academics, governments, statistical agencies, WHO and the UN. Testing should represent member states from all WHO regions to ensure feedback from different language and cultural groups.

Possible methodologies for the alpha phase

Activity	Purpose
Literature review	To demonstrate the need for the classification, its role in health information, the basis of the structure and the process of development.
Information Sessions	To present information about the classification to interested delegates at the conference: Receive feedback about the appropriateness of the classification for stakeholders: and Enlist attendees to join a focus group.
Focus Groups	Designed to be appropriate to participants; Provide information about the classification; and Receive feedback about the appropriateness of the classification for stakeholders
Workshops	Presentation and feedback as per focus groups; Application of classification to mini case studies.
Concept Evaluation	Using key stakeholders and academics, discuss and receive feedback about the appropriateness of the definitions and concepts in the classification.
Key informants	Using a structured questionnaire or interview.

At the end of the alpha phase, the submitting organization will present the classification to the FDC and, should the candidate classification meet the principles, to the Network meeting. WHO-FIC Council will grant beta status if the classification is acceptable. Documents required include:

1. A copy of the classification or links to an electronic version
2. Submission aligned to the principles in this document.
3. Administration record/ registration

Should the candidate classification not meet the principles, the FDC will make recommendations to the Submitting organization. The candidate classification may be resubmitted if changes following the recommendations are made.

Beta phase

A second (Beta) phase, including field-testing, is to establish the feasibility and reliability of the classification in different settings and to address the issue of validity.

Beta testing should be carried out in a range of member states representing the WHO regions. The principles to be addressed are accessibility, resource implications and applicability of the classification (Principles 4-9).

Possible methodologies for the beta phase

Activity	Purpose
Literature review	To demonstrate the use of the classification and, for example, results of reliability and validity testing.
Translation and linguistic evaluation	Translation and back-translation to establish that the language of the classification is appropriate for WHO member states. Linguistic analysis to identify terms and definitions that may pose cultural difficulties. Recommend better terms for translation
Consensus conferences	Concept validation and issues of validity.
Key informants	Using a structured questionnaire or interview.
Feasibility and reliability of coding cases	Assigning codes under different situations for live cases Inter-rater reliability Test-retest reliability A questionnaire with questions about ease of use of the classification
Feasibility and reliability of coding case summaries or vignettes	As above, but using case records or prepared summaries or vignettes.

The submitting organization will need to construct a test methodology that is appropriate for the purpose and state of development of the classification.

The quality of the classification should be demonstrated using the WHO-FIC Protocol. The results of the beta phase should demonstrate that the classification is fit for purpose based on use in the field. The candidate classification should be presented to the FDC and subsequently the WHO-FIC Network. If acceptable, the classification will be admitted to the WHO-FIC as a standard.

Documents required include:

1. A copy of the classification or links to an electronic version
2. Submission aligned to the principles in this document.
3. Administration record/ registration

6.3 Existing classifications submitted as members of the WHO-FIC

An established classification, which has been used for a specific purpose in one or several countries, may be considered for registration in the WHO-FIC without going through alpha and beta phases. The quality of the classification should be demonstrated using the WHO-FIC Protocol. A description against the principles and evidence of use in the field are required to demonstrate that the classification is fit for an identified place in the WHO-FIC matrix before presentation to the Family Development Committee and subsequently the WHO-FIC.

6.3.1 Derived classifications

Derived classifications require specific approval by WHO and related review processes. Derived classifications may be developed outside the WHO-FIC Network, by an expert group drawn from a clinical speciality, for example, but need to comply with the criteria and processes for design and release of a classification, be part of the common Foundation and be fully compatible with it, and to have a suitable use case for approval for inclusion in the WHO-FIC. The process of development will include WHO and member(s) of the Network. The approval could set appropriate conditions, for example, concerning its updating and term of approval.

6.3.2 Related classifications

WHO and the WHO-FIC Network welcome approaches from stewards of health and health-related classifications to consider seeking to become a related classification within the WHO Family.

Relevant considerations include the purpose of the classification, the additional classification capacity that it would bring to the WHO-FIC, the quality of the classification (assessed against the WHO-FIC's classification characteristics), access arrangements and willingness to work with the WHO and the WHO-FIC Network to improve alignment among the WHO-FIC.

6.4 WHO-FIC Network promotion of classifications

WHO-FIC will recommend and promote related and other classifications alongside WHO reference classifications as being an international standard for the purpose indicated.

The stewards of related classifications are expected to engage with the WHO-FIC Network actively. Collaboration between WHO-FIC Network members and mutual use of classifications should be encouraged and pursued. This allows them to engage with

representatives of the WHO-FIC Collaborating Centres, make presentations about the classification, exchange information and improve relationships between reference, derived and related classifications in a coordinated and systematic way.

The WHO-FIC Network will advise its members of testing of proposed new members of the WHO-FIC and involve them in the testing as appropriate.

WHO will update any documentation to include the new member and post this information on its website.

It is expected that increasing the range of classifications in the WHO-FIC will mean improved data for international comparisons on a range of health and social service issues.

6.5 Considerations for inclusion of classifications

It is essential that additional classifications cover health data elements not adequately covered by the WHO reference classifications. Any possible redundancy or overlapping of the classification or concepts with other related classifications should be identified and will be considered in the process of assessing the candidate classification. Classifications must include a clear statement about the scope, units of classification and organization of the classification.

6.5.1 Purpose and definition of the classification

If a classification is to be considered for membership of the WHO-FIC, its submission must adhere to certain formal requirements, including:

- Provisions of a classification title, clear definition and expression of the scope of the classification.
- Presentation of well-described categories in standard format backed up by explanatory notes, coding indexes, codes and correspondence tables to related classifications when applicable.
- The extent to which classification categories reflect the realities of the field (i.e., the population) to which they relate should be carefully considered. For example, in a classification of diseases, the categories should reflect the total picture of diseases of the specific population.
- Consideration of the key stakeholders and likely users of the classification should be demonstrated in the submission. The submitting organization should ensure that these groups are consulted regarding classification development and use.

6.5.2 Technical qualities of the classification

The following technical qualities should be demonstrated to enable decision making about the inclusion of a classification in the WHO-FIC:

- Each classification should have a hierarchical or multi-axial structure such that it is possible to aggregate data from individual codes into broader categories

- Classification categories should be exhaustive and mutually exclusive
- The categories are stable, i.e. they are not changed too frequently or without proper review, justification and documentation (see also 'development and update cycles' in section 3)
- A concept within a classification that is of importance should have its own category.
- Categories within a classification should facilitate the description of phenomena in a way that allows unambiguous understanding by others, including statistical users.
- Each category or concept should have a unique definition
- Terms should not be ambiguous, and the relationship between terms should be consistent
- The classification should not have categories at the same level in its hierarchy that are too disparate in their population size, i.e. there should be consistent granularity.
- Derived classifications are always embedded in the core classification
- The process and rationale of design needs to be documented

6.5.3 International accessibility and applicability of the classification

The WHO endeavours to make classifications accessible to the broadest possible cross-section of interested bodies. It is preferable to make classifications readily available without restrictions by publishing in several formats and making them freely available (neither royalties nor fees nor required memberships).

- Stewards of classifications may work together with the relevant Committee or Reference Group to prepare guidelines for interpretations of classifications at the applied level and to develop guidance and training materials that make explicit the classification's relationship to the WHO-FIC.
- Availability of the classification in a variety, preferably electronic, formats and as user-friendly applications to make the classifications widely used is strongly encouraged.
- Making classifications widely available in many languages and formats such as Braille, large print, machine-readable and audio broadens the sphere of accessibility.
- Classifications in the WHO-FIC:
    - Are available, or should be made available, with consistent meaning in the languages of the WHO member states
    - Enable data derived from the classification to be of a standard suitable for international comparisons
    - Are acceptable internationally
    - Are valid for the purposes for which they have been developed
    - Can be used reliably, i.e. there is inter-rater reliability and test-retest reliability in coding using the classification.
    - Are supported by appropriate reference material and training.
    - Stewards should collaborate as necessary in the preparation of correspondence tables between reference and related classifications and instructions for data collection, coding and analysis for those using the classification.

    - When a reference classification changes, the other members of the Family should work for consistency with the changes made at the international level.
- The WHO-FIC should be relatively easy to use, unambiguous and well presented.
- All members of the WHO-FIC should be made available as an international public good on the same basis as the reference classifications (https://icd.who.int/en/docs/ICD-11-license.pdf)

6.5.4 Resource implications

Including a classification in the WHO-FIC should bring added value to users through readily available, internationally endorsed products to support health and related data collection.

When considering a classification for inclusion in the WHO-FIC, resource implications should be considered for both its development and ongoing maintenance.

Stewards must demonstrate adequate consideration of the resource implications (costs) involved with:

- Development and implementation of a new classification.
- Ongoing implementation and use of the classification; and
- Ongoing maintenance and updating of the classification.
- Stewards should state who has the main financial responsibility for the maintenance and updating of a classification.
- Stewards should also consider the levels at which these costs will incur (i.e., WHO, national, multinational, or private).

Resources for classifications development and maintenance should be consistent with the WHO framework of engagement on collaboration with non-state actors (FENSA) (http://www.who.int/about/collaborations/non-state-actors/en/).

6.5.5 Maintenance and update processes (role of users, transparency, sign-off)

Stewards should have a plan for editing and updating a classification or group of related classifications. The timing of these updates and revisions should, if possible, be coordinated with Stewards of other classifications in the WHO-FIC.

- Stewards should specify the location of the persons, offices, or committees responsible for the preparation or maintenance of the classification.
- The updating and revision process will be improved through the release of classification timetables for major work on the classifications on a WHO-FIC Classifications Website, allowing those interested in the process to contribute at appropriate moments. Similarly, announcing the timings of hearing, updates, and revision meetings will ensure that valuable opportunities for direct dialogue are not missed.
- The relations to the WHO Network

- Stewards or their representatives must register the candidate classification.
- Classifications that are members of the WHO-FIC will be promoted alongside WHO reference classifications as being an international standard for the purpose indicated
- There will be no changes to intellectual property status as a result of becoming a member of the WHO-FIC.
- Representatives of the Steward or submitting organization will be eligible to attend Network meetings to engage with representatives of the Collaborating Centres and make presentations about the member classification. Knowledge and awareness of the new member classifications will be enhanced, and it is hoped that increased implementation of member classifications will mean improved data for international comparisons on a range of health and social service issues.
- The Representatives of the Steward or submitting organization will be part of the Network to exchange information and work to improve the relationships between reference and related and derived classifications in a coordinated and systematic way.

7 Governance - Process

The WHO-FIC Family Development Committee (FDC) advises WHO in the development of the WHO-FIC as an integrated, consistent and comprehensive set of classifications. It also aims to make sure that the WHO-FIC has a logical structure so that the classifications needed for each component and setting within the health system can be identified.

After consideration of a submission and the classification by the FDC, it will be presented to the WHO-FIC Network annual meeting for endorsement by the Network Council to advise WHO of the new classification as a member of the WHO Family. The FDC may recommend that further work is needed on the classification before presentation to WHO-FIC Council.

CAT will advise Regional Offices or member states of testing of proposed new members of WHO-FIC and involve them in the testing as appropriate.

WHO will update any documentation to include the new member and post the information on the website. There is no need to inform the WHO Executive Board and the World Health Assembly of new classifications in the WHO-FIC.

Adaptation of one of the WHO-FIC reference classifications requires permission by WHO and shall follow the guidance set out in this document.

Proposals for the possible inclusion of related classifications in the WHO-FIC are also welcome.

Further information may be obtained from WHO-FIC@who.int.

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