ICD-11
Implementation or Transition Guide

About this document

This document is a part of the ICD11 implementation package[1] developed by the World Health Organization. This document also provides some background related to the development of the ICD11 and its components. The document outlines essential issues that countries need to consider in the lead up to and during the transition from an existing ICD environment to the eventual implementation of ICD11.

Because of the vast differences and varying complexities in the local settings, and between area to area, this guide can provide only an overview of transition and implementation. This guide supports decisionmakers in planning the implementation of the new ICD11 in their jurisdictions.

All elements of ICD11 are available on icd.who.int and readers are encouraged to take a virtual tour, and gain hands-on experience.

The document has two parts, where Part 1 provides an overview and background to the 11th Revision, while Part 2 is concerned with transitional activities.

Acknowledgements

The production of this guide would not have been possible without the collaboration and support of numerous organizations, institutions and individuals. It is based on requirements from the field and has been compiled in collaboration between all WHO Regional Offices, Headquarters, the WHOFIC Network[2], and Member States[3.]

ICD11 in a Nutshell

The International Classification of Diseases and Related Health Problems (ICD) is the international standard for systematic recording, reporting, analysis, interpretation and comparison of mortality and morbidity data. The 11th revision (ICD11) is the result of a collaboration with clinicians, statisticians, epidemiologists, coders, classification and IT experts from around the world. ICD-11 is a scientifically rigorous product which accurately reflects contemporary health and medical practice, and representing a significant upgrade from earlier Revisions.

ICD–11 allows countries to count and identify their health issues by using a current and clinically relevant classification system. Health conditions or accidents are assigned ICD–11 codes, resulting in data that can be used by governments to design effective public health policies, and measure their impact, allocate resources, improve treatment, improve prevention, or be used for clinical recording.

For the first time, ICD is fully electronic, currently providing access to 17 000 diagnostic categories, with over 100 000 medical diagnostic index terms. The index-based search algorithm interprets more than 1.6 million terms. ICD–11 is easy to install and use online or offline, using free 'container' software.

ICD11 is easier to use than ever before, cost of coding is low, and data capture is more accurate for best quality output, thanks to the use of modern technology. The innovative structure and digital format ensure interoperability with existing IT infrastructure.

ICD11 covers a broad range of uses including, clinical recording, the collection and study of mortality and morbidity statistics, epidemiological research, casemix studies, quality and safety interventions and planning, primary care and more.

It offers more than disease diagnoses for statistical purposes– it also allows for the coding of signs, findings, causes of injury and harm, rare diseases, medical devices, medicaments, anatomy, severity scales, histopathology, work or sports activities, and and much more. It links clinical terminology with statistics.

ICD11 is now available for implementation, following its adoption at the World Health Assembly on 25 May 2019.

The Reference Guide provides fully detailed comprehensive information on ICD11, its maintenance, significant changes and differences between ICD10 and ICD11[4].

ICD11 and its implementation package are available freely online and can be used as is. No additional tools or terminologies are necessary.

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[4] https://icd.who.int/icd11refguide/en/index.html

General Background to ICD

The ICD provides a common language for the classification of diseases, injuries and causes of death, and for the standardised reporting and monitoring of health conditions. It is designed to map health conditions to corresponding generic categories together with specific variations, assigning to these a designated code, up to six characters long. These data form the basis of comparison and sharing between health providers, regions and countries, and over periods.

In addition to this essential core function, the ICD can also inform a wide range of related activities. It is used for health insurance reimbursement; in national health programme management; by data collection specialists and researchers; for tracking progress in global health; and to determine the allocation of health resources. Patient quality and safety documentation is also heavily informed by the ICD.

Revised cyclically by WHO, the ICD is presented to the World Health Assembly for adoption and implementation into national data collection and reporting systems. During its lifetime, WHO has undertaken routine maintenance and published minor updates annually, and major updates triennially.

The ICD system is designed to promote international comparability in the collection, processing, classification, and presentation of health statistics, and health information in general. However, data quality is directly linked to the fitness of the classification system, and the use of ICD10, which was adopted by the WHA in 1990, has become increasingly problematic due to its outdated content. In the longer term, it will only become less fit for accurate and meaningful classification. Additionally, the many parallel but inconsistent modifications used worldwide, have restricted the comparability of data at the international level. The final update for ICD10 is scheduled for 2019, after which time WHO will no longer maintain it.

Currently, 117 countries report causes of death to WHO. Seventy per cent of the world's health resources are allocated based on ICD data. Current uses include cancer registration, pharmacovigilance, and more than 20,000 scientific articles cite ICD10.

Low and middle income countries bear a significant burden of disease with health systems having limited resources, for treatment, prevention and collection of information for health planning. The effective deployment of ICD11 will facilitate the use and collection of health information and therefore, facilitate quantitatively informed decisions.

ICD is a core classification of the WHO Family of International Classifications, as are the International Classification for Functioning Disability and Health (ICF) and the International Classification for Health Interventions core classifications.

1. Introduction to ICD

The ICD11 has been updated for the 21st century to reflect the significant progress in science and medicine over the past 30 years and has been designed for use with digital health applications and information systems. These systems are integral to the capture of data using ICD11 and can produce digital documentation to a very fine-granular level, while also retaining the simplicity of the structure to allow paper-based coding. The digital platform for ICD11 can be accessed online or downloaded remotely 5free of charges, and in multiple languages via the online Browser. For the first time, ICD11 will enable dual coding of traditional medicine diagnoses alongside mainstream medicine and now also permits the generation of a functioning score based on the WHO Disability Assessment Scheme (WHODAS).

As an international public good, and in line with WHO's commitment to transparency and collaboration with stakeholders, the revision process for ICD11 has been open to all interested parties from the outset, for the first time in the history of ICD revisions. Hundreds of specialists from more than 270 institutions and 99 countries have submitted proposals to the classifications team in WHO, via an online platform. The proposals related to the content of the classification, and the platform allowed for discussions between participants, as well as clear documentation of the process and decision-making.

The Reference Guide serves as the first source of comprehensive instruction on the use of the classification. The Reference Guide also clarifies components, taxonomical aspects, and explains changes from ICD10. Countries will be able to add to the Reference Guide to reflect additional standards or guidelines necessary at their national level of reporting while maintaining internationally consistent coding and reporting of statistics.

ICD11 is easier to use than earlier revisions for both low and high resource settings, leading to better data capture, and offering the tools to monitor and improve individual country's health with reduced costs.

Part 1 Why ICD11?

The goal of having ICD in place for health data collection is to generate comparable health data at the international level. Additionally, 70% of the world's health expenditures use ICD coding for reimbursement and resource allocation; 110 countries that collectively account for 60% of the world's population use ICD cause-of-death data for health planning and monitoring in a systematic fashion; and, ICD10 alone is cited in more than 20,000 scientific articles. The usefulness of such critical data can only be supported by a robust and correct classification, only.

ICD11 means

> Easier use and better coding quality - at lower cost

Updated structure and content reflecting the state of science

Improved utility - individual sections for antimicrobial resistance, patient safety, functioning assessment and better representation of causes of injuries, cancers, devices, medicaments, substances, severity and more

> Simple embedding in any software

> Clinicians can now code without loss of detail or disruption of their daily workflow

> Implementation package comprising all tools and guidance for implementation of ICD11

The 11th Revision of ICD is long overdue – the 10th Revision was adopted in 1990!

Additionally, many divergent local modifications of ICD limit data comparability, development of guidelines and linkage to knowledge bases, and result in a lack of uniformity in translated terms. The need is clear for an internationally standardised system that accurately reflects contemporary practice and generates the best and most useful data possible. However, ICD11 also revolutionises the way conditions are classified and coded in the clinical setting.

As with previous revisions, WHO has reviewed all existing classifications, their categorizations and their codes to reflect the best scientific knowledge and practice. ICD11 is presented to the World Health Assembly in May 2019 for adoption and to replace all earlier Revisions from 1 January 2022.

1.1. The ICD11

In short, ICD11 is two things:

- A revised classification system with much more than diseases,

- in digital format

1.1.1. A revised classification system

Based on a rigorous review of existing classification and current science and research, with input from experts and through extensive public consultation, the 11th ICD Revision has resulted in a reformulated chapter structure and indexing system. It comprises over 55 000 entities.

Besides diseases, ICD includes disorders, injuries, external causes, signs and symptoms, substances, medicaments, anatomy, devices, histopathology, severity and much more and 120 000 clinical terms (and can code millions of terms), with thousands of new categories and updated classification schemes, and is intended to supersede the 10th Revision, which is now more than 28 years old and clinically outdated.

The new coding structure also allows for greater flexibility of application than in previous versions, and health condition may be described to any level of detail, by combining codes. Simple coding can be done, as well as coding of complex clinical detail.

1.1.2. In digital format

Unlike any previous Revision of ICD, it is digital, comprising tools and software for using the classification to generate accurate descriptions of health event information. It is designed to integrate with local health information systems rather than to introduce an additional layer of administration. It may be used either online or offline, for example, where internet stability is less reliable. Core functionality and support are provided by API 'out of the box'. It is Digital health or e-Health compatible and is interoperable with Health Information Systems. By integrating with local IT infrastructure, the classification also becomes a data collection system, that is, rather than having multiple steps of transcription from paper, using the Browser to generate a correct code also enables that code to be directly recorded. There is no longer a need to search or memorise codes – entering a term into the Coding Tool leads the clinician or the coder to the correct ICD code.

The main structural innovation of ICD11 is its Foundation Component which is an underlying ontological database containing all ICD entities: diseases, disorders, injuries, symptoms and so on, from very broad to finely specified. This content is the equivalent of the Tabular List and Alphabetic Index in ICD10. The Foundation is structured in a standardised manner to facilitate point-of-care data capture but also provides terminology for diseases and related health conditions, and the structures necessary for incorporation into digital health information systems.

A Content Model is a structured framework for defining each ICD entity in a standard way and provides the basis for ICD entities to allow for computerisation. Items used in other

members of the WHO Family of Classifications have been aligned with or linked to, for consistency wherever possible, as have other classifications and terminologies. The more traditional statistical classification for mortality and morbidity is obtained from the Foundation component of ICD–11 as a tabular list. Extension codes are used to limit the content volume while allowing for a detailed description of disease entities.

1.2. Advantages of ICD11

1.2.1. Up-to-date scientific knowledge

Medicine is a continuously evolving applied science, incorporating new technologies at an unprecedented rate. Therefore, the ICD needs the ability to reflect this evolution and to capture clinical detail in the field accurately.

Since its First Edition in 1900, up to its Tenth Revision in 2016, the ICD has grown from a list of 179 categories to over 12 000 categories, demonstrating how much medical knowledge and technology has evolved. The 11th Revision contains more than 55 000 unique entities, more than 120 000 derived from the latest scientific knowledge and reflecting current practices and diagnostic concepts. These entities point to some 17000 categories. ICD11 flexibility and accuracy allow for the resulting health information to be used in a wide range of applications, including improvement of patient outcomes, patient safety and quality analysis; population health reporting; integrated care; strategic planning and delivery of health care services. Its ontological structure allows to code millions of clinical terms using combinations of abovementioned categories and entities, and still preserving the integrity for meaningful data aggregation for the different uses of ICD.

1.2.2. Improvements and additions

In the extensive review and overhaul of ICD content and structure, the ICD team in WHO headquarters received over 10 000 proposals for the revision of ICD11 and unprecedented involvement of health care workers in collaborative meetings and proposal development. The following are some of the major areas and concepts developed and included in the ICD11:

- New primary care concepts for application in settings where simple diagnoses are made;

- A section on the documentation of patient safety events has been fully overhauled and systematically tested. It allows for all necessary detail and complies with the WHO patient safety framework;

- Coding for Antimicrobial Resistance, which was missing in ICD10 to enable data documentation and analysis consistent with the WHO Global Antimicrobial Resistance Surveillance System (GLASS);

- HIV coding has been updated with new subdivisions and removal of outdated detail, as well as codes for differentiating 'HIV with malaria or tuberculosis';

- New supplementary section for Functioning Assessment. This section allows Monitoring of functional status through the recording before and after the intervention, and permits the calculation of a summary functioning score using the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) or the WHO Model Disability Survey (MDS) (both a domain specific or an overall summary score);

- In collaboration with several partners, including OrphaNet, ICD11 has incorporated all rare diseases. Only a few of these have an individual code, but all have their own Uniform Resource Identifier (URI), allowing rare disease Registries and researchers access to detailed epidemiological data on conditions of interest;

- The use of the URI facilitates linkage with other information interchange products and terminologies;

- Traditional Medicine is an integral part of health services provided in many countries, such as China, India, Japan, and the Republic of Korea. It has not been based on standard classification, nor been possible for health authorities to monitor or compare internationally or regionally. A new Supplementary Chapter for Traditional Medicine provides standardised descriptions for data capture and allows for country-level monitoring through dual documentation alongside mainstream practice, as well as international comparison.

1.2.3. Ease of use

The new technological infrastructure of ICD11 results in more straightforward coding. The digital structure allows the Coding Tool to be embedded into the local digital record and IT systems, using either a local or web-based version of the system provided by WHO (known as the Application Programming Interface or API). Clinicians can search for diagnosis using natural or preferred terminology, which then relates this to the correct technical code (without requiring the clinician to memorise these). Its integration with existing digital record systems combines recording with coding, reducing the number of steps needed to obtain complete documentation and increasing user compliance. This also results in lowered costs and times for training.

The ontological core of ICD11 can be quickly expanded to include new terms, synonyms, and concepts, or for improved user guidance, in all language versions. Speciality customised versions facilitate the use in departments with very focused practices, such as for mental health. For situations where paper-based documentation is used, a printed index or relevant subsets can provide quick access to the code.

1.2.4. Multiple applications to meet health system priorities

Historically, the ICD was intended for mortality data recording, but since its Sixth Revision has progressively been used for morbidity data. This reflects the growing public health needs for such data, with a range of applications including

international reporting of mortality and morbidity statistics,

- primary care reporting for all levels of resource settings,

- epidemiology and population health,

- research,

- health system performance,

- patient safety and quality, and

- casemix or activity-based funding.

Previous revisions of the ICD have responded to these needs in an ad-hoc way and are therefore limited, inflexible or outdated in their application. In contrast, the ICD11 has been developed from the outset to address these uses and to allow the most accurate and best quality capture of morbidity data.

ICD11 can capture levels of detail to satisfy the varying needs of clinical practice and research: documentation may be produced to the broadest or most detailed level of specificity for epidemiological, casemix or other management purposes. This is facilitated by combining codes of the core classification 'stem codes' and adding optional codes in the form of 'extension codes', as for anatomy, histopathology, medicaments, severity, or injury research.

1.2.5. The ICD11 package and components

1.2.5.1. ICD11 Browser

The web-based browser tool allows the user to retrieve concepts by searching terms, anatomy or any other element of the ICD11th Revision. The ICD11 Browser application includes context sensitive help, which you may access by clicking on the icon located in several different locations within the application. The browser also allows users to contribute to updates and continuous improvement of ICD, via a proposal platform. Such input is reviewed for consideration for inclusion on an annual basis.

1.2.5.2. ICD11 Coding Tool

The Coding Tool works by searching ICD content as the user types in a term, for example "neoplasm". It generates (and dynamically updates) three different outputs: a word list; matched entities with a link to the Browser; and, the chapters associated with the target term.

1.2.5.3. Foundation Component - Index, Guidance

The Foundation Component is the underpinning repository or database of all ICD entities. These entities comprise diseases, disorders, injuries, external causes of injury and signs and symptoms, and the relationships among them. Entities may be very broad or more detailed and are not necessarily mutually exclusive, but all are fully defined. The Foundation represents the entirety of the ICD universe, and it is from this which the Tabular List and Alphabetic Index are derived. The ICD11 Foundation content is structured in a standardised manner to facilitate point-of-care data capture. It does this by housing content and terminology for diseases and related health conditions, and the structures necessary for incorporation into digital health information systems.

1.2.5.4. Linearization for Mortality and Morbidity Statistics (MMS)

It is from the Foundation that the subsets which create the reference tabulation lists for mortality and morbidity statistics (MMS) are drawn, as are all speciality purpose versions of the ICD (for example for use with Mental and Behavioural Disorders, and Infectious Diseases).

Linearizations are analogous to the classical print versions of the ICD Tabular List (e.g. Volume I of ICD10 or other previous editions) and may be built to different levels of granularity, use case or other purposes such as for Primary Care, Clinical Care or Research. Because linearizations are always drawn from the digital foundation component, consistent use of the ICD is ensured.

1.2.5.5. The Translation Tool

Part of the ICD11 Maintenance Platform, the translation tool allows for specific language users centres to build their translations that are faithful to the original. The tool also notifies other registered translators of changes and provides the same set of outputs in multiple languages. The provisions for the use of the tool require registration of users with WHO HQ, so work is transparent and verified. At the time of writing, the most developed translation of ICD11 is into Spanish, followed by Chinese, with several others having commenced translation work.

1.2.5.6. Application Programming Interface (API services)

ICD API[6] allows programmatic access to the International Classification of Diseases (ICD). Users must first register via the site and may then use it to access up-to-date documentation on using the API as well as managing the keys needed for using the API.

1.2.6. Digital health (eHealth) compatibility and interoperability with Health Information Systems

The ICD11 Foundation allows for standardised 'point-of-care' data capture by housing content that essentially forms what was the Tabular List and Alphabetic Index in ICD10, terminology for diseases and related health conditions, and the structures necessary for incorporation into digital health information systems.

Each ICD11 entity has an exclusive identity linked to a Uniform Resource Identifier (URI) and back-end web services to provide easy access to up-to-date ICD content. Links to external terminologies can also be facilitated using the URIs. The URI remains attached to a single entity, regardless of any subsequent updates.

The ICD11 has been developed to enhance the ease and accuracy of coding from both classification and IT perspective, via a range of features. These include:

- An implementation assessment and training tool for the coding of diagnostic terms in both the ICD11 and the ICD10, in multiple languages;

- Web services for full search and coding functionality in any software;

- Online services which allow the use of ICD11 without need for local software;

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[6] Available at https://icd.who.int/icdapi

- Offline services with the same functionality as web services to download for use on local computers or network. Regularly scheduled updates can be made via the internet;

- Output tooling to produce files in formats according to user needs (e.g. Comma separated value (CSV), Classification mark-up language (ClaML), application programming interface (API), and others as necessary);

- Transition (mapping) tables to view disease classification in ICD10 format, and to convert data for comparison with ICD11;

- A proposal and commenting tool to permit participation in suggestions and discussion;

- Notification settings to advise of changes implemented.

1.2.7. Linkages with other classifications and terminologies

The ICD11 incorporates or links with the following classifications and terminologies through the ICD11 Foundation:

- International Classification of Disease for Oncology – ICD-O

- International Classification of External Causes of Injury – ICECI

- International Classification of Functioning, Disability and Health – ICF

- International Classification of Primary Care – ICPC

- Other terminologies such as OrphaNet and SNOMED-CT

An example of how ICD11 incorporates linked classifications, is the embedded Section on Functioning and categories in Chapter 24 *Factors influencing health status or contact with health services*, which link to the ICF. This enables the generation of a person's functioning in daily life, via a set of questions and the calculation of a summary score.

The World Organization of Family Doctors (WONCA[7]) and the WHO have cooperated to fill the gaps in previous ICD revisions relating to primary care and family medicine. New versions of the WONCA's ICPC plan to share a common set of categories with ICD11. Hence, there is now the potential for future cross-sectoral comparability where different systems are used, for example, between family medicine, primary care and secondary care hospital activity.

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[7] World Organization of National Colleges, Academies and Academic Associations of General Practitioners/ Family Physicians

1.2.8. Maintenance of ICD

All classification systems require routine maintenance and updating to meet users' needs in content and terminology. ICD11 has been developed with the continuously and rapidly evolving field of medical science in mind and the goal of continuing international consistency.

1.2.8.1. Oversight of the maintenance process

Maintenance of the ICD11 is an open and transparent international activity, undertaken by WHO together with the Network of the WHO Family of International Classifications (WHOFIC). WHOFIC membership is composed mainly of country representatives who have oversight for classification activities within their own countries.

Maintenance includes oversight and provision of expertise by the advisory bodies which were established during the ICD11 Revision process. These advisory bodies include the Classification and Statistics Advisory Committee (CSAC), which is informed by the Medical and Scientific Advisory Committee (MSAC), the Mortality Reference Group (MRG) and Morbidity Reference Group (MbRG). The CSAC in considering proposals to ICD11 also seeks advice and expertise on highly specific issues from other recognised groups, when necessary.

As the principal ICD11 advisory committee to the WHO, the CSAC also advises on updates for other WHO classifications, notably the International Classification of Functioning, Disability and Health (ICF) and the International Classification on Health Interventions (ICHI);

The MRG and the MbRG are comprised of members of the WHOFIC Network, who prepare and provide subject-specific advice on proposals. These reference groups advise CSAC on the maintenance of the ICD in the areas of mortality and morbidity classification and coding;

The MSAC comprises approximately 18 scientific experts of different disciplines. It advises the CSAC on medical and scientific content for the ICD11.

1.2.8.2. Proposal platform

The maintenance and updating process continues from that used during the development of ICD11, which used a permanent internet-based proposal platform to allow contributions to ICD content. This platform will now be used in the ongoing updating process throughout the lifetime of ICD11. The advantages of this mechanism are:

- It is open to all interested parties, allowing them to make proposals and to see and comment on contributions made by others,

- The platform can be reviewed all year round, rather than at set dates;

- A digital curating process to enhance discussion and review processes is possible;

- Any final inclusion to the classification is provided in a digital format with capacity for print format;

- Translation into many languages from a single platform is enabled, supporting a wider range of users than predominantly English-speakers, and equally providing output formats for all languages.

- All countries benefit from contributing to an international classification via the proposal platform, as it facilitates input of WHO Member State expertise, and shares real world experience with others.

1.2.8.3. Updating

The use of ICD in the specific context of country systems may identify the need for country-specific detail or additions to the ICD11, for example, due to specific settings or reimbursement system requirements. Such changes and updates will be subject to the same international process as all other changes to ICD to avoid diverging regional modifications of the ICD and instead retain one international classification system. The additions would become part of the Foundation Component, ideally before their implementation in the requesting country.

Individual countries may need to develop standards or guidelines around how they use specific features of ICD11 to ensure consistency in mortality and morbidity (including primary care) coding and reporting nationally and internationally.

More in-depth and detailed information on all processes, structures, and content is to be found in the ICD11 Reference Guide.

Part 2 Moving towards ICD11

The goal of the WHO in designing ICD11 is to produce an updated classification to reflect current practices and, additionally, which can capture health concepts in a way that is compatible with contemporary information systems. Classifying healthcare issues with more precision enriches the output information used for population-based health initiatives.

While the transition to a new classification system comes with challenges and potential resistance to change, the longer-term benefits are in the ability to identify macro-trends, spotting trends, and in reducing overheads in clinical settings. By engaging in the transition early, especially for piloting and testing, health care organizations will be able to identify problems or local needs better, to anticipate disruptions, and to design change management approaches.

2. Implementing or transitioning from existing systems of ICD

Countries with an existing system of ICD10 in place (and its modifications or earlier revisions) are referred to as legacy countries or as having legacy systems. The timeframe and processes required for moving to ICD11 for classification and data collection are referred to as the transition period. It is anticipated that this period will last between two and three years from initiation to final implementation of ICD11 as the primary system. However, it is essential to note that this will vary, depending on existing local health systems and infrastructure, and needs for translation and workforce.

Countries without legacy systems in place may take the option of a fast-tracked implementation of ICD11, because of a reduced need to align with or replace, existing infrastructures.

2.1. Implementation considerations for ICD11

2.1.1. Mortality coding

Mortality data have been reported in an internationally standardised way for many years. Continuing this while transitioning to ICD11 requires a series of critical but relatively straightforward steps. The minimum ICD11 reporting requirement for mortality will be at the level of stem codes.

As the minimum mandatory requirement for country health data reporting to WHO, a history of international cooperation has developed around the use of the ICD for mortality

data. Certain countries currently use automated coding, for example, the Iris[8] ICD cause-of-death selection coding, to identify and report the underlying cause of death, thus providing a basis for international comparability of mortality data.

Well-developed processes of transition from ICD-9 to ICD10 mortality coding have been demonstrated, for example, by Australia, Germany, and the US and, and these experiences can inform transition for others. International cooperation on ICD11 to assist countries with local uptake, has commenced with the updating of decision tables and mortality rules by the WHO Mortality Reference Group.

2.1.2. Morbidity coding

In contrast to mortality, morbidity coding has evolved at the national level in divergent ways, in response to emerging needs and local practices in healthcare provision. Therefore, the transition to ICD11 for legacy countries will require a more tailored approach to allow for differences in reporting, rules and coding, and to move toward an internationally consistent output. Other adapted approaches to transition will be necessary where ICD10 modifications or other classification systems are in use, for example, in primary care or different specialised settings.

While arrangements for international morbidity reporting to WHO are yet to be finalised, the morbidity rule base has been amended based on experiences with ICD10. The minimum requirement for morbidity will be reporting of ICD11 stem codes, together with a description of the main condition (as outlined in the Reference Guide). Ideally, international reporting would evolve to include more detailed reporting of conditions, beyond the stem code, as the full statistical potential of the rich content of the ICD11 is realised. The possibility exists to build internationally consistent or relatable casemix systems if national classification systems follow internationally standardised diagnosis coding rules.

Widespread use of ICD11 for morbidity data collection can form the basis for the joint international development of tools for analysis and reporting, for example, to support patient safety and quality measurement.

ICD11 has been designed to be flexible and adaptable enough for morbidity coding, to pre-empt the need for national modifications. It is anticipated that dual coding studies undertaken during the transition will highlight this and further verify the completeness of ICD11 (see: 'Dual Coding Studies' later in this document). Any need for adaptation in classification identified at the local level should be directed back via the ICD11 proposal platform, to maintain international standardisation in reporting.

Some specific settings may elect to take advantage of the unique content of ICD11 and apply it to patient safety reporting systems, traditional medicine, or for providing diagnostic guidance in mental health.

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[8] Iris is an automatic system for coding multiple causes of death and for the selection of the underlying cause of death, based on ICD-10
https://www.dimdi.de/dynamic/en/classifications/iris-institute/

2.2. Looking to early-adopters and pilot testing

Some countries have already moved toward the transition to ICD11. For example, in 2017 the Pan American Health Organization (PAHO), in collaboration with the WHO, carried out a series of systematic self-assessments for fifteen countries, to identify classification requirements and current status for the transition from ICD10 to ICD11. The same was refined in several workshops with other regions. The results have been grouped and presented in Appendix 1 of this document. While this provides an excellent basis from which to begin planning for implementation, it is recommended that all countries conduct their self-assessment.

Centralised pilot testing of ICD11 in all regions has been undertaken using the English version of the ICD11 Browser and educational materials such as coding scenarios, together with general field testing and evaluation of ICD11 in other countries around the world. This has generated results from 28 countries, using 61 065 code assignments and feedback from 600 participants who rated the system. These results have in turn been used to fine-tune ICD11 structure and content and may inform others as to their needs for transition

Since early 2019, early adopters are starting the implementation of ICD11 in all regions.

2.3. Stakeholder involvement and agreement

Stakeholder engagement has been initiated by WHO in other areas, with an initial focus on disseminating information about ICD11, providing hands-on experience in using the browser and coding, and in scoping the costs and benefits of the transition. Dedicated training workshops for the use of ICD11 have been held in all WHO regions, and ongoing individual support will be provided to facilitate implementation in the Member States.

At the country or area level, stakeholder engagement should be initiated by responsible parties at the national level, as the starting point for transition, and directed at all levels of implementation. This includes the necessity to engage extensively with coders, clinical personnel, potential suppliers, but also with other countries where implementation is already underway.

2.4. Key recommended actions

Transitioning to a new system requires careful planning and should ideally occur within a project management framework. Because the responsibility for national ICD11 data management and hospital administration varies significantly from country-to-country, it is not possible to prescribe a standard approach for every situation. However, the following section sets out recommendations to be considered for transition to ICD11, to phase out of the old system and implementation of the new.

2.4.1. Establishing a National Centre of Excellence

The establishment of a National Centre of Excellence is highly recommended to provide coordination and focused leadership. This could, for example, be based in existing WHO collaborating centres, and comprise personnel from relevant agencies and areas of

expertise. A National Centre offers country level visibility and transparency of the process, and centralisation of efforts. Stakeholder engagement should be coordinated from this centre, to facilitate information-sharing about implementation, and its progress, with all involved parties and organisations.

2.4.2. Maintenance of existing system during the transition

The maintenance of current classification for a defined period – allowing for an overlap of at least 18 months with the use of the new system – is encouraged, until the complete implementation of the 11th revision into local systems and infrastructure is realised.

This provides several important benefits:

- Stability of reporting, and therefore data continuity during changeover;

- Ability to undertake transition studies and assess the impact on longitudinal statistics through analysis of the data;

- Data capture for dual coding studies (see below) which can also inform needs for workforce changes;

- Bridge-coding and crosswalks between Revisions and country modifications to ensure consistency with time series analysis, casemix systems, resource allocation schemes and stability analysis, to identify areas of difference where more specificity may be required in the ICD11;

- Detection of errors or problems in transition and implementation, identification of user issues;

- Continuity of trained coders during the transition, with the ability to learn the new system and the development of new coders;

- Assessment of training needs for managers, physicians, data personnel and other concerned parties;

2.4.3. Project management and strategic planning

A designated project manager and core team would nominate key individuals and decisionmakers for each aspect of the transition project. This team is responsible for careful and inclusive project planning and oversight and for determining readiness and priority-setting following self-assessment. It is advisable that the transition is managed with clearly articulated pre-transition; implementation; and, post-implementation phases.

A strategic plan outlines the goals of the implementation and the necessary steps to achieve those goals, including the allocation of resources to each step, and be informed by a collaborative approach incorporating stakeholder feedback and surveys to determine local needs and cost estimates. The resulting document should include a timeframe for the transition to implementation.

Strategic planning is based on requirements and cost-benefit analyses of potential approaches to implementation and includes budget planning for all components and

personnel requirements. It should also inform the project team if the conditions and criteria for a successful transition are in place and if certain pitfalls can be avoided.

In the case where there are serious obstacles to transition, the project team also sets priorities for minimum initial implementation initially, and timelines mapping out full implementation.

2.4.4. Self-Assessment

Self-assessment is a fundamental part of any transition planning, perhaps especially where upgrading from paper-based systems to the fully digital capability of ICD11. Self-assessment allows project leaders to identify a clear picture of what and how much is necessary to progress, identify potential obstacles and to inform a 'before and after' analysis. It is critical in guiding budgetary and personnel needs and for correctly estimating timeframes.

In undertaking a thorough self-assessment, the following are suggested starting points:

1. What kind of information and reporting infrastructure is currently available?

   a. Is updating of national reporting standards and guidelines necessary?

   b. Is there a need to adapt or create infrastructure for systems integration, data storage and reporting?

   c. Computer availability and internet access:

      i. Hospitals

      ii. Doctors' offices

      iii. Other primary care and community care settings

      iv. Local administration for health data and statistics

      v. Regional administration for health data and statistics

      vi. National or Central administration for health data and statistics

   d. Limitations to internet access at the country level that could impact implementation, considering that ICD11 can be made available offline.

   e. What is the necessary lead time for updating the relevant IT infrastructure needs?

   f. What are the local language translation work needs?

2. What is the current level of ICD Implementation and current uses of coded data?

   a. Elaborate on: where, why, by whom and how it is used

   b. Which version of ICD is in use and since when?

3. What would you like to see changed in ICD10 (i.e. past or present problem with the ICD classification itself or with its implementation)?

4. What are the training needs for successful ICD11 implementation?

5. What new ICD11 features are likely to be of benefit in the country?

6. What are the potential benefits of implementing ICD11?
   Do they include the potential for aligned statistical information across the health sector, encompassing mortality, hospitals and primary care?

Do they include the potential for alignment and better linkage between clinical information systems and statistical and casemix or management systems?

7. What needs to be done in the country to ensure a smooth transition from ICD10 to ICD11?

8. What other WHOFIC or other classifications are currently in use (e.g. ICF, Interventions)?

    a. Is there potential opportunity to facilitate the use of WHOFIC classifications together, or to plan for more combined use with, for example, the use of the International Classification of Health Interventions (ICHI) in the future?

    b. Elaborate on: the classifications used and where, why, by whom and how they are used?

9. What work needs to be done to adapt statistical collation and reporting work in the country, and to support international statistical comparisons?

10. What are the costs for all aspects of the transition?
    Will there be savings relating to any aspects of the use of ICD11 compared with the use of ICD10 – for example because of reduced needs for local modifications for morbidity use?

11. Who are the stakeholders in the country, and what are the decision-making processes? Who are the decision-makers for mortality and morbidity?

12. Could any aspects of implementation be undertaken in cooperation with other countries to save resources and to aim for optimal alignment and comparability of future statistics?

13. What are the awareness and education costs (for mortality and morbidity clinical coders, clinicians and other data users, IT staff), Health Information Management or Health Informatics and clinical coder curriculum development;

14. Casemix/Activity Based Funding classifications and costing/pricing impacts;

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As cited earlier in this document, a summary of country-level self-assessments undertaken in 2018, is presented in Appendix 1 of this document.

2.4.5. Crosswalks (mapping) and comparability

The term 'crosswalk' is the process of finding equivalent codes from two different classification Revisions (or editions of the same classification) to enable data users to interpret data recorded in various classifications, for example in longitudinal studies. Crosswalks are particularly important for time series data analysis and for grouping data using casemix or DRG software, as each ICD version comprises a specific set of disease and intervention codes. DRG grouping logic may need to be reviewed for decisions about whether cluster coding can be utilised within DRG Grouper software, or if an unbundling of code clusters is required.

There are two main types of crosswalks: forward and backward. In both types, codes may be assigned as 'historical' or 'logical' maps.

- A forward crosswalk uses codes from an earlier classification to map to corresponding codes in a later classification. Forward crosswalks are used to group old data using new grouper software, and to compare reports of mortality or health service use over time.

- A backward crosswalk uses codes from a currently used classification to maps to codes from earlier classifications, to use a previous version of the grouper or make a time-series analysis.

- Historical crosswalks refer to the selection of a code map which achieves the most appropriate coding and clinical meaning. Due to changes between classification revisions, this may consist of one or more codes. Historical crosswalks for general purposes are useful for large-scale crosswalks applications but should be assessed for usefulness on a case-by-case basis for specific subsets of data or analysis for other purposes.

- Logical (or special purpose) crosswalks can be made for casemix grouping purposes. In this case, it relates each code to the most clinically similar code that achieves the appropriate DRG assignment.

Crosswalks show some loss of information as the precision of ICD codes vary between Revisions, depending on the evolution of scientific understanding and the resulting classification changes: data mapped from ICD10 to ICD11 will not be exactly equivalent to data initially reported in ICD10. For example, the code for "Malignant neoplasm of breast" is classified in ICD10 only by site, whereas in ICD11 it is organized by site and histopathology. Therefore, caution should be exercised when interpreting health data collection after implementation of new Revision. Analyses of temporal or regional trends,

where multiple classification systems have been in use, should carefully track the condition under study (for example, in dual coding studies).

Importantly for grouping purposes, countries transitioning to ICD11 must rely on code crosswalks for a suggested period of two years, before they can further refine their DRG classification systems. For casemix purposes, crosswalks need to be systematically reviewed, which involves repeated scrutiny of backward maps against forward maps to ensure consistency at the DRG level.

Adjusting systems:

- Need for consequent modification of any casemix or Diagnosis Related Groups (DRG) classification systems in use (mainly where countries use DRGs for reimbursement purposes);

- Impacts on the clinical coder workforce;

- Effects on existing statistical systems (e.g. mortality, hospitals, primary care)

- Education/training of clinical coders, clinicians and other users and generators of input

2.4.6. Dual Coding Studies

Dual coding studies involve the comparison of mortality or morbidity data, derived from coding the same episodes, in two ICD versions. In the first instance, dual coding studies may require additional time and resources, but in the longer term these studies can be used to identify coding variations, and to predict the impact on the clinical coder workforce and revenue of introducing a new classification system. Dual coding studies can also provide information on the effect of crosswalks on trend-series analysis and casemix grouping, as well as funding and to establish comparability factors in long term analysis of trends.

Dual coding studies for mortality have been facilitated by the automated mortality coding arrangements used in many countries. Such coding is not commonplace for morbidity reporting, so dual coding studies for morbidity are less simple but possible.

2.4.7. Use of ICD11 with terminologies and electronic health records

ICD11 can be used as it is with electronic health records. It does not need any other tools, systems or terminologies to record all clinical content in a way that is clinically useful and that seamlessly integrates with the clinical workflow.

However, where a system records diagnostic and related information using a third-party terminology, a system can be set up to map or link the third-party codes directly to the ICD11 codes for use in statistical and other outputs. It is also possible that ICD11 codes can also be captured, and depend on the development of appropriate links between the ICD11 and third-party terminology within the local system.

ICD11 has been created to complement existing software and IT systems to support the electronic health record. The in-built interoperability components of ICD11 enhance data retrievability and integration of other functions, such as pharmacy and laboratory data. Modification to health information software systems is required to accommodate the new composition of codes and the mechanisms within the ICD11. Necessary changes include the adaptation to the new code structure of ICD11, use of the coding API (offline or online; it replaces the index), and ideally also features for clustering.

2.4.8. Technical requirements and lead time for health information system changes mortality and morbidity coding tools and casemix groupers

Determining the appropriate technical requirements and lead time will vary enormously from site to site, with current infrastructures, investments made in health systems and staff as a limiting factor. It is not possible to provide a one-size-fits-all framework, and these requirements should be articulated in the site-specific self-assessment and strategic planning undertaken by those moving to implementation. The necessary lead-time should be determined and agreed through iterative consultation with local and regional personnel and IT specialists.

Existing health information systems used to collect morbidity and mortality data would need to be changed to incorporate the ICD11. These changes would need to involve vendors of the systems (with whom the WHO has been communicating about the ICD11), and the Iris system, as noted above.

Consideration would need to be given to the extent to which the role that linkages between the ICD11 and other terminologies play, in local implementations and if it is necessary to replicate pre- and postcoordinated or clusters, in a way that allows them to be constructed for international comparability. For example, some countries already collect 'diagnosis timing' flags (such as, 'present on admission' and 'developed after admission') outside the ICD coding system but the ICD11 incorporates these flags as extension codes. However, countries may choose to continue to record the flags outside the ICD system and combine them for reporting outputs, rather than record them within the ICD11 system implementation. This also includes considerations to program the software to retain in electronic records, even the URI of the terms. This would permit to be independent of any versioning and to maintain all clinical detail at the source.

Another consideration is the role of the ICD11 Coding Tool. This tool is a major advance for ICD and forms a ready basis for implementation in many situations. It replaces the print index as a reference for coding and provides considerable flexibility is search and recording events.

3. Appendices

3.1. Appendix - Template timetable for implementation

This section shows topics that are relevant for moving to a new revision of ICD.

The table is the result of consultations with countries. This section received particular input from the Member States of the American region, with extensive support by the WHO AMRO/PAHO office.

Activities	WHO Tooling available	Year 1				Year 2			
FIRST: Form a national taskforce for implementation, including all relevant stakeholders and ensure support by highest government levels.		**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Priority area 1: Completion of the ICD11 language version for implementation									
Finalize the translation of the Classification, tools and materials	Translation tool	X	X	X	X	X	X	X	X
Carry out manual coding and transcription tests on computer systems to make the necessary adjustments.	ICD11 FIT (Field implementation test platform)			X	X				
Priority area 2: Capacity building									
Evaluate existing ICD coding capacity in the country	WHOFIC platform	X	X						
Develop training programs applicable to different profiles (as coders, staff, systems, researchers)	ICD11 training tool			X	X				
Provide training in the use of ICD11 and its tools. Levels: medical information coding instructors, coders, statisticians, analysts, and public health experts	ICD11 training tool	X	X	X	X	X	X	X	X
Provide training in the use of computer tools to coders, statisticians, and other key personnel	Info sheet	X	X	X	X	X	X	X	X
Provide training in the use and implementation of Iris Automated coding system for causes of death	Specialist training	To be determined by the member state							
Provide training for mortality and morbidity data analysis and of the quality of the information	Specialist training			X	X	X	X		

Activities	WHO Tooling available	Year 1				Year 2			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
FIRST: Form a national taskforce for implementation, including all relevant stakeholders and ensure support by highest government levels.									
Evaluate the impact of training activities for coders, physicians and other personnel on quality indicators	ICD11 FIT			X	X	X	X		
Develop a coder profile and certification	WHOFIC Curriculum		X	X	X				
Priority area 3: Information technology infrastructure									
Carry out a technology needs assessment.		X	X						
Promote having appropriate computer tools (PC and reliable internet access)		X	X	X	X				
Integrate IT personnel into the transition team for developing an integral transition plan				X	X	X	X	X	X
Adjust national information systems (and subsystems) for the implementation of ICD11, as revision, updating of catalogues and variables.						X	X	X	X
Explore the interoperability between the ICD11 coding application and national health systems				X	X	X	X	X	X
Initial testing of ICD11 on-line and off-line versions	ICD11 online and container offline version					X	X	X	X
Implement Automated coding system for causes of death	IRIS - other	To be determined by the member state							
Adapt the current information system to avoid unnecessary changes		To be determined by the member state.							
Priority area 4: Ensure comparability and quality of data									
Monitor indicators of information quality for mortality and morbidity recommended internationally	ANACOD 3	X	X	X	X	X	X	X	X
Make available transition tables to map ICD10 and ICD11	ICD11 toolkit				X				

Activities	WHO Tooling available	Year 1				Year 2			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
FIRST: Form a national taskforce for implementation, including all relevant stakeholders and ensure support by highest government levels.									
Conduct studies on the impact analysis of mortality and morbidity data due to the change from ICD10 to ICD11: - reimbursement schemes - casemix - mortality and morbidity statistics - legal frameworks				X	X				
Carry out comparability studies in selected cases in different areas to evaluate the quality of coding					X				
Conduct bridge studies, double codification, with ICD10 and ICD11, for priority subjects of public health						X			
Monitor specific changes that will be made as part of the transition and implementation of ICD11									
Priority area 5: Advocacy and dissemination									
Create and strengthen committees, councils or inter-institutional centres (Health, Statistics, Social Security and Civil Registry), health information, and inform stakeholders			X	X	X	X	X	X	X
Integrate professional associations, colleges, universities, doctors and other sectors into national commissions to implement training and analysis activities			X	X	X	X	X	X	X
Raise awareness of the importance of the correct use of classifications for different users and environments		Continuous activity							
Develop a national transition and implementation plan for ICD10 to ICD11 aligned with the country's health information improvement plan	This table	X	X	X	X	X	X	X	X

3.2. Appendix - Content of Implementation Package

A suite of tools and functionality facilitate the implementation and use of ICD11.

- **Advocacy materials**
    - o ICD11 fact sheet
    - o ICD11 transition guide

- **Coding tool (multilingual)**
    - o Index based searching of classification
    - o Spelling-synonyms no problem
    - o Offline versions

- **API (multilingual application programming interface)**
    - o Software can access ICD11
    - o An offline and online version

- **ICD11 browser (multilingual)**
    - o Compare between releases
    - o Access to all information material and tools
    - o Offline and online

- **Reference Guide**
    - o Learn what ICD11 is, how to use it and what is new in ICD11
    - o Mortality and morbidity coding rules
    - o Medical certificate of cause of death

- **Unique Reference Identifier (URI) and code combinations**
    - o Retain all detail as reported at the source, e.g. rare diseases
    - o Analyze and tabulate complex information
    - o Enable linkages other systems

- **Proposal platform**
    - o Make suggestions and discuss them
    - o Notifications

- **Field implementation test platform (ICD-FIT)**
    - Coding of diagnostic terms in ICD11 and ICD10
    - Test your translation in multiple languages
    - Test your trainees
- **Translation tool**
    - Translate in your language
- **Mapping tables from and to ICD10**
    - Download maps

3.3. Appendix - Overview of Development of the ICD11

The ICD11 has had several phases of development since the formal launch of the Revision process in 2007 and has incorporated a wide range of clinical, scientific and technical advice, and requirements of future users of the classification for statistical and clinically-related purposes.

Firstly, a list of known issues relating to the use of the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD10), and which could not be resolved in its classification structure, was compiled and possible solutions formulated.

Secondly, Topic Advisory Groups (TAGs) were established to advise on key subject areas, with a focus on the clinical perspective. Cross-cutting Topic Advisory Groups were formed to take an overview of mortality, morbidity, quality and safety and functioning issues. Experts on the clinical TAGs provided advice on content and structural development of specific ICD Chapters whilst the technical TAGs provided guidance on the overall and cross-cutting development of the ICD11 from a use-case perspective.

In the latter stages of the ICD11 development cycle, centralised editing occurred at the WHO with advice from the ICD11 Joint Task Force (JTF). The JTF included experts in the use of ICD for mortality and morbidity coding (for hospital and primary care patients), data collection and reporting of statistics. The JTF also provided strategic and technical advice to the WHO for the finalisation of the classification's development. Input to the classification has drawn on scientific recommendations, where recommended by the JTF and WHO.

During these latter stages, the WHO in collaboration with the World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONCA) International Classification Committee (WICC) worked together and included all concepts necessary for primary care recording and reporting. In general, it is recommended to use the full international reference Tabular List, ICD11 MMS because it contains all concepts, including the ones relevant for primary care. A subset of the

complete list focusses mostly on broader concepts. It is intended for possible use in low diagnostic resources-settings with a more paper based documentation.

Finally, the WHO (with advice from the JTF) addressed any content discrepancies generated by the multiple independent expert groups in the early phases of revision. Work was also undertaken to ensure the consistent overall structure of the ICD11and that it was practicable for users of mortality and morbidity statistics. The application of guiding principles for sound classification development was essential, particularly during this phase.

A version of the ICD11 was released for WHO Member State comment at the ICD11 Revision Conference in Tokyo on 12 October 2016. Following this, focused field trials of the classification, through WHOFIC collaborating centres occurred in the latter half of 2016, and more extensive and specialised field trials continued during 2017.

Member State comments and feedback from the field trials and statistical stakeholders and few remaining proposals submitted within the deadlines were used by the WHO to prepare a fit for purpose ICD11 (i.e. for mortality and morbidity coding, data collection and reporting) for preparing implementation from June 2018.

ICD has been adopted by the World Health Assembly in 2019 to come into effect from 1st January 2022.

3.4. Appendix - Glossary of Terms

API – Application Programming Interface

Crosswalks (mapping) –The term 'crosswalk' is used to describe the process of finding

CSAC – Classification and Statistics Advisory Committee

Dual coding or bridge coding – The collection and comparison of the same mortality or morbidity data episodes coded using two (or more) ICD versions.

ICD10 – The International Statistical Classification of Diseases and Related Health Problems, Tenth Revision

ICD11 – The International Classification of Diseases, 11th Revision

ICD11 MMS – ICD11 for Mortality and Morbidity Statistics

ICD Browser – a web application which allows users to browse through the ICD11 content

ICD Coding Tool – a web application to help the users of ICD search and find categories that they are looking for

ICD Foundation – a multidimensional collection of all ICD entities.

ICF – International Classification of Functioning, Disability and Health

ICHI – International Classification of Health Interventions

Implementation – putting ICD11 into effect as the primary MMS data collection system

Legacy countries – Those countries with an existing ICD data collection system in place

MbRG – Morbidity Reference Group

MMS – Mortality and Morbidity Statistics

Morbidity data – data on the presence of disease or an adverse health event, illness, injury or disability.

Mortality data – data by age, sex and cause of death, as reported annually by the Member States from their civil registration systems.

MRG – Mortality Reference Group

MSAC – Medical and Scientific Advisory Committee

Transition – The phase of preparing for moving from an existing ICD system to a more current Revision, and its implementation, including all necessary activities

Update – changes to content or structure within the lifetime of an ICD Revision (e.g. within ICD10)

URI – Uniform Reference Identifier

WHOFIC – Network of the WHO Family of International Classifications