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Perspectives on Quality

Enhanced capture of healthcare-related harms and injuries in the 11th revision of the International Classification of Diseases (ICD-11)

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Abstract

The World Health Organization (WHO) plans to submit the 11th revision of the International Classification of Diseases (ICD) to the World Health Assembly in 2018. The WHO is working toward a revised classification system that has an enhanced ability to capture health concepts in a manner that reflects current scientific evidence and that is compatible with contemporary information systems. In this paper, we present recommendations made to the WHO by the ICD revision's Quality and Safety Topic Advisory Group (Q&S TAG) for a new conceptual approach to capturing healthcare-related harms and injuries in ICD-coded data. The Q&S TAG has grouped causes of healthcare-related harm and injuries into four categories that relate to the source of the event: (a) medications and substances, (b) procedures, (c) devices and (d) other aspects of care. Under the proposed multiple coding approach, one of these sources of harm must be coded as part of a cluster of three codes to depict, respectively, a healthcare activity as a 'source' of harm, a 'mode or mechanism' of harm and a

consequence of the event summarized by these codes (i.e. injury or harm). Use of this framework depends on the implementation of a new and potentially powerful code-clustering mechanism in ICD-11. This new framework for coding healthcare-related harm has great potential to improve the clinical detail of adverse event descriptions, and the overall quality of coded health data.

Introduction

The World Health Organization's (WHO) International Classification of Diseases (ICD) is the most commonly used system for the classification of specific causes of morbidity and mortality [1]. Its organized codes allow health information to be used in disease surveillance activities, analyses that inform health system financing, epidemiologic and health services research and measurement of quality of care including provider and hospital performance [2–6].

In 2017, the WHO plans to release the 11th revision of the ICD [7]. Key contributors to the revision process are 'Topic Advisory Groups' (TAGs) [8], which *serve as the planning and coordinating advisory body for specific issues that are key topics in the update and revision process* [9]. In addition to multiple 'vertical' TAGs with responsibility to provide recommendations on specific clinically defined sections or chapters of the classification such as mental health, eye diseases and cancers, there are also 'horizontal' TAGs, which focus on 'use cases' that apply to all clinical sections of the ICD. The Quality and Safety TAG (Q&S TAG) is one such horizontal TAG, whose mandate is to advise the WHO in the ICD revision process so that it can produce a better and more enabled ICD-11 coding system for the capture of quality of care and patient safety concepts [7].

The current version of the ICD, the 10th revision (ICD-10), is not optimal for the capture of healthcare-related harm and injury events. One concern is that ICD-10 has codes for 'misadventures in care' that may not be used by coders given the somewhat accusatory nature of the 'misadventure' concept. Other deficiencies relating to quality and safety concepts are apparent in the ICD-10 code ranges for T80–T88 ('Complications of surgical and medical care, not elsewhere classified'), and also for Y40–Y84 ('Complications of medical and surgical care'). Further, there is a duplication of some healthcare-related harm concepts and an inability to link related concepts in clinical clusters of information (aside from the harm–injury linkage possible between 'Injury, poisoning and certain other consequences of external causes' in Chapter 19 of ICD-10 and 'External causes of morbidity and mortality' in Chapter 20 of ICD-10). Thirdly, there is no mechanism for effectively linking a complication of care with its consequences, whether harm to the patient or a requirement for additional services.

Recognizing these shortcomings of ICD-10 in the realm of healthcare quality and safety, the Q&S TAG convened a series of international meetings spanning two calendar years, in which an iterative and deliberative process of concept development was undertaken. This has resulted in the development of a new framework for the coding and capture of healthcare related harm. Based on this work, the Q&S TAG has made formal recommendations to the WHO for a significantly enhanced ICD-11 classification for the quality and safety use case.

In this paper, we present the core elements of the new conceptual approach for capturing healthcare quality and safety information in ICD-coded data. The foundation for this new framework for ICD-11 has been guided by concepts developed and presented in the WHO's International Classification for Patient Safety (ICPS) [9] and the Agency for Healthcare Research and Quality (AHRQ) Common Formats [10]. The ICPS has evolved in WHO strategy to a Minimal Information Model (MIM) for Patient Safety. The original notion of the ICPS was that it might become a stand-alone classification system, distinct from the ICD and other WHO classification systems. Through the ICD revision process, however, it has been recognized that a rich ICD-11 can be the classification system for capturing information on adverse events and/or harms arising in the context of healthcare. Indeed, the ICPS heavily informed the process of ICD revision in the domain of patient safety, and its evolution from ICPS to the MIM for patient safety reflects the significant value that it has produced, i.e. by serving as an information model that transcends any one classification system. Any international jurisdictions that are not using ICD will still have opportunity to benefit from the MIM for patient safety framework, as it is generic and applicable to all contexts [11–13].

Crucial to the use of this new framework is the availability of a new and potentially powerful code-clustering mechanism that has been designed and planned for ICD-11. This paper describes what had been proposed by the Q&S TAG and characteristics of the draft of ICD-11. A noteworthy characteristic of the draft ICD-11, relevant to the matters presented in this paper, is that various versions of the classification (referred to as 'linearizations'), each designed to serve a particular purpose (or 'use case'), will be derived from an underlying foundation ICD-11. The most important of these is the version of ICD-11 that is being developed as the international default standard for coding causes of death and causes of hospitalized morbidity (the 'Joint Linearization for Mortality and Morbidity Statistics', JLMMS). The JLMMS provides capabilities similar to ICD-10 (which is mainly used to code causes of death) enhanced to provide capabilities like those of the 'clinical modifications' of ICD-10 that have been developed in about ten countries to allow more detailed classification, largely for clinical purposes. A reason to enhance ICD-11 in this way is to facilitate internationally harmonized coding of hospital data. (Coding of causes of death has long been harmonized.) Countries will still have the ability to develop national adaptations of the JLMMS, although the extent to which this will be done remains unknown.

Framework for the coding of healthcare-related harm in ICD-11

The new information model for capturing healthcare-related harm or injury builds on the existing mechanism of 'post-coordination' of coded concepts, which allows the coder to link the likely cause of the injury with the injury or resultant harm by juxtaposing codes from Chapters 19 and 20 in ICD-10. In the domain of healthcare-related harms, the potential existing ICD-10 codes include Y40–Y84: *Complications of medical and surgical care*'; 'T36–T65: *poisoning and toxic effects of drugs and chemicals*; X40–X49: *Accidental poisoning by and exposure to noxious substances*; 'X60–X69: *Accidental poisoning by and exposure to noxious*

substances, administration with suicidal or homicidal intent, or intent to harm, or in other circumstances and T80–T88 *Complications of surgical and medical care, not elsewhere classified* as well as certain codes found elsewhere in the classification, particularly blocks of codes in several chapters of ICD-10 for *post-procedural disorders.*

The newly proposed information model for healthcare-related injuries in ICD-11 provides a more flexible, yet still simple and non-duplicative, approach to recording quality and safety events in ICD-coded data. This approach also takes into account a broader proposal from the Injury TAG for revision and enhancement of the external cause and injury chapters.

The model

The Q&S TAG has developed a coding approach comprising three elements, to be linked by a code-clustering method (Fig. 1). The three elements depict:

1. A healthcare-related activity that is the 'source or context' of harm;
2. A 'mode' or 'mechanism' of harm; and
3. The harmful consequences of the event (most importantly *injury or other harm to the patient*).

Four primary types of *source or context* of harm are distinguished, each of which reflects a type of healthcare activity that can became complicated: (a) therapeutic use of medications and other substances, (b) procedures, (c) devices and (d) other aspects of care. Codes are provided for subtypes of each of the four primary types of healthcare activity and for modes or mechanisms of harm that correspond to each of the primary types.

For ICD-11, our proposal results in a substantially revised 'External causes of morbidity and mortality' chapter, with separate sections for each of the four main sources and contexts of harm in healthcare-related activities and sections for codes on modes or mechanisms of harm. The latter allow coding in ICD-11 of aspects of harmful events in health care that are currently not able to be captured in ICD-10. Considering events arising from therapeutic use of medications, for example, the proposal allows for recording the substance or type of substance involved (e.g. an anticoagulant) and the way in which its use may have led to harm (e.g. too little or too much of

the drug; provision at the wrong time; provision of the incorrect drug). The main consequence of the event (i.e. injury or other harm) is then recorded by using the most appropriate diagnosis code from anywhere in ICD-11 (e.g. *Haemorrhagic disorder due to circulating anticoagulants*). Codes and clinical concepts in this model are given in Tables 1–4.

The concept of code clustering for 'post-coordination' of codes is not a significant departure from the possibilities that exist in ICD-10 and earlier revisions of ICD to link codes from the 'Injury, poisoning and certain other consequences of external causes' and 'External causes of morbidity and mortality' chapters. Moreover, many countries have used a dagger-asterisk system [14] available for ICD-10 that allows the linkage of two code concepts: a disease etiology and a manifestation of the disease. The importance of the newly proposed code-clustering mechanism for ICD-11 lies in its flexibility and power to link more than just two codes into a cluster, which as a whole represents a clinical concept.

Two methods have been proposed for clustering. The method most likely to be applied requires the addition to ICD-11 codes of a single-digit alphanumeric suffix to record the cluster to which the code belongs. The method can allow up to 34 distinct clusters to be recorded for a record, by virtue of there being 10 Arabic numerals and 24 available letters in the English alphabet (O and I are omitted because they look like 0 and 1). If a hospital record being coded to ICD-11 describes an episode of healthcare-related harm, then the coder would enter a code for each of the three elements of the Q&S model, drawing the three together as a cluster by adding the same suffix character to each of them (perhaps 1 if this is the first cluster in the record).

Tables 1–5 present key elements of the new code set for healthcare-related harms and injuries. The complete code set is available for viewing in an online Appendix, available at http://apps.who.int/classifications/icd11/browse/f/en.

Other coding enhancements to support the healthcare quality and safety use case

The Q&S TAG and other groups working in the ICD-11 code revision process have introduced other code concepts and new coding rule mechanisms that further enhance the ICD coding system [2–6]. These
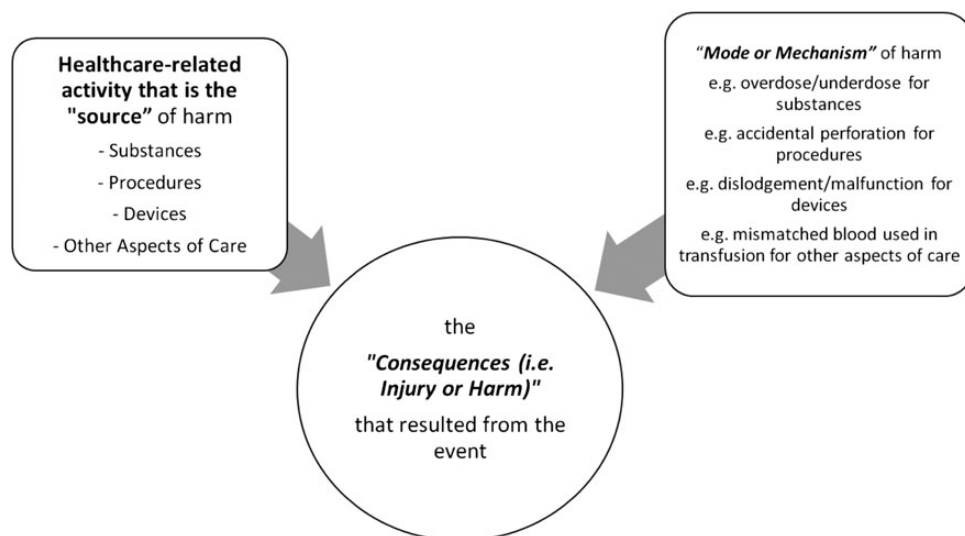

Figure 1 A cluster of codes to denote the context, mode/mechanism and the nature of injury.

Table 1 Example of medications and substance codes along with the associated Mode/Mechanism codes for harm/injury associated with medications/substances in Chapter 23 of ICD-11

Sources of harm	Mode/mechanism
• Systemic antibiotics • Other systemic anti-infectives and antiparasitics • Hormones and their synthetic substitutes and antagonists, not elsewhere classified • Primarily systemic agents • Agents primarily affecting blood constituents • Analgesics, antipyretics and anti-inflammatory drugs • Antiepileptics and antiparkinsonism drugs • Sedatives, hypnotics and antianxiety drugs • Anesthetics and therapeutic gases • Psychotropic drugs, not elsewhere classified • Central nervous system stimulants, not elsewhere classified • Drugs primarily affecting the autonomic nervous system • Agents primarily affecting the cardiovascular system • Agents primarily affecting the gastrointestinal system • Agents primarily affecting water-balance and mineral and uric acid metabolism • Agents primarily acting on smooth and skeletal muscles and the respiratory system • Topical agents primarily affecting skin and mucous membrane and ophthalmological, otorhinolaryngological and dental drugs • Other and unspecified drugs and medicaments • Bacterial vaccines • Other and unspecified vaccines and biological substances • Complementary and Traditional Medicines • Other specified drugs medicaments and biological substances associated with injury or harm in therapeutic use • Drugs medicaments and biological substances associated with injury or harm in therapeutic use, unspecified	• Overdose of substance • Incorrect substance • Drug or substance interactions • Drug-related injury or harm in context of correct administration and dosage • Unspecified appropriateness of dosing or administration • Underdosing • Incorrect route of administration • Medication or substance that is known to be an allergen • Medication or substance unknown to be an allergen • Medication or substance that is known to be contraindicated for the patient • Incorrect duration of administration or course of therapy • Expired or deteriorated medication or substance • Other specified mode of injury or harm associated with exposure to a drug, medicament or biological substance • Mode of injury or harm associated with exposure to a drug, medicament or biological substance, unspecified

Table 2 The full listing of medical devices available for coding as sources of healthcare related harm, along with associated Modes/Mechanisms of Harm

Source of harm	Mode/mechanism
• Anesthesiology devices associated with adverse incidents[a] • Cardiovascular devices associated with adverse incidents[a] • Otorhinolaryngological devices associated with adverse incidents[a] • Gastroenterology and urology devices associated with adverse incidents[a] • General hospital and personal use devices associated with adverse incidents[a] • Neurological devices associated with adverse incidents[a] • Obstetric and gynecological devices associated with adverse incidents[a] • Ophthalmic devices associated with adverse incidents[a] • Radiological devices associated with adverse incidents[a] • Orthopedic devices associated with adverse incidents[a] • Physical medicine devices associated with adverse incidents[a] • General and plastic surgery devices associated with adverse incidents[a] • Other and unspecified medical devices associated with adverse incidents[a] • Surgical and other medical devices associated with injury or harm in therapeutic use, unspecified	• Functional device failure • Structural device failure • Operator error • Combination or interaction of operator error and device failure • Unintentional dislodgement, misconnection or de-attachment • Obstruction of device (occlusion, thrombosis, embolization) • Infection of device • Other specified mode of injury or harm associated with a surgical or other medical device • Mode of injury or harm associated with a surgical or other medical device, unspecified

[a]Sub-categories include diagnostic and monitoring devices, therapeutic, nonsurgical and rehabilitative devices, prosthetic and other implants, materials and accessory devices, surgical instruments, materials and devices, miscellaneous devices, not elsewhere classified, other specified or unspecified.

include: (i) the introduction of a diagnosis-timing capacity (i.e. distinguishing present on admission (POA) vs. arising during hospital stay); and (ii) a revised set of codes in ICD-11's Chapter 24 capturing 'Factors influencing health status and contact with health services'. We proceed to discuss these briefly.

Diagnosis timing

Three countries currently have diagnosis-timing mechanisms in their national coding systems for inpatient hospital cases: Canada (which pioneered this approach), the USA and Australia. These mechanisms differ slightly among countries, but all involve the use of

Table 3 Full listing of medical procedures available for coding, along with associated mode/mechanisms of harm associated with procedures

Source of harm	Mode/mechanism
• Medical or surgical procedure as the cause of injury • Neurological procedure as the cause of injury[a] • Cardiac procedure as the cause of injury[a] • Thoracic procedure as the cause of injury[a] • Gastrointestinal procedure as the cause of injury[a] • Endocrine procedure as the cause of injury[a] • Gynecological procedure as the cause of injury[a] • Urological procedure as the cause of injury[a] • Obstetric procedure as the cause of injury[a] • Orthopedic procedure as the cause of injury[a] • Vascular procedure as the cause of injury[a] • Ear, nose and throat procedure as the cause of injury[a] • Dental procedure as the cause of injury[a] • Plastic surgery procedure as the cause of injury[a] • Other specified procedure as the cause of injury[a] • Other specified medical or surgical procedure as the cause of injury[a] • Medical or surgical procedure as the cause of injury, unspecified • Other medical procedure as cause of injury • Aspiration or drainage of body cavity or fluid collection • Biopsy procedure, not elsewhere classified • Endoscopic procedure. not elsewhere classified • Radiation therapy • Dialysis • Insertion of tube • Manipulative therapies • Acupuncture and related therapies • Lumbar puncture • Bone marrow aspiration and biopsy • Joint aspiration • Injection or infusion for therapeutic or diagnostic purposes • Other specified medical procedure as cause of injury • Other specified other medical procedure as cause of injury • Other medical procedure as cause of injury, unspecified • Other specified procedure as the cause of injury or harm • Unspecified procedure as the cause of injury or harm • Other specified surgical and other medical procedures associated with injury or harm in therapeutic use • Surgical and other medical procedures associated with injury or harm in therapeutic use, unspecified	• Cut or puncture • Perforation • Burn arising during procedure • Embolization • Foreign body accidentally left in body • Failure of sterile precautions • Pressure • Procedure undertaken at wrong site (includes wrong side) • Other specified mode of injury or harm associated with a surgical or other medical procedure • Mode of injury or harm associated with a surgical or other medical procedure, unspecified

[a]Sub-categories include open approach, percutaneous approach, endoscopic approach or approach unspecified.

supplementary data fields in ICD-coded data with a POA or 'onset' flag (also called 'diagnosis timing indicator') to designate whether a particular diagnosis was acquired while in hospital or was acquired prior to admission [3]. In the context of quality and safety, the ability to make this important temporal distinction is an important enhancement to ICD-coded health data, because it allows coders and data users to distinguish diagnoses such as infections acquired in hospital (e.g. pneumonia or urinary tract infection) from similar infections acquired in the community. If acquired in hospital, such diagnoses may be related to quality of healthcare in that facility, whereas diagnoses POA may reflect quality in other settings of care or the patient's underlying illness. Diagnosis timing is a promising and important variable in classification systems, and indeed, this mechanism has provided a functionality that contributes to the development of potentially powerful health performance indicators such as the Classification of Hospital Acquired Diagnoses (CHADx) system [15].

The recommended approach to code diagnosis timing in ICD-11 is still being finalized by the WHO at this time (September 2015). One

proposal is for diagnosis timing codes to reside in a new 'Extension codes' section of the ICD-11. The exact status and mode of use of this new section remain to be finally resolved, though the plan is for this new section to be available primarily for coding causes of hospital morbidity. (It will be less applicable to the mortality coding use case.) Constructs to be captured in the new Extension codes section of ICD-11 include the diagnosis-timing concept discussed here, as well as code concepts for laterality (i.e. left vs right side of body), 'family history of . . .', 'personal history of . . .' and a diagnostic 'rule out . . .' concept.

Most relevant to this paper, information on timing of diagnosis will be captured by linking, through clustering, an Extension Chapter code for 'diagnosis arising during hospital stay' with a diagnosis code for the condition in question that arose during hospitalization. This mechanism is the leading idea for diagnosis timing in ICD-11 because it resides within the classification itself, where it will be available internationally in a unified format. Such an approach avoids the need for creation by individual countries of new coding fields such as those that

Table 4 Full listing of 'Causes of harm-related to other aspects of care'

Sources of harm related to other aspects of care

- Non-administration of necessary drug
- Non provision of necessary procedure
- Problem associated with physical transfer of patient
- Mismatched blood used in transfusion
- Other problem associated with transfusion
- Problem associated with physical restraints
- Problem associated with isolation of patient
- Problem associated with clinical documentation
- Problem associated with transitions of care/handoffs/handovers
- Problem associated with delayed treatment (includes delayed administration of a needed medication, delayed surgery, etc.)
- Problem associated with diagnosis
  - Delay in diagnosis
  - Missed diagnosis
  - Incorrect diagnosis
- Other specified cause of harm associated with other aspects of care
- Cause of harm associated with other aspects of care, unspecified

Table 5 New Chapter 24 codes

New Chapter 24 codes

- Conditions associated with medical facility or provider performance
  - Provider performance compromised by insufficient training
  - Provider performance compromised by insufficient or inadequate supervision
  - Provider performance compromised by sleep deprivation
  - Provider performance compromised by excessive workload
  - Provider performance compromised by substance use or abuse
  - Failure to connect with or identify the need for various needed services provided by medical facility
  - Insufficient medical facility staffing
  - Medical services not available in current medical facility

capture diagnosis-timing in Canada, the USA and Australia, where there is a lack of international standardization.

Factors influencing health status and contact with health services

Section 24 of ICD-11 contains a listing of supplementary codes for a miscellaneous collection of 'other factors' influencing health status or contact with health services. Among these is a subset of codes focusing on 'conditions associated with medical facility and provider performance'. Table 5 lists the new codes that currently exist in this section. These new codes capture concepts relating to the training of healthcare providers, staffing levels in a facility, availability of needed facilities and miscellaneous other factors that can influence care and outcomes.

Moving toward the 2018 launch of ICD-11

As mentioned at the outset, the WHO is aiming for a 2018 approved release of ICD-11. Currently, the WHO is in a process of finalization and testing. The Q&S TAG is undertaking a series of field trials that are focusing on the ability of the new codes and coding framework to capture healthcare quality and patient safety concepts. These field trials seek to address matters of: (i) code coverage for complete capture of quality and patient safety concepts; (ii) completeness of code

concept descriptions and definitions; (iii) performance of coding rules and mechanisms, in particular, those for code clustering and diagnosis timing; and (iv) user perspectives on the new classification's conceptual clarity and usability.

Through the creation of TAGs, the WHO is drawing on an international community of experts to produce evidence and recommendations that will inform the development of a new, more powerful, and also more flexible global classification system—ICD-11. The members of the Q&S TAG have unanimously endorsed the exciting new coding framework and mechanism described here, recognizing the very real potential for improved health data in the domain of healthcare quality and safety. The information presented here exemplifies how the TAG model for ICD revision created by the WHO is informing the development of an enhanced disease classification system.

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