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A World Health Organization field trial assessing a proposed ICD-11 framework for classifying patient safety events

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ABSTRACT

Objective: To assess the utility of the proposed World Health Organization (WHO)'s International Classification of Disease (ICD) framework for classifying patient safety events.
Setting: Independent classification of 45 clinical vignettes using a web-based platform.
Study participants: The WHO's multi-disciplinary Quality and Safety Topic Advisory Group.
Main outcome measure(s): The framework consists of three concepts: harm, cause and mode. We defined a concept as 'classifiable' if more than half of the raters could assign an ICD-11 code for the case. We evaluated reasons why cases were nonclassifiable using a qualitative approach.
Results: Harm was classifiable in 31 of 45 cases (69%). Of these, only 20 could be classified according to cause and mode. Classifiable cases were those in which a clear cause and effect relationship existed (e.g. medication administration error). Nonclassifiable cases were those without clear causal attribution (e.g. pressure ulcer). Of the 14 cases in which harm was not evident (31%), only 5 could

be classified according to cause and mode and represented potential adverse events. Overall, nine cases (20%) were nonclassifiable using the three-part patient safety framework and contained significant ambiguity in the relationship between healthcare outcome and putative cause.
Conclusions: The proposed framework enabled classification of the majority of patient safety events. Cases in which potentially harmful events did not cause harm were not classifiable; additional code categories within the ICD-11 are one proposal to address this concern. Cases with ambiguity in cause and effect relationship between healthcare processes and outcomes remain difficult to classify.

Key words: International Classification of Diseases, World Health Organization, patient safety, quality indicators

Introduction

The World Health Organization (WHO) is currently revising its International Classification of Diseases (ICD). The revision work is being conducted by a number of topic advisory groups or 'TAGs' whose work is being coordinated centrally by a Revision Steering Group and Task Force [1]. For the first time, the ICD revision process has included consideration of how the coding system can lead to effective measurement of quality and safety [2]. This work is being conducted by the Quality and Safety TAG (QS-TAG), consisting of international experts representing several domains including: quality and safety research, coding and classification, clinical care and health system leadership [3].

The QS-TAG efforts have led to a series of recommendations related to the classification of adverse events and other patient safety events. Most importantly, QS-TAG recommended the formulation of a common patient safety framework that considers each patient safety event from three perspectives [2]: the harm experienced by the patient, the cause of the harm and the mode by which the harm occurred. For this classification system, the 'harm' represents an actual outcome experienced by the patient and is classified using any code within the ICD; the 'cause' represents the underlying healthcare intervention and is classified using a set of codes classifying healthcare interventions in four subcategories (drugs, devices, procedures and other aspects of care); and the 'mode' is the mechanism by which the cause led to harm and is classified using unique mode/mechanism codes for each of the four subcategories of causes of harm. In addition to the safety framework, the QS-TAG has made a series of recommendations to add or delete codes with the goal of ensuring users' ability to code events completely and nonambiguously.

We recently performed a field trial (i.e. applied testing of coding performance of the new ICD-11 system) to assess the new approach. Our evaluation was performed to achieve two objectives. First, we wanted to assess whether the patient safety framework was applicable to a range of commonly occurring patient safety events and, for those cases in which it was not applicable, to understand the reasons why it was not. Second, we wanted to determine content coverage by the proposed classification system. We are reporting on the results of this field trial as the results have implications beyond the development of the ICD-11.

Methods

Clinical cases

We created a coding field trial exercise by identifying a total of 45 clinical vignette scenarios relating to patient safety. The vignettes were obtained by selecting 15 case scenarios from each of three sources. First, we obtained 15 events from learning examples within the Canadian Institute for Health Information's Canadian Coding Standards for Version 2012 ICD-10-CA and CCI [4]. These learning examples are used to train health information management professionals and are based on real cases of complications occurring in Canadian Hospitals. Second, we obtained 15 vignettes that summarize safety events detected in a recent prospective safety evaluation conducted in the 75 bed medical service of a large teaching hospital (The Ottawa Hospital, Canada). Third, we obtained 15 patient safety event summaries from the US Agency for Healthcare Research and Quality's Web M&M: Morbidity & Mortality Rounds on the Web, Cases & Commentaries (used with permission) [5].

The patient safety events include a brief description of the incident, usually two to four sentences in length. Participants did not have access to the source material from which the description was derived or know who had written each description. We selected cases to represent an array of clinical scenarios, to limit redundancy and to purposely provide differing levels of detail. The full set of case vignettes and their sources is presented in Appendix 1, where the three sources described above are designated, respectively, as CIHI, Surveillance and AHRQ.

Field trial subjects

The study subjects for this field trial were the members of the QS-TAG. This is a diverse group, including ($n = 16$) members from (six) countries in three continents, among whom there is expertize in (with some individuals counted twice) health services research and epidemiology ($n = 6$), coding and classification ($n = 6$), clinical care ($n = 7$) and health system management ($n = 3$). We sent an electronic invitation, containing a description of the task and detailed instructions, to all members of the committee. All of the QS-TAG members had been previously involved in the development of the newly-proposed ICD-11 coding system for healthcare-related adverse events. With such subjects doing the coding, the field trial was thus a first assessment of code system performance, in the hands of the new classification's developers.

Case review and coding process

We created an online platform to enable geographically and temporally disconnected study subjects to undertake case reviews and coding using the REDCap (Research Electronic Data Capture) tools hosted at the University of Calgary [6]. REDCap is a secure, web-based application designed to support data capture for research studies.

For each patient safety event, we asked reviewers to classify the: (1) harm/injury, (2) cause and (3) mode/mechanism. For each classification, the reviewers were asked to assign an ICD-11 code. To enable code selection, we provided access to the online 'ICD-11 Beta

Draft (Joint Linearization for Mortality and Morbidity Statistics)', September 2014 Frozen version (http://apps.who.int/classifications/icd11/frozen-2014-10-01/l-m/en). If the reviewer could not find an applicable code for the concept, we asked them to explain (i.e. we did not force them to enter a value).

Reviewers were permitted to save the survey and return later, to consult with colleagues and to revisit their ratings from prior cases, until submission of their entire survey for analysis.

Analysis

We performed quantitative and qualitative analyses. For the quantitative analysis, we counted the frequency with which reviewers classified each concept (harm, cause and mode) for each case, and assessed the consistency of classification between subjects. We then defined a concept as 'classifiable' for a case if more than half of the reviewers assigned a code to the concept. To assess the consistency of classification for the cases and concepts deemed classifiable, we assessed the fraction of cases coded a common way. For example, if 11 reviewers coded harm for a case and 8 coded the case using a similar code, then we assessed the consistency as 8/11 (or 88%).

Using these measures, we first grouped cases according to whether they could be classified. We then qualitatively reviewed the cases within each group to determine the nature of the events and gain a better understanding of the reasons for consistent or inconsistent classification. We used this information to generate formal recommendations to the WHO to revise both the code content of the evolving beta versions of ICD-11, and the associated reference manual for ICD-11 that defines coding rules for the new classification.

Results

Quantitative analysis

Fig. 1 and Table 1 describe the flow of cases according to our assessments of whether concepts were classifiable. Of all cases (n = 45), 31 (69%) were judged by the reviewers to be associated with clear instances of harm occurring to patients, whereas 14 (31%) cases were not. Of the 31 cases with harm, 20 (44%, overall) could be readily classified according to cause and mode. Of these 20 cases, 9 were from CIHI, 7 were from The Ottawa Hospital and 4 were from the AHRQ. The remaining 11 (24%, overall) cases with identifiable harms could not be classified by their cause and/or mode. Of these 11 cases, 3 were from CIHI, 5 were from The Ottawa Hospital and 3 were from the AHRQ.

Of the 14 cases with no harm, it was possible to identify healthcare-related factors that could be causes of harm within 5 (11%, overall) of the cases. Those potential causes of harm had associated modes/mechanisms of harm that could also be coded. These five cases include 'near-miss' scenarios where something goes wrong during care, but the patient does not suffer an actual classifiable injury or harm. Among these five cases, three were from CIHI, whereas two were from the AHRQ. The remaining nine (20%, overall) cases were not at all classifiable into the three-part harm/cause/mode model developed for ICD-11 by the QS-TAG. These cases represented three cases from The Ottawa Hospital and five cases from the AHRQ.

When concepts could be classified, reviewers did so in a consistent manner. For the 31 cases in which harm was present, the average consistency in ratings was 89% (range 56–100%); for the 30 cases in which a cause was coded, the average consistency was 77%

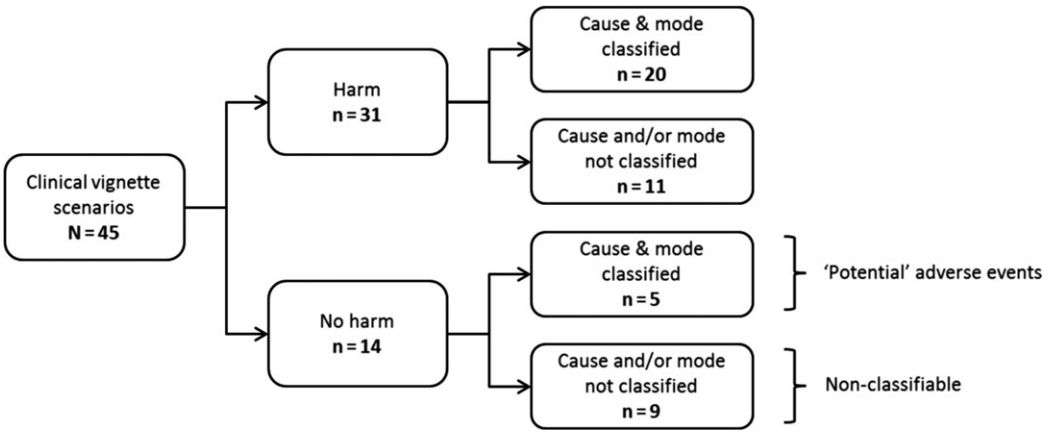

Figure 1 Groupings of events as determined by whether harm, cause and mode were classifiable.

Table 1 Distribution of event groups by source.

Group	Qualitative description of event	CIHI	Ottawa Hospital	AHRQ
n		15	15	15
Harm events with classifiable cause and mode	Adverse event with single visible action leading to harm	9	7	4
Harm events with unclassifiable cause and/or mode	Adverse event with many potential actions leading to harm	3	5	3
Nonharm events with classifiable cause and mode ('Near-miss')	Potential adverse event	3	0	2
Nonharm events with unclassifiable cause and/or mode ('Nonclassifiable')	Uncertain events	0	3	6

(range 44–100%) and for the 25 cases in which the mode was coded the average consistence was 72% (range 43–100%).

Qualitative analysis

Cases that were classifiable using the framework of harm, cause and mode: $n = 20$ cases (44%; Case IDs: 1, 2, 5, 6, 9, 11, 12, 13, 15, 16, 18, 21, 25, 27, 28, 29, 34, 36, 37, 42).

These 20 cases (44%) all represented adverse events (health outcome caused by healthcare intervention). The harm outcomes typically occurred shortly after the intervention implicated as the cause. In fact, for 18 of 20 events, they occurred during a single hospital encounter. For the other two events, the outcome occurred shortly after a recent hospitalization. In all cases, the outcome was highly visible (e.g. an adverse drug event due to a missed allergy check) and the intervention was a dominant explanation (i.e. there were no competing or alternative causes).

Cases that could only be classified with a diagnosis representing possible harm but where classifying cause and/or mode were problematic: $n = 11$ cases (24%; Case IDs: 4, 10, 14, 17, 19, 20, 26, 30, 31, 33, 44).

These 11 cases (24%) also represented adverse events, but it was more difficult to link a specific intervention or omission in care to the outcome. Several events represented hospital-acquired infections and one case was a pressure ulcer. It is not always possible to identify a specific cause for these conditions. For example, while it may be possible to implicate a specific procedure in a case of infected surgical incision, confident attribution of it may be impossible for a postoperative case of pneumonia. In these 11 cases, reviewers had difficulty classifying a mechanism because none was stated in the vignette. The mode (or mechanism) of a wound infection is likely multi-factorial and often cannot be known especially as described in the case notes of an adverse event.

Cases in which no harm was identified but in which it was possible to classify a healthcare-related factor that could have caused harm, and an associated mode/mechanism of harm: $n = 5$ cases (11%; Case IDs: 3, 7, 8, 39, 45).

These five cases all represented 'potential' adverse events. These were process errors that did not cause harm to the patient but had the potential to do so. Examples include a medication error that did not harm the patient, and a documentation error that was caught just in time. While the draft of ICD-11 used for this study included categories that allow coding of some other types of case that do not center on a diagnosis (e.g. examination and investigation of a person who was involved in a road crash, and who turned out to be uninjured) it lacked categories that were suitable for coding cases that involved a healthcare-related error that had potential to have caused harm, but did not.

Cases that were not classifiable: $n = 9$ cases (20%; Case IDs: 22, 23, 24, 32, 35, 38, 40, 41, 43).

These nine cases were characterized by at least one of several factors: lack of clarity as to the outcome, prolonged time between the care and the outcome, competing explanations for the outcome and uncertainty about possible omissions in optimal care. In these cases, the outcome reflected the natural course of the disease but its severity may or may not have been worse as a result of a delay in therapy, a diagnostic error, or a communication challenge (including documentation).

DISCUSSION

We performed this evaluation to assess the content coverage of the WHO's new ICD-11 classification including our proposed patient safety framework. Overall, the content and framework functioned well with most cases being classified according to at least two of the framework's three core concepts: harm, cause or mode. When concepts could be classified, experts assigned codes in a consistent manner. Furthermore, for the concepts that we could not fully classify, these gaps were most often related to the nature of the patient safety event as opposed to the adequacy and coverage of the proposed

Table 2 Suggested revisions to the WHO's international classification of diseases, 11th revision based on the field trial

Suggested change	Rationale	Example of recommendation
Revision of specific codes for harm, cause and mode	Clinical examples highlighted missing and ambiguous codes; these need to be added or revised to make the ICD code set mutually exclusive and completely exhaustive	Add new code for—'Wear, breakage or breakdown of device' with inclusion of 'Breakdown associated with prosthetic devices, grafts or implants' in Chapter 23[†]
Addition of coding rules for training material	Training material is required to ensure standard application of framework independent of setting	Need to include sanctioning rule to 'Drugs medicaments and biological substances associated with injury or harm in therapeutic use'—May code the specific drug responsible for injury or harm from the X-chapter drug listing
Ensuring capability to code near misses	Near misses are more common than adverse events; near misses and adverse events are caused by the same system defects; a common method of classifying all safety events is desired	Add new block of codes to Chapter 24[†]: Healthcare-related events influencing the episode of care, but without documented injury or harm, e.g. - Events associated with a surgical or other medical device influencing the episode of care, but without documented injury or harm - Events associated with a surgical or other medical procedure influencing the episode of care, but without documented injury or harm - Events associated with exposure to a drug, medicament or biological substance influencing the episode of care, but without documented injury or harm

[†]As per ICD-11 Beta version December 2015.

ICD-11 coding framework. However, the field trial did identify several specific areas to improve the ICD-11. These recommendations have now been incorporated into the ongoing iterative revision of the ICD-11.

This evaluation supports the WHO's ICD-11 revision process by providing insights on existing clinical content. This exercise resulted in several recommendations pertaining to coding patient safety events. First, the field trial identified specific healthcare-related *causes* and modes that required revision. Second, the field trial provided insight into specific coding rule modifications. These will be incorporated into the ICD-11 reference guide, which will be used as the reference tool for teaching and training future coders for ICD-11. Third, the field trial highlighted the common scenario of patient safety incidents that do not necessarily cause tangible harm to a patient (e.g. administration of the wrong drug without resulting harm), but nonetheless have significant learning value for healthcare providers. Table 2 provides a summary of the recommendations with examples.

The primary purpose of the ICD is to enable classification of diseases and injuries. When harm results from a patient safety event, it can usually be coded as a disease or injury. However, diagnosis codes are not applicable to 'near-miss' cases, in which a potentially harmful patient safety event occurs, but no harm is identified. The welcome absence of harm does not mean that there is no reason to record such events. Additional observation and investigations might be required to ensure that harm did not occur, and documentation has importance for preventative and other reasons. Current incentive systems make it unlikely these types of events will be captured in the medical record; however, they could be captured using voluntary reporting systems or more proactive surveillance [7]. It is desirable to monitor near misses because the underlying system defects causing them are the same as those causing adverse events. Therefore, a single coding system which classifies causes and mechanisms independently to whether harm occurs is desirable in all health systems [8]. This is consistent with current thinking with respect to the creation of just cultures within healthcare [9,10].

Accordingly, the Q&S TAG recommended to the WHO that capability to code 'near-miss' patient safety events should be provided in ICD-11. ICD-11 includes a chapter to enable coding of 'Factors influencing health status and contact with health services', which are not themselves diagnoses but are relevant to healthcare. The Q&S TAG recommended the insertion into this chapter of a block of codes for 'healthcare-related events influencing the episode of care, but without documented injury or harm'. The proposed additional codes will make it possible to code a larger proportion of the patient safety/quality of care cases strengthening the quality and safety use case for ICD-11.

This work has implications beyond the development of ICD-11. We found that most safety events were classifiable using a framework of harm, cause and mode. This gives us confidence that the approach we used for the ICD-11 is sound and reassures us that the decision to incorporate concepts for patient safety documentation from the AHRQ Common Formats [8] and the International Classification of Patient Safety [11] was effective. This suggests that developers of incident management systems, indicator systems, surveillance tools or other safety learning systems could use the ICD-11 as a foundation to detect and classify cases [11,12].

This study has some caveats and limitations. Most notably, the 45 clinical cases tested represent a modest spectrum of clinical scenarios, tested by individuals who were involved in developing the new ICD-11 coding framework for quality and safety. Future work will need to include greater number and diversity of reviewers and cases, and will also need to assess consistency of ratings in a more robust way. Further, future field trial work will need to assess use of ICD-11's novel features under more 'real-world' coding scenarios. For this field trial, reviewers were instructed to report all cases in a prescribed manner, forcing all adverse event descriptions into a three-part framework focusing on harm, cause and mode/mechanism. In the field, users of ICD-11, will not be—and need not be—similarly constrained. These caveats notwithstanding, this early Q&S TAG field trial has provided information that informs iterative ICD-11 revision and future evaluations.

In conclusion, we have established a framework and code set that enables the classification of most of the patient safety events we sampled. In instances where the three-part framework did not fully apply, we found that key elements of the framework could still be adapted and applied. We support ongoing efforts to improve the ICD-11 as reflected in our recommendations. It remains to be seen whether it will be possible to incorporate the proposed framework into safety learning systems with explicit instructions regarding how to handle cases when one of the concepts is not present. We predict ongoing improvements in both the ability to classify concepts using this classification approach, and the consistency of classification. Further field trials are currently underway testing the classification system in conditions that more closely resemble real-world use.

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References

1. ICD Revision Topic Advisory Groups, World Health Organization: http://www.who.int/classifications/icd/TAGs/en. Accessed 20 April 2016.
2. Southern DA, Pincus HA, Romano PS *et al.* Enhanced capture of healthcare-related harms and injuries in the 11th revision of the International Classification of Diseases (ICD-11). *Int J Qual Health Care* 2016;**28**:136–42.
3. Topic Advisory Group for Quality and Safety, World Health Organization: http://www.who.int/classifications/qstag/en. Accessed 20 April 2016.
4. Canadian Institute for Health Information. Canadian Coding Standards for Version 2012 ICD-10-CA and CCI, Revised September 2012. Ottawa, Ont.: CIHI; 2012.

5. WebM&M Cases & Commentaries, Agency for Healthcare Research and Quality: https://psnet.ahrq.gov/webmm. Accessed 20 April 2016.
6. Harris PA, Taylor R, Thielke R *et al*. Research electronic data capture (REDCap) – a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009 Apr;**42**:377–81.
7. Maass C, Kuske S, Lessing C *et al*. Are administrative data valid when measuring patient safety in hospitals? A comparison of data collection methods using a chart review and administrative data. *Int J Qual Health Care* 2015;**27**:305–13.
8. Harrison R, Cohen AWS, Walton M. Patient safety and quality of care in developing countries in Southeast Asia: a systematic literature review. *Int J Qual Health Care* 2015;**27**:240–54.
9. Carinci F, Van Gool K, Mainz J *et al*. Towards actionable international comparisons of health system performance: expert revision of the OECD framework and quality indicators. *Int J Qual Health Care* 2015;**27**:137–46.
10. Tedesco D, Hernandez-Boussard T, Carretta E *et al*. Evaluating patient safety indicators in orthopedic surgery between Italy and the USA. *Int J Qual Health Care* 2016;**28**:486–91.
11. Patient Safety Organization (PSO) Program, Common Formats, Agency for Healthcare Research and Quality: https://pso.ahrq.gov/common. Accessed 22 April 2016.
12. World Health Organization. The conceptual framework for the international classification for patient safety, Version 1.1, Technical Report, January 2009. *World Health Organization* 2009;1–149.
13. Betjemann J, Josephson SA. A 'reflexive' diagnosis in primary care [Spotlight]. AHRQ WebM&M [serial online]. April 2014. Available at: http://webmm.ahrq.gov/case.aspx?caseID=320.
14. Ventres W. After-visit confusion. AHRQ WebM&M [serial online]. March 2014. Available at: http://webmm.ahrq.gov/case.aspx?caseID=318.
15. Lee LA. Blind spot. AHRQ WebM&M [serial online]. June 2005. Available at: http://webmm.ahrq.gov/case.aspx?caseID=100.
16. Baez-Escudero JL, Levine GN. Coming undone: failure of closure device. AHRQ WebM&M [serial online]. September 2007. Available at: http://webmm.ahrq.gov/case.aspx?caseID=160.
17. Goldstein MK. Deciphering the code. AHRQ WebM&M [serial online]. February 2006. Available at: http://webmm.ahrq.gov/case.aspx?caseID=117.
18. Ilan R. Don't use that port: insert a PICC. AHRQ WebM&M [serial online]. May 2013. Available at: http://webmm.ahrq.gov/case.aspx?caseID=301.
19. Bogner MS. Feeling no pain. AHRQ WebM&M [serial online]. July 2003. Available at: http://webm.m.ahrq.gov/case.aspx?caseID=23.
20. Bosk CL Is the 'surgical personality' a threat to patient safety? [Spotlight]. AHRQ WebM&M [serial online]. April 2006. Available at: http://webmm.ahrq.gov/case.aspx?caseID=122.
21. Kaushal R. Medication overdose. AHRQ WebM&M [serial online]. April 2003. Available at: http://webmm.ahrq.gov/case.aspx?caseID=9.
22. Wu AW. Near miss with bedside medications [Spotlight]. AHRQ WebM&M [serial online]. November 2011. Available at: http://webmm.ahrq.gov/case.aspx?caseID=254.
23. Alaghehbandan R, Raab SS. Pathologic mistake. AHRQ WebM&M [serial online]. March 2013. Available at: http://webmm.ahrq.gov/case.aspx?caseID=295.
24. Eytan T. Recurrent hypoglycemia: a care transition failure? [Spotlight] AHRQ WebM&M [serial online]. October 2008. Available at: http://webmm.ahrq.gov/case.aspx?caseID=185.
25. Sabin JE. Standard deviations [Spotlight]. AHRQ WebM&M [serial online]. December 2009. Available at: http://webmm.ahrq.gov/case.aspx?caseID=209.
26. Farnan JM, Arora VM. The perils of cross coverage [Spotlight]. AHRQ WebM&M [serial online]. May 2012. Available at: http://webmm.ahrq.gov/case.aspx?caseID=266.
27. Starling JIII. Turn the other cheek. AHRQ WebM&M [serial online]. March 2012. Available at: http://webmm.ahrq.gov/case.aspx?caseID=265.

Appendix 1 Full set of case vignettes and sources

CASE	Case summary	Source	Consistency of classifying		
			Harm	Cause	Mode
1	Patient experienced an unexpected burn to chest wall as a result of radiation therapy for lung cancer. The documentation reveals that the exposure time was inadvertently prolonged. Cold compresses were applied to relieve the patient's discomfort.	CIHI	9/11	9/11	6/11
2	The patient sustained multiple rib fractures associated with chest compressions during cardiopulmonary resuscitation.	CIHI	11/11	8/10	6/8
3	Patient presented in labor. An epidural was administered to the patient. When it was noted that the epidural was not working, it was discovered that penicillin G had been administered into the epidural space rather than the usual anesthetic mixture (incorrect IV bag). No treatment was given to the patient, other than close observation for signs and/or symptoms of an allergic reaction, which did not occur.	CIHI	NC	4/7	7/8
4	Patient was readmitted 2 days following discharge post-radical hysterectomy. The final diagnosis was pneumonia.	CIHI	9/9	5/7	NC
5	Patient had excision of a colon segment for cancer. On postoperative day one, the patient got out of the hospital bed without assistance and fell. The result was a fractured hip.	CIHI	10/10	6/10	4/8
6	Following hip replacement surgery, this patient has femoral palsy which is documented as being secondary to a retractor used during the surgery	CIHI	9/9	8/10	6/9
7	Patient had left hip replacement performed. The operative report documents that after closure of the wound and while the patient was still in the operating room, one surgical sponge was noted to be missing in the sponge count. Intraoperative X-ray confirmed a sponge marker within the acetabulum; the patient was prepped and draped again. The incision was reopened to remove the sponge.	CIHI	NC	8/9	9/9

Table continued

Continued

CASE	Case summary	Source	Consistency of classifying		
			Harm	Cause	Mode
8	During a laparoscopic cholecystectomy one ligature clip fell within the patient. The surgeon was unable to retrieve it and opted to leave it in place. The patient was discharged home.	CIHI	NC	6/7	8/8
9	Following infusion of blood products while in ICU, patient develops symptoms that are documented as a mild transfusion reaction.	CIHI	9/10	4/9	3/7
10	Patient diagnosed with streptococcal sepsis following left-side oophorectomy for ovarian malignancy.	CIHI	8/8	8/8	NC
11	A patient had an abdominal hysterectomy and was discharged home. She returned to hospital with a wound infection.	CIHI	7/8	9/9	4/7
12	The patient was admitted for a mechanical valve replacement. As the incision was being closed, she arrested on the operating room table. An open cardiac massage was performed but was unsuccessful and the patient died in the operating room.	CIHI	8/10	9/10	5/7
13	Two days following elective surgery for graft repair of an abdominal aortic aneurysm, patient develops respiratory failure requiring ventilator support.	CIHI	8/10	8/10	4/7
14	Patient had an inguinal hernia repair and developed nausea and vomiting following surgery which settled quickly on its own.	CIHI	7/8	6/7	NC
15	Patient admitted for revision of total hip replacement due to loosening and displacement of the hardware.	CIHI	6/9	6/8	5/6
16	Patient admitted for Anasarca. Patient developed metabolic alkalosis secondary to aggressive diuresis. COMORBIDITIES: A Fib [Atrial Fibrilation] / CHF [Congestive Heart Failure] / Chronic Kidney Disease [chronic renal failure] / Hip replacement / Hypertension / Mitral Valve Replacement / Pulmonary Hypertension / Rheumatoid arthritis.	Surveillance	9/9	6/9	3/6
17	Patient admitted for Acute Respiratory Distress Syndrome. Patient developed new pressure ulcer in the hospital. COMORBIDITIES: DM2 [Diabetes Mellitus Type 2]-NIDDM / Morbid obesity.	Surveillance	9/9	NC	NC
18	Patient admitted for Cellulitis. Patient had a fall in ER and fractured elbow. COMORBIDITIES: BPH / Dementia / DVT [Deep Venous Thrombosis] / Dyslipidemia / Fracture, Elbow / GERD [Gastroesophageal Reflux Disease] / Glaucoma, Acute Angle-Closure / Hypercholesterolemia / Osteoarthritis / PE [Pulmonary Embolism] / UTI [Urinary Tract Infection].	Surveillance	8/8	7/8	7/8
19	Patient admitted for Chronic Obstructive Pulmonary Disease. Patient developed hospital-acquired pneumonia. COMORBIDITIES: A Fib [Atrial Fibrilation] / Compression Fracture / COPD [Chronic Obstructive Pulmonary Disease] / Hernia / Herniated Disc / Osteoporosis.	Surveillance	9/9	NC	NC
20	Patient admitted for Deep Venous Thrombosis. Patient experienced benzodiazepine withdrawal as it was stopped for delirium. Patient had urinary tract infection and pneumonia. COMORBIDITIES: Angina (Angina Pectoris) / Gout / Polymyalgia Rheumatica / Urosepsis.	Surveillance	8/8	7/8	NC
21	Patient admitted for Failure to cope. Patient had difficult death due to aggressive management of a patient with limited prognosis. Challenging relationship between care delivery team and patient's family due to conflict over goals of care. Complications from medical treatment include sepsis from either Foley catheter or percutaneous endoscopic gastrostomy dislodgement. COMORBIDITIES: Breast Cancer / Dysphagia / Lymphoma, Hodgkin / Multiple Myeloma.	Surveillance	8/9	6/8	6/7
22	Patient admitted for Hepatitis, Alcoholic. Patient had a fall. COMORBIDITIES: Alcohol abuse (Alcoholism) / Alcohol Withdrawal / Gastritis / GI bleed (Upper) / Pancreatitis.	Surveillance	NC	NC	NC
23	Patient admitted for level of consciousness not yet diagnosed. Patient experienced delays in assessment and treatment of gait disorder. COMORBIDITIES: Dementia / Parkinson Disease / Restrictive Lung Disease.	Surveillance	NC	NC	NC
24	Patient admitted for Pancreatitis. Patient required soft restraints to keep nasogastric tube in place. COMORBIDITIES: None.	Surveillance	NC	NC	NC
25	Patient admitted for Pneumonia. Patient experienced urethra trauma likely secondary to urinary catheter. COMORBIDITIES: COPD [Chronic Obstructive Pulmonary Disease] / Dementia / DM2 [Diabetes Mellitus Type 2]-NIDDM / Hypertension / Narcolepsy / Prostate Cancer / Psoriasis.	Surveillance	9/9	5/7	5/6
26	Patient admitted for Pneumonia. Patient had a massive wound infection; patient's incision and drainage postponed for 72 hours. COMORBIDITIES: Alcohol abuse (Alcoholism) / Dementia / Hypotension / Hypothyroidism / Status Epilepticus.	Surveillance	6/6	NC	NC
27	Patient admitted for Sepsis. Patient had a traumatic bleed secondary to urinary catheter. COMORBIDITIES: Back pain / Carpal Tunnel Syndrome / COPD [Chronic Obstructive Pulmonary Disease] / DM2 [Diabetes Mellitus Type 2]-NIDDM / Hypertension.	Surveillance	8/9	7/9	6/7
28	Patient admitted for Sepsis. Patient needed urgent hemodialysis. Multiple attempts to inset a line which caused hematoma. COMORBIDITIES: Chronic Kidney Disease [chronic renal failure] / Depression / DM2 [Diabetes Mellitus Type 2]-NIDDM / Fracture, Pelvic / Hypertension.	Surveillance	6/8	9/11	7/9
29	Patient admitted for Urinary Tract Infection. Patient developed urinary catheter associated bleeding. COMORBIDITIES: Chronic Kidney Disease [chronic renal failure] / COPD [Chronic Obstructive Pulmonary Disease] / GI bleed (lower) / Hypertension.	Surveillance	8/9	6/9	6/9

Table continued

Continued

CASE	Case summary	Source	Consistency of classifying		
			Harm	Cause	Mode
30	Patient admitted for Acute kidney Injury (Acute Renal Failure). Patient had symptomatic hypokalemia not recognized for 2 days. COMORBIDITIES: Anemia, Iron deficiency / Cancer, remote > 5 years / Colon cancer / Colostomy / DM2 [Diabetes Mellitus Type 2]-NIDDM / Dyslipidemia / GERD [Gastroesophageal Reflux Disease] / Hypertension.	Surveillance	6/7	NC	NC
31	Despite new back pain and worsening symptoms of tingling, pain and weakness bilaterally, in both hands and feet, a man recently diagnosed with peripheral neuropathy was not sent for further testing after repeated visits to a primary care clinic. By the time neurologists saw him, they diagnosed critical cervical cord compression, which placed the patient at risk for permanent paralysis.	AHRQ [13]	7/7	NC	NC
32	A teenager presented to an urgent care clinic with new bumps and white spots near her tongue. Although she was diagnosed with herpetic gingivostomatitis, the after-visit summary incorrectly populated the diagnosis of 'thrush' from the triage information, which was not updated with the correct diagnosis. The mistake on the printout caused confusion for the patient's mother and necessitated several follow-up communications to clear up.	AHRQ [14]	NC	NC	NC
33	A woman undergoes surgery and immediately has blurry vision, mistakenly attributed to ointment. Two weeks later, she returns complaining of blindness in one eye.	AHRQ [15]	9/9	6/7	NC
34	A man underwent coronary angiography; one stent was placed and bypass surgery was scheduled for 4 days later. He developed bleeding at the catheter site and returned to the hospital. A CT scan revealed a large retroperitoneal hematoma, which was repaired surgically. While in the hospital awaiting the delayed bypass surgery, the patient had a cardiac arrest and died.	AHRQ [16]	7/11	9/11	5/7
35	Failure to enter documentation of a DNR order causes a severely ill elderly man to be resuscitated against his wishes. Shortly thereafter, the patient's wife confirms his wishes and within minutes, the patient dies.	AHRQ [17]	NC	NC	NC
36	A woman was emergently admitted for surgery for acute appendicitis. Although the patient had a chest port for breast cancer chemotherapy, the surgeon demanded that a peripherally inserted central catheter (PICC) be placed. The patient developed blood clots from the PICC, and surgery was canceled. Significant complications, including perforation, peritonitis and prolonged hospitalization, arose from managing the appendicitis conservatively.	AHRQ [18]	4/9	5/8	3/6
37	Following hysterectomy, a PCA pump is mistakenly continued in a woman suffering an adverse reaction to morphine, noticed only when her respiratory status set off an alarm.	AHRQ [19]	7/8	8/9	6/9
38	Because members of the OR team were reluctant to speak up to a senior surgeon with a reputation for yelling, a child undergoing surgery experiences a complication and has a delay in chemotherapy.	AHRQ [20]	NC	NC	NC
39	A boy received an overdose of phenytoin due to ambiguous use of abbreviations.	AHRQ [21]	NC	5/6	6/8
40	An elderly man discharged from the emergency department with syringes of anticoagulant for home use mistakenly picked up a syringe of atropine left by his bedside. At home the next day, he attempted to inject the atropine, but luckily was not harmed.	AHRQ [22]	NC	NC	NC
41	A woman with abdominal pain, bloating and weight loss went to her primary physician, who ordered imaging and a biopsy. Lymph node pathology was reported as Castleman disease. A specialist felt the presentation and test results were atypical for this diagnosis. Further testing revealed adult-onset celiac disease.	AHRQ [23]	NC	NC	NC
42	An elderly, non–English-speaking man with diabetes was admitted to the hospital twice in 8 days due to hypoglycemia. At discharge, the patient was instructed not to take any antidiabetic medications. In between hospitalizations, he saw his primary care physician, who restarted an antidiabetic medication.	AHRQ [24]	5/7	6/8	7/8
43	A man with a history of IV drug use is admitted to the hospital and found to have an epidural abscess with surrounding osteomyelitis. Although the treatment plan required weeks of IV antibiotics, the patient (who fought with the nursing staff and threatened to leave against medical advice [AMA]) was discharged after 2 weeks on oral antibiotics. His condition worsened, and he returned 3 weeks later, but he ultimately left AMA and was lost to follow-up.	AHRQ [25]	NC	NC	NC
44	Inadequate signout to the members of the night float team prevented them from appreciating a patient's mental status changes. Found comatose by the weekend cross-coverage team, the patient had a prolonged ICU stay.	AHRQ [26]	5/6	NC	NC
45	Following biopsies for two skin lesions on his left cheek, a patient was sent to an outside surgeon for excision of squamous cell carcinoma. Although the referral included a description and diagram, the wrong lesion was removed.	AHRQ [27]	NC	5/6	4/6

Text box

1. Existing clinical content within the classification system that required revision, diagnosis code labels and/or definitions.
2. Specific healthcare-related 'cause of harm' codes and mode/mechanism codes that needed to be revised and/or refined. Some additional cause and mode/mechanism codes were added to the ICD-11 beta version as a result.
3. Specific coding rule modifications and/or clarifications for the ICD-11 reference guide, which will be used as the reference tool for teaching and training future coders for ICD-11.
4. Highlighted the common scenario of patient safety incidents that do not necessarily cause tangible harm to a patient (e.g. administration of the wrong drug without resulting harm), but nonetheless have significant learning value for healthcare providers. This situation arose in several cases