International coding upgrade affects clinical research and reviews

When patients are admitted into any US hospital for treatment, their diagnoses are recorded by staff using a highly specific coding system. An episode of food poisoning from eating shellfish at a local restaurant is entered as code T61.72. A bacterial infection resulting from a cat scratch translates to A28.1. These codes, adapted from the International Classification of Diseases (ICD), exist for variations of practically every known ailment.

As the US moves to fully implement the tenth edition of the system, ICD-10, which has five times the number of procedural codes as its predecessor, some clinical researchers feel burdened with the task of revising their studies to accommodate the more detailed definitions of certain disorders. On the flipside, the authors of a report published last month from the US National Research Council (NRC) say that the ICD-10 doesn't go far enough and call for additional classifications that reflect the molecular basis of disease.

The ICD has its roots in the 1850s and is currently drafted by the World Health Organization, based in Geneva. Although countries such as Canada and Australia integrated the ICD-10 codes into their systems more than five years ago, the US has remained stuck on ICD-9 since 1979. That's set to change by 1 October 2013, the date that the US Centers for Medicare and Medicaid Services has mandated that the country's healthcare industry upgrade to the tenth edition.

Changing codes will have a ripple effect on clinical studies and meta-analyses, according to some biomedical researchers. For instance, Sandro Galea, who chairs the epidemiology department at Columbia University's Mailman School of Public Health in New York, notes that the switch necessitates complicated updates to his case-control trial looking at how traumatic brain injury might link to post-traumatic stress disorder (PTSD). "Any taxonomic change toward the ICD-10 will change who qualifies as a 'case' in our research," he explains. Because the criteria for diagnosing PTSD have become more stringent in the ICD-10, he has had to add survey questions for participants and revamp the algorithms used to analyze the data collected in his study.

Clive Adams, who is based in Nottingham, UK, edits schizophrenia-related reviews for the Cochrane Collaboration, a nonprofit organization that systematically reviews biomedical research evidence. He believes that overly detailed parameters for diagnosing disease can actually be unhelpful to the research community. "We've got far too many trials with beautifully diagnosed cases that don't reflect the real world," he says.

To illustrate his point, he notes that the ICD-10 code categories for schizophrenia diagnosis require that people aren't taking illicit drugs and that they don't have central nervous system trauma, both of which could mimic the symptoms of the psychiatric disease. "But many people with core schizophrenia do smoke cannabis and have been dropped on their heads as a child or have had dramatic symptoms only for a few weeks," says Adams. Rather than being classified as schizophrenic, these people would be categorized as having psychosis due to psychoactive substance use or as having schizophrenia-like psychosis—under a completely different ICD-10 code. They "may be actively excluded from trials in the pursuit of a perfect diagnosis," says Adams.

Up for review

David Tovey, editor-in-chief of *The Cochrane Library*, based in London, points to the effects of the ICD-10 upgrade beyond ongoing trials—namely, on reviews and meta-analyses. "Reviews, by definition, are retrospective," Tovey says. "So there is definitely a challenge in trying to make judgments relating to one classification of a disease when the trials were put together under a previous classification." As an example, he points to autism and autism spectrum disorders. "The way we categorize autism spectrum disorders has changed quite dramatically over the last 20 years," he says.

The NRC has weighed in by proposing a "new taxonomy" for diseases in their November report. They recommend new codes to complement the ICD-10, which would reflect underlying molecular causes of disease, rather than just symptoms. The big idea is to integrate the vast database of electronic medical records with patients' genome data in order to form a knowledge base that is up to date with biomedical research, notes Charles Sawyers of the Memorial Sloan-Kettering Cancer Center in New York, who co-chaired the committee that wrote the report. "ICD coding is behind the time," he says. "It just can't react fast enough to the explosion in biology and clinical medicine." If this new taxonomy were to exist, he adds, "ICD [experts] could tap into this knowledge network and revise the diagnosis of diseases to include relevant genetic mutations that predict outcome."

Whether researchers like it or not, the code changes are imminent. "There is no question that it will make the task of reviewing and conducting clinical trials more complex," Tovey says. But, ultimately, "it is definitely important that we review classifications of disease."

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The difference is in the details: examples of ICD-9 versus ICD-10.

Arm burn	
ICD-10: T22.311A: Burn of third degree of right forearm, initial encounter.	ICD-9: 943.31: Full-thickness skin loss due to burn (third degree NOS) of forearm.
Difference: In the ICD-10, characters in the code identify right versus left arm and whether the injury is an initial encounter or subsequent encounter. By comparison, with ICD-9, if you came in for a burn on right arm, and then again for a burn on the left arm, the code would be the same for both; it wouldn't record these as separate injuries.	
Arm fracture	
ICD-10: S52.521A: Torus fracture of lower end of right radius, initial encounter for closed fracture.	ICD-9: 813.45: Torus fracture of radius alone.
Difference: The ICD-10 gives additional detail of where on the arm the fracture is (in this case, the lower end of the arm), which arm (in this case the right) and whether it's an initial injury or follow-up.	
Lung blood clot	
ICD-10: I26.01: Septic pulmonary embolism with acute cor pulmonale.	ICD-9: 415.0: Acute cor pulmonale; 415.12: septic pulmonary embolism.
Difference: This illustrates how combination codes have been incorporated into ICD-10, compared with ICD-9, allowing a single code to express multiple elements of diagnosis.	