Monitoring traumatic brain injury in China

Traumatic brain injury (TBI) has been recognised as a public health problem in China, but more population-level evidence on care utilisation and quality of care is needed.[1] To better monitor health-care outcomes after TBI, we propose the use of data from the hospital quality-monitoring system, with a minor change on the standardised format of the front page of inpatient medical records.

The hospital quality-monitoring system is a national database managed by the National Health Commission that collects information from the front page of inpatient medical records from all tertiary hospitals in China since 2013. This information has already been used as the data source for the national reports on the quality and safety of health care from 2015 to 2017,[2] as well as the annual reports from the China kidney disease network.[3] Data submission was mandatory for over 900 tertiary hospitals from 31 provinces and the system had collected over 40 million records by the end of 2015.[3] The template of the front page of inpatient medical records contained primary and secondary diagnoses coded using the international classification of diseases (ICDs), as well as data on operations, meaning that the records of patients with TBI (which include information on comorbidities and treatments) can be identified. Information on masked patient identifier and discharge status (ie, transfer to other hospitals or death) are also included so that further analyses on the in-hospital mortality and readmission of patients with TBI are feasible.

One of the potential problems of using the front page of inpatient medical records to analyse outcome quality measures of TBI (eg, mortality, readmission, and safety indicators) is that there are no data in these records to indicate the severity of TBI. The front page of inpatient medical records contains six variables, that especially pertain to patients with craniocerebral injuries,[4] including the duration of coma before (ie, in days) and after (ie, in hours and minutes) hospitalisation.

It would be very helpful if one of these variables could be changed to the injury severity score, which is internationally recognised and would allow to document the severity of the brain injury. These data for severity would then serve as an important variable for clinical research and risk adjustment. This change is also necessary because software cannot be used to convert diagnostic codes into severity scores (such as the abbreviated injury scale). To do so, diagnoses would need to be coded in the clinical modification of the US ICD-10 (ICD-10-CM) instead of the ICD-10-CM of China, which does not include anatomic injury codes.[5] We believe that, by use of the hospital quality monitoring system database and promotion of such change on the front page of inpatient medical records, research on TBI can be more diversified and the treatment outcomes of TBI can be better explored in China.

We declare no competing interests.

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1 Jiang J, Gao G, Feng J, et al. Traumatic brain injury in China. *Lancet Neurol* 2019; **18:** 286–95.
2 National Health Commission. 2017 National report on the services, quality and safety in medical care system. Beijing: Scientific and technical documentation press, 2018.
3 Saran R, Steffick D, Bragg-Gresham J: The China kidney disease network (CK-NET): "Big data—big dreams". *Am J Kidney Dis* 2017; **69:** 713–16.
4 National health and family planning commission of the people's republic of China. Requirements on the national survey system of health resources and medical services (2012 version). http://www.nhc.gov.cn/mohbgt/s6693/201301/d09bc944bb57409f8522f94874694e5c.shtml (accessed July 6, 2018).
5 Clark DE, Black AW, Skavdahl DH, Hallagan LD. Open-access programs for injury categorization using ICD-9 or ICD-10. *Inj Epidemiol* 2018, **5:** 11.

Authors' reply

We thank Xueyan Han and Huixuan Zhou for their interest in our Review and for their invaluable concerns on data collection for traumatic brain injury (TBI) in China. They propose that, to better monitor health-care outcomes for TBI, data from the hospital quality-monitoring system (with a minor change on the standardised format of the front page of inpatient medical records) ought to be used.

However, we deemed the data from the hospital quality-monitoring system insufficient, both spatially and temporally, for our Review, which intended to present a whole picture of the country spanning previous decades. Xueyan and Huixuan mention a very good example of data collection on kidney disease from the hospital quality-monitoring system, which involved over 900 tertiary hospitals. However, patients with kidney disease are admitted in tertiary hospitals, but the majority of patients with TBI are admitted in local hospitals due to the urgency and severity of their presentations. Besides, by the end of 2017, there were 2340 tertiary hospitals and 8422 secondary hospitals which were affiliated with a medium size city, county, or district. Additionally, no data before the year 2013 are available in the hospital quality-monitoring system. The hospital quality monitoring system is therefore, at least for the moment, not a good data source for monitoring TBI.

We noted with interest that Xueyan and Huixuan suggest to amend details (ie, by including the injury severity score) on the front page of inpatient medical records to enhance information collection for TBI. It would actually be more helpful if the hospital quality-monitoring system included the Glasgow coma scale (to show clinical features), cranial CT characteristics (to show imaging features), and intracranial pressure (to show pathophysiological features) for every patient with TBI. In brief, improvement of the front page of

inpatient medical records for TBI is necessary for guaranteeing a high quality data source.

For guaranteeing the ability of the hospital quality-monitoring system to handle the high number of patients, which is essential when using hospital administrative data as a comprehensive data source, this monitoring system should be used in the majority of tertiary and secondary hospitals that admit the most cases of TBI. Also, it is important to propose new policies (similar to those reporting cancer diseases, infectious diseases, and maternal mortality) that make it mandatory to input TBI data in the system. We hope that the use of hospital administrative data to evaluate TBI will be feasible in the near future.

We declare no competing interests.

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The risks and uses of dietary supplements

Your Editorial[1] on "*The risks of ignoring scientific evidence*" did not clarify that the actions of the US Food and Drug Administration (FDA) do not strengthen regulations on dietary supplements or further protect patients from unsafe or ineffective supplements. The agency merely enforced the long-standing Dietary Supplement Health and Education Act of 1994 (DSHEA, Code of Federal Regulations title 21, parts 101 and 111), which regulates supplements and prohibits manufacturers from making illegal disease or health claims. They warned dietary-supplement manufacturers that they must comply with DSHEA, not make health claims about treating Alzheimer's disease and dementia, and must restrict their advertising to the allowed structure and function claims or claims of wellbeing. In effect, the FDA is protecting the marketers who follow the rules from those who do not.

US consumers will continue to face edgy advertisements that are allowed with DSHEA. Examples of advertisements that are likely to be familiar to elderly television viewers are those for unspecified components of jellyfish and silkworm cocoons, which purportedly "help mild memory loss associated with aging", "improves memory", "uniquely supports brain function", or "keeps your mind sharp and your memory strong". The advertisements that make these claims say nothing explicit about treating or preventing Alzheimer's disease or dementia, which would be an illegal health claim, but the implication is clear. Nevertheless, these promotional statements are legal structure and function claims, that are permitted under DSHEA.

It is important to know that the FDA does not approve any dietary supplement or structure and function claim that might be associated with it. A manufacturer needs only to provide a basis for concluding that a certain supplement is expected to be safe, and to notify the FDA that a structure and function claim will be made. The manufacturer needs also to provide a disclaimer that the product is not intended to diagnose, treat, cure, or prevent any disease—often delivered at a low volume at the end of the commercials.

By merely enforcing DSHEA—ie, by regulating what a dietary supplement manufacturer can say about a product—the FDA does not protect the public as much as your readers might think. Rather, their enforcement actions protect the manufacturers so that they can fairly compete with each other on the basis of structure and function claims and of claims of general wellbeing, and suppress any temptation to skirt the law by making disease claims. Thus, television viewers only have to sort out what "healthy brains" and "sharp minds" are, and not claims about dementia or Alzheimer's disease.

For the FDA to protect the public from ineffective dietary supplements, DSHEA must be amended to require efficacy evidence for the proffered structure and function claims and claims of wellbeing. Making this amendment, however, requires taking on the dietary-supplement industry, which in turn requires an Act of Congress, for which the US Congress has no appetite.

I report grants from Eli Lilly, Merck, Roche/Genentech, Biogen, Novartis, and Biohaven and personal fees from Eli Lilly, Merck, Roche/Genentech, Avraham Ltd, Boehringer Ingelheim, Neurim Ltd, Neuronix Ltd, Cognition, Eisai, Takeda, vTv, and Abbott outside the submitted work.

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1 The Lancet Neurology. The risks of ignoring scientific evidence. *Lancet Neurol* 2019; **18:** 415.

I am writing to comment on your Editorial about the risks of ignoring scientific evidence on dietary supplements.[1] While I support sanctioning the unscientific use of some dietary supplements, I wish to emphasise that accepted scientific evidence supports the use of several dietary supplements in medical conditions. For example, betaine and folic acid are effective at reducing hyperhomocysteinemia, an established risk factor for cardiovascular disease,[2] and Cochrane evidence shows that creatine can improve muscle strength in muscular dystrophies.[3] By contrast, your Editorial risks casting an ominous shadow on all dietary supplements, and to discredit them within the medical community. While nobody can disagree with the need to avoid and denounce claims not supported by scientific evidence, we should be aware that dietary supplements have a role in the treatment of several neurological conditions, as in the aforementioned examples. As it is often the case,

For the **US FDA compliance guide on structure and function claims** see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims

For the **FDA actions on dietary supplements** see https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary

For **DSHEA, Code of Federal Regulations title 21, part 101 and 111** see https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=101 and https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=111cfm?cfrpart=111