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## **Records of medical malpractice litigation**

*A potential indicator of healthcare quality in China*

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**Abstract:**

**Objective:** To assess the characteristics and incidence of medical litigation in China and the potential usefulness of the records of such litigation as an indicator of healthcare quality.

**Methods:** We investigated 13,620 cases of medical malpractice litigation that ended between 2010 and 2015 and were reported to China's Supreme Court. We categorized each case according to location of the court, the year the litigation ended, the medical specialization involved, the severity of the reported injury, the type of allegation raised by the plaintiff—including any alleged shortcomings in the healthcare received—and the outcome of the litigation.

**Findings:** The annual incidence of medical malpractice litigation increased from 75 in 2010 to 6,947 in 2014. Most cases related to general surgery (1,350 litigations), internal medicine (3,500 litigations), obstetrics and gynaecology (1,251 litigations) and orthopaedics (1,283 litigations). Most of the reported injuries were either minor (1,358 injuries) or fatal (4,111 deaths). The most frequent allegation was of lack of consent or notification (1,356 litigations), followed by misdiagnosis (1,172 litigations), delay in treatment (1,145 litigations) and alteration or forgery of medical records (975 litigations). Of the 11,014 plaintiffs with known litigation outcomes, 7,482 (67.9%) received monetary compensation.

**Conclusion:** Over our study period, the incidence of litigation over potential medical malpractice increased in China. As many of the cases related to alleged inadequacies in the quality of healthcare, records of medical malpractice litigation in China may be worth exploring as an indicator of healthcare quality.

**Keywords:** China, medical litigation, medical malpractice, quality of healthcare

**Tables and figure:** at the end of the paper.

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## Introduction

The quality of health care can be difficult to measure,<sup>1</sup> but many potentially relevant indicators have been investigated. In high-income countries, case report cards are frequently and widely used to record health outcomes – including adverse outcomes that may sometimes be attributable to poor health care – and health providers may also employ quality assurance systems such as error-reporting mechanisms. In many low- and middle-income countries, however, the lack of such records and systems is a major obstacle to measuring the quality of health care.<sup>2</sup>

In theory, patients should be protected from some aspects of poor health care by the litigation relating to medical malpractice. Such litigation can lead to financial compensation for patients who have suffered as the result of medical negligence and can encourage physicians to maintain at least basic standards of health care.<sup>1</sup> In high-income countries, such as the United States of America (USA), researchers have examined the quality of health care from the perspective of medical errors and have concluded that – even though “to err is human” – most errors in the provision of health care could be prevented.<sup>3</sup> However, as an effective approach to prevent medical errors in particular and to increase the quality of health care in general, the operation of the medical malpractice system in the USA is far from ideal.<sup>4</sup>

Litigation records have rarely been used as an external data source for studies on medical malpractice.<sup>5–8</sup> However, in the investigation of health-care quality, a potential strength of using such records is that health providers may lack the incentive to report comprehensively and honestly unless they are in court and being accused of negligence. Litigation records may also allow the quality of care to be assessed from the perspective of both patient and provider. Although such records may cover only a very small proportion of all adverse outcomes,<sup>9,10</sup> they can still be useful indicators of the general quality of health care in a country. When, for example, patient injury claims from Finnish hospital registries for 1998–2003 were investigated, some more

traditional indicators of poor hospital care – such as high prevalences of infection – were found to be significantly associated with the incidence of claims and compensation.<sup>11</sup>

We need a better understanding of the relationship between adverse health outcomes, medical malpractice claims and poor health care. Donabedian divided the measurement of health-care quality into three categories: (i) outcomes, that is the health status of patients after they had received care; (ii) process, i.e. the procedures involved in diagnosis and treatment; and (iii) structure, i.e. the human and material resources available and the infrastructure of the health system.<sup>12</sup> The relationship between the structural components of quality and patient outcomes has been investigated.<sup>13,14</sup> Not all adverse health outcomes can be attributed to health care of poor quality. In addition, attempts to improve the quality of health-care services may not always result in improved health outcomes.<sup>15</sup> For example, if litigation is increased to reduce medical negligence, physicians may become so fearful of being sued that they turn towards so-called defensive medicine<sup>4</sup> – which may well be suboptimal in terms of the health outcomes of the physicians' patients.

It should be possible to use litigation records, from a fault-based legal system, to identify the court cases where adverse outcomes were not attributed to the poor quality of care, i.e. where there was litigation but no consequent compensation. Such records are unlikely to reveal any medical negligence that did not adversely affect the health outcomes of the patients involved. They also give no indication of the numbers of patients who, although they have suffered adverse consequences of medical negligence, chose not to seek any compensation in a court of law.

In China, although public hospitals provide approximately 90% of health-care services, health care from the private sector has grown rapidly since 2009, when national reform of health care promoted universal health coverage.<sup>16</sup> Over the same period, there appears to have been a deterioration in the general relationship between patients and providers and an increase in medical litigation and violence against health

professionals.<sup>17-21</sup> There is a need to resolve such issues but data on health-care quality and useful indicators of such quality are rare in China.<sup>22,23</sup> Some hospitals are investing in systems based on electronic medical records but such systems are not well integrated and the recorded data are rarely shared between hospitals or assimilated at regional level.<sup>24</sup>

Some shortcomings in the quality of health care in China were revealed when 1086 records of medical malpractice litigation, from a third-party database, were investigated – but the sample selection method employed to create the database could not be determined.<sup>5</sup> Of the 504 physicians recorded in a cross-sectional survey in the Chinese city of Shenzhen, only 10 (2.0%) reported that they had been involved in medical malpractice litigation.<sup>25</sup> Despite the apparent rarity of such litigation, we wondered if, in China, the analysis of records of medical malpractice might provide a useful – and previously under-researched – method of assessing health-care quality and the temporal trends in such quality. We therefore collected and investigated the publicly available records, from the Supreme Court of China, of cases of medical malpractice litigation that ended between 2010 and 2015.

## Methods

### Setting

In China, when a negligence-related adverse outcome occurs, the patient or the patient's family members may negotiate directly with the health-care provider – over liability and compensation – or they may file a lawsuit. For the lawsuits, which usually end in a civil judgement or civil ruling, all the related information on the plaintiff and defendant, any medication involved, the adverse outcomes, the evidence of potential negligence, the legal debates, the relevant legislation and case outcome should be recorded, submitted to the Supreme Court of China and then made available publicly via an electronic database called China Judgments Online.<sup>26</sup> By November 2016, this database covered over 20 million litigation records and had had over 3.9 billion visits.<sup>26</sup>

## **Selection of records**

We searched China Judgments Online for records – of litigation cases that ended between 1 January 2010 and 5 November 2015 – that included the phrase “medical malpractice”. We then excluded records that did not include compensation disputes or claims of medical malpractice liability, records from which any basic information was missing and duplicate records of individual cases (Fig. 1). If one case was reported in multiple records, we only kept the record of the final judgement.

## **Data extraction and analysis**

Using Python version 2.7.9 (Python Software Foundation, Beaverton, USA), we extracted relevant data – i.e. location of the court, the year the litigation ended, the medical specialization involved, the severity of any reported injury (Box 1), the type of allegation raised by the plaintiff – including any alleged shortcomings in the health care received – and the outcome of the litigation – from the selected records. We used the reported disease or injury to categorize each case into one of 14 medical specializations. We then used Stata version 13 (StataCorp. LP, College Station, USA) to produce summaries of the extracted data.

### **Box 1: Categories of the severity of injury, China, 2002**

#### *Death*

#### *Severe disability*

- Level 1: for example, persistent vegetative state, quadriplegia

#### *Medium disability*

- Level 2: for example, blindness, loss of one kidney
- Level 3: for example, loss of one eye, loss of one lung
- Level 4: for example, loss of entire stomach, loss of bladder
- Level 5: for example, incontinence, loss of swallowing function

#### *Minor disability*

- Level 6: for example, loss of three quarters of stomach, loss of half of liver
- Level 7: for example, loss of two thirds of stomach, loss of third of liver
- Level 8: for example, loss of half of stomach, loss of quarter of liver
- Level 9: for example, loss of two thirds of an auricle
- Level 10: for example, thyroid hypofunction

Source: Chinese Ministry of Health.<sup>27</sup>

## **Results**

Of the 13 620 litigation records included in our analysis, about 65% (8893) resulted in a civil judgement and the rest in a civil ruling (Table 1). About half and a third of the records related to court proceedings in eastern and central China, respectively (Table 1). According to the data held in China Judgments Online, the annual numbers of cases of medical malpractice litigation increased substantially over our study period, from just 75 in 2010 to 6947 in 2014 (Table 1). Over 80% of the cases we investigated were represented by just four medical specializations: internal medicine, general surgery, orthopaedics and obstetrics and gynaecology (Table 1). Nearly all (5469; 89.6%) of the 6105 cases for which injury severity was recorded were either fatal cases or cases of minor injury (Table 1). Among the 5408 plaintiffs for whom allegations were recorded, the most frequently proposed allegation was a lack of consent or notification (1356;

25.1%), followed by misdiagnosis (1172; 21.7%), delay in treatment (1145; 21.2%) and alteration or forgery of medical records (975; 18.0%). For 11 014 cases, information on whether the plaintiff withdrew the lawsuit before a verdict, received compensation or did not receive compensation after a verdict was available. The records of the other cases focused on the administrative procedures of the trials, such as applications for retrial, rather than on decisions as to whether or not medical malpractice had occurred. Of the plaintiffs with known litigation outcomes, 7482 (67.9%) received monetary compensation, for instance to compensate for death or disability, emotional harm, funeral expenses and/or the living expenses of dependents, and 2121, or about 19%, withdrew their lawsuits (Table 1).

Over our study period, the numbers of cases of medical malpractice litigation and the incidences of such litigation – both per million population and per 1000 physicians – generally appeared higher in eastern and central China than in western China (Table 2).

## Discussion

The health system reform in China, launched in 2009, was designed to promote universal health coverage and has already led to some remarkable achievements. Between 2005 and 2011, for example, coverage of the national population with health insurance increased from less than 50% to about 95%.<sup>29</sup> However, concerns have been raised that, at least in rural China, health-care reforms may be focused too much on cost containment and may pay too little attention to care quality.<sup>30</sup> As mean per-capita incomes and insurance coverage increase in China, the population's demand for health care – and particularly for high-quality medical services – also increases.

While there is no official system for the measurement of health-care quality in China,<sup>31</sup> the mandatorily submitted records of medical malpractice litigation could form a nationally representative sample of medical malpractice. While most other indicators of health care – e.g. routine medical records – tend to focus on clinical signs and



symptoms, litigation records provide information not only on treatment but also on adverse outcomes associated with mistakes or other shortcomings in health care. Analysis of the features of – and temporal trends in – malpractice litigation may also allow the development of more effective methods for improving health-care quality. In addition, the wider dissemination of data on malpractice litigation may reduce the future incidence of medical malpractice.

Our study indicates that, in China, medical malpractice litigation has become much more common than previously reported.<sup>5,25</sup> However, we cannot determine if the increasing frequency of such litigation reflects a decrease in the general quality of health care. Between 2010 and 2015, similar increases in the annual numbers of cases of medical malpractice litigation have been observed in Japan,<sup>32</sup> Mexico<sup>33</sup> and the USA.<sup>6</sup>

The geographical differences that we observed – in the total number of medical malpractice cases, the number of cases per million population and the number of cases per 1000 physicians, can probably be partially explained in terms of the uneven distribution of health-care resources across China. The more developed eastern China tends to have more medical resources than central or western China.<sup>34</sup> Eastern China also appears to have relatively high incidences of medical malpractice litigation per million population and per 1000 physicians – although we were unable to determine what proportions of the incidence recorded for a study area were represented by the residents of the study area and by people from other areas who had travelled for treatment. One aim of the health system reforms in China is to reinvigorate health-care services in the country's less developed areas. Our study results may re-emphasize the importance of a more equal allocation of health-care resources across China.

Another possible factor in the uneven geographical distribution of medical malpractice litigation across China is geographical variation in access to – and/or attitudes towards – justice. In some areas of Central and Latin America, nongovernmental organizations have assisted plaintiffs in litigation for access to

essential medicines.<sup>35</sup> It seems possible that, in the more developed areas of China, patients or patients' families may be more likely to be encouraged to file lawsuits by nongovernmental organizations or other forms of social assistance.

Internal medicine, general surgery, orthopaedics and obstetrics and gynaecology were found to be the leading specializations of malpractice litigations, which is consistent with the previous literature.<sup>5,6,36</sup> The three most common allegations – misdiagnosis, delay in treatment and lack of consent or notifications – were all aspects of process quality.

Most of the litigation cases we investigated were associated with either the most severe or minor adverse outcomes. Severe adverse outcomes are probably those most likely to result in litigation while malpractice with minor adverse outcomes may be relatively common simply because most adverse outcomes are of minor severity. It has been suggested that medical error may be the third leading cause of death in the USA.<sup>37</sup> In China, fatal medical errors require much more attention.

Of the cases we investigated, 68% ended with monetary compensation. This percentage is close to the corresponding values previously reported in China (67%), Japan (60%) and the USA (56%) but substantially higher than the value reported for Canada (33%).<sup>5,6,32,38</sup> The between-country differences in this proportion probably reflect between-country differences in legal and medical systems and socioeconomic backgrounds.

Our study had several limitations. First, medical malpractice cases presumably represent only a small proportion of the patients who receive health care of poor quality. Second, we only analysed data from a single online database and it seems unlikely that this database held records for all of the cases of medical malpractice litigation that occurred in China over our study period. The proportion of such cases that were included in the database may also have changed during our study period. Third, in our analysis we ignored some variables that were recorded in the database, e.g. the amount

of compensation awarded and the relative contributions made, to each lawsuit, by lawyers and insurers. Finally, if we are to use litigation records as an indicator of health-care quality, we probably have to assume that the judiciary system involved is fair, independent and strong and that the collection of data on medical malpractice litigation is reasonably comprehensive or, at least, nationally representative.

In conclusion, in the absence of more robust and traditional indicators, analysis of medical litigation records may give useful information on health-care quality. Medical malpractice is both a legal issue and a health system issue, since it involves governments, health providers, insurance companies, legal systems and patients. More studies are necessary on this topic, not only for studying health-care quality but also, ultimately, for strengthening health systems.

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Table 1. Records of medical malpractice litigation, China, 2010–2015

| <b>Category</b>                           | <b>No. of records with relevant data (%)</b> |
|---|--|
| <b>Legal category (n = 13 620)</b>        |  |
| Civil judgement                           | 8893 (65.3)                                  |
| Civil ruling                              | 4727 (34.7)                                  |
| <b>Region (n = 13 587)<sup>a</sup></b>    |  |
| Central                                   | 4365 (32.1)                                  |
| Eastern                                   | 6283 (46.2)                                  |
| Western                                   | 2939 (21.6)                                  |
| <b>Year litigation ended (n = 13 453)</b> |  |
| 2010                                      | 75 (0.6)                                     |
| 2011                                      | 97 (0.7)                                     |
| 2012                                      | 213 (1.6)                                    |
| 2013                                      | 1359 (10.1)                                  |
| 2014                                      | 6947 (51.6)                                  |
| 2015                                      | 4762 <sup>b</sup> (35.4)                     |
| <b>Primary claim (n = 5408)</b>           |  |
| Allergic reactions                        | 115 (2.1)                                    |
| Alteration or forgery of medical records  | 975 (18.0)                                   |
| Delay in treatment                        | 1145 (21.2)                                  |
| Improper treatment                        | 306 (5.7)                                    |
| Lack of consent or notifications          | 1356 (25.1)                                  |
| Lack of prevention                        | 41 (0.8)                                     |
| Lack of professional qualifications       | 59 (1.1)                                     |
| Misdiagnosis                              | 1172 (21.7)                                  |
| Other adverse reactions                   | 239 (4.4)                                    |
| <b>Medical specialization (n = 8945)</b>  |  |
| Dermatology and venereology               | 136 (1.5)                                    |
| Emergency                                 | 124 (1.4)                                    |
| General surgery                           | 1350 (15.1)                                  |
| Infectious diseases                       | 110 (1.2)                                    |
| Internal medicine                         | 3500 (39.1)                                  |
| Obstetrics and gynaecology                | 1251 (14.0)                                  |
| Oncology                                  | 296 (3.3)                                    |
| Ophthalmology and otolaryngology          | 411 (4.6)                                    |
| Orthopaedics                              | 1283 (14.3)                                  |
| Paediatrics                               | 160 (1.8)                                    |
| Plastic surgery                           | 32 (0.4)                                     |
| Psychiatric                               | 138 (1.5)                                    |
| Reproductive health                       | 139 (1.6)                                    |
| Traditional Chinese medicine              | 15 (0.2)                                     |

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|   |             |
|---|-------------|
| <b>Severity (n = 6105)</b>                |             |
| Death                                     | 4111 (67.3) |
| Medium injury                             | 493 (8.1)   |
| Minor injury                              | 1358 (22.2) |
| Severe injury                             | 143 (2.3)   |
| <b>Outcome of litigation (n = 11 014)</b> |             |
| Case withdrawn                            | 2121 (19.3) |
| Compensation                              | 7482 (67.9) |
| No compensation                           | 1411 (12.8) |

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<sup>a</sup> For our analyses, central China was represented by the provinces of Anhui, Heilongjiang, Henan, Hubei, Hunan, Jiangxi, Jilin and Shanxi, eastern China by the provinces of Beijing, Fujian, Guangdong, Hainan, Hebei, Jiangsu, Liaoning, Shandong, Shanghai, Tianjin and Zhejiang, and western China by the provinces of Chongqing, Gansu, Guizhou, Qinghai, Shaanxi, Sichuan and Yunnan and the Guangxi, Inner Mongolia, Ningxia, Tibet and Xinjiang autonomous regions. No corresponding data were available for Chinese Taipei or the Hong Kong Special Administrative Region or Macau Special Administrative Region.

<sup>b</sup> Number recorded by 5 November.

Note: Inconsistencies arise in some values due to rounding.



Table 2. Cases of medical malpractice litigation, China, 2010–2015

| Area                          | No. of cases |                   |                                     |                                  |
|-------------------------------|--------------|-------------------|-------------------------------------|----------------------------------|
|                               | Total        | With compensation |                                     |                                  |
|                               |              | Total             | Per million population <sup>a</sup> | Per 1000 physicians <sup>a</sup> |
| <b>Provinces</b>              |              |                   |                                     |                                  |
| Anhui, central China          | 842          | 422               | 7.1                                 | 5.0                              |
| Beijing, eastern China        | 721          | 477               | 23.6                                | 6.8                              |
| Chongqing, western China      | 500          | 240               | 8.2                                 | 4.8                              |
| Fujian, eastern China         | 243          | 132               | 3.5                                 | 2.2                              |
| Gansu, western China          | 147          | 62                | 2.4                                 | 1.5                              |
| Guangdong, eastern China      | 652          | 315               | 3.0                                 | 1.9                              |
| Guizhou, western China        | 162          | 90                | 2.6                                 | 2.0                              |
| Hainan, eastern China         | 19           | 9                 | 1.0                                 | 0.6                              |
| Hebei, eastern China          | 605          | 348               | 4.8                                 | 2.8                              |
| Heilongjiang, central China   | 113          | 63                | 1.6                                 | 0.2                              |
| Henan, central China          | 1578         | 839               | 8.9                                 | 5.4                              |
| Hubei, central China          | 554          | 269               | 4.7                                 | 2.8                              |
| Hunan, central China          | 577          | 322               | 4.9                                 | 2.8                              |
| Jiangsu, eastern China        | 1150         | 584               | 7.4                                 | 4.3                              |
| Jiangxi, central China        | 161          | 137               | 3.1                                 | 2.2                              |
| Jilin, central China          | 389          | 202               | 4.6                                 | 3.4                              |
| Liaoning, eastern China       | 522          | 254               | 9.2                                 | 1.4                              |
| Qinghai, western China        | 27           | 16                | 2.8                                 | 1.8                              |
| Shaanxi, western China        | 415          | 171               | 4.6                                 | 2.6                              |
| Shandong, eastern China       | 1131         | 660               | 6.9                                 | 3.5                              |
| Shanghai, eastern China       | 612          | 495               | 21.1                                | 9.5                              |
| Shanxi, central China         | 151          | 82                | 2.3                                 | 1.0                              |
| Sichuan, western China        | 588          | 301               | 3.7                                 | 2.0                              |
| Tianjin, eastern China        | 171          | 91                | 6.7                                 | 3.0                              |
| Yunnan, western China         | 173          | 114               | 2.5                                 | 1.8                              |
| Zhejiang, eastern China       | 457          | 255               | 4.7                                 | 2.0                              |
| <b>Autonomous regions</b>     |              |                   |                                     |                                  |
| Guangxi, western China        | 465          | 260               | 5.6                                 | 3.5                              |
| Inner Mongolia, western China | 96           | 56                | 2.3                                 | 1.0                              |
| Ningxia, western China        | 88           | 47                | 7.4                                 | 3.8                              |
| Tibet, western China          | 3            | 2                 | 0.7                                 | 0.5                              |
| Xinjiang, western China       | 275          | 152               | 6.5                                 | 2.9                              |

<sup>a</sup> For our analyses, the size of the population and number of physicians in each study area were assumed to be those recorded in 2011.<sup>28</sup>

Fig. 1. Flowchart of the selection of records of medical litigation, China, 2010–2015

