BMJ Open

Moving towards a better path? An examination of China's reforms to remedy medical corruption from pharmaceutical firms

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018513
Article Type:	Research
Date Submitted by the Author:	04-Jul-2017
Complete List of Authors:	Shi, Jianwei Liu, Rui Jiang, Hua Wang, Chunxu Xiao, Yue Liu, Nana Wang, Zhaoxin Shi, Leiyu
Primary Subject Heading:	Ethics
Secondary Subject Heading:	Ethics, Health economics, Health services research
Keywords:	Medical corruption, Evaluation, Effectiveness, China

Moving towards a better path? An examination of China's reforms to remedy medical corruption from pharmaceutical firms

Jianwei Shi, PhD[1,2#], Rui Liu[3#], Hua Jiang[4], Chunxu Wang[5], Yue Xiao[5], Nana Liu[5], Zhaoxin Wang[1,5]*, Leiyu Shi[2]*

1. Shanghai Yangpu Hospital, Tongji University School of Medicine, Shanghai, 200090, China

2. Department of Health Policy and Management, Primary Care Policy Center, Johns Hopkins University, Baltimore, Maryland, 21205, USA

3. Shanghai Tenth People's Hospital, Tongji University School of Medicine, Shanghai, 200072, China

4. Department of Family Medicine, Shanghai East Hospital, Tongji University School of Medicine, Shanghai, China

5. Tongji University School of Medicine, Shanghai, 200092, China

Jianwei Shi: shijianwei_amy@126.com

Rui Liu: liurui@tongji.edu.cn

Hua Jiang: Huajiang2013@tongji.edu.cn

Chunxu Wang: chunxuchn@163.com

Yue Xiao: 18817554320@163.com

Nana Liu: stonenn@163.com

Zhaoxin Wang: supercell002@sina.com

Leiyu Shi: lshi2@jhu.edu

 # These authors are co-first authors on this paper.

*** These authors are co-corresponding authors on this work.**

Corresponding author1: Zhaoxin Wang, 1239 Si Ping RD, Shanghai, 200092, China, Email: supercell002@sina.com.

Corresponding author2: Leiyu Shi, 624 North Broadway, Baltimore, MD 21205, USA. Email: lshi2@jhu.edu.

Moving towards a better path? An examination of China's reforms to remedy medical corruption from pharmaceutical firms

ABSTRACT

Objectives: Few studies have systematically examined the effects of the existing regulations for corruption and whether the corruption has been alleviated. This study aimed at assess whether China's reforms to curb medical corruption were effective.

Methods: Using semi structured key informant interviews, we examined the effect of the existing measures on opposing medical corruption based on the Donabedian model. We analyzed quantitative data from "China Judgements Online" to support the evaluation.

Results: There are three main categories of countermeasures to oppose medical corruption in China. First, the level of fines and criminal penalties for medical corruption behaviors were insufficient. Second, regarding the health policy regulations, although NRDL (National Reimbursement Drug List) and EDL (Essential Drug List) were implemented well, they were incomplete and the adjustment of lists created new corruption space. Additionally, the new program that centralized the purchase of pharmaceuticals was found that most purchasing committees were not independent, and the selection criteria for bidding was short of scientific evidence. Third, reporting scheme for Commercial Bribery Records by the health bureau is currently being executed poorly. Lastly, quantitative data from "China Judgements Online" showed no obvious decrease of institutional medical corruption in recent years, and most criminals

committed crimes for a long time before getting caught.

Conclusions: The existing countermeasures are far from ideal and cannot fundamentally reduce the medical corruption in China. To change the situation, the combined efforts of legislation and administrative mechanisms should be improved.

Keywords: Medical corruption; Evaluation; Effectiveness; China

Strength and limitations

- Few studies have systematically examined the effects of the existing regulations for corruption and whether the corruption has been alleviated.
- This study aimed at assess whether China's reforms to curb medical corruption were effective.
- This study can help improve and foster better therapeutic and practical innovations to combat medical corruption in the Chinese health sector, and is a good source of evidence for similar developing regions as China to curb medical corruption.

INTRODUCTION

Medical corruption is pervasive across cultures and endemic in countries regardless if they are small or large, poor or rich, and capitalist or socialist[1-3]. Though medical corruption is costly for all countries, it seems to be an especially important problem in developing and transitional economies where public resources are scarce[4]. Undoubtedly, there is no exception with China. Since the China's reform and opening up policy in 1979, public hospitals in urban and rural areas

have remained under central government ownership. However, they were required to undertake a certain degree of responsibility for financing money and administering institutions by themselves. This privatization of healthcare financing required hospitals to rely more on the sale of services, drug prescriptions, and medical examinations to earn revenues[5]. The National Development and Reform Commission's price guidelines for basic health services (routine examinations, surgeries, standard diagnostic tests, and pharmaceuticals in health institutions) were supposed to be low enough to ensure that the services would be affordable for patients. Moreover, hospitals were prohibited from earning more than 15% markup from regulated tests and drugs[6]. However, the privatization of healthcare financing combined with price regulation put most public hospitals in China at serious financial risk[5-6]. To compensate for the retrenchment of government health outlays, many public hospitals in China began to earn revenue illegally by making alliances with the pharmaceutical firms to procure pharmaceuticals and medical equipment. Gradually, medical bribery permeated the health sectors in China[7-8].

Specifically, there are three major forms of medical corruption: (1) patient payments to secure medical treatments or improve their quality, (2) physicians' use of free public facilities for private patients, and (3) illegal payments usually from industry (mostly pharmaceutical and medical equipment producers) to health professionals or officials, that is called institutional corruption [9]. Among these forms of medical corruption, the institutional one seems to be more common and usually involves the largest amount of payments[10]. Usually, pharmaceutical firms' certain practices corrupt medical research, the production of medical knowledge, the practice of medicine, drug safety, and the administration's oversight of pharmaceutical marketing, etc.[11]. It was estimated that in the United States, the pharmaceutical industry spent up to $42 billion in

promotion every year, or on average, $61,000 per physician, to influence their prescribing habits and generate profits[12]. In China in 2000s, numerous incidents regarding medical corruption emerged and exposed again the severity of corruption in China's healthcare industry[7]. For instance, in 2013, all public hospitals in Zhangzhou, Fujian Province were reported to be involved in medical corruption. A total of 1088 doctors and 133 administrators from 73 hospitals in Zhangzhou were found to be taking bribes and kickbacks from pharmaceutical firms, that amounted to $3.34 million and was a great shock to the public[13]. In this study, we focused on the type of medical corruption that caused by pharmaceutical firms. Usually, the interactions between pharmaceutical companies and hospitals or physicians are guided by their financial interests, and can be in the form of drug or device promotion, kickbacks, and financial incentives to influence physician prescribing behaviors[14-15]. Studies showed that medical corruption can undermine the quality of healthcare, lead to inappropriate treatments, raise the cost of care, and damage physician-patient relationships, negatively impacting the whole health care system[8, 6-18].

Confronted with severe medical corruption, many countries have implemented various anti-corruption strategies, such as creating fines and criminal penalties[19], tax policy for pharmaceutical companies[20], health regulations by insurance institutions(i.e. new forms of prescription drug pricing)[9,21-22], and improved accreditation, certification, and rating systems [23-24]. However, due to the varying attributes of health systems and severity of medical corruption in different countries, the solutions designed or taken usually differ by country. In China, the government began implementing a wave of activities to combat medical corruption as part of its 2005 health care reforms. In detail, there are three categories of solutions: (1) the fines

and criminal penalties created by legal and regulatory bodies, such as the "Penal Law" (Amended, 2006), "Anti-unfair Competition Law" (1993) and "Interim Provisions on Anti-commercial bribery"(1996)[25], (2)There are health policies that aim to reduce possible corruption in the process of drug selection and procurement. The first method is the establishment of the National Reimbursement Drug List (NRDL, 2000) and the Essential Drug List (EDL, 2009). The NRDL is established by a national medicine selection system. Drugs on the NRDL have a subsidized price, but this also means that these get higher scrutiny of their prices. As a part of the national reimbursed drug list, the essential drugs are selected to ensure the accessibility and quality of basic drugs available in health institutions[26]. The second regulation by the health department is the new program that centralizes purchase of pharmaceuticals and controls costs by public tenders, bidding, and auction processes as required by the China Food and Drug Administration since 2009[27]. (3) Finally, the National Health Bureau created a reporting scheme for commercial Bribery Records. As required by the National Health Bureau, regional health bureaus must blacklist "manufacturers, operators or distributors" involved in commercial bribery, and instruct health administrations to discipline responsible persons, including both people in the health institutions and companies[28].

In our literature review, we found that though much information has been accumulated on how to develop regulations and countermeasures that restrain medical corruption in various countries, there is little existing research that systematically examines the effects of these regulations on the elimination or alleviation of medical corruption from pharmaceutical firms. Thereby, with the understanding that Chinese leadership is combating the rampant corruption within its society, this study sought to assess whether China's reforms to curb medical corruption were effective. This

study can help improve and foster better therapeutic and practical innovations to combat medical corruption in the Chinese health sector. Additionally, we think this study may provide good suggestions to other developing countries that may be suffering from similar problems during their economic and social transition periods.

METHODS

Analytic framework

To examine the effects of existing countermeasures for curbing medical corruption, we formulated an interview instrument based on the Donabedian model[29]. According to the Donabedian model, information about the countermeasure programs can be drawn from three categories: structure, process, and outcomes. Questions designed for experts were related to the design of the regulations, their implementation, and their effectiveness. Main discussion questions were as follows:

- What do you think are the regulations for medical corruption in China?
- How would you describe each kind of regulation for curbing medical corruption, including its design, execution/implementation, and effectiveness in China?
- Can you identify any countermeasures in other countries that can help stop the medical corruption in China?

In addition, to support the evaluation, particularly the "outcome" section of the framework, we analyzed quantitative data of the current medical corruption in China.

Data source

Qualitative data

To evaluate the current countermeasures for medical corruption in China, we interviewed eight experts in health policy from universities in the city of Shanghai in the health policy area, and four officers in drug procurement agencies in Shanghai and Beijing, for a total of 12 voluntary participants. Interviews were conducted from March 1, 2017 to April 9, 2017.

Quantitative data

There is no specific and sound reporting system for medical corruption in China today. Therefore, in order to reflect the current state of institutional medical corruption in China, we referred to "China Judgements Online," an online database of case verdicts in the whole China. The database was established in 2010 by the Supreme People's Court contains case verdicts from every field. In the initial period when the system was established, only the serious verdicts released by the Supreme People's Court must be released. From 2013, the local and intermediate courts in different provinces were also encouraged to send verdicts to this system[30]. We retrieved case verdicts related to medical corruption that occurred from January 1, 2010 to December 31, 2016, using the keywords “medical,” “corruption,” and “health institution”. We chose to collect data starting from 2010, the year in which the online system was launched. We found that there were fewer released verdicts before the year 2013 than after, likely because the government did not make it compulsive to upload verdicts until 2013. Therefore, we discarded data before 2013 and used data from 2013 to 2016. We found a total of 856 related verdicts. Though the sample size was

relatively small, the data uploaded provide a representative sample from each province.

Data analysis

Two trained researchers analyzed the qualitative data using NVivo10 to sort the interview answers and the Donabedian model as an a priori organizational framework. Using a hierarchical coding structure, the researchers deductively identified all themes, then coded and analyzed those that were relevant. In addition, we conducted a literature review of medical corruption governance in both developing and developed countries so that to search for ideas to curb medical corruption in China.

When screening the verdicts from "China Judgements Online", we first eliminated duplicate cases. Second, we asked two of the authors who were health policy experts to carefully conduct a review of the verdicts. The criterion was that the included verdicts needed to depict institutional medical corruption, specifically relating to the procurement of drugs and devices. After conducting two rounds of review, we kept a total of 336 verdicts for descriptive analysis of the current status of medical corruption in China. In our analysis, we reviewed the year the verdict was released, the level of the court that decided the verdict, the amount of illegal money involved, the institutions of those bribed, and the period during which the corruption took place.

Ethics statement

All research activities were conducted with integrity and in line with generally accepted ethical principles. Verbal consent forms for participation and publication were obtained from all interviewees.

RESULTS

Qualitative evaluation on regulations for institutional medical corruption in China

Evaluation of fines and criminal penalties

Since its 2005 health reforms to restructure the health care system, China has strived to establish more effective laws to curb medical corruption. The experts interviewed stated that there were currently three major categories of countermeasures to oppose medical corruption in China. The experts agreed that imposing fines and criminal penalties was the easiest and best preventative measure to curb institutional medical corruption.

However, many experts also pointed out that this type of regulation was not ideal because it was poorly structured. Punitive policies for medical corruption, including fines and imprisonment, did not effectively restrain bribers, nor were they uniformly rigorous. For example, the fine amount set by the Anti-unfair Competition Law (1993), 10,000 RMB (approximately $1,450) and 200,000 RMB (approximately $29,000), is too small to effectively restrain bribers. Although the Anti-unfair Competition Law was newly amended in February 2017 to increase the fine amount to 10% to 30% of illegal revenue obtained, experts believe that this is still too small to be effective. Moreover, because firms usually pay these fines, bribers are not effectively deterred from conducting illegal activities. Additionally, penalties imposed on those making and accepting bribes are strikingly different depending on their affiliation to different types of institutions. Penalties are usually milder for parties associated with multinational firms compared to those associated with domestic firms. Lastly, individuals working in public health institutions (i.e. physicians) receive greater punishment than individuals working in private health institutions, as

they are regarded as civil servants of China.

Evaluation of related health policy regulations

a. The establishment of the National Reimbursement Drug List (NRDL) and the Essential Drug List (EDL)

The government created the National Reimbursement Drug List (NRDL) so it could select the highest therapeutic and cost-efficient drugs. Though being listed on the NRDL is positive development for drug producers, because listed drugs are paid completely or at least in part by China's Health Insurance Department, being listed also means that there is higher scrutiny of its prices. The Essential Drug List (EDL), as part of the NRDL, was established in 2009 with the purpose of selecting essential drugs to be made available in all public health facilities, with particular emphasis on elemental health institutions[26]. Additionally, health institutions are required to obey the "zero-profit drug" policy, meaning the EDL drugs must be sold at purchasing prices[5]. Experts said that by far, this policy helped proper prescription of drugs and further reduce the space for medical corruption.

However, most experts noted that regarding policy design, the main problem was that the initial established lists contained limited(i.e. for the EDL, there were only 307 kinds of drugs) kinds of drugs for the whole nation, and always needed big change in nearly all provinces. But the selection of drugs in various provinces was lack of scientific criteria. The experts proposed that when revising the list by province, new corruption space would easily come into being. Since the provincial selection was set by leaders in the health bureau without use of the necessary scientific processes and criteria, many pharmaceutical firms may have interfered in the process, leading to corruption. Many of the drugs on the NRDL that are not on the EDL can still be sold at prices 15%

higher than the purchasing price, which means health institutions, particularly hospitals, have opportunities to create alliances with pharmaceutical firms for illegal profits. Usually, hospitals will purchase drugs that are not on the NRDL if they generate profits.

b. The new program for centralized purchase of pharmaceuticals

Centralized purchase policy was proposed as early as 2000 as a means of restraining health institutions' power to directly negotiate and purchase drugs from the pharmaceutical companies. This policy set a separate third-party committee as the purchasing entity, though still usually affiliated with the health bureau. However, it was not well executed and many hospitals can still buy drugs directly. And not until 2009, the new centralized purchase policy was released by China's Ministry of Health and made specific regulations to shift purchasing power from public hospitals to the governments. Specifically, it is the provincial committees' obligation to select suppliers through a competitive bidding process and then distribute the products to all hospitals under their jurisdiction. According to the new policy, drugs are competitively tendered at the provincial levels. It is also reported that central purchasing programs at the provincial level have reduced drug prices by 30% in Beijing[31], 41% in Hebei[32], and 46% in Shandong[33].

Although studies showed that decreasing the cost of medicines might reduce the corruption space, experts pointed out there were still two problems with the purchasing committees. First, in many provinces, the committees that manage the purchasing platforms are not independent. Most of these committees are affiliated with the health bureau. In some areas, there is not even a formal committee in which the responsibilities are assumed by different departments under the health bureau. In this case, buck-passing would occur between various departments. Undoubtedly, this easily may lead to the monopoly. Experts proposed that if a central selection committee has the

monopoly power, then it's easy to see that medical firms may bribe key decision makers in the selection process. Second, experts indicated that there were defects in the criteria for bidding. Many indexes were difficult for bidding judges to quantify and evaluate. For instance, choices for judges in the index of clinical effect and security are typically listed as "obviously superior to others," "a little superior to others," "similar to others," and "worse than others." The lack of scientific and quantified standards provide chances for bidding judges to participate in corruption. Another major problem with the bidding criteria is that they usually overemphasize the weight of price. Sometimes, in order to win, bidding companies set bidding prices lower than actual cost prices of drugs. This may lead to the bidding companies reducing the quality of their drugs. For example, the cost price per kilo of the drug radix isatidiswas 3.7 RMB, but the bidding price was only 1.4 RMB—far lower than the actual cost. So the companies used the apple peel instead of radix isatidis. The principle of those with lower price win may also induce bidding companies to make the alliance to provide artificially lowered prices when bidding and share the profits afterwards, leading to a disruption of the competitive market balance.

Evaluation of reporting scheme for medical corruption in China

In late 2013, the Chinese central government responded that ethical regulations should be used to curb medical corruption. The "Establishment of Commercial Bribery Records in the Purchase and Sale of Medicines and devices" then came into being[28]. This reporting scheme for Commercial Bribery Records blacklists "manufacturers, operators or distributors" involved in commercial bribery, and instructs health administrative departments to discipline responsible persons, including physicians (who may lose their licenses).

However, experts noted that the biggest problem with this reporting scheme was that it was

poorly executed in the past few years. Only a few provinces have released the records of illegal commercial bribery, and of these limited released records, many were outdated. It remains to be seen if this policy will have real impact at the provincial and local levels from an ethical perspective.

Quantitative evaluation of regulations on institutional medical corruption in China

As shown in Table 2, although the Supreme People's Court of China required courts to report verdicts to the online system since 2010, we found that until 2013, there was only a small number of released verdicts. Most of the verdicts (80.06%) were from the Basic People's Courts. We were surprised to find that in most cases, bribes were above 100,000 RMB, and in 11.31% of the cases, individuals taking bribes received more than 1,000,000 RMB. Usually, individuals taking bribes were from public hospitals. Among these individuals were physicians, directors and deans of different departments, and officers from the health bureaus. In addition, most of the criminal activities reported had been undetected for a long time, with 58.53% of corruption behaviors lasting more than 5 years. This indicates that the inspection policies are not strict.

DISCUSSION

Our evaluation showed that while many of China's regulations on medical corruption operate well, they still have many problems. Compared to other countries implementing policies to curb medical corruption, China implements relatively mild penalties that do not abide by a "zero-tolerance" policy. In the United States, if pharmaceutical firms promoted drugs unlawfully, they will receive great fines. For instance, we can look to cases concerning atypical antipsychotics. In 2010, the multinational pharmaceutical company Astra-Zeneca paid $520 million for illegally

marketing the drug Seroquel for uses not approved by the Food and Drug Administration by paying kickbacks to physicians. In 2012, Johnson & Johnson settled for $1.2 billion on charges of off-label promotion and failure to disclose information on adverse reactions to the drug Risperdal[19]. According to Public Citizen[34], from 1991 to 2012, drug companies have paid $30 billion in criminal fines in the United States for Medicare fraud, unlawful drug promotion, kickbacks, monopoly practices, and the concealment of study findings. In China, the fines for medical corruption are much smaller. Even the shocking multinational case of GSK's bribery in 2013 ended with the highest fine being 30 billion RMB (approximately 4.36 billion US dollar) [35]. If the fine amounts are not significantly increased, it will remain profitable for drug companies to engage in corruption practices that undermine public health[3].

Although the Chinese government strived to reduce medical corruption by establishing the NRDL and EDL, our evaluation showed that without scientific and fair criteria for drug selection, it is difficult to resolve problems related to modifying these lists and with the defective bidding process. In many developed countries, health technology assessment has also been used to the selection of drug plans by comparing drug costs with their therapeutic benefits. This has become central in determining the prices of pharmaceutical products. Health technology assessment was also proven to be effective in establishing the modalities for access and reimbursement of drugs [22]. This technology makes evidence-based medicine (rather than marketing-based medicine) central to the architecture of the pharmaceutical market because it directly aligns financial incentives with improving health outcomes. Thereby, the health technology assessment should be applied to facilitate Chinese governments' decision making as soon as possible.

Our results showed that problems with the central purchasing program were related to the lack

of independent committees and the monopolies created by local health bureaus. To effectively solve these problems, many developed countries use marketization management of pharmaceutical products purchasing. Originated in the US, an entity called Group Purchasing Organization (GPO) is one kind of purchasing platform in the market. The GPO is created to leverage the purchasing power of a group of businesses to obtain discounts from vendors based on the collective buying power of the GPO members. The GPOs are intermediary agencies, and health organizations can voluntarily sign up to be a member of any GPO in US. It was found that GPO can help effectively prevent medical corruption[36]. However, while many large cities in China such as Shanghai and Beijing have tried to establish independent GPOs, still, it was not mature[37], which can't well functioned to curb the medical corruption.

Overall, the reason for improper use of drugs should also be attributed to physicians and patients. Physicians may be indifferent to high prices of drugs if prescribed pharmaceutical products or inspections make them profitable. Additionally, when patients buy pharmaceutical products on the NDRL, they rarely pay the full price themselves. To restrict the behaviors of physicians and patients, the health insurance department should not only supervise the current payment budget for public hospitals, but also design effective regulations to inspect authenticity of therapies [38]. In Germany, the United States, and other countries, insurance institutions, usually health insurance companies, can trace the behavior of physicians or hospitals. Most drug coverage systems in these countries can specify which drugs will be reimbursed through methods such as managing drug formularies or requiring generic products to be used when available[22]. Some states in the US now require the full disclosure of every payment received by physicians from drug companies[19]. These policies impose restriction on physicians.

Miller(2013) notes that companies initiate most corporate social responsibility initiatives to avoid negative reputational consequences that may induce greater burden than the illegal earned profits. Accreditation, certification, and rating systems have proven useful in curbing medical corruption to a certain extent, as these systems help align market forces with trustworthy practices[23]. However, under the "Guanxi" society where relationship plays an important role in China[39], the reporting system for medical corruption is not well executed. To improve this situation, we suggest that the adverse results should be made open to the public compulsorily.

As revealed by much of the literature, the root of institutional corruption lies first and foremost in the fact that physicians' remuneration is set at a low level in China[39-40]. Low compensation may lead to physicians taking significant payments for high-cost diagnostic and therapeutic interventions in China. Therefore, this issue must be tackled by improving the financial incentives for physicians and the moral environment within China's health reform. Finally, the main limitations of this study were related to the quantitative section. Though the quantitative data from the online system were helpful in supporting the qualitative data, the small sample size may have caused the low reliability error.

CONCLUSIONS

Our study found that though China has made efforts to tackle institutional medical corruption in drug procurement for many years, corruption issues continue to be a concern. In analyzing the current regulations, we found that existing countermeasures such as fines, imprisonment penalties, health policy regulations, and reporting schemes, still have many defects. We suggest creating more rigorous legislation and well-functioning administrative mechanisms that select drugs for the

NRDL or EDL and establish prices using scientific criteria. We also suggest more rigorously supervising health insurance departments in China. To address the root of medical corruption however, the financial structure of physicians' income should be adjusted within China's health reform.

Abbreviations

NRDL: National Reimbursement Drug List

EDL: Essential Drug List

Acknowledgements

We sincerely acknowledge and appreciate the interviewees and institutions' contributions to this study.

Funding

The design of this study was financially supported by the Shanghai Health Policy Program (2016HP043). Data collection, analysis and interpretation were funded by Key Developing Disciplines of Shanghai Municipal Commission of Health and Family Planning(2015ZB0602) and the International Postdoctoral Exchange Fellowship Program(2017(32)), and the writing and revision of the manuscript was funded by the Natural Science Foundation of China (71603182).

Authors' contributions

Conceived and designed the experiments: JWS, ZXW and LYS. Analysed the data: JWS, RL and CXW. Contributed reagents/materials/analysis tools: HJ, YX and NNL. Wrote the paper: JWS and LYS.

Data sharing statement

All relevant data from the "China Judgements Online" can be shared to the public.

Competing interests

The authors have declared that they have no competing interests.

REFERENCES

[1] Chattopadhyay S. Corruption in healthcare and medicine: Why should physicians and

bioethicists care and what should they do? Indian J Med Ethics, 2013; 10(3):153-159.

[2] Godlee F. Medical corruption in the UK.BMJ, 2015; 350.doi: https://doi.org/10.1136/bmj.h506.

[3] Rose-Ackerman S, Tan YQ. Corruption in the procurement of pharmaceutical and medical equipment in China: The incentives facing multinationals, domestic firms and hospital official. UCLA Pac Basin Law J, 2014; 32(1):1-53.

[4] Vian T. Corruption and the Health Sector. USAID and Management Systems Internationals, 2002.

[5] Chen Y, Dai T. International experience and revelation of the compensation mechanism reform of public hospitals. Chinese Hospital(Chinese Journal), 2011;15(7): 16-19.

[6] Chen Y, Zhu XL, Xiao LH. The theoretical and practical analysis on the finance compensation mechanism of public hospitals in China. Medicine and Society(Chinese Journal), 2010; 23(12):36-38.

[7] Zhang Y, Yu YS, Tang ZH, Chen XH, Zang GQ. Crack down on medical corruption: An urgent matter in China. Eur J Intern Med, 2014; 25(1):e2-e3.

[8] Editor. Doctors and pharma in China. Lancet, 2013;382:102.

[9] Manea T. Medical bribery and the ethics of trust: The Romanian case. J Med Philos, 2015, 40(1):26-43. doi: 10.1093/jmp/jhu049. Epub 2014 Dec 10.

[10] Elliott C. White coat, black hat: Adventures at the dark side of medicine. Boston: Beacon Press, 2010.

[11] Rodwin MA. Institutional corruption and the pharmaceutical policy. Legal Studies Research Paper Series 2013,12:13-25. Available from: http://ssrn.com/abstract=2298140.

[12] Gagnon MA, Lexchin J. The cost of pushing pills: A new estimate of pharmaceutical promotion

expenditures in the United States. PLoS Medicine, 2008; 5(1): 29-33.

[13] Yan A. 1,100 medical staff held over drug kickbacks in Zhangzhou. Available from: http://www.scmp.com/news/china/article/1290060/1100-medical-staff-held-overdrug-kickbacks-zhangzhou. [Accessed April 2, 2017].

[14] Rodwin MA. Conflicts of interest and the future of medicine(Oxford: Oxford University Press, 2011); Institute of Medicine, Conflicts of Interest in Medical Research, Education, and Practice. Washington, DC: National Academies Press, 2009.

[15] Mintzes B, Lexchin J, Sutherland JM, et al. Pharmaceutical sales representatives and patient safety: A comparative prospective study of information quality in Canada, France and the United States. J Gen Intern Med, 2013; 28(10): 1368-75.

[16] Dyer O. New report on corruption in health. Bulletin of the World Health Organization, 2006; 84: 81-160.

[17] Berger D. Corruption ruins the doctor-patient relationship in India. BMJ, 2014;348:g3169.

[18] Hesketh T, Wu D, Mao L, Ma N. Violence against doctors in China. BMJ, 2012;345:e5730.

[19] Gagnon MA. Corruption of pharmaceutical markets: Addressing the misalignment of financial incentives and public health. J Law Med Ethics, 2013;41(3):571-80. doi: 10.1111/jlme.12066.

[20] Baumol WJ. On taxation and the control of externalities. Am Econ Rev 1972; 62(3): 307-322.

[21] Lee JL, Fischer MA, Shrank WH, et al. A systematic review of reference pricing: Implications for US prescription drug spending. Am J Manag Care, 2012; 18(11): e429-437.

[22] Gorry P, Montalban M, Smith A. When medical science meets economics & politics: The institutionalization of health technology assessment within the European government of

pharmaceuticals. GEDI working paper, 2011.

[23] Miller JE. From bad pharma to good pharma: aligning market forces with good and trustworthy practices through accreditation, certification, and rating. J Law Med Ethics, 2013; 41(3):601-10. doi: 10.1111/jlme.12069.

[24] Transparency International. Global corruption report 2006: corruption and health. Available from: http://www.transparency.org/whatwedo/pub/global_corruption_report_2006_corruption_and_health.[Accessed April 2, 2017].

[25] Song DL. The defect of the current centralized pharmaceuticals purchase system and improvement. Southwest University of Political Science and Law. Master's Thesis(China). 2013.

[26] National Health and Family Planning Commission. Notification on implementing the national essential drug system. Available from: http://www.sda.gov.cn/WS01/CL0056/51391.html. [Accessed April 2, 2017].

[27] China Food and Drug Administration. Notification on further standardizing the centralized drug purchasing in medical institutions. Available from: http://www.sda.gov.cn/WS01/CL0056/35597.html. [Accessed April 2, 2017].

[28] National Health and Family Planning Commission. Provision on establishing adverse record of medical corruption in the health sector. Available from: http://www.nhfpc.gov.cn/fzs/s3577/201312/ef92cb05dee341a18fff7b3e00eb1156.shtml. [Accessed April 2, 2017].

[29] Donabedian A. The quality of care: How can it be assessed?. JAMA 1988;260 (12):

1743-8. doi:10.1001/jama.1988.03410120089033. PMID 3045356.

[30] China Judgements Online. Available from: http://wenshu.court.gov.cn/. [Accessed May 1, 2017].

[31] Wen R. The price of 519 drugs will be reduced 30% in Beijing and the central purchasing for EDL will take action. SohuNews(Sep 22, 2012). Available from: http://news.sohu.com/20120922/n353726981.shtml. [Accessed May 1, 2017].

[32] Geng J. Hebei's initiative central purchasing online made the price reduce significantly. Xinhua News (Dec 16, 2010). Available from: http://news.xinhuanet.com/health/2010-12/16/c_12888150.htm. [Accessed May 1, 2017].

[33] Wang K. Shandong's regular drugs in hospitals in counties reduced an average of 46.7%, Phoenix News (Jul 19, 2013). Available from: http://sd.ifeng.com/news/fengguanqilu/detail_2013_07/19/1010704_0.shtml. [Accessed May 1, 2017].

[34] Almashat S, Wolfe S. Pharmaceutical industry criminal and civil penalties: An update, report for public citizen, 2012, 27:1-50.

[35] Neville S. GlaxoSmithKline fined 3bn after bribing doctors to increase drugs sales. The Guardian(July 3, 2012). Available from:https://www.theguardian.com/business/2012/jul/03/glaxosmithkline-fined-bribing-doctors-pharmaceuticals. [Accessed May 1, 2017].

[36] DeBenedette V. The evolution of group purchasing organizations. Drug Topics (Oct 2016). Available from: http://drugtopics.modernmedicine.com/drug-topics/news/evolution-group-purchasing-org

anizations. [Accessed May 1, 2017].

[37] Liu ZY. Dispute on the drug purchase by using GPO. Health News(Chinese Newspaper, April 11, 2017). Available from: http://www.jkb.com.cn/news/depth/2017/0411/407607.html. [Accessed May 1, 2017].

[38] Hu J, Mossialos E. Pharmaceutical pricing and reimbursement in China: When the whole is less than the sum of its parts. Health Policy 2016;120(5):519-34. doi: 10.1016/j.healthpol.2016.03.014. Epub, 2016 Apr 12.

[39] Chen XY. Defensive medicine or economically motivated corruption? A Confucian reflection on physician care in China today. J Med Philos, 2007;32(6):635-648.

[40] Vian T, Nordberg C. Corruption in the health sector. Available from:www.u4.no/publications/corruption-in-the-health-sector-2/. 2008, U4 Issue: 1-87. [Accessed May 1, 2017].

Table 1 Experts' evaluation on existing countermeasures for restraining institutional medical corruption

	Countermeasures	Content	Structure	Process	Outcome
1	Fines and criminal penalties ruled by the "Penal Law"(Amended, 2006), the "Anti-unfair Competition Law"(1993), and the "Interim Provisions on Anti-commercial bribery"(1996)	Financial fines, imprisonment, and cancellation of physician licenses	(1)The fines are not high enough to effectively restrain bribery. (2)The punishment differs strikingly when bribers or bribees are in different institutions	(1) It is well implemented	(1) Imposing fines and criminal penalties is the easiest and most direct way to restrain medical corruption
2	Health policy regulations, especially those regarding drugs				
2.1	The establishment of the National Reimbursement Drug List (NRDL, 2000) and the Essential Drug List (EDL, 2009)	To select the most therapeutic and economical drugs by the government	(1)The initial lists are incomplete. The adjustment of the lists may induce corruption	(1) Many of the drugs on the NRDL can still be sold at prices higher than the purchasing price; (2) Hospitals will only purchase drugs that are not on the NRDL if they generate profits	(1) It makes the drugs on the lists under the government's high supervision; (2) The "zero-profit drug" policy for the EDL can shrink the benefit space
2.2	The new centralized purchase policy(2009)	Public tenders, bidding, and auction processes relating to the purchase of drugs are mostly operated by provincial governments	(1)Usually, the purchasing committee is affiliated with the health bureau, and purchasing decision is not made independently. Additionally, many areas have one purchasing institute, leading to monopoly of drug procurement (2)There are many defects in the selection criteria	(1) From 2009 according to the strict regulation by National Health Bureau, the purchasing of drugs or equipments has formal process for execution	(1) Shifting purchasing power from public hospitals to governments can reduce medical corruption to a large extent
3	Reporting scheme for medical corruption(2013)	Establishment of a reporting and record-keeping scheme of commercial bribery records	(1) The reporting scheme focuses on adverse behaviors. A comprehensive rating system to rating the companies' reputation should be established	(1)The reporting scheme is poorly implemented	(1) The public can be a constraint force for the corruption

Table 2 Verdicts involving institutional medical corruption from "China Judgements Online" (N=336)

Variable	Classification	n	(%)
Year of verdicts	2013	15	4.46
	2014	105	31.25
	2015	64	19.05
	2016	152	45.24
Level of the court	Supreme people's court	4	1.19
	Intermediate people's court	63	18.75
	Basic people's court	269	80.06
Amount of money involved in the bribery(RMB)	[14,900-100,000)	87	25.89
	[100,000-500,000)	164	48.81
	[500,000-1,000,000)	47	13.99
	[1,000,000-2,000,000)	16	4.76
	[2,000,000-6,959,000)	22	6.55
Institutions of individuals taking bribes	Hospitals	307	91.37
	Health bureaus	33	9.82
Time span of the committed corruption(year)	[1-2)	15	4.46
	[2-5)	124	36.90
	[5-10)	158	47.02
	[10-15]	39	11.61

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6-7
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8
Bias	9	Describe any efforts to address potential sources of bias	*9*
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8-9
		(*b*) Describe any methods used to examine subgroups and interactions	8-9
		(*c*) Explain how missing data were addressed	8-9
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	10-14
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	17-18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Moving towards a better path? A cross sectional examination of China's reforms to remedy medical corruption from pharmaceutical firms

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018513.R1
Article Type:	Research
Date Submitted by the Author:	28-Sep-2017
Complete List of Authors:	Shi, Jianwei; Shanghai Yangpu Hospital, Tongji University School of Medicine; Department of Health Policy and Management, Primary Care Policy Center, Johns Hopkins University Liu, Rui; Shanghai Tenth People's Hospital, Tongji University School of Medicine Jiang, Hua; Department of Family Medicine, Shanghai East Hospital, Tongji University School of Medicine Wang, Chunxu; Tongji University School of Medicine Xiao, Yue; Tongji University School of Medicine Liu, Nana; Tongji University School of Medicine Wang, Zhaoxin; Shanghai Tenth People's Hospital, Tongji University School of Medicine; Tongji University School of Medicine Shi, Leiyu; Department of Health Policy and Management, Primary Care Policy Center, Johns Hopkins University
Primary Subject Heading:	Ethics
Secondary Subject Heading:	Ethics, Health economics, Health services research
Keywords:	Medical corruption, Evaluation, Effectiveness, China

Moving towards a better path? A cross sectional examination of China's reforms to remedy medical corruption from pharmaceutical firms

Jianwei Shi, PhD[1,2#], Rui Liu[3#], Hua Jiang[4], Chunxu Wang[5], Yue Xiao[5], Nana Liu[5], Zhaoxin Wang[3,5]*, Leiyu Shi[2]*

1. Shanghai Yangpu Hospital, Tongji University School of Medicine, Shanghai, 200090, China

2. Department of Health Policy and Management, Primary Care Policy Center, Johns Hopkins University, Baltimore, Maryland, 21205, USA

3. Shanghai Tenth People's Hospital, Tongji University School of Medicine, Shanghai, 200072, China

4. Department of FamilyMedicine, Shanghai East Hospital, Tongji University School of Medicine, Shanghai, China

5. Tongji University School of Medicine, Shanghai, 200092, China

Jianwei Shi: shijianwei_amy@126.com

Rui Liu: liurui@tongji.edu.cn

Hua Jiang: Huajiang2013@tongji.edu.cn

Chunxu Wang: chunxuchn@163.com

Yue Xiao: 18817554320@163.com

Nana Liu: stonenn@163.com

Zhaoxin Wang: supercell002@sina.com

Leiyu Shi: lshi2@jhu.edu

 # These authors are co-first authors on this paper.

***These authors are co-corresponding authors on this work.**

Corresponding author1: Zhaoxin Wang, 1239Si Ping RD, Shanghai, 200092, China, Email:supercell002@sina.com.

Corresponding author2: Leiyu Shi, 624North Broadway, Baltimore, MD 21205, USA. Email: lshi2@jhu.edu.

Moving towards a better path? A cross sectional examination of China's reforms to remedy medical corruption from pharmaceutical firms

ABSTRACT

Objectives: Few studies have systematically examined the effects of the existing regulations for alleviating corruption. This study assesses the effectiveness of China's reforms to curb medical corruption.

Methods: Using semi-structured key informant interviews, we designed the evaluation questions and examined the effect of the existing different kinds of countermeasures to oppose medical corruption based on the Donabedian model. Using the quantitative data from the online database of the "China Judgements Online", which lists the case verdicts related to medical corruption, we also showed the tendency, characteristics and seriousness of medical corruption in recent years.

Results: Since 1990s, China has implemented three main categories of countermeasures to oppose medical corruption: fines and criminal penalties, health policy regulations and reporting scheme policy. First, the level of fines and criminal penalties for medical corruption behaviors may not be sufficient. Second, health policy regulations are also insufficient because although the National Reimbursement Drug List(NRDL) and Essential Drug List(EDL) were implemented, they were incomplete and created more opportunities for corruption. Additionally, the new program that centralized the purchase of pharmaceuticals found that most purchasing committees were not independent, and the selection criteria for bidding lacked scientific evidence. Third, reporting

scheme for Commercial Bribery Records by the health bureau is executed poorly. Lastly, quantitative data from "China Judgements Online" showed no obvious decrease of institutional medical corruption in recent years, and most criminals committed crimes for a long time before getting caught.

Conclusions: Although existing countermeasures have exerted certain effects according to the Chinese experts, much improvement is needed. Fundamentally, financial incentives for hospitals/physicians and the health insurance system should be improved.

Keywords: Medical corruption; Evaluation; Effectiveness; China

Strengths and limitations

- This study systematically examined the effects of existing regulations for curbing medical corruption in China.
- Using mainly qualitative data from interviews with experts, supported by the quantitative data from "China Judgements Online" that release the case verdicts about medical corruption, this study examined the effects comprehensively.
- The main limitations of this study were related with its data collection, since the selected interviewed experts were mostly from Shanghai and the quantitative data from the online system had a small sample size.

INTRODUCTION

Medical corruption is pervasive across cultures and endemic in countries regardless if they are small or large, poor or rich, or capitalist or socialist[1-3]. Though medical corruption is costly for

all countries, it seems to be an especially prevalent problem in developing and transitional economies where public resources are scarce, such as China[4]. Since the China's reform and opening up policy in 1979, public hospitals in urban and rural areas have remained under central government ownership. However, they were required to undertake a large degree of responsibility for financing money and administering institutions. This responsibility for healthcare financing required hospitals to rely more on the sale of services, drug prescriptions, and medical examinations to produce revenues[5]. The National Development and Reform Commission's price guidelines for basic health services(routine examinations, surgeries, standard diagnostic tests, and pharmaceuticals in health institutions) required prices to be low enough so services would be affordable for patients. Moreover, hospitals were prohibited from earning more than 15% markup from regulated tests and drugs[6]. However, the privatization of healthcare financing combined with price regulation put most public hospitals in China at serious financial risk[5-6]. To compensate for the retrenchment of government health outlays, many public hospitals in China began to earn revenue illegally through alliances with the pharmaceutical firms to procure pharmaceuticals and medical equipment. Meanwhile, pharmaceutical companies prefer establishing special arrangements for the hospitals since competition with other pharmaceutical companies is costly. Since the penalty cost is much lower than the illegal profit, special arrangements with hospitals creates a win-win situation for both entities[7,8-9]. Gradually, medical bribery permeated the health sectors in China[7, 10].

The illicit bribery from pharmaceutical firms to hospitals and health professionals or officials can lead to the medical corruption. Usually, certain pharmaceutical firms' practices corrupt medical research, the production of medical knowledge, the practice of medicine, drug safety, and the

administration's oversight of pharmaceutical marketing, etc.[11]. It was estimated that in the United States, the pharmaceutical industry spent up to $42 billion in promotion every year, or on average, $61,000 per physician, to influence their prescribing habits and generate profits[12]. In China in the 2000s, numerous incidents regarding medical corruption emerged and exposed the severity of corruption in China's healthcare industry[7]. For instance, in 2013, all public hospitals in Zhangzhou, Fujian Province were reported to be involved in medical corruption. A total of 1,088 doctors and 133 administrators from 73 hospitals in Zhangzhou were found to be taking bribes and kickbacks from pharmaceutical firms that amounted to $3.34 million[13]. In this study, we focused on the type of medical corruption resulting from pharmaceutical firm practices. Usually, the interactions between pharmaceutical companies and hospitals or physicians are guided by their financial interests, and can be in the form of drug or device promotion, kickbacks, and/or financial incentives to influence physician prescribing behaviors[14-15]. Studies showed that medical corruption negatively impacts the health care system by undermining the quality of healthcare, leading to inappropriate treatments, raising the cost of care, and damaging physician-patient relationships[10, 6-18].

Confronted with severe medical corruption, many countries have implemented various anti-corruption strategies, such as fines and penalties[19], reform of tax policy for pharmaceutical companies[20], health regulations by insurance institutions(i.e. new forms of prescription drug pricing)[9, 21-22], and improvement of accreditation, certification, and rating systems[23-24]. However, due to the varying characteristics of health systems and severity of medical corruption in different countries, the solutions usually differ by country. In China, the government began implementing a wave of activities to combat medical corruption as early as 1990s. In detail, there

are three categories of solutions: fines and criminal penalties, health policy regulations and reporting scheme policy. Specifically, (1)the fines and criminal penalties created by legal and regulatory bodies, such as the "Penal Law"(Amended, 2006), "Anti-unfair Competition Law"(1993) and "Interim Provisions on Anti-commercial bribery"(1996)[25], as part of its health care reforms, (2)There are health policies that aim to reduce possible corruption in the process of drug selection and procurement, including the establishment of the National Reimbursement Drug List(NRDL, 2000) and the Essential Drug List(EDL, 2009). The NRDL was established by a national medicine selection system. Drugs on the NRDL have a subsidized price, but are also highly scrutinized. As a part of the national reimbursed drug list, the essential drugs are selected to ensure the accessibility and quality of basic drugs available in health institutions[26]. The second regulation by the health department is the new program required by the China Food and Drug Administration since 2009[27]. The program centralizes purchase of pharmaceuticals and controls costs by public tenders, bidding, and auction processes. (3) Finally, the National Health Bureau created a reporting scheme for commercial bribery records. Regional health bureaus must blacklist "manufacturers, operators or distributors" involved in commercial bribery, and instruct health administrations to discipline responsible persons in the health institutions and pharmaceutical companies[28].

Though much information has been accumulated on how to develop regulations and countermeasures that restrain medical corruption in various countries[1-2,4,8,11], there is little research systematically examines the effects of these regulations on the elimination or alleviation of medical corruption from pharmaceutical firms specifically. Thereby, with the understanding that Chinese leadership is combating rampant corruption within its society, this study sought to

assess whether China's reforms to curb medical corruption were effective in the procurement of medicines and devices. This study can help improve and foster better therapeutic and practical innovations to combat medical corruption in the Chinese health sector. Additionally, we think this study may provide recommendations to other developing countries that may be suffering from similar problems during economic and social transition periods.

METHODS

Analytic framework

Through literature review, we collected various forms of countermeasures. Additionally, we consulted with the experts to reveal other regulations for medical corruption in China that were not exposed through the literature review to ensure the completeness of these countermeasures. These measures were then classified into three categories, with help from experts, based on the rigidity of implementation. Fines and criminal penalties were executed by the law sectors in which the punishments were very strict. Health policy regulations were issued by the national or local health departments and usually provided guidance. The reporting scheme for the medical corruption was not strict and its execution was loosely implemented.

Second, to examine the effects of existing countermeasures for curbing medical corruption, we formulated an interview instrument based on the Donabedian model[29]. The Donabedian model provides a framework to evaluate the effects of countermeasures on curbing medical corruption in three categories: structure, process, and outcomes. Questions designed for experts were related to the design of the regulations(structure), their implementation(process), and their

effectiveness(outcomes). Main discussion questions about the evaluation were as follows: How would you describe each kind of regulation for curbing medical corruption, including its design, execution/implementation, and effectiveness in China?

In addition, to support the evaluation, particularly the "outcome" section of the framework, we analyzed quantitative data of current medical corruption in China. Experts were also asked to identify any countermeasures in other countries that can help end medical corruption in China.

Data source

Qualitative data

To evaluate the current countermeasures for medical corruption in China, we chose experts that attended a professional forum in Shanghai about preventing and curbing medical corruption. All 16 interviewees were experts in the field of health economics and health policy. However, only 12 of the experts agreed to participate. Eight experts were from universities in the city of Shanghai, and four experts were officers in drug procurement agencies in Shanghai and Beijing. Interviews were conducted from March 1, 2017 to April 9, 2017.

Quantitative data

There is no specific and sound reporting system for medical corruption in China currently. Therefore, to reflect the current state of medical corruption in China, we referred to "China Judgements Online," a national online database of case verdicts. The database, established in 2010 by the Supreme People's Court, contains case verdicts from every field. When the system was

initially established, only the serious verdicts released by the Supreme People's Courtwere required to be released. As of 2013, the local and intermediate courts in different provinces were also encouraged to send verdicts to this system[30]. We retrieved case verdicts related to medical corruption that occurred from January 1, 2010 to December 31, 2016 using the keywords "medical," "corruption," and "health institution". We collected data starting from 2010, the year in which the online system was launched. However, since the government did not require verdicts to be uploaded into the system until 2013, we discarded data before 2013 and used data from 2013 to 2016. We found a total of 856 related verdicts. Though the sample size of the verdicts online was relatively small, the data uploaded provided a representative sample from each province.

Data analysis

Two trained researchers analyzed the qualitative data using NVivo10 to sort the interview answers. The Donabedian model was used as an a priori organizational framework. Using a hierarchical coding structure, the researchers deductively identified all themes, then coded and analyzed those that were relevant. In addition, we conducted a literature review of medical corruption governance in both developing and developed countries to search for methods to curb medical corruption in China.

When screening the verdicts from "China Judgements Online", we first eliminated duplicate cases. Second, we asked two of the authors(JWS and RL), who are health policy experts, to carefully conduct a review of the verdicts. As part of the criteria, verdicts needed to depict institutional medical corruption specifically relating to the procurement of drugs and devices. After conducting two rounds of review, we kept a total of 336 verdicts for descriptive analysis of the current status

of medical corruption in China. In our analysis, we reviewed the year the verdict was released, the level of the court that decided the verdict, the amount of illegal money involved, the institutions bribed, and the time period when the corruption took place.

Ethics statement

All research activities were conducted with integrity and in line with generally accepted ethical principles. Verbal consent forms for participation and publication were obtained from all interviewees.

RESULTS

Qualitative evaluation on regulations for institutional medical corruption in China

Evaluation of fines and criminal penalties

As early as 1990s, China has strived to establish more effective laws to curb medical corruption. In the 2000s, China implemented more health reforms to restructure the health care system. The experts interviewed stated that there were currently three major categories of countermeasures to oppose medical corruption in China(Table 1). The experts agreed that imposing fines and criminal penalties was the easiest and best preventative measure to curb institutional medical corruption.

However, many experts also pointed out that this type of regulation was poorly structured. Punitive policies for medical corruption, including fines and imprisonment, did not effectively restrain bribers, nor were they uniformly rigorous. For example, the fine amount set by the Anti-unfair Competition Law(1993), 10,000RMB(approximately $1,450) and 200,000RMB(approximately $29,000), was too small to effectively restrain bribers. Although the

Anti-unfair Competition Law was newly amended in February 2017 to increase the fine amount from 10% to 30% of illegal revenue obtained, experts believe that this fine is still too small to be effective. Moreover, because firms usually pay these fines, bribers are not effectively deterred from conducting illegal activities. Additionally, penalties imposed on those making and accepting bribes are strikingly different depending on their affiliation to different types of institutions. Penalties are usually milder for parties associated with multinational firms compared to those associated with domestic firms. Lastly, individuals working in public health institutions (i.e. physicians) receive greater punishment than individuals working in private health institutions, as they are regarded as civil servants of China.

Evaluation of related health policy regulations

a. The establishment of the National Reimbursement Drug List(NRDL) and the Essential Drug List(EDL)

The government created the National Reimbursement Drug List(NRDL) so it could select the highest therapeutic and cost-efficient drugs. Though being listed on the NRDL is a positive development for drug producers, being listed also means that there is higher scrutiny of its prices because listed drugs are paid completely or at least in part by China's Health Insurance Department. The Essential Drug List(EDL), as part of the NRDL, was established in 2009 with the purpose of selecting essential drugs to be made available in all public health facilities, with particular emphasis on grassroots health institutions[26]. Additionally, health institutions are required to obey the "zero-profit drug" policy, meaning the EDL drugs must be sold at purchasing prices[5]. Experts said that this policy helped proper prescription of drugs and further reduce the space for medical corruption to a certain extent.

Most experts noted that the main problem with this policy design was that the initial established lists contained limited(i.e. for the EDL, there were only 307 kinds of drugs) drugs for the whole nation, and varied widely between provinces. However, the selection of drugs in various provinces lacked scientific criteria. The experts proposed that when revising the list by province created opportunities for new corruption. Since the provincial selection was set by leaders in the health bureau without necessary scientific processes and criteria or effective supervision, it was easy for the pharmaceutical firm to interfere. For example, the selection of drugs was corrupt because pharmaceutical firms were able to bribe experts. Many of the drugs on the NRDL that are not on the EDL can still be sold at prices 15% higher than the purchasing price, which means health institutions, particularly hospitals, have opportunities to create alliances with pharmaceutical firms for illegal profits. Usually, hospitals will purchase drugs that are not on the NRDL if they generate profits.

b. The new program for centralized purchase of pharmaceuticals

Centralized purchase policy was proposed in 2000as a means of restraining health institutions' power to directly negotiate and purchase drugs from the pharmaceutical companies. This policy set a separate third-party committee as the purchasing entity that was usually affiliated with the health bureau. However, the policy was not properly executed and many hospitals were still able to buy drugs directly. A new centralized purchase policy was not released until 2009 by China's Ministry of Health that made specific regulations to shift purchasing power from public hospitals to the governments. Specifically, it is the provincial committees' obligation to select suppliers through a competitive bidding process and then distribute the products to all hospitals under their jurisdiction. According to the new policy, drugs are competitively offered at the provincial levels.

Central purchasing programs at the provincial level have reduced drug prices by 30% in Beijing[31], 41% in Hebei[32], and 46% in Shandong[33].

Although studies show that decreasing the cost of medicines might reduce corruption , experts pointed out there were still two problems with the purchasing committees. First, in many provinces, the committees that manage the purchasing platforms are not independent. Most of these committees are affiliated with the health bureau. In some areas, there is an informal committee in which the responsibilities are assumed by different departments under the health bureau. In this case, buck-passing would occur between various departments and could easily lead to a monopoly. Experts proposed that if a central selection committee has the monopoly power, then t medical firms may easily bribe key decision makers in the selection process. Secondly, experts indicated that there were defects in the criteria for bidding. Many indexes were difficult for bidding judges to quantify and evaluate. The lack of scientific and quantified standards provides chances for bidding judges to participate in corruption. Another major problem with the bidding criteria is that they usually overemphasize the weight of price. Sometimes, in order to win, bidding companies set bidding prices lower than actual cost prices of drugs. This may lead to the bidding companies reducing the quality of their drugs. For example, the cost price per kilo of the drug radix isatidiswas 3.7 RMB, but the bidding price was only 1.4 RMB—far lower than the actual cost. Thus, the company used apple peel instead of radix isatidis. Requiring companies to bid for the lowest price may artificially lowered prices and share profits afterwards, leading to a disruption of the competitive market.

Evaluation of reporting scheme for medical corruption in China

In late 2013, the Chinese central government stated that ethical regulations should be used to curb

medical corruption. The government created the "Establishment of Commercial Bribery Records in the Purchase and Sale of Medicines and Devices"[28]. This reporting scheme for Commercial Bribery Records blacklists "manufacturers, operators or distributors" involved in commercial bribery, and instructs health administrative departments to discipline responsible persons, including physicians, who may lose their licenses.

However, experts noted that the biggest problem with this reporting scheme was that it was poorly executed. Only a few provinces have released the records of illegal commercial bribery, and of which, many were outdated. It remains to be seen if this policy will have real impact at the provincial and local levels from an ethical perspective.

Quantitative evaluation of regulations on institutional medical corruption in China

As shown in Table 2, although the Supreme People's Court of China required courts to report verdicts to the online system since 2010, until 2013, there was only a small number of released verdicts. Most of the verdicts(80.06%) were from the Basic People's Courts. In most cases, bribes were above 100,000 RMB, and in 11.31% of the cases, bribes were more than 1,000,000 RMB. Usually, individuals, such as physicians, directors, deans of departments from public hospitals, and officers from the health bureaus, were taking bribes from pharmaceutical firms. In addition, most of the criminal activities reported had been undetected for a long time, with 58.53% of corruption behaviors lasting more than 5 years.

DISCUSSION

Our evaluation on the experts' interviews, supported by the quantitative data from "China

Judgements Online", showed that while many of China's regulations on medical corruption operate well, problems persist. Compared to other countries implementing policies to curb medical corruption, China implements relatively mild penalties that do not abide by a strict "zero-tolerance" policy. In the United States, if pharmaceutical firms promoted drugs unlawfully, they would receive great fines. For instance, we can look to cases concerning a typical antipsychotics. In 2010, the multinational pharmaceutical company Astra-Zeneca paid $520 million for illegally marketing the drug Seroquel for uses not approved by the Food and Drug Administration by paying kickbacks to physicians. In 2012, Johnson & Johnson settled for $1.2 billion on charges of off-label promotion and failure to disclose information on adverse reactions to the drug Risperdal[19]. According to Public Citizen[34], from 1991 to 2012, drug companies have paid $30 billion in criminal fines in the United States for Medicare fraud, unlawful drug promotion, kickbacks, monopoly practices, and the concealment of study findings. In China, the fines for medical corruption are much smaller. Even the shocking multinational case of GSK's bribery in 2013 ended with the highest fine being 30 billion RMB(approximately 4.36 billion US dollar)[35]. If the fine amounts are not significantly increased, it will remain profitable for drug companies to engage in corruption practices that undermine public health[3].

Although the Chinese government strived to reduce medical corruption by establishing the NRDL and EDL, our evaluation showed that without scientific and fair criteria for drug selection, it is difficult to resolve problems related to modifying these lists and the flawed bidding process. In many developed countries, health technology assessment has also been used to select drug plans by comparing drug costs with their therapeutic benefits. This has become central in determining the prices of pharmaceutical products. Health technology assessment was also proved to be

effective in establishing the modalities for access and reimbursement of drugs[22]. This technology makes evidence-based medicine(rather than marketing-based medicine) central to the architecture of the pharmaceutical market because it directly aligns financial incentives with improving health outcomes. Thereby, the health technology assessment should be applied to facilitate Chinese governments' decision-making as soon as possible.

Our results showed that problems with the central purchasing program were related to the lack of independent committees and the monopolies created by local health bureaus. To effectively solve these problems, many developed countries use marketization management of pharmaceutical products purchasing. Created in the US, an entity called Group Purchasing Organization(GPO) is one kind of purchasing platform in the market. The GPO leverages the purchasing power of a group of businesses to obtain discounts from vendors based on the collective buying power of the GPO members. The GPOs are intermediary agencies, and health organizations can voluntarily sign up to be a member of any GPO. It was found that GPOs can help effectively prevent medical corruption[36]. However, while many large cities in China such as Shanghai and Beijing have tried to establish independent GPOs[37], their efforts are still immature and thereby insufficient to curb medical corruption.

Miller(2013) notes that companies initiate most corporate social responsibility initiatives to avoid negative reputational consequences due to the illegal earned profits. Accreditation, certification, and rating systems have proven useful in curbing medical corruption to a certain extent, as these systems help align market forces with trustworthy practices[23]. However, since its execution is not supervised, the reporting system for medical corruption is not properly executed. To improve this situation, we suggest that companies should be required to be open transparent to the public

about the adverse results of their illegal activities.

As revealed by much of the literature, the root of difficulties to curb medical corruption may first lie in the financial pressure on public hospitals. The privatization of healthcare financing combined with price regulation put most public hospitals in China at serious financial risk. Under this condition, hospitals/physicians' remuneration is set at a low level in China[38-39]. Meanwhile, the financial subsidies for the public health institutions were not sufficient. For instance, the EDL was established to curb medical corruption and health institutions are required to obey the "zero-profit drug" policy on essential drugs. Fiscal policy also required local governments to provide enough subsidies to public health institutions. However, the fiscal subsidies were not sufficient or not provided by the local government in many parts of China[40]. All in all, although many of the countermeasures were proposed and implemented, under the background of financial pressure, the consistent low compensation may lead to hospitals/physicians receiving bribes from pharmaceutical companies, since the penalty cost for both of them is much lower than the illegal profit[7,8-9]. Second, the weak Chinese insurance market may fuel medical corruption and weaken current countermeasures. The insurance market in China is composed of the social medical insurance provided by the government(90% coverage) and the private insurance(<10% coverage)[41]. However, because many of the drugs, especially the imported drugs from multinational corporations, are not on the NRDL and are not covered by the social medical insurance, and exacerbated by the weak private insurance in China, there is room for corrupt payoffs to be added into the price of many of these drugs. For instance, usually, patients are willing to pay more for foreign drugs than for ones from domestic suppliers[3]. Therefore, these issues must be tackled by improving the proper financial incentives for hospitals/physicians and

perfecting the health insurance system within China's health reform.

There were a few limitations to this study. First, there may be selection bias since the selected experts were mostly from Shanghai. Second, though the quantitative data from the online system "China Judgements Online" were helpful in supporting the qualitative data, the small sample size of the released verdicts about medical corruption may not accurately reflect the effects of the current countermeasures. More data is needed to conduct a more robust evaluation.

CONCLUSIONS

Our study found that though China has made efforts to tackle institutional medical corruption in drug procurement for many years, corruption issues continue to be a concern. In analyzing the qualitative material on the subject by Chinese health policy experts and quantitative data from the online database, we found that existing countermeasures such as fines, imprisonment penalties, health policy regulations, and reporting schemes, still have many defects. We suggest creating more rigorous legislation and well-functioning administrative mechanisms to select drugs for the NRDL or EDL and to establish prices using scientific criteria. To address the root of medical corruption however, we suggest improving the financial incentives for hospitals/physicians and the health insurance system within China's health reform.

Abbreviations

NRDL: National Reimbursement Drug List

EDL: Essential Drug List

Acknowledgements

We sincerely acknowledge and appreciate the interviewees and institutions' contributions to this study.

Funding

The design of this study was financially supported by the Shanghai Health Policy Program(2016HP043). Data collection, analysis and interpretation were funded by Key Developing Disciplines of Shanghai Municipal Commission of Health and Family Planning(2015ZB0602) and the International Postdoctoral Exchange Fellowship Program(2017(32)), and the writing and revision of the manuscript was funded by the Natural Science Foundation of China (71603182).

Authors' contributions

Conceived and designed the experiments: JWS, ZXW and LYS. Analysed the data: JWS, RL and CXW. Contributed reagents/materials/analysis tools: HJ, YX and NNL. Wrote the paper: JWS and LYS.

Data sharing statement

All relevant data from the "China Judgements Online" can be shared to the public.

Competing interests

The authors have declared that they have no competing interests.

REFERENCES

[1]Chattopadhyay S. Corruption in healthcare and medicine: Why should physicians and bioethicists care and what should they do? Indian J Med Ethics, 2013; 10(3):153-159.

[2]Godlee F. Medical corruption in the UK.BMJ, 2015; 350.doi: https://doi.org/10.1136/bmj.h506.

[3]Rose-Ackerman S, Tan YQ. Corruption in the procurement of pharmaceutical and medical equipment in China: The incentives facing multinationals, domestic firms and hospital official. UCLA Pac Basin Law J,2014; 32(1):1-53.

[4]Vian T. Corruption and the Health Sector. USAID and Management Systems Internationals, 2002.

[5]Chen Y, Dai T. International experience and revelation of the compensation mechanism reform of public hospitals. Chinese Hospital(Chinese Journal),2011;15(7): 16-19.

[6]Chen Y, Zhu XL, Xiao LH. The theoretical and practical analysis on the finance compensation mechanism of public hospitals in China. Medicine and Society(Chinese Journal), 2010;23(12):36-38.

[7] Zhang Y, Yu YS, Tang ZH, Chen XH, Zang GQ. Crack down on medical corruption: An urgent matter in China. Eur J Intern Med, 2014; 25(1):e2-e3.

[8] Manea T. Medical bribery and the ethics of trust: The Romanian case. J Med Philos, 2015, 40(1):26-43. doi: 10.1093/jmp/jhu049. Epub 2014 Dec 10.

[9]Elliott C. White coat, black hat: Adventures at the dark side of medicine. Boston: Beacon Press, 2010.

[10] Editor. Doctors and pharma in China. Lancet, 2013;382:102.

[11]Rodwin MA. Institutional corruption and the pharmaceutical policy.Legal Studies Research Paper Series 2013,12:13-25. Available from: http://ssrn.com/abstract=2298140.

[12]Gagnon MA, Lexchin J. The cost of pushing pills: A new estimate of pharmaceutical promotion expenditures in the United States.PLoS Medicine, 2008; 5(1): 29-33.

[13]Yan A. 1,100 medical staff held over drug kickbacks in Zhangzhou. Available from: http://www.scmp.com/news/china/article/1290060/1100-medical-staff-held-overdrug-kick backs-zhangzhou. [Accessed April2, 2017].

[14]Rodwin MA. Conflicts of interest and the future of medicine(Oxford: Oxford University Press, 2011); Institute of Medicine, Conflicts of Interest in Medical Research, Education, and Practice. Washington, DC: National Academies Press, 2009.

[15]Mintzes B, Lexchin J, Sutherland JM, et al. Pharmaceutical sales representatives and patient safety: A comparative prospective study of information quality in Canada, France and the

United States. J Gen Intern Med, 2013; 28(10): 1368-75.

[16]Dyer O. New report on corruption in health. Bulletin of the World Health Organization,2006; 84: 81-160.

[17]Berger D. Corruption ruins the doctor-patient relationship in India. BMJ, 2014;348:g3169.

[18]Hesketh T, Wu D, Mao L, Ma N. Violence against doctors in China. BMJ, 2012;345:e5730.

[19]Gagnon MA. Corruption of pharmaceutical markets: Addressing the misalignment of financial incentives and public health. J Law Med Ethics, 2013;41(3):571-80. doi: 10.1111/jlme.12066.

[20]Baumol WJ. On taxation and the control of externalities.Am Econ Rev1972; 62(3): 307-322.

[21]Lee JL, Fischer MA, Shrank WH, et al. A systematic review of reference pricing: Implications for US prescription drug spending. Am J Manag Care, 2012; 18(11): e429-437.

[22]Gorry P, Montalban M, Smith A. When medical science meets economics & politics: The institutionalization of health technology assessment within the European government of pharmaceuticals. GEDI working paper, 2011.

[23]Miller JE. From bad pharma to good pharma: Aligning market forces with good and trustworthy practices through accreditation, certification, and rating. J Law Med Ethics, 2013; 41(3):601-10. doi: 10.1111/jlme.12069.

[24]Transparency International. Global corruption report 2006: Corruption and health. Available from: http://www. transparency.org/whatwedo/pub/global_corruption_report_2006_corruption_and_health.[Accessed April2, 2017].

[25]Song DL. The defect of the current centralized pharmaceuticals purchase system and

improvement. Southwest University of Political Science and Law. Master's Thesis(China). 2013.

[26]National Health and Family Planning Commission. Notification on implementing the national essential drug system. Available from: http://www.sda.gov.cn/WS01/CL0056/51391.html. [Accessed April2, 2017].

[27]China Food and Drug Administration. Notification on further standardizing the centralized drug purchasing in medical institutions. Available from: http://www.sda.gov.cn/WS01/CL0056/35597.html. [Accessed April2, 2017].

[28]National Health and Family Planning Commission. Provision on establishing adverse record of medical corruption in the health sector. Available from:http://www.nhfpc.gov.cn/fzs/s3577/201312/ef92cb05dee341a18fff7b3e00eb1156.shtml.[Accessed April2, 2017].

[29]Donabedian A. The quality of care: How can it be assessed?. JAMA1988;260 (12): 1743-8. doi:10.1001/jama.1988.03410120089033. PMID 3045356.

[30]China Judgements Online. Available from:http://wenshu.court.gov.cn/. [Accessed May 1, 2017].

[31]Wen R. The price of 519 drugs will be reduced 30% in Beijing and the central purchasing for EDL will take action. SohuNews(Sep 22, 2012).Available from: http://news.sohu.com/20120922/n353726981.shtml. [Accessed May 1, 2017].

[32]Geng J. Hebei's initiative central purchasing online made the price reduce significantly. Xinhua News (Dec 16, 2010). Available from: http://news.xinhuanet.com/health/2010-12/16/c_12888150.htm.[Accessed May 1, 2017].

[33]Wang K. Shandong's regular drugs in hospitals in counties reduced an average of 46.7%, Phoenix News (Jul 19, 2013). Available from: http://sd.ifeng.com/news/fengguanqilu/detail_2013_07/19/1010704_0.shtml.[Accessed May 1, 2017].

[34]Almashat S, Wolfe S. Pharmaceutical industry criminal and civil penalties: An update, report for public citizen, 2012, 27:1-50.

[35]Neville S. GlaxoSmithKline fined 3bn after bribing doctors to increase drugs sales. The Guardian(July 3, 2012). Available from:https://www.theguardian.com/business/2012/jul/03/glaxosmithkline-fined-bribing-doctors-pharmaceuticals. [Accessed May 1, 2017].

[36]DeBenedette V. The evolution of group purchasing organizations. Drug Topics (Oct 2016). Available from: http://drugtopics.modernmedicine.com/drug-topics/news/evolution-group-purchasing-organizations. [Accessed May 1, 2017].

[37] Liu ZY. Dispute on the drug purchase by using GPO. Health News(Chinese Newspaper, April 11, 2017). Available from: http://www.jkb.com.cn/news/depth/2017/0411/407607.html. [Accessed May 1, 2017].

[38]Chen XY. Defensive medicine or economically motivated corruption? A Confucian reflection on physician care in China today. J Med Philos, 2007;32(6):635-648.

[39]Vian T, Nordberg C. Corruption in the health sector. Available from: www.u4.no/publications/corruption-in-the-health-sector-2/. 2008, U4 Issue: 1-87.[Accessed May 1, 2017].

[40]Li YH. Evaluation on the implementation of zero-profit essential medicines in health care institutions of one province in China. Dalian Medical University. Master's thesis(China). 2015.

[41]Li J. A Research on the model of the private insurance companies' participation in administrating social medical insurance. Southwestern University of Finance and Economics. Master's thesis(China). 2012.

512 Table 1 Experts' evaluation on existing countermeasures for restraining institutional medical corruption

	Countermeasures	Content	Structure	Process	Outcome
1	Fines and criminal penalties ruled by the "Penal Law"(Amended, 2006), the "Anti-unfair Competition Law"(1993), and the "Interim Provisions on Anti-commercial bribery"(1996)	Financial fines, imprisonment, and cancellation of physician licenses	(1)The fines are not high enough to effectively restrain bribery. (2)The punishment differs strikingly when bribers or bribees are in different institutions	(1)It is well implemented	(1)Imposing fines and criminal penalties is the easiest and most direct way to restrain medical corruption
2	Health policy regulations, especially those regarding drugs				
2.1	The establishment of the National Reimbursement Drug List (NRDL,2000) and the Essential Drug List(EDL, 2009)	To select the most therapeutic and economical drugs by the government	(1)The initial lists are incomplete. The adjustment of the lists may induce corruption	(1)Many of the drugs on the NRDL can still be sold at prices higher than the purchasing price; (2)Hospitals will only purchase drugs that are not on the NRDL if they generate profits	(1) It makes the drugs on the lists under the government's high supervision; (2) The "zero-profit drug" policy for the EDL can shrink the benefit space
2.2	The new centralized purchase policy(2009)	Public tenders, bidding, and auction processes relating to the purchase of drugs are mostly operated by provincial governments	(1)Usually, the purchasing committee is affiliated with the health bureau, and purchasing decision is not made independently. Additionally, many areas have one purchasing institute, leading to monopoly of drug procurement (2)There are many defects in the selection criteria	(1)From 2009 according to the strict regulation by National Health Bureau, the purchasing of drugs or equipments has formal process for execution	(1)Shifting purchasing power from public hospitals to governments can reduce medical corruption to a large extent
3	Reporting scheme for medical corruption(2013)	Establishment of a reporting and record-keeping scheme of commercial bribery records	(1)The reporting scheme focuses on adverse behaviors. A comprehensive rating system to rating the companies' reputation should be established	(1)The reporting scheme is poorly implemented	(1)The public can be a constraint force for the corruption

Table 2 Verdicts involving institutional medical corruption from "China Judgements Online" (N=336)

Variable	Classification	n	(%)
Year of verdicts	2013	15	4.46
	2014	105	31.25
	2015	64	19.05
	2016	152	45.24
Level of the court	Supreme people's court	4	1.19
	Intermediate people's court	63	18.75
	Basic people's court	269	80.06
Amount of money involved in the bribery(RMB)	[14,900-100,000)	87	25.89
	[100,000-500,000)	164	48.81
	[500,000-1,000,000)	47	13.99
	[1,000,000-2,000,000)	16	4.76
	[2,000,000-6,959,000)	22	6.55
Institutions of individuals taking bribes	Hospitals	307	91.37
	Health bureaus	33	9.82
Time span of the committed corruption(year)	[1-2)	15	4.46
	[2-5)	124	36.90
	[5-10)	158	47.02
	[10-15]	39	11.61

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6-7
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8
Bias	9	Describe any efforts to address potential sources of bias	*9*
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8-9
		(*b*) Describe any methods used to examine subgroups and interactions	8-9
		(*c*) Explain how missing data were addressed	8-9
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	10-14
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	17-18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Moving towards a better path? A mixed-method examination of China's reforms to remedy medical corruption from pharmaceutical firms

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018513.R2
Article Type:	Research
Date Submitted by the Author:	06-Dec-2017
Complete List of Authors:	Shi, Jianwei; Shanghai Tenth People's Hospital, Tongji University School of Medicine; Department of Health Policy and Management, Primary Care Policy Center, Johns Hopkins University Liu, Rui; Shanghai Tenth People's Hospital, Tongji University School of Medicine Jiang, Hua; Department of Family Medicine, Shanghai East Hospital, Tongji University School of Medicine Wang, Chunxu; Tongji University School of Medicine Xiao, Yue; Tongji University School of Medicine Liu, Nana; Tongji University School of Medicine Wang, Zhaoxin; Shanghai Tenth People's Hospital, Tongji University School of Medicine; Tongji University School of Medicine Shi, Leiyu; Department of Health Policy and Management, Primary Care Policy Center, Johns Hopkins University
Primary Subject Heading:	Ethics
Secondary Subject Heading:	Ethics, Health economics, Health services research
Keywords:	Medical corruption, Evaluation, Effectiveness, China

Moving towards a better path? A mixed-method examination of China's reforms to remedy medical corruption from pharmaceutical firms

Jianwei Shi[1,2#], Rui Liu[1#], Hua Jiang[3], Chunxu Wang[4], Yue Xiao[4], Nana Liu[4], Zhaoxin Wang[1,4]*, Leiyu Shi[2]*

1. Shanghai Tenth People's Hospital, Tongji University School of Medicine, Shanghai, 200072, China

2. Department of Health Policy and Management, Primary Care Policy Center, Johns Hopkins University, Baltimore, Maryland, 21205, USA

3. Department of Family Medicine, Shanghai East Hospital, Tongji University School of Medicine, Shanghai, 200120, China

4. Tongji University School of Medicine, Shanghai, 200092, China

Jianwei Shi: shijianwei_amy@126.com

Rui Liu: liurui@tongji.edu.cn

Hua Jiang: Huajiang2013@tongji.edu.cn

Chunxu Wang: chunxuchn@163.com

Yue Xiao: 18817554320@163.com

Nana Liu: stonenn@163.com

Zhaoxin Wang: supercell002@sina.com

Leiyu Shi: lshi2@jhu.edu

These authors are co-first authors on this paper.

* **These authors are co-corresponding authors on this work.**

Corresponding author1: Zhaoxin Wang, 1239 Si Ping RD, Shanghai, 200092, China, Email: supercell002@sina.com.

Corresponding author2: Leiyu Shi, 624 North Broadway, Baltimore, MD 21205, USA. Email: lshi2@jhu.edu.

Moving towards a better path? A mixed-method examination of China's reforms to remedy medical corruption from pharmaceutical firms

ABSTRACT

Objectives: Few studies have systematically examined the effects of the existing regulations for alleviating corruption in China. This study assesses the effectiveness of China's reforms to curb medical corruption.

Methods: We used mixed methods for the evaluation of existing countermeasures. First, qualitative informant interviews based on the Donabedian model were conducted to obtain experts' evaluation of various kinds of countermeasures. Second, by using data from "China Judgements Online", we analyzed the occurrence trend and characteristics of the medical corruption cases in recent years to reflect the overall effects of these countermeasures in China.

Results: Since 1990s, China has implemented three main categories of countermeasures to oppose medical corruption: fines and criminal penalties, health policy regulations, and reporting scheme policy. Information from the interviews showed that first, the level of fines and criminal penalties for medical corruption behaviors may not be sufficient. Second, health policy regulations are also insufficient. Although the National Reimbursement Drug List(NRDL) and Essential Drug List(EDL) were implemented, they were incomplete and created additional opportunities for corruption. Moreover, the new program that centralized the purchase of pharmaceuticals found that most purchasing committees were not independent, and the selection criteria for bidding lacked scientific evidence. Third, reporting scheme for Commercial Bribery Records by the health

bureau was executed poorly. In addition, quantitative online data showed no obvious decrease of institutional medical corruption in recent years, and most criminals committed crimes for a long time before getting detected, which further demonstrated the low effectiveness of the above countermeasures.

Conclusions: Although existing countermeasures have exerted certain effects according to Chinese experts, more rigorous legislation and well-functioning administrative mechanisms are needed. Fundamentally, financial incentives for hospitals/physicians and the health insurance system should be improved.

Keywords: Medical corruption; Evaluation; Effectiveness; China

Strengths and limitations

- This study systematically examined the effects of existing regulations for curbing medical corruption in China.
- Using mainly qualitative data from interviews with experts, supported by the quantitative data from "China Judgements Online" that release the case verdicts about medical corruption, this study examined the effects comprehensively.
- The main limitations of this study were related with its data collection, since the selected interviewed experts were mostly from Shanghai and the quantitative data from the online system had a small sample size.

INTRODUCTION

Medical corruption is pervasive across cultures and endemic in countries regardless if they are

small or large, poor or rich, or capitalist or socialist[1-3]. Though medical corruption is costly for all countries, it seems to be an especially prevalent problem in developing and transitional economies where public resources are scarce, such as China[4]. Since the China's reform and opening up policy in 1979, public hospitals in urban and rural areas have remained under central government ownership. However, they were required to undertake a large degree of responsibility for financing money and administering institutions. This responsibility for healthcare financing required hospitals to rely more on the sale of services, drug prescriptions, and medical examinations to produce revenues[5]. The National Development and Reform Commission's price guidelines for basic health services(routine examinations, surgeries, standard diagnostic tests, and pharmaceuticals in health institutions) required prices to be low enough so services would be affordable for patients. Moreover, hospitals were prohibited from earning more than 15% markup from regulated tests and drugs[6]. However, the privatization of healthcare financing combined with price regulation put most public hospitals in China at serious financial risk[5-6]. To compensate for the retrenchment of government health outlays, many public hospitals in China began to earn revenue illegally through alliances with the pharmaceutical firms to procure pharmaceuticals and medical equipment[3,7,8]. Meanwhile, pharmaceutical companies prefer establishing special arrangements for the hospitals since competition with other pharmaceutical companies is costly. Since the penalty cost is much lower than the illegal profit, special arrangements with hospitals creates a win-win situation for both entities[7,9-10]. Gradually, medical bribery permeated the health sectors in China[7,8].

The illicit bribery from pharmaceutical firms to hospitals and health professionals or officials can lead to the medical corruption. Usually, certain pharmaceutical firms' practices corrupt medical

research, the production of medical knowledge, the practice of medicine, drug safety, and the administration's oversight of pharmaceutical marketing, etc.[11]. It was estimated that in the United States, the pharmaceutical industry spent up to $42 billion in promotion every year, or on average, $61,000 per physician, to influence their prescribing habits and generate profits[12]. In China in the 2000s, numerous incidents regarding medical corruption emerged and exposed the severity of corruption in China's healthcare industry[7]. For instance, in 2013, all public hospitals in Zhangzhou, Fujian Province were reported to be involved in medical corruption. A total of 1,088 doctors and 133 administrators from 73 hospitals in Zhangzhou were found to be taking bribes and kickbacks from pharmaceutical firms that amounted to $3.34 million[13]. In this study, we focused on the type of medical corruption resulting from pharmaceutical firm practices. Usually, the interactions between pharmaceutical companies and hospitals or physicians are guided by their financial interests, and can be in the form of drug or device promotion, kickbacks, and/or financial incentives to influence physician prescribing behaviors[14-15]. Studies showed that medical corruption negatively impacts the health care system by undermining the quality of healthcare, leading to inappropriate treatments, raising the cost of care, and damaging physician-patient relationships[8, 6-18].

Confronted with severe medical corruption, many countries have implemented various anti-corruption strategies, such as fines and penalties[19], reform of tax policy for pharmaceutical companies[20], health regulations by insurance institutions(i.e. new forms of prescription drug pricing)[10,21-22], and improvement of accreditation, certification, and rating systems[23-24]. However, due to the varying characteristics of health systems and severity of medical corruption in different countries, the solutions usually differ by country. In China, the government began

implementing a wave of activities to combat medical corruption as early as 1990s. In detail, there are three categories of solutions: fines and criminal penalties, health policy regulations and reporting scheme policy. Specifically, (1)the fines and criminal penalties created by legal and regulatory bodies, such as the "Penal Law"(Amended, 2006), "Anti-unfair Competition Law"(1993) and "Interim Provisions on Anti-commercial bribery"(1996)[25], as part of its health care reforms, (2)There are health policies that aim to reduce possible corruption in the process of drug selection and procurement, including the establishment of the National Reimbursement Drug List(NRDL, 2000) and the Essential Drug List(EDL, 2009). The NRDL was established by a national medicine selection system. Drugs on the NRDL have a subsidized price, but are also highly scrutinized. As a part of the national reimbursed drug list, the essential drugs are selected to ensure the accessibility and quality of basic drugs available in health institutions[26]. The second regulation by the health department is the new program required by the China Food and Drug Administration since 2009[27]. The program centralizes purchase of pharmaceuticals and controls costs by public tenders, bidding, and auction processes. (3) Finally, the National Health Bureau created a reporting scheme for commercial bribery records. Regional health bureaus must blacklist "manufacturers, operators or distributors" involved in commercial bribery, and instruct health administrations to discipline responsible persons in the health institutions and pharmaceutical companies[28].

Though much information has been accumulated on how to develop regulations and countermeasures that restrain medical corruption in various countries[1-2,4,9,11], there is little research that systematically examines the effects of these regulations on the elimination or alleviation of medical corruption from pharmaceutical firms specifically. Thereby, with the

understanding that Chinese leadership is combating rampant corruption within its society, this study sought to assess whether China's reforms to curb medical corruption were effective in the procurement of medicines and devices. This study can help improve and foster better therapeutic and practical innovations to combat medical corruption in the Chinese health sector. Additionally, we think this study may provide recommendations to other developing countries that may be suffering from similar problems during economic and social transition periods.

METHODS

Analytic framework

Through literature review, we collected various forms of countermeasures. Additionally, we consulted with the health system experts to reveal other regulations for medical corruption in China that were not exposed through the literature review to ensure the completeness of these countermeasures. These measures were then classified into three categories, with help from experts, based on the rigidity of implementation. Fines and criminal penalties were executed by the law sectors in which the punishments were very strict. Health policy regulations were issued by the national or local health departments and usually provided guidance. The reporting scheme for the medical corruption was not strict and its execution was loosely implemented.

Second, to examine the effects of existing countermeasures for curbing medical corruption, we formulated an interview instrument based on the Donabedian model[29]. The Donabedian model provides a framework to evaluate the effects of countermeasures on curbing medical corruption in three categories: structure, process, and outcomes. Questions designed for experts were related to

the design of the regulations(structure), their implementation(process), and their effectiveness(outcomes). Main discussion questions about the evaluation were as follows: How would you describe each kind of regulation for curbing medical corruption, including its design, execution/implementation, and effectiveness in China?

To quantitatively support the evaluation, we analyzed released online data of current medical corruption cases in China to reflect the overall effects of the countermeasures. In addition, experts were also asked to identify any countermeasures in other countries that can help end medical corruption in China.

Data source

Qualitative data

To evaluate the current countermeasures for medical corruption in China, we chose experts that attended a professional forum in Shanghai about preventing and curbing medical corruption. All sixteen interviewees were experts in the field of health economics and health policy. However, only twelve of the experts agreed to participate. Eight experts were from universities in the city of Shanghai, and four experts were officers in drug procurement agencies in Shanghai and Beijing. Interviews were conducted from March 1, 2017 to April 9, 2017.

Quantitative data

There is no specific and sound reporting system for medical corruption in China currently. Therefore, to reflect the current state of medical corruption in China, we referred to "China

Judgements Online," a national online database of case verdicts. The database, established in 2010 by the Supreme People's Court, contains case verdicts from every field. When the system was initially established, only the serious verdicts released by the Supreme People's Court were required to be released. As of 2013, the local and intermediate courts in different provinces were also encouraged to send verdicts to this system[30]. We retrieved case verdicts related to medical corruption that occurred from January 1, 2010 to December 31, 2016 using the keywords "medical," "corruption," and "health institution". We collected data starting from 2010, the year in which the online system was launched. However, since the government did not require verdicts to be uploaded into the system until 2013, we discarded data before 2013 and used data from 2013 to 2016. We found a total of 856 related verdicts and after selection, 336 verdicts relating to the procurement of drugs and devices were kept. Though the sample size of the verdicts online was relatively small, the data uploaded provided a representative sample from each province.

Data analysis

Two trained researchers analyzed the qualitative data using NVivo 10 to sort the interview answers. The Donabedian model was used as an a priori organizational framework. Using a hierarchical coding structure, the researchers deductively identified all themes, then coded and analyzed those that were relevant. In addition, we conducted a literature review of medical corruption governance in both developing and developed countries to search for methods to curb medical corruption in China.

When screening the verdicts from "China Judgements Online", we first eliminated duplicate cases. Second, we asked two of the authors(JWS and RL), who are health policy experts, to carefully

conduct a review of the verdicts. As part of the criteria, verdicts needed to depict institutional medical corruption specifically relating to the procurement of drugs and devices. After conducting two rounds of review, we kept a total of 336 verdicts for descriptive analysis of the current status of medical corruption in China. In our analysis, we reviewed the year the verdict was released, the level of the court that decided the verdict, the amount of illegal money involved, the institutions bribed, and the time period when the corruption took place.

Ethics statement

All research activities were conducted with integrity and in line with generally accepted ethical principles. Verbal consent forms for participation and publication were obtained from all interviewees.

RESULTS

Qualitative evaluation on regulations for institutional medical corruption in China

Evaluation of fines and criminal penalties

As early as 1990s, China has strived to establish more effective laws to curb medical corruption. In the 2000s, China implemented more health reforms to restructure the health care system. The experts interviewed stated that there were currently three major categories of countermeasures to oppose medical corruption in China(Table 1). The experts agreed that imposing fines and criminal penalties was the easiest and best preventative measure to curb institutional medical corruption.

However, many experts also pointed out that this type of regulation was poorly structured. Punitive policies for medical corruption, including fines and imprisonment, did not effectively

restrain bribers, nor were they uniformly rigorous. For example, the fine amount set by the Anti-unfair Competition Law(1993), 10,000 RMB(approximately $1,450) and 200,000 RMB(approximately $29,000), was too small to effectively restrain bribers. Although the Anti-unfair Competition Law was newly amended in February 2017 to increase the fine amount from 10% to 30% of illegal revenue obtained, experts believe that this fine is still too small to be effective. Moreover, because firms usually pay these fines, bribers are not effectively deterred from conducting illegal activities. Additionally, penalties imposed on those making and accepting bribes are strikingly different depending on their affiliation to different types of institutions. Penalties are usually milder for parties associated with multinational firms compared to those associated with domestic firms. Lastly, individuals working in public health institutions(i.e. physicians) receive greater punishment than individuals working in private health institutions, as they are regarded as civil servants of China.

Evaluation of related health policy regulations

a. The establishment of the National Reimbursement Drug List(NRDL) and the Essential Drug List(EDL)

The government created the National Reimbursement Drug List(NRDL) so it could select the highest therapeutic and cost-efficient drugs. Though being listed on the NRDL is a positive development for drug producers, being listed also means that there is higher scrutiny of its prices because listed drugs are paid completely or at least in part by China's Health Insurance Department. The Essential Drug List(EDL), as part of the NRDL, was established in 2009 with the purpose of selecting essential drugs to be made available in all public health facilities, with particular emphasis on grassroots health institutions[26]. Additionally, health institutions are

required to obey the "zero-profit drug" policy, meaning the EDL drugs must be sold at purchasing prices[5]. Experts said that this policy helped proper prescription of drugs and further reduce the space for medical corruption to a certain extent.

Most experts noted that the main problem with this policy design was that the initial established lists contained limited(i.e. for the EDL, there were only 307 kinds of drugs) drugs for the whole nation, and varied widely between provinces. However, the selection of drugs in various provinces lacked scientific criteria. The experts proposed that when revising the list by province created opportunities for new corruption. Since the provincial selection was set by leaders in the health bureau without necessary scientific processes and criteria or effective supervision, it was easy for the pharmaceutical firm to interfere. For example, the selection of drugs was corrupt because pharmaceutical firms were able to bribe experts. Many of the drugs on the NRDL that are not on the EDL can still be sold at prices 15% higher than the purchasing price, which means health institutions, particularly hospitals, have opportunities to create alliances with pharmaceutical firms for illegal profits. Usually, hospitals will purchase drugs that are not on the NRDL if they generate profits.

b. The new program for centralized purchase of pharmaceuticals

Centralized purchase policy was proposed in 2000 as a means of restraining health institutions' power to directly negotiate and purchase drugs from the pharmaceutical companies. This policy set a separate third-party committee as the purchasing entity that was usually affiliated with the health bureau. However, the policy was not properly executed and many hospitals were still able to buy drugs directly. A new centralized purchase policy was not released until 2009 by China's Ministry of Health that made specific regulations to shift purchasing power from public hospitals

to the governments. Specifically, it is the provincial committees' obligation to select suppliers through a competitive bidding process and then distribute the products to all hospitals under their jurisdiction. According to the new policy, drugs are competitively offered at the provincial levels. Central purchasing programs at the provincial level have reduced drug prices by 30% in Beijing[31], 41% in Hebei[32], and 46% in Shandong[33].

Although studies show that decreasing the cost of medicines might reduce corruption, experts pointed out there were still two problems with the purchasing committees. First, in many provinces, the committees that manage the purchasing platforms are not independent. Most of these committees are affiliated with the health bureau. In some areas, there is an informal committee in which the responsibilities are assumed by different departments under the health bureau. In this case, buck-passing would occur between various departments and could easily lead to a monopoly. Experts proposed that if a central selection committee had the monopoly power, then medical firms may easily bribe key decision makers in the selection process. Secondly, experts indicated that there were defects in the criteria for bidding. Many indexes were difficult for bidding judges to quantify and evaluate. The lack of scientific and quantified standards provides chances for bidding judges to participate in corruption. Another major problem with the bidding criteria is that they usually overemphasize the weight of price. Sometimes, in order to win, bidding companies set bidding prices lower than actual cost prices of drugs. This may lead to the bidding companies reducing the quality of their drugs. For example, the cost price per kilo of the drug radix isatidis was 3.7 RMB, but the bidding price was only 1.4 RMB - far lower than the actual cost. Thus, the company used apple peel instead of radix isatidis. Requiring companies to bid for the lowest price may artificially lowered prices and share profits afterwards, leading to a

disruption of the competitive market.

Evaluation of reporting scheme for medical corruption in China

In late 2013, the Chinese central government stated that ethical regulations should be used to curb medical corruption. The government created the "Establishment of Commercial Bribery Records in the Purchase and Sale of Medicines and Devices"[28]. This reporting scheme for Commercial Bribery Records blacklists "manufacturers, operators or distributors" involved in commercial bribery, and instructs health administrative departments to discipline responsible persons, including physicians, who may lose their licenses.

However, experts noted that the biggest problem with this reporting scheme was that it was poorly executed. Only a few provinces have released the records of illegal commercial bribery, and of which, many were outdated. It remains to be seen if this policy will have real impact at the provincial and local levels from an ethical perspective.

Quantitative evaluation of regulations on institutional medical corruption in China

As shown in Table 2, although the Supreme People's Court of China required courts to report verdicts to the online system since 2010, until 2013, there was only a small number of released verdicts. However, there was no obvious decrease of institutional medical corruption from 2013 to 2016. Most of the verdicts(80.06%) were from the Basic People's Courts. In most cases, bribes were above 100,000 RMB(74.11%), and in 11.31% of the cases, bribes were more than 1,000,000 RMB. Usually, more of the individuals(physicians, directors, deans of departments) who took bribes were from hospitals(91.37%). In addition, most of the criminal activities reported had been undetected for a long time, with 58.63% of corruption behaviors lasting five years or more before

being detected.

DISCUSSION

Our evaluation on the experts' interviews, supported by the quantitative data from "China Judgements Online", showed that while many of China's regulations on medical corruption operate well, problems persist. Compared to other countries implementing policies to curb medical corruption, China implements relatively mild penalties that do not abide by a strict "zero-tolerance" policy. In the United States, if pharmaceutical firms promoted drugs unlawfully, they would receive great fines. For instance, we can look to cases concerning a typical antipsychotics. In 2010, the multinational pharmaceutical company Astra-Zeneca paid $520 million for illegally marketing the drug Seroquel for uses not approved by the Food and Drug Administration by paying kickbacks to physicians. In 2012, Johnson & Johnson settled for $1.2 billion on charges of off-label promotion and failure to disclose information on adverse reactions to the drug of Risperdal[19]. According to Public Citizen[34], from 1991 to 2012, drug companies have paid $30 billion in criminal fines in the United States for Medicare fraud, unlawful drug promotion, kickbacks, monopoly practices, and the concealment of study findings. In China, the fines for medical corruption are much smaller. Even the shocking multinational case of GSK's bribery in 2013 ended with the highest fine being 30 billion RMB(approximately 4.36 billion US dollar)[35]. If the fine amounts are not significantly increased, it will remain profitable for drug companies to engage in corruption practices that undermine public health[3].

Although the Chinese government strived to reduce medical corruption by establishing the NRDL and EDL, our evaluation showed that without scientific and fair criteria for drug selection, it is

difficult to resolve problems related to modifying these lists and the flawed bidding process. In many developed countries, health technology assessment has also been used to select drug plans by comparing drug costs with their therapeutic benefits. This has become central in determining the prices of pharmaceutical products. Health technology assessment was also proved to be effective in establishing the modalities for access and reimbursement of drugs[22]. This technology makes evidence-based medicine(rather than marketing-based medicine) central to the architecture of the pharmaceutical market because it directly aligns financial incentives with improving health outcomes. Thereby, the health technology assessment should be applied to facilitate Chinese governments' decision-making as soon as possible.

Our results showed that problems with the central purchasing program were related to the lack of independent committees and the monopolies created by local health bureaus. To effectively solve these problems, many developed countries use marketization management of pharmaceutical products purchasing. Created in the US, an entity called Group Purchasing Organization(GPO) is one kind of purchasing platform in the market. The GPO leverages the purchasing power of a group of businesses to obtain discounts from vendors based on the collective buying power of the GPO members. The GPOs are intermediary agencies, and health organizations can voluntarily sign up to be a member of any GPO. It was found that GPOs can help effectively prevent medical corruption[36]. However, while many large cities in China such as Shanghai and Beijing have tried to establish independent GPOs[37], their efforts are still immature and thereby insufficient to curb medical corruption.

Miller(2013) notes that companies initiate most corporate social responsibility initiatives to avoid negative reputational consequences due to the illegal earned profits. Accreditation, certification,

and rating systems have proven useful in curbing medical corruption to a certain extent, as these systems help align market forces with trustworthy practices[23]. However, since its execution is not supervised, the reporting system for medical corruption is not properly executed. To improve this situation, we suggest that companies should be required to be open transparent to the public about the adverse results of their illegal activities.

As revealed by much of the literature, the root of difficulties to curb medical corruption may first lie in the financial pressure on public hospitals. The privatization of healthcare financing combined with price regulation put most public hospitals in China at serious financial risk. Under this condition, hospitals/physicians' remuneration is set at a low level in China[38-39]. Meanwhile, the financial subsidies for the public health institutions were not sufficient. For instance, the EDL was established to curb medical corruption and health institutions are required to obey the "zero-profit drug" policy on essential drugs. Fiscal policy also required local governments to provide enough subsidies to public health institutions. However, the fiscal subsidies were not sufficient or not provided by the local government in many parts of China[40]. All in all, although many of the countermeasures were proposed and implemented, under the background of financial pressure, the consistent low compensation may lead to hospitals/physicians receiving bribes from pharmaceutical companies, since the penalty cost for both of them is much lower than the illegal profit[7,9-10]. Second, the weak Chinese insurance market may fuel medical corruption and weaken current countermeasures. The insurance market in China is composed of the social medical insurance provided by the government(90% coverage) and the private insurance(<10% coverage)[41]. However, because many of the drugs, especially the imported drugs from multinational corporations, are not on the NRDL and are not covered by the social medical

insurance, and exacerbated by the weak private insurance in China, there is room for corrupt payoffs to be added into the price of many of these drugs. For instance, usually, patients are willing to pay more for foreign drugs than for ones from domestic suppliers[3]. Therefore, these issues must be tackled by improving the proper financial incentives for hospitals/physicians and perfecting the health insurance system within China's health reform.

There were a few limitations to this study. First, there may be selection bias since the selected experts were mostly from Shanghai. Second, though the quantitative data from the online system "China Judgements Online" were helpful in supporting the qualitative data, the small sample size of the released verdicts about medical corruption may not accurately reflect the effects of the current countermeasures. More data is needed to conduct a more robust evaluation.

CONCLUSIONS

Our study found that though China has made efforts to tackle institutional medical corruption in drug procurement for many years, corruption issues continue to be a concern. In analyzing the qualitative material on the subject by Chinese health policy experts and quantitative data from the online database, we found that existing countermeasures such as fines, imprisonment penalties, health policy regulations, and reporting schemes, still have many defects. We suggest creating more rigorous legislation and well-functioning administrative mechanisms to select drugs for the NRDL or EDL and to establish prices using scientific criteria. To address the root of medical corruption however, we suggest improving the financial incentives for hospitals/physicians and the health insurance system within China's health reform.

Abbreviations

NRDL: National Reimbursement Drug List

EDL: Essential Drug List

Acknowledgements

We sincerely acknowledge and appreciate the interviewees and institutions' contributions to this study.

Funding

The design of this study was financially supported by the Shanghai Health Policy Program(2016HP043). Data collection, analysis and interpretation were funded by Key Developing Disciplines of Shanghai Municipal Commission of Health and Family Planning(2015ZB0602) and the International Postdoctoral Exchange Fellowship Program(2017(32)), and the writing and revision of the manuscript was funded by the Natural Science Foundation of China(71603182).

Authors' contributions

Conceived and designed the experiments: JWS, ZXW and LYS. Analysed the data: JWS, RL and CXW. Contributed reagents/materials/analysis tools: HJ, YX and NNL. Wrote the paper: JWS and LYS. Revised the paper: JWS and LYS.

Data sharing statement

All relevant data from the "China Judgements Online" can be shared to the public.

Competing interests

The authors have declared that they have no competing interests.

REFERENCES

[1]Chattopadhyay S. Corruption in healthcare and medicine: Why should physicians and bioethicists care and what should they do? Indian J Med Ethics, 2013; 10(3):153-159.

[2]Godlee F. Medical corruption in the UK. BMJ, 2015; 350. doi: https://doi.org/10.1136/bmj.h506.

[3]Rose-Ackerman S, Tan YQ. Corruption in the procurement of pharmaceutical and medical equipment in China: The incentives facing multinationals, domestic firms and hospital official. UCLA Pac Basin Law J, 2014; 32(1):1-53.

[4]Vian T. Corruption and the Health Sector. USAID and Management Systems Internationals,

2002.

[5]Chen Y, Dai T. International experience and revelation of the compensation mechanism reform of public hospitals. Chinese Hospital(Chinese Journal), 2011;15(7): 16-19.

[6]Chen Y, Zhu XL, Xiao LH. The theoretical and practical analysis on the finance compensation mechanism of public hospitals in China. Medicine and Society(Chinese Journal), 2010;23(12):36-38.

[7]Zhang Y, Yu YS, Tang ZH, Chen XH, Zang GQ. Crack down on medical corruption: An urgent matter in China. Eur J Intern Med, 2014; 25(1):e2-e3.

[8]Editor. Doctors and pharma in China. Lancet, 2013;382:102.

[9]Manea T. Medical bribery and the ethics of trust: The Romanian case. J Med Philos, 2015, 40(1):26-43. doi: 10.1093/jmp/jhu049. Epub 2014 Dec 10.

[10]Elliott C. White coat, black hat: Adventures at the dark side of medicine. Boston: Beacon Press, 2010.

[11]Rodwin MA. Institutional corruption and the pharmaceutical policy. Legal Studies Research Paper Series, 2013;12:13-25.

[12]Gagnon MA, Lexchin J. The cost of pushing pills: A new estimate of pharmaceutical promotion expenditures in the United States. PLoS Medicine, 2008; 5(1): 29-33.

[13]Yan A. 1,100 medical staff held over drug kickbacks in Zhangzhou. Available from: http://www.scmp.com/news/china/article/1290060/1100-medical-staff-held-overdrug-kick backs-zhangzhou. [Accessed April2, 2017].

[14]Rodwin MA. Conflicts of interest and the future of medicine(Oxford: Oxford University Press, 2011); Institute of Medicine, Conflicts of Interest in Medical Research, Education, and

Practice. Washington, DC: National Academies Press, 2009.

[15]Mintzes B, Lexchin J, Sutherland JM, et al. Pharmaceutical sales representatives and patient safety: A comparative prospective study of information quality in Canada, France and the United States. J Gen Intern Med, 2013; 28(10): 1368-75.

[16]Dyer O. New report on corruption in health. Bulletin of the World Health Organization,2006; 84: 81-160.

[17]Berger D. Corruption ruins the doctor-patient relationship in India. BMJ, 2014;348:g3169.

[18]Hesketh T, Wu D, Mao L, Ma N. Violence against doctors in China. BMJ, 2012;345:e5730.

[19]Gagnon MA. Corruption of pharmaceutical markets: Addressing the misalignment of financial incentives and public health. J Law Med Ethics, 2013;41(3):571-80. doi: 10.1111/jlme.12066.

[20]Baumol WJ. On taxation and the control of externalities. Am Econ Rev1972; 62(3): 307-322.

[21]Lee JL, Fischer MA, Shrank WH, et al. A systematic review of reference pricing: Implications for US prescription drug spending. Am J Manag Care, 2012;18(11): e429-437.

[22]Gorry P, Montalban M, Smith A. When medical science meets economics & politics: The institutionalization of health technology assessment within the European government of pharmaceuticals. GEDI working paper, 2011.

[23]Miller JE. From bad pharma to good pharma: Aligning market forces with good and trustworthy practices through accreditation, certification, and rating. J Law Med Ethics, 2013; 41(3):601-10. doi: 10.1111/jlme.12069.

[24]Transparency International. Global corruption report 2006: Corruption and health. Available from: http://www.

transparency.org/whatwedo/pub/global_corruption_report_2006_corruption_and_health.[Accessed April 2, 2017].

[25]Song DL. The defect of the current centralized pharmaceuticals purchase system and improvement. Southwest University of Political Science and Law. Master's Thesis(China). 2013.

[26]National Health and Family Planning Commission. Notification on implementing the national essential drug system. Available from: http://www.sda.gov.cn/WS01/CL0056/51391.html. [Accessed April 2, 2017].

[27]China Food and Drug Administration. Notification on further standardizing the centralized drug purchasing in medical institutions. Available from: http://www.sda.gov.cn/WS01/CL0056/35597.html. [Accessed April2, 2017].

[28]National Health and Family Planning Commission. Provision on establishing adverse record of medical corruption in the health sector. Available from:http://www.nhfpc.gov.cn/fzs/s3577/201312/ef92cb05dee341a18fff7b3e00eb1156.shtml.[Accessed April2, 2017].

[29]Donabedian A. The quality of care: How can it be assessed?. JAMA,1988;260 (12): 1743-8. doi:10.1001/jama.1988.03410120089033. PMID 3045356.

[30]China Judgements Online. Available from: http://wenshu.court.gov.cn/. [Accessed May 1, 2017].

[31]Wen R. The price of 519 drugs will be reduced 30% in Beijing and the central purchasing for EDL will take action. Sohu News(Sep 22, 2012). Available from: http://news.sohu.com/20120922/n353726981.shtml. [Accessed May 1, 2017].

[32]Geng J. Hebei's initiative central purchasing online made the price reduce significantly. Xinhua News (Dec 16, 2010). Available from: http://news.xinhuanet.com/health/2010-12/16/c_12888150.htm. [Accessed May 1, 2017].

[33]Wang K. Shandong's regular drugs in hospitals in counties reduced an average of 46.7%, Phoenix News (Jul 19, 2013). Available from: http://sd.ifeng.com/news/fengguanqilu/detail_2013_07/19/1010704_0.shtml. [Accessed May 1, 2017].

[34]Almashat S, Wolfe S. Pharmaceutical industry criminal and civil penalties: An update, report for public citizen, 2012, 27:1-50.

[35]Neville S. GlaxoSmithKline fined 3bn after bribing doctors to increase drugs sales. The Guardian(July 3, 2012). Available from:https://www.theguardian.com/business/2012/jul/03/glaxosmithkline-fined-bribing-doctors-pharmaceuticals. [Accessed May 1, 2017].

[36]DeBenedette V. The evolution of group purchasing organizations. Drug Topics (Oct 2016). Available from: http://drugtopics.modernmedicine.com/drug-topics/news/evolution-group-purchasing-organizations. [Accessed May 1, 2017].

[37] Liu ZY. Dispute on the drug purchase by using GPO. Health News(Chinese Newspaper, April 11, 2017). Available from: http://www.jkb.com.cn/news/depth/2017/0411/407607.html. [Accessed May 1, 2017].

[38]Chen XY. Defensive medicine or economically motivated corruption? A Confucian reflection on physician care in China today. J Med Philos, 2007;32(6):635-648.

[39]Vian T, Nordberg C. Corruption in the health sector. Available from:www.u4.no/publications/corruption-in-the-health-sector-2/.2008, U4 Issue: 1-87.[Accessed May 1, 2017].

[40]Li YH. Evaluation on the implementation of zero-profit essential medicines in health care institutions of one province in China. Dalian Medical University. Master's thesis(China). 2015.

[41]Li J. A Research on the model of the private insurance companies' participation in administrating social medical insurance. Southwestern University of Finance and Economics. Master's thesis(China). 2012.

514 Table 1 Experts' evaluation on existing countermeasures for restraining institutional medical corruption

	Countermeasures	Content	Structure	Process	Outcome
1	Fines and criminal penalties ruled by the "Penal Law"(Amended, 2006), the "Anti-unfair Competition Law"(1993), and the "Interim Provisions on Anti-commercial bribery"(1996)	Financial fines, imprisonment, and cancellation of physician licenses	(1)The fines are not high enough to effectively restrain bribery; (2)The punishment differs strikingly when bribers or bribees are in different institutions	(1)It is well implemented	(1)Imposing fines and criminal penalties is the easiest and most direct way to restrain medical corruption
2	Health policy regulations, especially those regarding drugs				
2.1	The establishment of the National Reimbursement Drug List (NRDL, 2000) and the Essential Drug List(EDL, 2009)	To select the most therapeutic and economical drugs by the government	(1)The initial lists are incomplete. The adjustment of the lists may induce corruption	(1)Many of the drugs on the NRDL can still be sold at prices higher than the purchasing price; (2)Hospitals will only purchase drugs that are not on the NRDL if they generate profits	(1) It makes the drugs on the lists under the government's high supervision; (2) The "zero-profit drug" policy for the EDL can shrink the benefit space
2.2	The new centralized purchase policy(2009)	Public tenders, bidding, and auction processes relating to the purchase of drugs are mostly operated by provincial governments	(1)Usually, the purchasing committee is affiliated with the health bureau, and purchasing decision is not made independently. Additionally, many areas have one purchasing institute, leading to monopoly of drug procurement; (2)There are many defects in the selection criteria	(1)From 2009 according to the strict regulation by National Health Bureau, the purchasing of drugs or equipments has formal process for execution	(1)Shifting purchasing power from public hospitals to governments can reduce medical corruption to a large extent
3	Reporting scheme for medical corruption(2013)	Establishment of a reporting and record-keeping scheme of commercial bribery records	(1)The reporting scheme focuses on adverse behaviors. A comprehensive rating system to rating the companies' reputation should be established	(1)The reporting scheme is poorly implemented	(1)The public can be a constraint force for the corruption

Table 2 Verdicts involving institutional medical corruption from "China Judgements Online" (N=336)

Variable	Classification	n	(%)
Year of verdicts	2013	15	4.46
	2014	105	31.25
	2015	64	19.05
	2016	152	45.24
Level of the court	Supreme people's court	4	1.19
	Intermediate people's court	63	18.75
	Basic people's court	269	80.06
Amount of money involved in the bribery(RMB)	[14,900-100,000)	87	25.89
	[100,000-500,000)	164	48.81
	[500,000-1,000,000)	47	13.99
	[1,000,000-2,000,000)	16	4.76
	[2,000,000-6,959,000)	22	6.55
Institutions of individuals taking bribes	Hospitals	307	91.37
	Health bureaus	33	9.82
Time span of the committed corruption(year)	[1-2)	15	4.47
	[2-5)	124	36.90
	[5-10)	158	47.02
	[10-15]	39	11.61

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6-7
Methods			
Study design	4	Present key elements of study design early in the paper	7-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-9
Bias	9	Describe any efforts to address potential sources of bias	*9*
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	8-9
		(*c*) Explain how missing data were addressed	8-9
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	10-15
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15-18
Generalisability	21	Discuss the generalisability (external validity) of the study results	17-18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.