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A grounded theory study of patient safety culture in China: a framework and findings from six maternal and child health institutions

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ABSTRACT

Background Patient safety culture (PSC) is an issue highly concerned for Patient safety (PS) and quality services. Maternal and child health (MCH) is another issue of high concern globally and MCH institutions have been playing a core role in the hierarchical administrative network for MCH in China. The aim of this study was to fundamentally and theoretically explore the concept of PSC in China and build a framework of PSC in MCH institutions.

Methods A qualitative approach was conducted based on the grounded theory. Stratified purposive sampling methods were used to recruit participants from six MCH institutions in two provinces (Hebei and Beijing). A total of 118 participants (20 managers, 59 frontlines and 39 patients) were investigated through in-depth interviews. The transcript data were coding analyzed by using of NVivo 8.0 software.

Results PS was coded as six hierarchical levels: public security, medical safety, privacy and information security, financial security, psychological safety and demands been met. Patients were more likely to regard psychological safety and financial security which they felt directly. PSC was coded into two parts: the general module (11 dimensions and 61 items) and the MCH specific module (1 dimension and 8 items). Human factors (working perception, continuous learning and staffing) were highlighted by all groups, patient involvement was more valued by patients and the emerging dimension of provider's defensive behaviors was introduced into PSC in this study.

Conclusions The framework of PSC could be applied both in MCH institutions and in other institutions with the general module. Multi-conflicts among managers, frontlines, patients and the political and social environment were great threats for PS and PSC. Comprehensive strategies should be launched both within institutions and in a larger context to nourish a safer culture to ensure PS and quality healthcare delivery.

Strengths and limitations of this study

- This study used a grounded theory study to dig the concept of PSC in China and investigated a large sample for interviews.
- Coding validity and reliability were analyzed to guarantee the analyzing processing.
- Because of less patient safety events reported in interviews, the classification of PS was a rough cognitive pathway of progressive layers, but not an operational taxonomy to be used directly in practice.

INTRODUCTION

Patient safety (PS) was a key principle in medical practice. Patient safety culture (PSC), defined as 'the

shared values, beliefs, norms and procedures related to patient safety among members of the organization',[1] was a really relevant and important issue for PS highly concerned worldwide.[2-6] PS climate and PS attitudes were two related terms despite little differences from PSC. Culture was passed on and relatively enduring;[7] climate provided a snapshot of medical staff' perceptions of culture;[8 9] and attitudes referred to medical staff' attitudes and perceptions on PS.[10] PS culture, climate or attitudes, whatever name called, had been proved particularly effective to bring out safer behaviors, processes and outcomes in a growing body of literatures.[5 11-13]

Maternal and child health (MCH) was another highly-concerned issue all over the world. As a core role in the hierarchical administrative network for MCH, 3,071 MCH institutions had been established in China by the end of June 2016,[14] which mainly focused on four categories of MCH-related services: (1) maternity care: including premarital, progestational, pregnant, laboring, postpartum, etc; (2) children's care: including neonatal, growth and development, nutrition, mental health, ENT care, rehabilitation, diagnosis and treatment of children's common diseases, TCM applied in children's care, etc; (3) women's care: including adolescence care, menopause care, geriatric care, mental health, nutrition, breast care, diagnosis and treatment of women's common diseases, reproductive care, TCM applied in women's care, etc; (4)family planning: including health education, technical services, guides of prepotency, contraceptive distribution, information consultation, follow-up, reproductive care, trainings, etc.. Besides these MCH-related services, MCH institutions consisted of three levels: province-level, prefecture-level and county-level, which were responsible for MCH administrative management in the authority area, including health statistics, health education, development and promotion of appropriate technologies, trainings and supervisions of MCH services provided by other healthcare and medical institutions in the authority area.[15] A huge amount of policies, regulations, strategies, financial funding, researches and NGO activities had been devoted to strengthen infrastructures, equipments and devices, educations and trainings, standardized procedures and guidelines, network information, etc. to promote quality health services and PS.[16-18] However, little attention had been paid to PSC in MCH institutions.

Assessment tools were helpful to comprehend such an abstract concept of PSC. There had been several assessment tools developed and personified in various frameworks and dimensions. Among those tools, Hospital Survey on Patient Safety Culture (HSPSC),[19] Patient Safety Climate in Healthcare Organizations (PSCHO)[20] and Safety Attitudes Questionnaire (SAQ)[10] were more commonly applied and multi-versioned in a wide range of countries, institutions and departments.[21-23] All of three tools had been modified in Chinese versions.[24-28] Those existing tools had provided a variety of frameworks and dimensions on PSC for researchers and managers to evaluate and intervene in practice.

Nevertheless, it was still necessary to conduct such a grounded theory study on PSC of MCH institutions in China. Besides the specific characteristics of MCH institutions, the important reason was those Chinese versions had referred more to fixed frameworks in original editions than to culture itself in Chinese institutions. Since culture had the nature of profundity and abstruseness,[29] it was needed to fundamentally and theoretically dig the concept of PSC again and again, in order to nourish novel innovations and strategies for researchers and managers to pursue PS and quality improving.

The grounded theory could provide a qualitative approach from original data to general theory,[30] which was well suitable to building a theoretical framework of PSC of MCH institutions in China. It was worth mentioning that the significance of qualitative methodologies preferred blossoming 'new knowledge' than representativeness. What's more, just like many other PSC assessment tools for specific institutions or units,[31-33] the framework had been supposed to include two modules: one was

general module which could be generalized for other hospitals and medical institutions; the other was specific module which was specialized for MCH institutions.

METHODS

Setting and sample

This was a qualitative study based on the grounded theory approach, which had been carried out in 6 MCH institutions in two provinces (Hebei and Beijing), 3 institutions in per province. The filed investigation was conducted between November 2014 and April 2015. The general characteristics of these institutions were seen in Appendix Table 1.

In this study, stratified purposive sampling methods were applied to recruit participants. In each MCH institution, firstly all departments had been divided into 4-5 layers: administration departments (general office, medical administrative department, nursing administrative department, infection control unit, etc.), MCH clinic departments (pediatric, gynecological, obstetrical, NICU, etc.), MCH public health departments (children's health care, women's health care, preventive health care, etc.), auxiliary departments (pharmacy, ultrasound, radiology, laboratory, etc.) and non-MCH clinic departments (if any, like internal, surgery, dental, TCM, etc.).

Then, several administration managers, frontline staff (clinicians, nurses, public health professionals, midwives, auxiliaries, etc.) and patients (including caregivers of children) were recruited from each layer to individually participate into in-depth interviews. The sample size depended on whether reach to the endpoint of information saturation and no new topics emerged. A total of 118 participants were investigated in this study, including 20 (16.9%) administrative managers, 59 frontline staff (50.0%) and 39 (33.1%) patients. The general characteristics of these participants were seen in Appendix Table 2-3.

Data collection, processing and analysis

In-depth interviews were undertaken with care providers and patients to examine their perceptions of PS, behaviors and actions to ensure PS, attitudes and perspectives of PSC, and any experience or feeling regarding PS or PSC. Interview guides, which had been pre-tested and employed in an earlier study,[34] provided a prompt list of questions, but interviews were flexible, not limited to those questions.

With prior informed consent, each interview was conducted by trained-interviewers within 15-50 minutes, both audio-recorded and literal-recorded at the time. All audio records were transcribed verbatim, making literal records as supplementary when audio records were not clear.

The transcript data were then coding analyzed based on a grounded theory approach[30] by using of NVivo 8.0 software. The first step was initial coding, in which initial codes originated from raw data or even original words in order to reflect the panorama of data and were numerous. The second step was focused coding, in which focused codes condensed key themes of a paragraph materials. Finally, the third step was axial coding, in which axial codes were further abstracted into categories from scattered focused codes. In this study, for easy to comprehend and convenient for follow-up studies, 'item' and 'dimension' were adopted, respectively instead of 'focused code' and 'axial code'.

Coding validity and reliability

To assure the validity of coding, all transcript data were parallel coded by two researchers.[35 36] Firstly, two researchers respectively formed an original list of codes from the transcript data; then discussed

together and merged their original codes into an operational list of codes; subsequently according to the operational list of codes, respectively analyzed all transcript data; and finally discuss together again, adapt the operational codes and then merge their coding results into a framework of final codes. The modifying process of main dimensions coded by two parallel researchers could be seen in Appendix Figure 1.

The reliability of coding was tested as well. With a probability sampling ratio of 10% approximately, 12 cases of transcript data (including 2 administrative managers, 6 frontline staff and 4 patients) were randomly selected according to the randomized table. Using the final list of codes, two researchers respectively coded these 12 cases of transcript data again, and then merge their coding results together again. The reliability was indicated by percentage agreement (=number of agreed codes/number of all codes * 100%),[37 38] both comparing two researchers' codes in re-test and comparing between merged codes in pre-test and in re-test. The former was termed 'consistency reliability between researchers', ranging from 63.3% to 100% of each case; and the latter was termed 're-test reliability', ranging from 62.2%-82.5% of each case. Detailed reliability indictors were seen in Appendix Table 4.

RESULTS

Patient safety (PS)

In this study, *PS* was categorized into six hierarchical levels: public security as other public places, medical safety in the whole process of medical services provided, privacy and information security, financial security prevented from unnecessary interventions, psychological safety whether unsafe events happened or not, and demands been met or problems be solved. Managers and frontlines responded more emphasis on medical safety (65.0% and 52.5%) and public security (55.0% and 35.6%); however, patients responded more concerns on psychological safety whether unsafe events happened or not (53.8%) and financial security prevented from unnecessary interventions (38.5%). Detailed codes of *PS* in total and each group were seen in Table 1.

It could be seen that patients were more concerned with psychological safety and financial security which they felt directly, rather than medical safety and public security which they hardly involved unless relevant incidents had happened.

> *'Illness is a painful and stressful experience… I hope doctors or nurses alleviate my anxieties and doubts by their professional answers and supports in psychology.'(Patient)*
>
> *'I often encounter patients suffering from postnatal depression, with kinds of worries and fears… It may be more effective to psychologically comfort them, even a hug or a slightly tough, to make patients feel better, rather than to prescribe drugs.'(Frontline)*
>
> *'Some doctors would like to prescribe lots of pills, infusions and examinations, whether or not you should, just only for profit-making.' (Patient)*
>
> *'Taking this laboratory examination reporting sheet (in his hand) as an example, I would not feel safe if not listening to doctors to take such examination. My doctors read it and then told me 'it is okay and there is nothing to be worried', I felt safe at once no matter whether necessary to do it or how much money I paid.'(Patient)*

Table 1 Codes of patient safety in MCH institutions

Codes	Descriptions of codes	Providers(n1=79)		Patients (n4=39)	Total (N=118)
		Managers (n2=20)	Frontlines (n3=59)		
1.Public security	Incidents as happened in general public places, e.g. falls, fires, thefts of property and babies, etc.	11(55.0%)	21(35.6%)	5(12.8%)	37(31.4%)
2.Medical safety	Bias of diagnostic & treatment plans and unintended outcomes	13(65.0%)	31(52.5%)	9(23.1%)	53(44.9%)
3. Privacy and information security	Violation of privacy & disclosure of information	5(25.0%)	3(5.1%)	1(2.6%)	9(7.6%)
4. Financial security	Financial wastages due to unnecessary excessive diagnostic examinations, treatments and health care services	6(30.0%)	6(10.2%)	15(38.5%)	27(22.9%)
5. Psychological safety	Worry or anxious of above unsafe events due to any reason, no matter whether happened or not	5(25.0%)	10(16.9%)	21(53.8%)	36(30.5%)
6. Demands be met	Health demands and relevant problems have been met or solved	6(30.0%)	12(20.3%)	6(15.4%)	24(20.3%)

Patient safety culture (PSC)

According to the above concept of PS, PSC was summarized into two modules: general module and MCH specific module. The former included 11 dimensions (61 items) and the latter included 1 dimension (8 items), added up to 12 dimensions (69 items) in total, which were coded as: management support (6 items), regulation and procedure (6 items), staffing (3 items), teamwork (5 items), non-punitive (6 items), openness to adverse events (8 items), risk awareness and warning (6 items), continuous learning (6 items), working perception (5 items), providers' defensive behaviors (4 items), patient involvement (6 items), and MCH specific(8 items).Top 5 dimensions more frequently mentioned by managers were working perception (100.0%), management support (95.0%), regulation and procedure (95.0%), continuous learning (95.0%) and non-punitive (85.0%); top 5 dimensions among frontlines were continuous learning (93.2%), working perception (91.5%), regulation and procedure (91.5%), management support (89.8%) and staffing (88.1%); and top 5 dimensions among patients were working perception (94.9%), patient involvement (87.2%), continuous learning (51.3%), management support (43.6%) and staffing (41.0%). Dimensions of *PSC* in total and each group were seen in Table 2 (Detailed dimensions and items could be seen in Appendix Table 5).

No matter among managers, frontlines or patients, PSC was heavily attributed to human factors, kind of working perception, continuous learning and staffing, and thereby punishment of individuals were considered as indispensable.

> *'We have summarized common causes of medical incidents, including poor communication, lack of knowledge and skills, not obeying guidelines and procedures and so on. All of these causes belong to individual's responsibilities. Punishment to departments or individuals, however to be complained sometimes, is helpful to reduce the number of incidents and to make rules and regulations work.' (Manager)*
>
> *'A person who often makes mistakes is incompetent and should be fired.' (Manager)*
>
> *'Punishment to individuals is fair to others who made no mistake.' (Frontline)*
>
> *'Medical errors and incidents are associated with personal attitudes and skills.' (Patient)*

It is more likely that patients were interested in patient involvement in seeking services than providers, in many ways of informed consents of intervention plans, engagement of decision-making, patient educations, and advocacy of patients' rights and interests.

> *'Now young parents are well-educated and usually learn relevant information in internet before seeking care for their babies, they would like to ask for more detailed and accurate explanations than before.'(Frontline)*
>
> *'Communication is very important. No matter what conditions or risks, patients must be informed totally.'(Patient)*

Providers' defensive behaviors was important part of PSC emerging in this study, for example, rejections of patients with high-risk conditions, compromises with patients' irrational requests and introducing unnecessary interventions, in order to avoid disputes and confrontations, which aggravated the scarred relationship between providers and patients and even harmed PS in some occasions.

> *'If a pregnant woman refuses to take the blood test in prenatal care, we suggest our doctors to write it down in medical records, which are evidence to avoid dispute in case of anemia.' (Manager)*

'I prefer referrals to superior hospitals as much as possible to prevent premature infants from any unexpected consequence I cannot afford.'(Frontline)

'Doctors relay on machines too much because they don't want take any risk.'(Patient)

Table 2 Dimensions of patient safety culture in MCH institutions

Dimensions	Descriptions of dimensions	Providers(n1=79)		Patients (n4=39)	Total (N=118)
		Managers (n2=20)	Frontlines (n3=59)		
1. Management support	Priority to PS; justice of management	19(95.0%)	53(89.8%)	17(43.6%)	89(75.4%)
2.Regulation and procedure	Rationality and continuous amendment; empowerment to frontlines	19(95.0%)	54(91.5%)	13(33.3%)	86(72.9%)
3.Staffing	Staffing and workloads	16(80.0%)	52(88.1%)	16(41.0%)	84(71.2%)
4.Teamwork	Teamwork within departments, across departments and across institutions	13(65.0%)	47(79.7%)	5(12.8%)	65(55.1%)
5.Non-punitive	Non-punitive response to adverse events; cause analysis and feedbacks	17(85.0%)	42(71.2%)	6(15.4%)	65(55.1%)
6.Openness to adverse events	Adverse events reporting; open communication with colleagues and patients	10(50.0%)	38(64.4%)	0(0.0%)	48(40.7%)
7.Risk awareness and warning	Attitudes and awareness of medical risks, errors and potential flaws	15(75.0%)	44(74.6%)	13(33.3%)	72(61.0%)
8.Continuous learning	Continuous learning; training; not limited to knowledge and skills	19(95.0%)	55(93.2%)	20(51.3%)	94(79.7%)
9.Working perception	Individual perceptions and affections of his/her work	20(100.0%)	54(91.5%)	37(94.9%)	111(94.1%)
10.Providers' defensive behaviors	Providers' defensive behaviors to avoid risk or dispute, but may harm PS	9(45.0%)	22(37.3%)	9(23.1%)	40(33.9%)
11.Patient involvement	Promoting patients to engage in PS	15(75.0%)	44(74.6%)	34(87.2%)	93(78.8%)
12.MCH specific	MCH specific issues on management support, staffing, teamwork and prejudice	6(30.0%)	6(10.2%)	0(0.0%)	12(10.2%)

External influence factors of PS and PSC

Cultures are shared values, beliefs and norms among members of the organization, so all dimensions and items of PSC coded in this study were inner themes of MCH institutions. However, there were also external factors outside of organizations significantly influencing members' values, beliefs, norms and behaviors of PS, summarized in four aspects as bellow.

One aspect was of political factors, including that unreasonable or flawed political regulations brought out heavier workloads or higher risks, limited the development of MCH institutions (like staffing, personnel development, infrastructures and devices, etc.), harmed to patients' benefits and safety (like the accessibility of restricted drugs and services) and that the government did not provide sufficient financial supports to MCH institutions. All of these political factors resulted in so enormous barriers that MCH institutions and staff were hardly able to make PS a priority in practice.

'With the purpose of social stability, hospitals are always compelled to compensate medical dispute profiteers, regardless who are wrong.' (Manager)

'The government usually emphasizes the importance of public health in words but not in action. Because of lack of funds, public health tasks always were done as the least as possible in fact.'(Manager)

'After institutional reforms in our region, county-level MCH institutions are not allowed to supply some drugs and services as before, which is a broad-brush way without considering of specific circumstances.' (Frontline)

Another aspect was of social factors, such as intolerant propaganda of medical accidents spread by mass media and the opposites of providers and patients (distrusts and conflicting interests), which led that providers did not acquire trusts and respects as they should have done and even that safety of themselves were under threats.

'Our medical staffs are overloaded and the medicine industry is high-risk. However, patients cannot understand these things and medical accidents reported in mass media are always misleading and misinterpreted.' (Manager)

'Medical disputes probably happen in any hospital. The doubts of the whole industry spread out in social. Additionally, a small thing could be magnified in the media to aggravate distrusts.' (Frontline)

An additional aspect was of patients' awareness and capability of participating in PS, for example, shames on illnesses (especially among female patients), conception of exchanges between health and money, incomprehension, distrusts and unreasonable expectations of the medicine, less appreciation of care services than clinic services, passive position in decision-making, whether to be able to express their illnesses and problems clearly, whether to informed consent or comply with intervention plans, and whether recognize the inherent inevitability of making mistakes as a nature of human beings.

'People don't respect us. For example, some nurses had been physically attacked by parents because of failing to insert the scalp needle at the first time.' (Manager)

'Some patients consider treating human bodies as repairing machines. You must assure that they go better or they will make trouble on you.' (Frontline)

'I couldn't understand doctors perfectly and had to do as they told me.' (Patient)

The last but not least aspect was of patients' defensive behaviors. For instance, patients might identify

providers by institutions' grades, magnitudes, environments, attendances, providers' certified qualifications, social reputations and previous experiences from themselves and shared with peers; might take into account costs of time and money; verify providers by hiding symptoms themselves or seeking alternative opinions from other providers, peers and even internets; frequently seeking a provider once confidence built; as so forth. A demonstrative diagram was produced to show how patients made decisions in seeking services at different stages of pre-services, arrivals, encounters and separations, seen in Figure 1.

'Some patients did not trust us. They would see several doctors to verify mutually.' (Frontline)

'I choose this hospital because it is a big hospital, with a good environment and many people come here to seek MCH services.' (Patient)

'I trust my doctor, because one of my friends is acquainted with him.' (Patient)

'Before making decision of giving birth here, we nearly searched all comments of this hospital in internet.' (Patient)

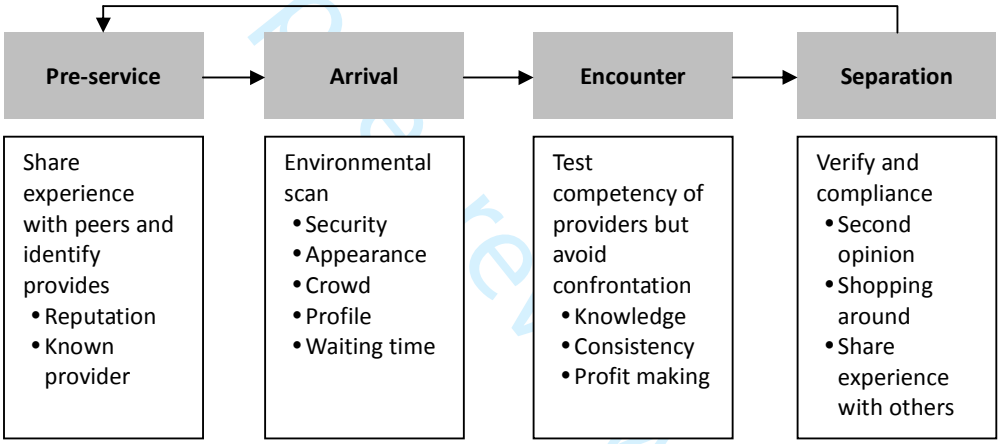

Figure 1 How patients make decisions in seeking health services

DISCUSSION

New findings on PS and PSC

In context of cultures in China, PS could not be limited within the definition of 'the reduction of risk of unnecessary harm (impairment of structure or function of the body and/or any deleterious effect arising there from) associated with health care to an acceptable minimum' given by WHO,[39] but was expanded to become a wider range. Besides physical harms and consequent effects as well concerned in previous studies,[40-42] the original and extended meanings of 'safety' were introduced by providers and patients when they talked about PS in this study. Public security was a kind of environmental scan when people entered hospitals, medical safety was associated with all segments of medical practices, privacy and information security regarded to private rights, financial security originated from the pay-for-profit motivate mechanism and the distrustful relationship between providers and patients,[43 44] and psychological safety and demands been met reflected further pursuits on PS beyond of avoiding from adverse events as above, while psychological safety to some extents was related with the distrustful relationship between providers and patients and inadequate informed consents.[45 46] Unfortunately, providers were less likely to speak out patient safety events that really happened in

their institutions, so the classification of PS was a rough cognitive pathway of progressive layers, but not an operational taxonomy to be used directly in practice.

Besides of MCH specific module, general module in the framework of PSC included 11 dimensions and 61 items. Nine of these eleven dimensions could been revealed faintly from previous assessment tools of PSC,[10 19 20 47] including management support, regulation and procedure, staffing, teamwork, non-punitive, openness to adverse events, risk awareness and warning, continuous learning and working perception, which were overwhelming issues associated with PSC around the world.[48-51] Another issue of patient involvement, which had drawn increasing attentions and evidence to promote PS in recent years,[52-54] was added as a dimension of PSC in this study. Providers' defensive behaviors, an additional dimension captured as well, could result in a series of consequences to harm PS probably, e.g. unnecessary interventions, poor confidence and cooperation between providers and patients, and professionalism yield to selfishness.[55-57] MCH specific module had underlined that there was in equality for non-profit public health departments in dimensions of PSC compared with profit-making clinic departments so that non-profit public health services could be not available or accessible and a profit-driven culture must damage PS indeed.[43 44]

Furthermore, it should be noted that human factors were highlighted in PSC from this study. Both providers and patients emphasized competency and devotion of individuals and indispensability of punishment. The system approach considers errors as consequences of 'upstream' systemic factors rather than causes and blaming individuals is emotionally more satisfying than targeting institutions.[39 58 59] The root cause analysis is recommended to focus errors or failures on the system rather than individuals.[60 61] Meaningwhile, error wisdom is also helpful for individuals to thwart some systemic failures at the last minute.[62]

Conflicts and environmental threats for PS and PSC

Conflicts among managers, frontlines and patients might be a significant threat of PS and PSC, mainly consisting of two aspects: cognitive conflicts and interest conflicts. Patients' perceptions of PS and PSC were weaker and patients were more likely to concern about financial security, psychological safety and patient involvement than providers. Further to compare within providers, frontlines' perceptions of PS and PSC were weaker in general and frontlines were more likely to talk about staffing, teamwork and openness to adverse events than managers. Interest conflicts between patients and providers had been emerged from their defensive behaviors to protect interests themselves and interest conflicts between frontlines and managers had been mainly displayed in inequality of management support and staffing. Both cognitive conflicts and interest conflicts would threaten understanding, trust and cooperation among them and thereby damage quality services and PS, as well proved in previous researches.[63-67]

Furthermore, PSC of the organization could be shaped by political and social factors to a large extent. A lot of literatures had pinpointed restrictions and conflicts of health services in China with such upper systemic causes as healthcare system, legal enforcement, incentive mechanism, positive propaganda and health education to the social public, which had threaten quality services, medical professionalism, patients' satisfaction and safety, and even safety of the industry and professionals themselves.[68-73]

Strategies for PS learned from this study

Nourishing a safety-centered culture of the organization is essential to ensure PS through encouraging

such organizational shared values among individuals. Comprehensive strategies should be launched both within institutions and in a larger context that is relevant, focusing on improving equality, non-punitive, patient rights and involvement, confidence and cooperation between providers and patients, and environmental supports from policies and societies.

Limitations and further studies

This study was conducted through a qualitative approach based on grounded theory, which more likely represented views from researchers themselves[30] and needed further evidence from subsequent quantitative studies. This study provided a theoretical basis, a qualitative assessment tool of PSC and an operational taxonomy of PS should be developed in future studies and would be helpful for researchers and managers to use in practice.

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Competing interests None declared.

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Data Sharing Statement The data supporting the conclusions of this article are included within the article in the form of interview excerpts. Full interview transcripts remain the property of Division of Maternal and Child Health, School of Public Health, Peking University Health Science Centre, which are accessible to contact with the corresponding author Prof. Wang Yan, email: wangyan@bjmu.edu.cn

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Appendix Table 1 The general characteristics of six MCH institutions

Province	MCH institution	Number of				
		Staff	Beds	Outpatients (*1000per year)	Hospitalized (*1000 per year)	Deliveries (*1000 per year)
Hebei	SJZ	1022	450	520	21	16
	MC	90	40	15	1.6	1
	XH	110	60	120	2	1
Beijing	HD	729	460	740	20	14
	CY	443	125	280	6	4
	FT	362	120	280	3.5	2.2

**Rough data provided by administrative managers of those MCH institutions.*

Appendix Table 2 The general characteristics of 118 participants

Characteristics		Providers(n1=79)		Patients (n4=39)	Total (N=118)
		Managers (n2=20)	Frontlines (n3=59)		
Sex	Male	5(25.0%)	3(5.1%)	13(33.3%)	21(17.8%)
	Female	15(75.0%)	56(94.9%)	26(66.7%)	97(82.2%)
Age	20-29 years	0(0.0%)	8(13.6%)	16(41.0%)	24(20.3%)
	30-39 years	7(35.0%)	33(55.9%)	13(33.3%)	53(44.9%)
	40-49 years	9(45.0%)	16(27.1%)	1(2.6%)	26(22.0%)
	50-59 years	3(15.0%)	1(1.7%)	4(10.3%)	8(6.8%)
	60 years or above	1(5.0%)	1(1.7%)	0(0.0%)	2(1.7%)
	Missing	0(0.0%)	0(0.0%)	5(12.8%)	5(4.2%)
Education	Primaryorunder	0(0.0%)	0(0.0%)	4(10.3%)	4(3.4%)
	Secondary	0(0.0%)	0(0.0%)	7(17.9%)	7(5.9%)
	Juniorcollege	3(15.0%)	23(39.0%)	6(15.4%)	32(27.1%)
	Undergraduate	10(50.0%)	25(42.4%)	6(15.4%)	41(34.7%)
	Masterorabove	2(10.0%)	9(15.3%)	2(5.1%)	13(11.0%)
	Missing	5(25.0%)	2(3.4%)	14(35.9%)	21(17.8%)

Appendix Table 3 Other general characteristics of 79 care providers

Characteristics		Administrative managers (n2=20)	Frontline staff (n3=59)	Total (n1=79)
Working years	0-4 years	0(0.0%)	3(5.1%)	3(3.8%)
	5-9 years	3(15.0%)	14(23.7%)	17(21.5%)
	10 years or above	17(85.0%)	42(71.2%)	59(74.7%)
Professional title*	Clinicians	7(35.0%)	14(23.7%)	21(26.6%)
	Public health	2(10.0%)	15(25.4%)	17(21.5%)
	Nurses	5(25.0%)	21(35.6%)	26(32.9%)
	Administrative	6(30.0%)	0(0.0%)	6(7.6%)
	Others	0(0.0%)	9(15.3%)	9(11.4%)

**Professional title is a qualification authenticated by health administrative bureaus, which qualifies medical professionals' specialty legally. Most administrative managers of medical institutions in China had been promoted from frontline staff rather than specialized administrative managers.*

Appendix Table 4 The coding reliability of 12 re-test cases

No. of cases	Group	Consistency reliability between researchers	Re-test reliability
1	Administrative manager	85.0%	68.2%
2	Administrative manager	68.8%	66.7%
3	Frontline staff	79.4%	62.2%
4	Frontline staff	85.0%	73.9%
5	Frontline staff	66.7%	69.2%
6	Frontline staff	63.3%	66.1%
7	Frontline staff	75.6%	76.1%
8	Frontline staff	82.9%	82.5%
9	Patient	100.0%	66.7%
10	Patient	88.2%	73.7%
11	Patient	92.9%	62.5%
12	Patient	75.0%	63.9%

Original codes		Operational codes	Final codes
Researcher A	*Researcher B*		
Concept of PS	Concept of PS	Concept of PS	Concept of PS
Patient factors	Environmental factors	Environmental factors	Management support
Medical industry			Regulation and procedure
Policies and regulations	Management support	Organizational structures	Staffing
Legal	Working atmosphere	Working atmosphere	Teamwork
social	Individual factors	Individual factors	Non-punitive
	Providers' defensive behaviors →	Providers' defensive behaviors →	Openness to adverse events
Organizational goals			Risk awareness and warning
Organizational structures	Patients' defensive behaviors	Patients' defensive behaviors	Continuous learning
Organizational environment and facilities			Working perception
Individual perceptions, attitudes, behaviors			Providers' defensive behaviors
			Patient involvement
			MCH specific
			Environmental factors
			Patients' defensive behaviors

Appendix Figure 1 The modifying process of main dimensions coded by two parallel researchers

**Not showing specific sub-dimensions and items in each main dimension, and some dimensions of final codes came from sub-dimensions of operational codes.*

Appendix Table 5 Dimensions and items of patient safety culture in MCH institutions

Dimensions/items	Providers(n1=79)		Patients (n4=39)	Total (N=118)
	Managers (n2=20)	Frontlines (n3=59)		
1. Management support	**19(95.0%)**	**53(89.8%)**	**17(43.6%)**	**89(75.4%)**
1.1 Management gives priority to PS, considering other goals like profits or reputations.	10(50.0%)	14(23.7%)	3(7.7%)	27(22.9%)
1.2 Management is committed to continuous improvement of PS.	13(65.0%)	27(45.8%)	2(5.1%)	42(35.6%)
1.3 Management is committed to create a good working atmosphere.	1(5.0%)	1(1.7%)	0(0.0%)	2(1.7%)
1.4 Management provides adequate allocation of resources to the department where I work.	2(10.0%)	15(25.4%)	0(0.0%)	17(14.4%)
1.5 Management thinks highly of improving organizational environments and medical facilities.	16(80.0%)	38(64.4%)	14(35.9%)	68(57.6%)
1.6 Management pays more attention to profit-making departments than others.	6(30.0%)	11(18.6%)	0(0.0%)	17(14.4%)
2.Regulation and procedure	**19(95.0%)**	**54(91.5%)**	**13(33.3%)**	**86(72.9%)**
2.1Innovations of regulations and procedures are rigorous and flexible.	6(30.0%)	10(16.9%)	1(2.6%)	17(14.4%)
2.2Motivatemechanism of the organization is fair and feasible.	9(45.0%)	30(50.8%)	0(0.0%)	39(33.1%)
2.3 Some regulations and procedures are unreasonable and lead to inconveniences, barriers or risks.	14(70.0%)	37(62.7%)	13(33.3%)	64(54.2%)
2.4Frontlines can obey regulations and procedures in the organization.	16(80.0%)	26(44.1%)	2(5.1%)	44(37.3%)
2.5Risk preventing and responding mechanism has been introduced to reduce or avoid errors.	6(30.0%)	15(25.4%)	0(0.0%)	21(17.8%)
2.6 Frontline staff can be able to involve in decision-making.	3(15.0%)	10(16.9%)	0(0.0%)	13(11.0%)
3.Staffing	**16(80.0%)**	**52(88.1%)**	**16(41.0%)**	**84(71.2%)**
3.1I often feel busy too much.	3(15.0%)	9(15.3%)	4(10.3%)	16(13.6%)
3.2Staffing is far from sufficient to deal with workload.	13(65.0%)	41(69.5%)	11(28.2%)	65(55.1%)
3.3 Because of overload working, we cannot provide patients the best services as we could.	13(65.0%)	48(81.4%)	10(25.6%)	71(60.2%)
4.Teamwork	**13(65.0%)**	**47(79.7%)**	**5(12.8%)**	**65(55.1%)**
4.1Referrals between the organization and other institutions are efficient to ensure PS.	5(25.0%)	9(15.3%)	3(7.7%)	17(14.4%)
4.2 Cross-department teamwork in the organization is not satisfying.	9(45.0%)	34(57.6%)	1(2.6%)	44(37.3%)
4.3Communication is not pleasant between supervisors and subordinates.	3(15.0%)	3(5.1%)	0(0.0%)	6(5.1%)
4.4Handoffs are handled seriously and carefully.	1(5.0%)	8(13.6%)	0(0.0%)	9(7.6%)

4.5 Teamwork is satisfying in the department where I work.	8(40.0%)	31(52.5%)	1(2.6%)	40(33.9%)
5.Non-punitive	**17(85.0%)**	**42(71.2%)**	**6(15.4%)**	**65(55.1%)**
5.1Frontlines might not report adverse events happened due to worries about punishments.	4(20.0%)	4(6.8%)	0(0.0%)	8(6.8%)
5.2 Frontlines are encouraged to report adverse events.	5(25.0%)	17(28.8%)	0(0.0%)	22(18.6%)
5.3 Adverse events are mostly attributed to individuals in the organization.	2(10.0%)	2(3.4%)	6(15.4%)	10(8.5%)
5.4 Feedback of adverse events reported is delivered in time.	3(15.0%)	7(11.9%)	0(0.0%)	10(8.5%)
5.5Effortsare much engaged in preventing adverse events to reoccur.	2(10.0%)	18(30.5%)	0(0.0%)	20(16.9%)
5.6 In the organization, it is preferred to learn from adverse events than blame or punish individuals.	17(85.0%)	41(69.5%)	0(0.0%)	58(49.2%)
6.Openness to adverse events	**10(50.0%)**	**38(64.4%)**	**0(0.0%)**	**48(40.7%)**
6.1If adverse event happen and might harm patients, I will report it.	8(40.0%)	21(35.6%)	0(0.0%)	29(24.6%)
6.2 If adverse event happen but nearly not harm patients, I will report it as well.	10(50.0%)	22(37.3%)	0(0.0%)	32(27.1%)
6.3 If adverse event happen to colleagues, I will report it as well.	5(25.0%)	20(33.9%)	0(0.0%)	25(21.2%)
6.4 If adverse event happen, individuals involved will be regarded by colleagues not as usual.	1(5.0%)	7(11.9%)	0(0.0%)	8(6.8%)
6.5 It is not superstitious to discuss adverse events among colleagues.	5(25.0%)	25(42.4%)	0(0.0%)	30(25.4%)
6.6 I am not worried about discussing my errors.	2(10.0%)	4(6.8%)	0(0.0%)	6(5.1%)
6.7 If adverse event happen and is not found by patient, he/she will be not informed to avoid dispute.	3(15.0%)	12(20.3%)	0(0.0%)	15(12.7%)
6.8 If adverse event happen, patient will be comforted to relieve feelings of unsafety.	5(25.0%)	6(10.2%)	0(0.0%)	11(9.3%)
7.Risk awareness and warning	**15(75.0%)**	**44(74.6%)**	**13(33.3%)**	**72(61.0%)**
7.1 Besides incidents, management pay much attention to errors or potential risks as well.	3(15.0%)	6(10.2%)	0(0.0%)	9(7.6%)
7.2 If potential risks emerge, efforts will be much engaged to avoid reoccurring.	7(35.0%)	17(28.8%)	0(0.0%)	24(20.3%)
7.3 I cannot ignore errors and potential risks in work.	1(5.0%)	5(8.5%)	0(0.0%)	6(5.1%)
7.4 I agree that most of errors are preventable.	6(30.0%)	16(27.1%)	2(5.1%)	24(20.3%)
7.5 I agree that 'to err is human'.	6(30.0%)	17(28.8%)	6(15.4%)	29(24.6%)
7.6 I consider my work as part of PS.	11(55.0%)	26(44.1%)	2(5.1%)	39(33.1%)
8.Continuous learning	**19(95.0%)**	**55(93.2%)**	**20(51.3%)**	**94(79.7%)**
8.1 Continuous learning is considered as an important thing in the organization.	15(75.0%)	40(67.8%)	4(10.3%)	59(50.0%)

8.2Colleagues always discuss how to improve work.	7(35.0%)	30(50.8%)	0(0.0%)	37(31.4%)
8.3 I am competent to handle my job.	16(80.0%)	39(66.1%)	19(48.7%)	74(62.7%)
8.4 I need to learn continuously.	12(60.0%)	35(59.3%)	2(5.1%)	49(41.5%)
8.5 New employees are trained enough to be acquainted with regulations and procedures.	7(35.0%)	17(28.8%)	0(0.0%)	24(20.3%)
8.6 Staff is trained enough (not limited to knowledge and skills).	10(50.0%)	40(67.8%)	1(2.6%)	51(43.2%)
9.Working perception	**20(100.0%)**	**54(91.5%)**	**37(94.9%)**	**111(94.1%)**
9.1 I have a sense of satisfaction and accomplishment in my work.	9(45.0%)	21(35.6%)	0(0.0%)	30(25.4%)
9.2 I feel tired of my work.	13(65.0%)	22(37.3%)	2(5.1%)	37(31.4%)
9.3 I can receive patients with compassion and empathy.	13(65.0%)	30(50.8%)	14(35.9%)	57(48.3%)
9.4 I can perform patience and kind attitudes in my work.	14(70.0%)	41(69.5%)	37(94.9%)	92(78.0%)
9.5 I work seriously and responsibly.	12(60.0%)	36(61.0%)	13(33.3%)	61(51.7%)
10.Providers' defensive behaviors	**9(45.0%)**	**22(37.3%)**	**9(23.1%)**	**40(33.9%)**
10.1 To avoid high risk, we might refuse patients who we are able to treat in fact.	2(10.0%)	9(15.3%)	0(0.0%)	11(9.3%)
10.2 To avoid dispute, I might yield to patient, rather than adhere to rules and guidelines.	5(25.0%)	15(25.4%)	2(5.1%)	22(18.6%)
10.3 To avoid dispute, we have to do massive informed consents in writing or orally to protect ourselves.	4(20.0%)	7(11.9%)	3(7.7%)	14(11.9%)
10.4Unnecessary interventions exist in the organization.	3(15.0%)	2(3.4%)	5(12.8%)	10(8.5%)
11.Patient involvement	**15(75.0%)**	**44(74.6%)**	**34(87.2%)**	**93(78.8%)**
11.1I inform patients (like alternative plans and risks) as enough as I can.	13(65.0%)	42(71.2%)	34(87.2%)	89(75.4%)
11.2I response to any question of patients.	0(0.0%)	9(15.3%)	13(33.3%)	22(18.6%)
11.3 We often take advice from patients.	7(35.0%)	13(22.0%)	12(30.8%)	32(27.1%)
11.4 We emphasize health education to patients.	5(25.0%)	19(32.2%)	7(17.9%)	31(26.3%)
11.5 I respect patient's willing and rights.	4(20.0%)	21(35.6%)	7(17.9%)	32(27.1%)
11.6 Patients are encouraged to participate in risk management in the organization.	4(20.0%)	13(22.0%)	9(23.1%)	26(22.0%)
12.MCH specific	**6(30.0%)**	**6(10.2%)**	**0(0.0%)**	**12(10.2%)**
12.1 Management doesn't support to complete all of public health tasks.	8(40.0%)	14(23.7%)	0(0.0%)	22(18.6%)
12.2 Staffing allocated on public health is insufficient.	4(20.0%)	7(11.9%)	0(0.0%)	11(9.3%)

12.3 Staffing allocation make priority to clinic departments rather than public health departments.	1(5.0%)	1(1.7%)	0(0.0%)	2(1.7%)
12.4Our cooperation with other MCH institutions is satisfying.	4(20.0%)	13(22.0%)	1(2.6%)	18(15.3%)
12.5 I agree that public health is very important and necessary part of a MCH institution.	6(30.0%)	4(6.8%)	0(0.0%)	10(8.5%)
12.6 I agree that public health should be given more attentions than is now.	3(15.0%)	1(1.7%)	0(0.0%)	4(3.4%)
12.7 Public health workers are neglected frequently.	0(0.0%)	1(1.7%)	0(0.0%)	1(0.8%)
12.8 Public health departments are prejudiced as 'special' in the organization.	0(0.0%)	3(5.1%)	0(0.0%)	3(2.5%)

Standards for Reporting Qualitative Research (SRQR)a

No.	Topic	Item	Checked
	Title and abstract		
S1	Title	Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	√
S2	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	√
	Introduction		
S3	Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	√
S4	Purpose or research question	Purpose of the study and specific objectives or questions	√
	Methods		
S5	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/interpretivist) is also recommended; rationaleb	√
S6	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	√
S7	Context	Setting/site and salient contextual factors; rationaleb	√
S8	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationaleb	√
S9	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	√
S10	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationaleb	√
S11	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	√
S12	Units of study	Number and relevant characteristics of participants, documents, or	√

		events included in the study; level of participation (could be reported in results)	
S13	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts	√
S14	Data analysis	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale [b]	√
S15	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale[b]	√
	Results/findings		
S16	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	√
S17	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	√
	Discussion		
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	√
S19	Limitations	Trustworthiness and limitations of findings	√
	Other		
S20	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	√
S21	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting	√

aThe authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

bThe rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

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Measuring patient safety culture in maternal and child health institutions in China: a qualitative study

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Measuring patient safety culture in maternal and child health institutions in China: a qualitative study

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ABSTRACT

Introduction Patient safety culture (PSC) plays a critical role in ensuring safe and quality care. Extensive PSC studies have been undertaken in hospitals. However, little is known about PSC in maternal and child health (MCH) institutions in China, which provide both population-based preventive services as well as individual care for patients.

Objectives This study aimed to develop a theoretical framework for conceptualizing PSC in MCH institutions in China.

Methods The study was undertaken in six MCH institutions (three in Hebei and three in Beijing). Participants (n=118) were recruited through stratified purposive sampling: 20 managers/administrators, 59 care providers and 39 patients. In-depth interviews were conducted with the participants. The interview data were coded using both inductive (based on the existing PSC theory developed by the Agency for Healthcare Research and Quality) and deductive (open coding arising from data) approaches. A PSC framework was formulated through axial coding that connected initial codes and selective coding that extracted a small number of themes.

Results The interviewees considered patient safety in relation to six aspects: safety and security in public spaces, safety of medical services, privacy and information security, financial security, psychological safety, and gap in services. A 12-dimensionalPSC framework was developed, containing69 items. While the existing PSC theory was confirmed by this study, some new themes emerged from the data. Patients expressed particular concerns about psychological safety and financial security. Defensive medical practices emerged as a PSC dimension that is associated with not only medical safety but also financial security and psychological safety. Patient engagement was also valued by the interviewees, especially the patients, as part of PSC.

Conclusions Although there are some common features in PSC across different healthcare delivery systems, PSC can also be context specific. In MCH settings in China, the meaning of "patient safety" goes beyond the traditional definition of patients. General wellbeing, health and disease prevention are important anchor points for defining PSC in such settings.

Strengths and limitations of this study

- The study explored the concept of patient safety and PSC from the points of view of managers/administrators, care providers and patients.
- The study was conducted in MCH institutions, which provided population-based preventive services as well as individual care for patients.
- The results are context specific and caution should be taken when generalizing the results.
- The study provides a high level classification of patient safety, which should not be treated as an operational taxonomy to be used directly in practices.

INTRODUCTION

Patient safety has become a global concern over the last two decades. It is agreed that patient safety culture(PSC),which is defined as the 'shared values, beliefs, norms and procedures related to patient safety among members of the organization',[1] is fundamental for safe and quality care.[2-6] In the literature, there are several distinct but related terms describing PSC, such as patient safety climate and patient safety attitudes. Culture is something that can be passed on and is relatively enduring.[7] It is reflected in normalized behaviors and practices. Climate, on the other hand, provides a snapshot of the overwhelming perceptions of people in regard to PSC.[8 9] Attitudes refer to how people see and

respond to matters associated with patient safety.[10] All of the three concepts are associated with safe behaviors, processes and outcomes.[5 11-13]

Maternal and child health (MCH) is a priority on the global development agenda, such as the sustainable development goals (SDGs) promoted by the United Nations.[14] China has achieved extraordinary success in MCH over the past few decades, thanks to the universal coverage of MCH care delivered by MCH institutions.[15 16] From 1990 to 2015, the maternal mortality ratio (MMR, maternal deaths per 100 000 live births) in China decreased from 114.2 to 17.7;[17] and under-five mortality rate (U5MR, deaths per 1000 live births) dropped from 55.9 to 12.3.[18] There are 3,071 MCH institutions in China, covering all counties and cities.[19] They are dedicated to providing four categories of MCH services: (1) maternal and obstetrical care such as premarital examinations, progestational consultations, and pregnancy, labor and postpartum services; (2) pediatric care including management of neonatal, infant and child growth and development, nutrition, mental health, as well as the diagnosis and treatment of childhood diseases; (3) women's health, ranging from adolescent health and reproduction to nutrition, mental health, breast care, menopause and aged care. Gynecological services are also provided; (4) family planning services, such as health education, preconception counseling, contraception, and reproductive healthcare services. The MCH institutions operate at provincial, municipal and county levels, forming a tiered comprehensive network.[20] A considerable number of policies and regulations have been devoted to strengthening the infrastructure, technologies, and procedures of MCH services.[15 16 21] However, scant attention has been paid to PSC in MCH institutions.

Measuring PSC is important to help health workers to increase awareness and develop a better understanding of patient safety. It can also provide information support to managers to improve their managerial practices. Several PSC measurement tools have been developed. Of those tools, the Hospital Survey on Patient Safety Culture (HSPSC)developed by the Agency for Healthcare Research and Quality,[22] the Patient Safety Climate in Healthcare Organizations (PSCHO)[23] and the Safety Attitudes Questionnaire (SAQ)[10] are most commonly used. They have been applied to a wide range of health institutions in various countries,[24-26] including in China.[27-31] However, the Chinese versions of these instruments followed a stringent translation protocol and considered little, if any, of the special contexts of Chinese health institutions.

This study aimed to explore the concept of patient safety and PSC in China's MCH institutions. Since culture has the nature of profundity and abstruseness,[32] it is essential to unveil its presentations and implications under specific contexts. The principles of qualitative research, in particular the grounded theory, fits well with the objectives of this study. It allows us to generate a new (or modified) PSC framework without necessarily being restricted to any existing theoretical framework.[33 34]

METHODS

Design

This is a qualitative study conducted by a multidisciplinary research team, comprising experts in MCH (YYW [female], YW[female] and HS [male]), research methodology (CL [male]), and health services management (CL [male]& WL [female]). In-depth interviews were undertaken with health workers (managers/administrators and care providers) and patients to examine their perceptions and experiences of patient safety and PSC.

Setting and sample

Data were collected between November 2014 and April 2015 in six MCH institutions: three in Hebei and three in Beijing. These institutions were purposively selected, considering diversities in staffing, resources (e.g. beds), and scope and volume of services (e.g. outpatient, inpatient and birth delivery). The number of beds in the participating MCH institutions ranged from 40 (at the county level) to 460 (a large metropolitan center). Further details of the participating MCH institutions can be found in Appendix Table 1.

A stratified purposive sampling strategy was adopted to recruit participants. In each MCH institution, the potential participants were divided into 4-5 groups: management/administration (e.g., general office, medical administration, nursing administration, infection control), MCH clinics (e.g., pediatrics, gynecology, obstetrics), population health services (e.g., child healthcare, women's healthcare, preventive care), allied health services (e.g., pharmacy, imaging, laboratory) and other clinical services (e.g., internal medicine, surgery, dental, traditional Chinese medicine). In each institution, between 2-5 managers/administrators, 7-12 care providers (including doctors, nurses, public health workers, midwives, and allied health professionals) and 5-8 patients (including caregivers of children) were invited to participate in the study. Three invited interviewees (1 doctor and 2 patients) withdrew due to disruption caused by other urgent matters. The final sample size was determined by the saturation of information when no new theme emerged from the coding. The saturation of information was deemed to be achieved when the entire research team (especially those who performed the interviews and coding) reached consensus. This resulted in a final sample size of 118, including 20 managers/administrators (16.9%), 59 care providers (50.0%) and 39 patients (33.1%). The characteristics of participants are presented in Appendix Tables 2 and 3.

Data collection, processing and analyses

This study used both inductive and deductive approaches in data collection, coding and analyses. The interview guides were developed based on a pre-tested tool in a previous study.[35] However, the interviewers were trained to respond to the interviewees in a flexible way in order to obtain in-depth information. They were encouraged to ask questions that were not listed in the interview guides. At the end of each interview session, the interviewers reviewed the interview guides to ensure that the interview had covered all the questions listed in the guides. No repeated interviews were undertaken.

All interviews were conducted face-to-face in the MCH institutions, led by two chief investigators (YYW [female] and HS [male]) and assisted by three trained interviewers (with a master or PhD degree). Prior to each interview session, the interviewers introduced themselves and the purpose, contents, ethical principles and declarations of the study and obtained written informed consent from the participants. Each interview lasted 15-50 minutes and was audio-recorded. The interviewers also took notes on the environment of the interview, the body language of respondents, self-reflection, and any other information they thought necessary.

Data analyses took place concurrently with data collection. Interview strategies (including the questions asked) were adjusted in subsequent interviews. The research team met regularly, discussing the findings and determining whether additional samples were needed.

All audio records were transcribed verbatim. We used NVivo 8.0 software to perform coding and analyses on the transcribed data and interview notes. The coding procedure followed the principles of grounded theory.[33] We started with open coding, which generated numerous codes from the raw data reflecting the panorama of the data. Original words were extracted to label the codes whenever it was possible. The second step involved axial coding. The initial codes were compared and condensed, with

similar codes being merged using a new label that could describe all of the merged initial codes. The connections between different codes were identified by referring back to the raw data. This reduced the number of codes significantly. The third step was selective coding, which further abstracted key themes from the scattered codes. The selective coding considered the fitness of the condensed codes into the existing PSC theoretical framework developed by the Agency for Healthcare Research and Quality. Additional themes were established for those codes that did not fit well into the existing framework. Finally, we translated the codes into "dimensions" (high level framework) and "items" embedded in each dimension (Appendix Table 5).

Reliability and validity of coding

All data were coded in parallel by two researchers (YYW [female] and HS [male]). This ensured the validity of coding.[36 37] First, both researchers developed their own initial codes from the data. They then shared and discussed their coding and agreed on an operational list of codes. The agreed operational list of codes was eventually used for coding all of the data by the two researchers independently. Finally, another round of coding discussion was held, with modifications being made to the operational codes and the coding of all of the data into the final list of codes. The coding process is illustrated in Appendix Figure 1.

The reliability of coding was tested through repeated coding.[38 39] About 10% (n=12) of interview records were randomly selected for repeated coding: 2 from managers/administrators, 6 from care providers, and 4 from patients. Two researchers recoded the data independently into the agreed operational list of codes. About 63.3% to 100% of the codes were consistent between the two researchers. The two researchers then discussed and reached a consensus on the final coding, which was compared with the coding done in the full data analyses. The percentage of agreement (=number of codes agreed upon / total number of codes * 100% for each interview record) in repeated coding ranged from 62.2% to 82.5% (Appendix Table 4).

We did not seek feedback from the interviewees on the transcripts and coding due to a lack of contact details.

RESULTS

What is patient safety?

In the MCH setting, the concept of patient safety was linked to unwanted health outcomes, not necessarily adverse events as a result of medical interventions. The interviewees were concerned about both adverse events and the shortage of good outcomes.

Patient safety was categorized into six aspects (Table 1): safety and security of public spaces (e.g., falls, fire, property loss and damage), safety of medical services (through the entire process), privacy and information security, financial security, psychological safety, and gap in services. Managers and care providers were more likely to highlight the safety of medical services (65.0% and 52.5%, respectively) and the safety and security of public spaces (55.0% and 35.6%, respectively) as a major concern in patient safety. By contrast, patients (53.8%) wanted more on assurance of safety or avoided events (psychological safety). They (38.5%) also believed that unnecessary interventions could lower their financial security, jeopardizing their ability to pay for necessary interventions. While excessive interventions might be associated with adverse events, a lack of necessary interventions might be associated with negative consequences that could otherwise be avoided. Concerns about privacy and information security were shared by both health workers and patients, albeit a small percentage (25.0%

by managers/administrators, 5.1% by care providers and 2.6% by patients).

'Illness is a painful and stressful experience… I hope doctors or nurses alleviate my anxieties and doubts with their professional answers and psychological support.'(Patient)

'I often encounter patients suffering from postnatal depression, with all kinds of worries and fears… It may be more effective to comfort them psychologically, even offering a hug or slightly tough love, to make patients feel better rather than to prescribe drugs.'(Provider)

'Some doctors like to prescribe lots of pills, infusions and examinations, whether or not they should, just to make a profit.' (Patient)

'Take this laboratory report (in his hand) as an example. I would not feel safe if I did not listen to the doctor's advice to take such a test. My doctors read it and then told me, 'it is okay, and there is nothing to be worried about'. I felt safe at once, no matter whether it was necessary to do it or how much money I paid.' (Patient)

Table 1Number (percentage) of codes associated with patient safety in MCH institutions

Code	Descriptions	Health workers(n1=79)		Patients (n4=39)	Total (N=118)
		Managers (n2=20)	Care providers (n3=59)		
1.Safety and security of public spaces	Incidents that happen in public spaces, e.g., falls, fires, property loss and damage	11(55.0%)	21(35.6%)	5(12.8%)	37(31.4%)
2. Safety of medical services	Errors in diagnostic and treatment procedures; unintended outcomes	13(65.0%)	31(52.5%)	9(23.1%)	53(44.9%)
3. Privacy and information security	Violation of privacy and disclosure of information	5(25.0%)	3(5.1%)	1(2.6%)	9(7.6%)
4. Financial security	Financial waste in unnecessary interventions and a lack of ability to pay for necessary interventions	6(30.0%)	6(10.2%)	15(38.5%)	27(22.9%)
5. Psychological safety	Worry or anxiety associated with unknown events	5(25.0%)	10(16.9%)	21(53.8%)	36(30.5%)
6. Gap in services	Gap between expectations and reality	6(30.0%)	12(20.3%)	6(15.4%)	24(20.3%)

Patient safety culture (PSC)

Corresponding to the conceptualization of patient safety, 12 dimensions (containing 69 items) emerged as key components of PSC: management support (6 items), regulations and procedures (6 items), staffing (3 items), teamwork (5 items), non-punitive response to adverse events (6 items), openness in communication (8 items), risk awareness (6 items), continuous learning (6 items), self-efficacy (5 items), defensive medical practices (4 items), patient engagement (6 items), and competing interest between public health and clinical services(8 items).Details on the PSC dimensions and items can be found in Appendix Table 5.

Different views were found between health workers and patients. The top 5 most frequently coded dimensions from the data were: self-efficacy (100.0%), management support (95.0%), regulations and procedures (95.0%), continuous learning (95.0%) and non-punitive response to adverse events (85.0%) for managers; continuous learning (93.2%), self-efficacy (91.5%), regulations and procedures (91.5%), management support (89.8%), and staffing (88.1%) for care providers; and self-efficacy (94.9%), patient engagement (87.2%), continuous learning (51.3%), management support (43.6%), and staffing (41.0%) for patients. It was common to blame individuals for medical errors across all three groups of interviewees.

> *'We have summarized the common causes of medical incidents, including poor communication, lack of knowledge and skills, not obeying guidelines and procedures, and so on. All of these causes are individual responsibilities. Punishment of departments or individuals, although sometimes attracts complains, is helpful for reducing the number of incidents and making rules and regulations work.' (Manager)*
>
> *'A person who makes mistakes often is incompetent and should be fired.' (Manager)*
>
> *'Punishment of individuals is fair to others who do not make mistakes.' (Provider)*
>
> *'Medical errors and incidents are associated with personal attitudes and skills.' (Patient)*

The 12-dimensional framework for PSC confirmed the existing theoretical framework developed by the Agency for Healthcare Research and Quality. However, some new themes emerged.

Patients demanded more involvement in decision making, whether it was in relation to planning and prevention or medical procedures. They advocated for patient rights. This component of PSC was supposed to address the "gap between expectations and reality". It also reflected the nature of MCH, a kind of service comprising both preventive and clinical care.

> *'Now young parents are well educated and usually learn relevant information on the Internet before seeking care for their babies; they would like more detailed and accurate explanations than before.'(Provider)*
>
> *'Communication is very important. No matter what the conditions or risks, patients must be completely informed.'(Patient)*

Defensive medical practices emerged as another important component of PSC. Defensive practices could be presented in multiple ways, for example: rejection of a patient with high risks (risk aversion); compromised clinical decision in response to irrational requests from patients; unnecessary interventions to show "obligations" that could favor health workers in disputes. Such practices eroded the trust between health providers and patients and would eventually bring harm to patients.

> *'If a pregnant woman refuses to take a prenatal blood test, we suggest that our doctors write it down in her medical records, which would provide evidence in a dispute over a case*

of anemia.' (Manager)

'I refer premature infants to higher level hospitals as much as possible to prevent unexpected complications I cannot afford.'(Provider)

'Doctors rely on machines too much because they don't want to take any risks.'(Patient)

There was competing interest between public health and clinical services in MCH institutions. Some health workers believed that managers might make clinical services a priority in the institution due to financial pressures. This was likely to divert much needed resources from public health services to clinical care, increasing the possibility of the occurrence of avoidable events.

Table 2Number (percentage) of codes associated with the 12 dimensions of patient safety culture in MCH institutions

Dimension	Description of dimension	Health workers (n1=79)		Patients (n4=39)	Total (N=118)
		Managers (n2=20)	Care providers (n3=59)		
1. Management support	Prioritize patient safety; good management practices	19(95.0%)	53(89.8%)	17(43.6%)	89(75.4%)
2.Regulations and procedures	Rational and adjustable regulations and policies, empowering health workers	19(95.0%)	54(91.5%)	13(33.3%)	86(72.9%)
3.Staffing	Staffing and workloads	16(80.0%)	52(88.1%)	16(41.0%)	84(71.2%)
4.Teamwork	Teamwork within departments, across departments and across institutions	13(65.0%)	47(79.7%)	5(12.8%)	65(55.1%)
5.Non-punitive response to adverse events	Non-punitive response to adverse events based on root cause analyses; feedback and learning	17(85.0%)	42(71.2%)	6(15.4%)	65(55.1%)
6.Openness in communication	Adverse event reporting; open communication with colleagues and patients	10(50.0%)	38(64.4%)	0(0.0%)	48(40.7%)
7.Risk awareness	Attitudes toward and awareness of medical risks, errors and potential flaws	15(75.0%)	44(74.6%)	13(33.3%)	72(61.0%)
8.Continuous learning	Continuous learning and training, not limited to knowledge and skills	19(95.0%)	55(93.2%)	20(51.3%)	94(79.7%)
9. Self-efficacy	Individual belief in one's ability to succeed in tasks	20(100.0%)	54(91.5%)	37(94.9%)	111(94.1%)
10.Defensive medical practices	Procedures serving for the purpose of self-defense in disputes	9(45.0%)	22(37.3%)	9(23.1%)	40(33.9%)
11.Patient engagement	Patient involvements in decision making	15(75.0%)	44(74.6%)	34(87.2%)	93(78.8%)
12. Competing interest between public health and clinical services	Priority setting and resource allocation between public health and clinical services	6(30.0%)	6(10.2%)	0(0.0%)	12(10.2%)

External factors associated with PSC

PSC can be shaped by some external factors. In this study, the interviewees identified policy and social environments, poor health literacy of consumers, and a lack of trust between patients and health workers as major factors influencing PSC in MCH institutions.

MHC institutions are subject to strict policy and regulatory rules. Some unintended consequences had arisen from this strong control. For example, staffing and personnel policies led to a shortage of staff and heavy workloads of health workers; insufficient government financial support limited the further development of MCH institutions, resulting in the profit-seeking behaviors of these institutions; MCH institutions at the county level had restricted access to a limited range of medicines. These policy arrangements had the potential to jeopardize patient safety and PSC.

'For social stability purposes, hospitals are always compelled to compensate medical dispute profiteers, regardless of who is wrong.' (Manager)

'The government usually emphasizes the importance of public health in words but not in actions. Because of a lack of funds, public health tasks are always done as little as possible in fact.'(Manager)

'Since the institutional reforms in our region, county-level MCH institutions are not allowed to supply some drugs and services anymore, which is a broad-brush approach that does not consider specific circumstances.' (Provider)

The public media played a significant role in shaping the opinions of consumers. The large amount of unverified or exaggerated reports about medical incidents were blamed by the interviewees for causing distrust and conflicts between patients and health providers, fueling the defensive practices of health workers.

'Our medical staff is overloaded and the medical industry is at high risk. However, patients cannot understand these things, and medical accidents are reported by the mass media in a way that is always misleading and misinterpreted.' (Manager)

'Medical disputes probably happen in all hospitals. Doubts about the whole industry have spread into society. Additionally, a small thing can be magnified by the media and aggravate distrust.' (Provider)

Health care is a co-production process in which patients play a critical role. Poor health literacy limited the ability of patients to engage in patient safety management. The interviewees reported that some patients felt ashamed of their illness (especially female patients), some treated health care as a simple financial transaction of services, some doubted the intention of medical decisions, some held unreasonable expectations of medicines and had a low appreciation of preventive care, some simply disengaged, some misunderstood medical advice and failed to cooperate with health workers. There was a low level of recognition of the inherent inevitability of making mistakes by human beings.

'People don't respect us. For example, some nurses have been physically attacked by parents for failing to insert the scalp needle on the first try.' (Manager)

'Some patients consider treating human bodies to be like repairing machines. You must ensure that they get better or they will make trouble for you.' (Provider)

'I couldn't understand the doctors perfectly, and I had to do what they told me.' (Patient)

The lack of trust led patients to believe that they had to choose health workers in order to ensure

safety. Accreditation, environments and the popularity of health facilities, and the professional title and qualifications of health workers could all serve for the purpose of provider selection. This information either came from their previous experiences or from sharing with others. Unfortunately, patients with a low income had to take into consideration the costs, compromising their choice of providers. The medical-seeking behaviors (Figure 1) of patients had a great influence on PSC. In some cases, patients might challenge doctors using a second opinion obtained from other providers, peers or even the Internet.

'Some patients did not trust us. They would see several doctors for verification.' (Provider)

'I choose this hospital because it is big hospital with a good environment and many people come here seeking MCH services.' (Patient)

'I trust my doctor because one of my friends is acquainted with him.' (Patient)

'Before making the decision to give birth here, we read nearly all the comments about this hospital on the internet.' (Patient)

DISCUSSION

An expanded definition of patient safety

In the context of MCH institutions in China, the concept of patient safety goes beyond the scope of the definition provided by the World Health Organization: 'the reduction of risk of unnecessary harm (impairment of structure or function of the body and/or any deleterious effect arising there from) associated with health care to an acceptable minimum'.[40] Patient safety is no longer limited to service-associated adverse events. The absence or shortage of the wanted services became a safety concern because it can also lead to potential harm to patients. Patients often seek services from MCH institutions for the assurance of safety. Studies show that psychological safety assurance is to some extent related to distrustful relationships between patients and providers and inadequate informed consent.[41 42]

Patient safety problems are not necessarily a result of medical errors. In this study, our interviewees expressed concerns about the environmental impacts on patient safety, such as the safety and security of public spaces. In resource-poor countries where consumers have to pay a large proportion of medical expenses out of pocket, patient safety can be jeopardized by a lack of financial security. Spending on unnecessary interventions may not only result in direct harm, it may also prevent patients from receiving much needed interventions.[43 44] Some other studies also expanded the definition of patient safety, although from quite a different angle.[45-47]

Special characteristics of PSC in MCH institutions

MCH institutions possess some unique characteristics which differentiate them from general hospitals. Service users in MCH institutions are predominantly women and children. They are usually disadvantaged with low socioeconomic status, and face significant barriers in engaging with healthcare decisions and getting access to medical services.[48] MCH services are focused on a special window of the life cycle (childhood, adolescence and reproduction) and their customers are usually healthy. They are more likely to experience a higher level of stress when things go wrong compared to those in illness conditions. MCH institutions in China are considered part of the public health system. They are obliged to place population health as a priority and work in partnership with various stakeholders.[20]

The 12 dimensions of PSC for MCH institutions share some common features of PSC for general

hospitals. Nine of the 12 dimensions resemble those identified in other PSC studies.[10 22 23 49] These are management support, regulations and procedures, staffing, teamwork, non-punitive response to adverse events, openness in communication, risk awareness, continuous learning and self-efficacy.[50-53] The three additional dimensions identified in this study are: patient engagement, defensive medical practices, and competing interest between public health and individual care. Patient engagement has recently attracted increasing attention from the international community.[54-56] Meaningful engagement of patients depends on good PSC. Patient safety culture should place the interest of patients at the center of medical practices. Defensive medical practices, although not always harmful, have switched the core value to the interest of care providers. Evidence shows that defensive practices often involve excessive and sometimes harmful interventions, exacerbating distrust and poor cooperation between patients and care providers.[57-59] Public health services are the most cost-effective interventions. But a profit-driven management culture often favors clinical interventions and disease treatment, leaving public health under-resourced. This will eventually lead to consequences in patient safety.[43 44]

It is important to note that both the health workers and patients who participated in this study emphasized the importance of individual competency and tended to endorse a punitive strategy for improving patient safety. This runs counter to a systems strategy, which places a strong emphasis on 'upstream' systemic factors. Although it is fundamental to address system flaws for achieving sustainable safety outcomes,[60 61] blaming individuals is often emotionally more satisfying.[40 62 63] Knowledge of errors may help individuals thwart some systemic failures.[64]

Challenges for nurturing PSC

The concept of PSC reflects the philosophy of patient-centered health care. In reality, however, the concerns of health workers may not always be aligned with those of the patients. There may exist cognitive conflicts and interest conflicts between health workers and patients. This study involved managers, care providers and patients as participants. We found that patients are more likely to focus on financial security, psychological safety assurance, and engagement in decision making; whereas, health workers are more concerned about the organization of technical services. This may impose serious barriers for health workers to communicate with patients effectively and involve patients in clinical decisions in a meaningful way. Interest conflicts between patients and providers make the situation even worse, fueling defensive behaviors from both sides. Cognitive and interest conflicts threaten mutual understanding, trust and cooperation between patients and health workers, and thereby damage the safety and quality of patient care.[65-69]

Poor PSC can also be shaped by broad policy and social environments. Health workers have to consider the interests of their employers and follow policy and regulatory requirements. Over the past few decades, MCH institutions in China have been exposed to intense market competitions. The low salary and high bonus system encourages health workers to increase services, but sometimes at the cost of sacrificing patient interests. The distrust of patients in health services is prevalent. In extreme cases, this has been transformed into medical violence. The legal system and the public media have played a small role, if at all, in the improvement of social environments.[70-75]

Limitations and further studies

This study was conducted in six MCH institutions and the results are context specific. Caution needs to be taken in relation to the generalization of the results. The study provides a high-level classification of patient safety, which should not be treated as an operational taxonomy to be used directly in practices.

The PSC framework was developed through a qualitative study. Further studies are needed to quantify the reliability and validity of the instrument. There is also a need to verify the association between PSC and patient care outcomes.

Conclusion

This study developed a 12-dimensional framework for PSC in MCH institutions in China. Despite general similarities between this instrument and existing instruments measuring PSC in hospitals, there are some features which are specific to MCH institutions. Three additional dimensions (patient engagement, defensive medical practices, and competing interest between public health and individual care) are included. The focus of our instrument is more about "health" rather than "diseases". Adverse events arising from MCH services as well as health consequences as a result of the absence of needed services (e.g. preventive care) are considered equally important in relation to patient safety.

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Data Sharing Statement The raw data supporting the conclusions of this article are included in the article as interview excerpts. The full interview transcripts remain the property of the Division of Maternal and Child Health, School of Public Health, Peking University Health Science Centre, which are accessible by contacting the corresponding author Prof. Yan Wang, email: wangyan@bjmu.edu.cn

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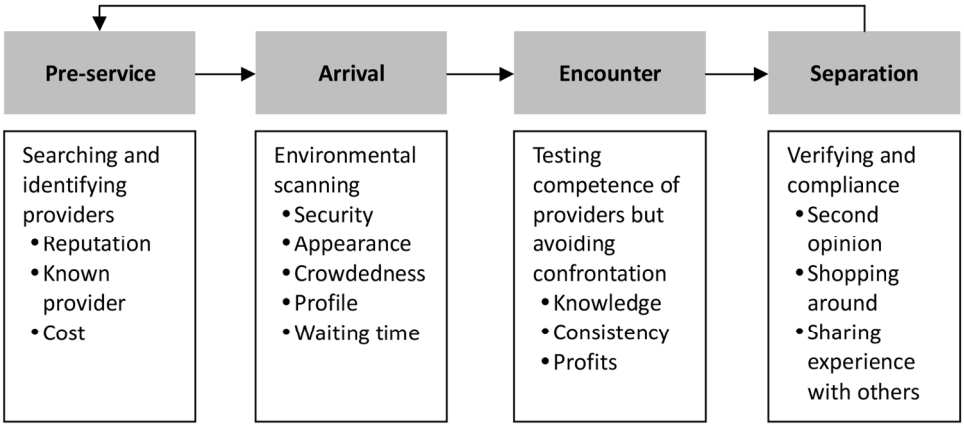

Figure 1 How patients make decisions when seeking health services

Figure 1 How patients make decisions when seeking health services

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Appendix Table 1 The general characteristics of six MCH institutions

Province	MCH institution	Number of				
		Staff	Beds	Outpatients (*1000per year)	Hospitalized (*1000 per year)	Deliveries (*1000 per year)
Hebei	SJZ	1022	450	520	21	16
	MC	90	40	15	1.6	1
	XH	110	60	120	2	1
Beijing	HD	729	460	740	20	14
	CY	443	125	280	6	4
	FT	362	120	280	3.5	2.2

**Rough data provided by administrative managers of those MCH institutions.*

Appendix Table 2 The general characteristics of 118 participants

Characteristics		Health workers(n1=79)		Patients (n4=39)	Total (N=118)
		Managers (n2=20)	Care providers (n3=59)		
Sex	Male	5(25.0%)	3(5.1%)	13(33.3%)	21(17.8%)
	Female	15(75.0%)	56(94.9%)	26(66.7%)	97(82.2%)
Age	20-29 years	0(0.0%)	8(13.6%)	16(41.0%)	24(20.3%)
	30-39 years	7(35.0%)	33(55.9%)	13(33.3%)	53(44.9%)
	40-49 years	9(45.0%)	16(27.1%)	1(2.6%)	26(22.0%)
	50-59 years	3(15.0%)	1(1.7%)	4(10.3%)	8(6.8%)
	60 years or above	1(5.0%)	1(1.7%)	0(0.0%)	2(1.7%)
	Missing	0(0.0%)	0(0.0%)	5(12.8%)	5(4.2%)
Education	Primaryorunder	0(0.0%)	0(0.0%)	4(10.3%)	4(3.4%)
	Secondary	0(0.0%)	0(0.0%)	7(17.9%)	7(5.9%)
	Juniorcollege	3(15.0%)	23(39.0%)	6(15.4%)	32(27.1%)
	Undergraduate	10(50.0%)	25(42.4%)	6(15.4%)	41(34.7%)
	Masterorabove	2(10.0%)	9(15.3%)	2(5.1%)	13(11.0%)
	Missing	5(25.0%)	2(3.4%)	14(35.9%)	21(17.8%)

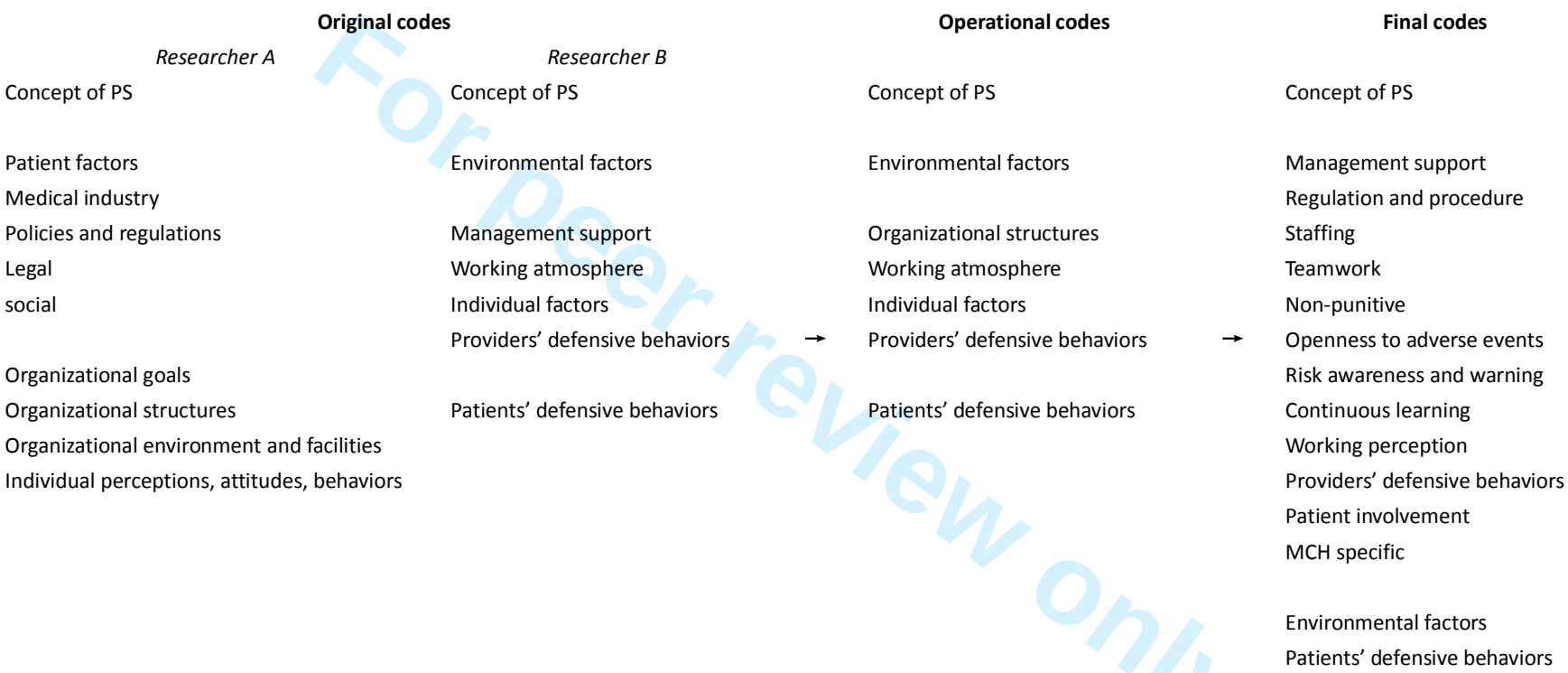
Appendix Table 3 Other general characteristics of 79 health workers

Characteristics		Managers (n2=20)	Care providers (n3=59)	Total (n1=79)
Working years	0-4 years	0(0.0%)	3(5.1%)	3(3.8%)
	5-9 years	3(15.0%)	14(23.7%)	17(21.5%)
	10 years or above	17(85.0%)	42(71.2%)	59(74.7%)
Professional title*	Clinicians	7(35.0%)	14(23.7%)	21(26.6%)
	Public health	2(10.0%)	15(25.4%)	17(21.5%)
	Nurses	5(25.0%)	21(35.6%)	26(32.9%)
	Administrative	6(30.0%)	0(0.0%)	6(7.6%)
	Others	0(0.0%)	9(15.3%)	9(11.4%)

**Professional title is a qualification authenticated by health administrative bureaus, which qualifies medical professionals' specialty legally. Most administrative managers of medical institutions in China had been promoted from frontline staff rather than specialized administrative managers.*

Appendix Table 4 The coding reliability of 12 re-test cases

No. of cases	Group	Consistency reliability between researchers	Re-test reliability
1	Manager	85.0%	68.2%
2	Manager	68.8%	66.7%
3	Care provider	79.4%	62.2%
4	Care provider	85.0%	73.9%
5	Care provider	66.7%	69.2%
6	Care provider	63.3%	66.1%
7	Care provider	75.6%	76.1%
8	Care provider	82.9%	82.5%
9	Patient	100.0%	66.7%
10	Patient	88.2%	73.7%
11	Patient	92.9%	62.5%
12	Patient	75.0%	63.9%



Appendix Figure 1 The modifying process of main dimensions coded by two parallel researchers

**Not showing specific sub-dimensions and items in each main dimension, and some dimensions of final codes came from sub-dimensions of operational codes.*

Appendix Table 5 Dimensions and items of patient safety culture in MCH institutions

Dimensions/items	Health workers (n1=79)		Patients (n4=39)	Total (N=118)
	Managers (n2=20)	Care providers (n3=59)		
1. Management support	**19(95.0%)**	**53(89.8%)**	**17(43.6%)**	**89(75.4%)**
1.1 Management gives priority to PS, considering other goals like profits or reputations.	10(50.0%)	14(23.7%)	3(7.7%)	27(22.9%)
1.2 Management is committed to continuous improvement of PS.	13(65.0%)	27(45.8%)	2(5.1%)	42(35.6%)
1.3 Management is committed to create a good working atmosphere.	1(5.0%)	1(1.7%)	0(0.0%)	2(1.7%)
1.4 Management provides adequate allocation of resources to the department where I work.	2(10.0%)	15(25.4%)	0(0.0%)	17(14.4%)
1.5 Management thinks highly of improving organizational environments and medical facilities.	16(80.0%)	38(64.4%)	14(35.9%)	68(57.6%)
1.6 Management pays more attention to profit-making departments than others.	6(30.0%)	11(18.6%)	0(0.0%)	17(14.4%)
2.Regulation and procedure	**19(95.0%)**	**54(91.5%)**	**13(33.3%)**	**86(72.9%)**
2.1Innovations of regulations and procedures are rigorous and flexible.	6(30.0%)	10(16.9%)	1(2.6%)	17(14.4%)
2.2Motivatemechanism of the organization is fair and feasible.	9(45.0%)	30(50.8%)	0(0.0%)	39(33.1%)
2.3 Some regulations and procedures are unreasonable and lead to inconveniences, barriers or risks.	14(70.0%)	37(62.7%)	13(33.3%)	64(54.2%)
2.4Frontlines can obey regulations and procedures in the organization.	16(80.0%)	26(44.1%)	2(5.1%)	44(37.3%)
2.5Risk preventing and responding mechanism has been introduced to reduce or avoid errors.	6(30.0%)	15(25.4%)	0(0.0%)	21(17.8%)
2.6 Frontline staff can be able to involve in decision-making.	3(15.0%)	10(16.9%)	0(0.0%)	13(11.0%)
3.Staffing	**16(80.0%)**	**52(88.1%)**	**16(41.0%)**	**84(71.2%)**
3.1I often feel busy too much.	3(15.0%)	9(15.3%)	4(10.3%)	16(13.6%)
3.2Staffing is far from sufficient to deal with workload.	13(65.0%)	41(69.5%)	11(28.2%)	65(55.1%)
3.3 Because of overload working, we cannot provide patients the best services as we could.	13(65.0%)	48(81.4%)	10(25.6%)	71(60.2%)
4.Teamwork	**13(65.0%)**	**47(79.7%)**	**5(12.8%)**	**65(55.1%)**
4.1Referrals between the organization and other institutions are efficient to ensure PS.	5(25.0%)	9(15.3%)	3(7.7%)	17(14.4%)
4.2 Cross-department teamwork in the organization is not satisfying.	9(45.0%)	34(57.6%)	1(2.6%)	44(37.3%)
4.3Communication is not pleasant between supervisors and subordinates.	3(15.0%)	3(5.1%)	0(0.0%)	6(5.1%)

4.4Handoffs are handled seriously and carefully.	1(5.0%)	8(13.6%)	0(0.0%)	9(7.6%)
4.5 Teamwork is satisfying in the department where I work.	8(40.0%)	31(52.5%)	1(2.6%)	40(33.9%)
5.Non-punitive response to adverse events	**17(85.0%)**	**42(71.2%)**	**6(15.4%)**	**65(55.1%)**
5.1Frontlines might not report adverse events happened due to worries about punishments.	4(20.0%)	4(6.8%)	0(0.0%)	8(6.8%)
5.2 Frontlines are encouraged to report adverse events.	5(25.0%)	17(28.8%)	0(0.0%)	22(18.6%)
5.3 Adverse events are mostly attributed to individuals in the organization.	2(10.0%)	2(3.4%)	6(15.4%)	10(8.5%)
5.4 Feedback of adverse events reported is delivered in time.	3(15.0%)	7(11.9%)	0(0.0%)	10(8.5%)
5.5Effortsare much engaged in preventing adverse events to reoccur.	2(10.0%)	18(30.5%)	0(0.0%)	20(16.9%)
5.6 In the organization, it is preferred to learn from adverse events than blame or punish individuals.	17(85.0%)	41(69.5%)	0(0.0%)	58(49.2%)
6.Openness to adverse events	**10(50.0%)**	**38(64.4%)**	**0(0.0%)**	**48(40.7%)**
6.1If adverse event happen and might harm patients, I will report it.	8(40.0%)	21(35.6%)	0(0.0%)	29(24.6%)
6.2 If adverse event happen but nearly not harm patients, I will report it as well.	10(50.0%)	22(37.3%)	0(0.0%)	32(27.1%)
6.3 If adverse event happen to colleagues, I will report it as well.	5(25.0%)	20(33.9%)	0(0.0%)	25(21.2%)
6.4 If adverse event happen, individuals involved will be regarded by colleagues not as usual.	1(5.0%)	7(11.9%)	0(0.0%)	8(6.8%)
6.5 It is not superstitious to discuss adverse events among colleagues.	5(25.0%)	25(42.4%)	0(0.0%)	30(25.4%)
6.6 I am not worried about discussing my errors.	2(10.0%)	4(6.8%)	0(0.0%)	6(5.1%)
6.7 If adverse event happen and is not found by patient, he/she will be not informed to avoid dispute.	3(15.0%)	12(20.3%)	0(0.0%)	15(12.7%)
6.8 If adverse event happen, patient will be comforted to relieve feelings of unsafety.	5(25.0%)	6(10.2%)	0(0.0%)	11(9.3%)
7.Risk awareness and warning	**15(75.0%)**	**44(74.6%)**	**13(33.3%)**	**72(61.0%)**
7.1 Besides incidents, management pay much attention to errors or potential risks as well.	3(15.0%)	6(10.2%)	0(0.0%)	9(7.6%)
7.2 If potential risks emerge, efforts will be much engaged to avoid reoccurring.	7(35.0%)	17(28.8%)	0(0.0%)	24(20.3%)
7.3 I cannot ignore errors and potential risks in work.	1(5.0%)	5(8.5%)	0(0.0%)	6(5.1%)
7.4 I agree that most of errors are preventable.	6(30.0%)	16(27.1%)	2(5.1%)	24(20.3%)
7.5 I agree that 'to err is human'.	6(30.0%)	17(28.8%)	6(15.4%)	29(24.6%)
7.6 I consider my work as part of PS.	11(55.0%)	26(44.1%)	2(5.1%)	39(33.1%)
8.Continuous learning	**19(95.0%)**	**55(93.2%)**	**20(51.3%)**	**94(79.7%)**

8.1 Continuous learning is considered as an important thing in the organization.	15(75.0%)	40(67.8%)	4(10.3%)	59(50.0%)
8.2Colleagues always discuss how to improve work.	7(35.0%)	30(50.8%)	0(0.0%)	37(31.4%)
8.3 I am competent to handle my job.	16(80.0%)	39(66.1%)	19(48.7%)	74(62.7%)
8.4 I need to learn continuously.	12(60.0%)	35(59.3%)	2(5.1%)	49(41.5%)
8.5 New employees are trained enough to be acquainted with regulations and procedures.	7(35.0%)	17(28.8%)	0(0.0%)	24(20.3%)
8.6 Staff is trained enough (not limited to knowledge and skills).	10(50.0%)	40(67.8%)	1(2.6%)	51(43.2%)
9.Working perception	**20(100.0%)**	**54(91.5%)**	**37(94.9%)**	**111(94.1%)**
9.1 I have a sense of satisfaction and accomplishment in my work.	9(45.0%)	21(35.6%)	0(0.0%)	30(25.4%)
9.2 I feel tired of my work.	13(65.0%)	22(37.3%)	2(5.1%)	37(31.4%)
9.3 I can receive patients with compassion and empathy.	13(65.0%)	30(50.8%)	14(35.9%)	57(48.3%)
9.4 I can perform patience and kind attitudes in my work.	14(70.0%)	41(69.5%)	37(94.9%)	92(78.0%)
9.5 I work seriously and responsibly.	12(60.0%)	36(61.0%)	13(33.3%)	61(51.7%)
10.Providers' defensive behaviors	**9(45.0%)**	**22(37.3%)**	**9(23.1%)**	**40(33.9%)**
10.1 To avoid high risk, we might refuse patients who we are able to treat in fact.	2(10.0%)	9(15.3%)	0(0.0%)	11(9.3%)
10.2 To avoid dispute, I might yield to patient, rather than adhere to rules and guidelines.	5(25.0%)	15(25.4%)	2(5.1%)	22(18.6%)
10.3 To avoid dispute, we have to do massive informed consents in writing or orally to protect ourselves.	4(20.0%)	7(11.9%)	3(7.7%)	14(11.9%)
10.4Unnecessary interventions exist in the organization.	3(15.0%)	2(3.4%)	5(12.8%)	10(8.5%)
11.Patient involvement	**15(75.0%)**	**44(74.6%)**	**34(87.2%)**	**93(78.8%)**
11.1I inform patients (like alternative plans and risks) as enough as I can.	13(65.0%)	42(71.2%)	34(87.2%)	89(75.4%)
11.2I response to any question of patients.	0(0.0%)	9(15.3%)	13(33.3%)	22(18.6%)
11.3 We often take advice from patients.	7(35.0%)	13(22.0%)	12(30.8%)	32(27.1%)
11.4 We emphasize health education to patients.	5(25.0%)	19(32.2%)	7(17.9%)	31(26.3%)
11.5 I respect patient's willing and rights.	4(20.0%)	21(35.6%)	7(17.9%)	32(27.1%)
11.6 Patients are encouraged to participate in risk management in the organization.	4(20.0%)	13(22.0%)	9(23.1%)	26(22.0%)
12.MCH specific	**6(30.0%)**	**6(10.2%)**	**0(0.0%)**	**12(10.2%)**
12.1 Management doesn't support to complete all of public health tasks.	8(40.0%)	14(23.7%)	0(0.0%)	22(18.6%)

12.2 Staffing allocated on public health is insufficient.	4(20.0%)	7(11.9%)	0(0.0%)	11(9.3%)
12.3 Staffing allocation make priority to clinic departments rather than public health departments.	1(5.0%)	1(1.7%)	0(0.0%)	2(1.7%)
12.4Our cooperation with other MCH institutions is satisfying.	4(20.0%)	13(22.0%)	1(2.6%)	18(15.3%)
12.5 I agree that public health is very important and necessary part of a MCH institution.	6(30.0%)	4(6.8%)	0(0.0%)	10(8.5%)
12.6 I agree that public health should be given more attentions than is now.	3(15.0%)	1(1.7%)	0(0.0%)	4(3.4%)
12.7 Public health workers are neglected frequently.	0(0.0%)	1(1.7%)	0(0.0%)	1(0.8%)
12.8 Public health departments are prejudiced as ‘special’ in the organization.	0(0.0%)	3(5.1%)	0(0.0%)	3(2.5%)

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No	Item	Guide questions/description	
Domain 1: Research team and reflexivity			
Personal Characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	Page 4
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*	Page1,4
3.	Occupation	What was their occupation at the time of the study?	Page 1,3
4.	Gender	Was the researcher male or female?	Page 3
5.	Experience and training	What experience or training did the researcher have?	Page 1,3,4
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	Page 4
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research*	Page 4
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*	Page 1,3,4
Domain 2: Study design			
Theoretical framework			
10.	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*	Page 4
11.	Method of approach	How were participants approached? e.g. *face-to-face, telephone, mail, email*	Page 4
12.	Sample size	How many participants were in the study?	Page 4
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	Page 4
Setting			
14.	Setting of data collection	Where was the data collected? e.g. *home, clinic, workplace*	Page 4
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	Page 4,14
16.	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*	Page 4
Data collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 4
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	Page 4
19.	Audio/visual	Did the research use audio or visual recording to	Page 4

	recording	collect the data?	
20.	Field notes	Were field notes made during and/or after the interview or focus group?	Page 4
21.	Duration	What was the duration of the interviews or focus group?	Page 4
22.	Data saturation	Was data saturation discussed?	Page 4
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No, because we did not keep contact details of the participants.
Domain 3: Analysis and findings			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	Page 5
25.	Description of the coding tree	Did authors provide a description of the coding tree?	Page 4-5
26.	Derivation of themes	Were themes identified in advance or derived from the data?	Page 4-5
27.	Software	What software, if applicable, was used to manage the data?	Page 4
28.	Participant checking	Did participants provide feedback on the findings?	No, because we did not keep contact details of the participants.
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number*	Page 6-12
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	Page 4-5, 12-14
31.	Clarity of major themes	Were major themes clearly presented in the findings?	Page 5-12
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Page 5-12

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Measuring patient safety culture in maternal and child health institutions in China: a qualitative study

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Measuring patient safety culture in maternal and child health institutions in China: a qualitative study

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ABSTRACT

Introduction Patient safety culture (PSC) plays a critical role in ensuring safe and quality care. Extensive PSC studies have been undertaken in hospitals. However, little is known about PSC in maternal and child health (MCH) institutions in China, which provide both population-based preventive services as well as individual care for patients.

Objectives This study aimed to develop a theoretical framework for conceptualizing PSC in MCH institutions in China.

Methods The study was undertaken in six MCH institutions (three in Hebei and three in Beijing). Participants (n=118) were recruited through stratified purposive sampling: 20 managers/administrators, 59 care providers and 39 patients. In-depth interviews were conducted with the participants. The interview data were coded using both inductive (based on the existing PSC theory developed by the Agency for Healthcare Research and Quality) and deductive (open coding arising from data) approaches. A PSC framework was formulated through axial coding that connected initial codes and selective coding that extracted a small number of themes.

Results The interviewees considered patient safety in relation to six aspects: safety and security in public spaces, safety of medical services, privacy and information security, financial security, psychological safety, and gap in services. A 12-dimensional PSC framework was developed, containing 69 items. While the existing PSC theory was confirmed by this study, some new themes emerged from the data. Patients expressed particular concerns about psychological safety and financial security. Defensive medical practices emerged as a PSC dimension that is associated with not only medical safety but also financial security and psychological safety. Patient engagement was also valued by the interviewees, especially the patients, as part of PSC.

Conclusions Although there are some common features in PSC across different healthcare delivery systems, PSC can also be context specific. In MCH settings in China, the meaning of "patient safety" goes beyond the traditional definition of patients. General wellbeing, health and disease prevention are important anchor points for defining PSC in such settings.

Strengths and limitations of this study

- The study explored the concept of patient safety and PSC from the points of view of managers/administrators, care providers and patients.
- The study was conducted in MCH institutions, which provided population-based preventive services as well as individual care for patients.
- The results are context specific and caution should be taken when generalizing the results.
- The study provides a high level classification of patient safety, which should not be treated as an operational taxonomy to be used directly in practices.

INTRODUCTION

Patient safety has become a global concern over the last two decades. It is agreed that patient safety culture (PSC), which is defined as the 'shared values, beliefs, norms and procedures related to patient safety among members of the organization',[1] is fundamental for safe and quality care.[2-6] In the literature, there are several distinct but related terms describing PSC, such as patient safety climate and patient safety attitudes. Culture is something that can be passed on and is relatively enduring.[7] It is reflected in normalized behaviors and practices. Climate, on the other hand, provides a snapshot of the overwhelming perceptions of people in regard to PSC.[8 9] Attitudes refer to how people see and

respond to matters associated with patient safety.[10] All of the three concepts are associated with safe behaviors, processes and outcomes.[5 11-13] The commonly accepted PSC elements cover a wide range of domains, including, but not limited to, leadership, communication, teamwork, error reporting, continuous learning, evidence-based practice, and non-punitive environment. [14 15]

Maternal and child health (MCH) is a priority on the global development agenda, such as the sustainable development goals (SDGs) promoted by the United Nations.[16] China has achieved extraordinary success in MCH over the past few decades, thanks to the universal coverage of MCH care delivered by MCH institutions.[17 18] From 1990 to 2015, the maternal mortality ratio (MMR, maternal deaths per 100 000 live births) in China decreased from 114.2 to 17.7;[19] and under-five mortality rate (U5MR, deaths per 1000 live births) dropped from 55.9 to 12.3.[20] There are 3,071 MCH institutions in China, covering all counties and cities.[21] They are dedicated to providing four categories of MCH services: (1) maternal and obstetrical care such as premarital examinations, progestational consultations, and pregnancy, labor and postpartum services; (2) pediatric care including management of neonatal, infant and child growth and development, nutrition, mental health, as well as the diagnosis and treatment of childhood diseases; (3) women's health, ranging from adolescent health and reproduction to nutrition, mental health, breast care, menopause and aged care. Gynecological services are also provided; (4) family planning services, such as health education, preconception counseling, contraception, and reproductive healthcare services. The MCH institutions operate at provincial, municipal and county levels, forming a tiered comprehensive network.[22] A considerable number of policies and regulations have been devoted to strengthening the infrastructure, technologies, and procedures of MCH services.[17 18 23].

Measuring PSC is important to help health workers to increase awareness and develop a better understanding of patient safety. It can also provide information support to managers to improve their managerial practices. Several PSC measurement tools have been developed. Of those tools, the Hospital Survey on Patient Safety Culture (HSPSC) developed by the Agency for Healthcare Research and Quality,[24] the Patient Safety Climate in Healthcare Organizations (PSCHO)[25] and the Safety Attitudes Questionnaire (SAQ)[10] are most commonly used. They have been applied to a wide range of health institutions in various countries,[26-28] including in China.[29-33] However, the Chinese versions of these instruments followed a stringent translation protocol and considered little, if any, of the special contexts of Chinese health institutions.

This study aimed to explore the concept of patient safety and PSC in China's MCH institutions. Internationally, there is a dearth of literature that examines PSC in MCH institutions. Due to the unique features of MCH services, PSC components that need to be addressed in MCH institutions could be different from those in general hospitals.[17 34] Since culture has the nature of profundity and abstruseness,[35] it is essential to unveil its presentations and implications under specific contexts. The principles of qualitative research, in particular the grounded theory, fits well with the objectives of this study. It allows us to generate a new (or modified) PSC framework without necessarily being restricted to any existing theoretical framework.[36 37] Instead of presenting details of PSC, this study intended to provide a high level classification of patient safety and PSC for the MCH institutions in China.

METHODS

Design

This is a qualitative study conducted by a multidisciplinary research team, comprising experts in MCH (YYW [female], YW[female] and HS [male]), research methodology (CL [male]), and health services

management (CL [male]& WL [female]). In-depth interviews were undertaken with health workers (managers/administrators and care providers) and patients to examine their perceptions and experiences of patient safety and PSC.

Setting and sample

Data were collected between November 2014 and April 2015 in six MCH institutions: three in Hebei and three in Beijing. These institutions were purposively selected, considering diversities in staffing, resources (e.g. beds), and scope and volume of services (e.g. outpatient, inpatient and birth delivery). The number of beds in the participating MCH institutions ranged from 40 (at the county level) to 460 (a large metropolitan center). Further details of the participating MCH institutions can be found in Appendix Table 1.

A stratified purposive sampling strategy was adopted to recruit participants. In each MCH institution, the potential participants were divided into 4-5 groups: management/administration (e.g., general office, medical administration, nursing administration, infection control), MCH clinics (e.g., pediatrics, gynecology, obstetrics), population health services (e.g., child healthcare, women's healthcare, preventive care), allied health services (e.g., pharmacy, imaging, laboratory) and other clinical services (e.g., internal medicine, surgery, dental, traditional Chinese medicine). In each institution, between 2-5 managers/administrators, 7-12 care providers (including doctors, nurses, public health workers, midwives, and allied health professionals) and 5-8 patients (including caregivers of children) were invited to participate in the study. Three invited interviewees (1 doctor and 2 patients) withdrew due to disruption caused by other urgent matters. The final sample size was determined by the saturation of information when no new theme emerged from the coding. The saturation of information was deemed to be achieved when the entire research team (especially those who performed the interviews and coding) reached consensus. This resulted in a final sample size of 118, including 20 managers/administrators (16.9%), 59 care providers (50.0%) and 39 patients (33.1%). The characteristics of participants are presented in Appendix Tables 2 and 3.

Data collection, processing and analyses

This study used both inductive and deductive approaches in data collection, coding and analyses. While the inductive approach tested the fitness of data into the existing PSC theories, the deductive approach guided by the grounded theory allowed the researchers to keep mind open and generate new theories through the data.[36]

The interview guides were developed based on a pre-tested tool in a previous study.[38] However, the interviewers were trained to respond to the interviewees in a flexible way in order to obtain in-depth information. They were encouraged to ask questions that were not listed in the interview guides. At the end of each interview session, the interviewers reviewed the interview guides to ensure that the interview had covered all the questions listed in the guides. No repeated interviews were undertaken.

All interviews were conducted face-to-face in the MCH institutions, led by two chief investigators (YYW [female] and HS [male]) and assisted by three trained interviewers (with a master or PhD degree). Prior to each interview session, the interviewers introduced themselves and the purpose, contents, ethical principles and declarations of the study and obtained written informed consent from the participants. Each interview lasted 15-50 minutes and was audio-recorded. The interviewers also took notes on the environment of the interview, the body language of respondents, self-reflection, and any other information they thought necessary.

Data analyses took place concurrently with data collection. Interview strategies (including the questions asked) were adjusted in subsequent interviews. The research team met regularly, discussing the findings and determining whether additional samples were needed.

All audio records were transcribed verbatim. We used NVivo 8.0 software to perform coding and analyses on the transcribed data and interview notes. The coding procedure followed the principles of grounded theory.[36] We started with open coding, which generated numerous codes from the raw data reflecting the panorama of the data. Original words were extracted to label the codes whenever it was possible. The second step involved axial coding. The initial codes were compared and condensed, with similar codes being merged using a new label that could describe all of the merged initial codes. The connections between different codes were identified by referring back to the raw data. This reduced the number of codes significantly. The third step was selective coding, which further abstracted key themes from the scattered codes. The selective coding considered the fitness of the condensed codes into the existing PSC theoretical framework developed by the Agency for Healthcare Research and Quality. Additional themes were established for those codes that did not fit well into the existing framework. Finally, we translated the codes into "dimensions" (high level framework) and "items" embedded in each dimension (Appendix Table 4).

Reliability and validity of coding

All data were coded in parallel by two researchers (YYW [female] and HS [male]). This ensured the validity of coding.[39 40] First, both researchers developed their own initial codes from the data. They then shared and discussed their coding and agreed on an operational list of codes. The agreed operational list of codes was eventually used for coding all of the data by the two researchers independently. Finally, another round of coding discussion was held, with modifications being made to the operational codes and the coding of all of the data into the final list of codes. The coding process is illustrated in Appendix Figure 1.

The reliability of coding was tested through repeated coding.[41 42] About 10% (n=12) of interview records were randomly selected for repeated coding: 2 from managers/administrators, 6 from care providers, and 4 from patients. Two researchers recoded the data independently into the agreed operational list of codes. About 63.3% to 100% of the codes were consistent between the two researchers. The two researchers then discussed and reached a consensus on the final coding, which was compared with the coding done in the full data analyses. The percentage of agreement (=number of codes agreed upon / total number of codes * 100% for each interview record) in repeated coding ranged from 62.2% to 82.5% (Appendix Table 5).

We did not seek feedback from the interviewees on the transcripts and coding due to a lack of contact details.

RESULTS

What is patient safety?

In the MCH setting, the concept of patient safety was linked to unwanted health outcomes, not necessarily adverse events as a result of medical interventions. The interviewees were concerned about both adverse events and the shortage of good outcomes.

Patient safety was categorized into six aspects (Table 1): safety and security of public spaces (e.g., falls, fire, property loss and damage), safety of medical services (through the entire process), privacy and information security, financial security, psychological safety, and gap in services. Managers and care

providers were more likely to highlight the safety of medical services (65.0% and 52.5%, respectively) and the safety and security of public spaces (55.0% and 35.6%, respectively) as a major concern in patient safety. By contrast, patients (53.8%) wanted more on assurance of safety or avoided events (psychological safety). They (38.5%) also believed that unnecessary interventions could lower their financial security, jeopardizing their ability to pay for necessary interventions. While excessive interventions might be associated with adverse events, a lack of necessary interventions might be associated with negative consequences that could otherwise be avoided. Concerns about privacy and information security were shared by both health workers and patients, albeit a small percentage (25.0% by managers/administrators, 5.1% by care providers and 2.6% by patients).

'Illness is a painful and stressful experience… I hope doctors or nurses alleviate my anxieties and doubts with their professional answers and psychological support.'(Patient)

'I often encounter patients suffering from postnatal depression, with all kinds of worries and fears… It may be more effective to comfort them psychologically, even offering a hug or slightly tough love, to make patients feel better rather than to prescribe drugs.'(Provider)

'Some doctors like to prescribe lots of pills, infusions and examinations, whether or not they should, just to make a profit.' (Patient)

'Take this laboratory report (in his hand) as an example. I would not feel safe if I did not listen to the doctor's advice to take such a test. My doctors read it and then told me, 'it is okay, and there is nothing to be worried about'. I felt safe at once, no matter whether it was necessary to do it or how much money I paid.' (Patient)

Table 1 Number (percentage) of codes associated with patient safety in MCH institutions

Code	Descriptions	Health workers(n1=79)		Patients (n4=39)	Total (N=118)
		Managers (n2=20)	Care providers (n3=59)		
1.Safety and security of public spaces	Incidents that happen in public spaces, e.g., falls, fires, property loss and damage	11(55.0%)	21(35.6%)	5(12.8%)	37(31.4%)
2. Safety of medical services	Errors in diagnostic and treatment procedures; unintended outcomes	13(65.0%)	31(52.5%)	9(23.1%)	53(44.9%)
3. Privacy and information security	Violation of privacy and disclosure of information	5(25.0%)	3(5.1%)	1(2.6%)	9(7.6%)
4. Financial security	Financial waste in unnecessary interventions and a lack of ability to pay for necessary interventions	6(30.0%)	6(10.2%)	15(38.5%)	27(22.9%)
5. Psychological safety	Worry or anxiety associated with unknown events	5(25.0%)	10(16.9%)	21(53.8%)	36(30.5%)
6. Gap in services	Gap between expectations and reality	6(30.0%)	12(20.3%)	6(15.4%)	24(20.3%)

Patient safety culture (PSC)

Corresponding to the conceptualization of patient safety, 12 dimensions (containing 69 items) emerged as key components of PSC: management support (6 items), regulations and procedures (6 items), staffing (3 items), teamwork (5 items), non-punitive response to adverse events (6 items), openness in communication (8 items), risk awareness (6 items), continuous learning (6 items), self-efficacy (5 items), defensive medical practices (4 items), patient engagement (6 items), and competing interest between public health and clinical services (8 items). Details on the PSC dimensions and items can be found in Appendix Table 4.

Different views were found between health workers and patients. The top 5 most frequently coded dimensions from the data were: self-efficacy (100.0%), management support (95.0%), regulations and procedures (95.0%), continuous learning (95.0%) and non-punitive response to adverse events (85.0%) for managers; continuous learning (93.2%), self-efficacy (91.5%), regulations and procedures (91.5%), management support (89.8%), and staffing (88.1%) for care providers; and self-efficacy (94.9%), patient engagement (87.2%), continuous learning (51.3%), management support (43.6%), and staffing (41.0%) for patients. It was common to blame individuals for medical errors across all three groups of interviewees.

> *'We have summarized the common causes of medical incidents, including poor communication, lack of knowledge and skills, not obeying guidelines and procedures, and so on. All of these causes are individual responsibilities. Punishment of departments or individuals, although sometimes attracts complains, is helpful for reducing the number of incidents and making rules and regulations work.' (Manager)*
>
> *'A person who makes mistakes often is incompetent and should be fired.' (Manager)*
>
> *'Punishment of individuals is fair to others who do not make mistakes.' (Provider)*
>
> *'Medical errors and incidents are associated with personal attitudes and skills.' (Patient)*

The 12-dimensional framework for PSC confirmed the existing theoretical framework developed by the Agency for Healthcare Research and Quality. However, some new themes emerged.

Patients demanded more involvement in decision making, whether it was in relation to planning and prevention or medical procedures. They advocated for patient rights. This component of PSC was supposed to address the "gap between expectations and reality". It also reflected the nature of MCH, a kind of service comprising both preventive and clinical care.

> *'Now young parents are well educated and usually learn relevant information on the Internet before seeking care for their babies; they would like more detailed and accurate explanations than before.'(Provider)*
>
> *'Communication is very important. No matter what the conditions or risks, patients must be completely informed.'(Patient)*

Defensive medical practices emerged as another important component of PSC. Defensive practices could be presented in multiple ways, for example: rejection of a patient with high risks (risk aversion); compromised clinical decision in response to irrational requests from patients; unnecessary interventions to show "obligations" that could favor health workers in disputes. Such practices eroded the trust between health providers and patients and would eventually bring harm to patients.

> *'If a pregnant woman refuses to take a prenatal blood test, we suggest that our doctors write it down in her medical records, which would provide evidence in a dispute over a case*

of anemia.' (Manager)

'I refer premature infants to higher level hospitals as much as possible to prevent unexpected complications I cannot afford.'(Provider)

'Doctors rely on machines too much because they don't want to take any risks.'(Patient)

There was competing interest between public health and clinical services in MCH institutions. Some health workers believed that managers might make clinical services a priority in the institution due to financial pressures. This was likely to divert much needed resources from public health services to clinical care, increasing the possibility of the occurrence of avoidable events.

Table 2 Number (percentage) of codes associated with the 12 dimensions of patient safety culture in MCH institutions

Dimension	Description of dimension	Health workers (n1=79)		Patients (n4=39)	Total (N=118)
		Managers (n2=20)	Care providers (n3=59)		
1. Management support	Prioritize patient safety; good management practices	19(95.0%)	53(89.8%)	17(43.6%)	89(75.4%)
2.Regulations and procedures	Rational and adjustable regulations and policies, empowering health workers	19(95.0%)	54(91.5%)	13(33.3%)	86(72.9%)
3.Staffing	Staffing and workloads	16(80.0%)	52(88.1%)	16(41.0%)	84(71.2%)
4.Teamwork	Teamwork within departments, across departments and across institutions	13(65.0%)	47(79.7%)	5(12.8%)	65(55.1%)
5.Non-punitive response to adverse events	Non-punitive response to adverse events based on root cause analyses; feedback and learning	17(85.0%)	42(71.2%)	6(15.4%)	65(55.1%)
6.Openness in communication	Adverse event reporting; open communication with colleagues and patients	10(50.0%)	38(64.4%)	0(0.0%)	48(40.7%)
7.Risk awareness	Attitudes toward and awareness of medical risks, errors and potential flaws	15(75.0%)	44(74.6%)	13(33.3%)	72(61.0%)
8.Continuous learning	Continuous learning and training, not limited to knowledge and skills	19(95.0%)	55(93.2%)	20(51.3%)	94(79.7%)
9. Self-efficacy	Individual belief in one's ability to succeed in tasks	20(100.0%)	54(91.5%)	37(94.9%)	111(94.1%)
10.Defensive medical practices	Procedures serving for the purpose of self-defense in disputes	9(45.0%)	22(37.3%)	9(23.1%)	40(33.9%)
11.Patient engagement	Patient involvements in decision making	15(75.0%)	44(74.6%)	34(87.2%)	93(78.8%)
12. Competing interest between public health and clinical services	Priority setting and resource allocation between public health and clinical services	6(30.0%)	6(10.2%)	0(0.0%)	12(10.2%)

External factors associated with PSC

PSC can be shaped by some external factors. In this study, the interviewees identified policy and social environments, poor health literacy of consumers, and a lack of trust between patients and health workers as major factors influencing PSC in MCH institutions.

MHC institutions are subject to strict policy and regulatory rules. Some unintended consequences had arisen from this strong control. For example, staffing and personnel policies led to a shortage of staff and heavy workloads of health workers; insufficient government financial support limited the further development of MCH institutions, resulting in the profit-seeking behaviors of these institutions; MCH institutions at the county level had restricted access to a limited range of medicines. These policy arrangements had the potential to jeopardize patient safety and PSC.

'For social stability purposes, hospitals are always compelled to compensate medical dispute profiteers, regardless of who is wrong.' (Manager)

'The government usually emphasizes the importance of public health in words but not in actions. Because of a lack of funds, public health tasks are always done as little as possible in fact.'(Manager)

'Since the institutional reforms in our region, county-level MCH institutions are not allowed to supply some drugs and services anymore, which is a broad-brush approach that does not consider specific circumstances.' (Provider)

The public media played a significant role in shaping the opinions of consumers. The large amount of unverified or exaggerated reports about medical incidents were blamed by the interviewees for causing distrust and conflicts between patients and health providers, fueling the defensive practices of health workers.

'Our medical staff is overloaded and the medical industry is at high risk. However, patients cannot understand these things, and medical accidents are reported by the mass media in a way that is always misleading and misinterpreted.' (Manager)

'Medical disputes probably happen in all hospitals. Doubts about the whole industry have spread into society. Additionally, a small thing can be magnified by the media and aggravate distrust.' (Provider)

Health care is a co-production process in which patients play a critical role. Poor health literacy limited the ability of patients to engage in patient safety management. The interviewees reported that some patients felt ashamed of their illness (especially female patients), some treated health care as a simple financial transaction of services, some doubted the intention of medical decisions, some held unreasonable expectations of medicines and had a low appreciation of preventive care, some simply disengaged, some misunderstood medical advice and failed to cooperate with health workers. There was a low level of recognition of the inherent inevitability of making mistakes by human beings.

'People don't respect us. For example, some nurses have been physically attacked by parents for failing to insert the scalp needle on the first try.' (Manager)

'Some patients consider treating human bodies to be like repairing machines. You must ensure that they get better or they will make trouble for you.' (Provider)

'I couldn't understand the doctors perfectly, and I had to do what they told me.' (Patient)

The lack of trust led patients to believe that they had to choose health workers in order to ensure

safety. Accreditation, environments and the popularity of health facilities, and the professional title and qualifications of health workers could all serve for the purpose of provider selection. This information either came from their previous experiences or from sharing with others. Unfortunately, patients with a low income had to take into consideration the costs, compromising their choice of providers. The medical-seeking behaviors (Figure 1) of patients had a great influence on PSC. In some cases, patients might challenge doctors using a second opinion obtained from other providers, peers or even the Internet.

'Some patients did not trust us. They would see several doctors for verification.' (Provider)

'I choose this hospital because it is big hospital with a good environment and many people come here seeking MCH services.' (Patient)

'I trust my doctor because one of my friends is acquainted with him.' (Patient)

'Before making the decision to give birth here, we read nearly all the comments about this hospital on the internet.' (Patient)

DISCUSSION

An expanded definition of patient safety

In the context of MCH institutions in China, the concept of patient safety goes beyond the scope of the definition provided by the World Health Organization (WHO): 'the reduction of risk of unnecessary harm (impairment of structure or function of the body and/or any deleterious effect arising there from) associated with health care to an acceptable minimum'. [43] Patient safety is no longer limited to service-associated adverse events. The absence or shortage of the wanted services became a safety concern because it can also lead to potential harm to patients. Patients often seek services from MCH institutions for the assurance of safety. Studies show that psychological safety assurance is to some extent related to distrustful relationships between patients and providers and inadequate informed consent.[44 45]

Patient safety problems are not necessarily a result of medical errors. In this study, our interviewees expressed concerns about the environmental impacts on patient safety, such as the safety and security of public spaces. In resource-poor countries where consumers have to pay a large proportion of medical expenses out of pocket, patient safety can be jeopardized by a lack of financial security. Spending on unnecessary interventions may not only result in direct harm, it may also prevent patients from receiving much needed interventions.[46 47] Some other studies also expanded the definition of patient safety, although from quite a different angle.[48-50]

Special characteristics of PSC in MCH institutions

MCH institutions possess some unique characteristics which differentiate them from general hospitals. Service users in MCH institutions are predominantly women and children. They are usually disadvantaged with low socioeconomic status, and face significant barriers in engaging with healthcare decisions and getting access to medical services.[51] MCH services are focused on a special window of the life cycle (childhood, adolescence and reproduction) and their customers are usually healthy. They are more likely to experience a higher level of stress when things go wrong compared to those in illness conditions. MCH institutions in China are considered part of the public health system. They are obliged to place population health as a priority and work in partnership with various stakeholders.[22]

Nine of the 12 dimensions resemble those identified in other PSC studies.[10 24 25 52] These are

management support, regulations and procedures, staffing, teamwork, non-punitive response to adverse events, openness in communication, risk awareness, continuous learning and self-efficacy. The three additional dimensions identified in this study are: patient engagement, defensive medical practices, and competing interest between public health and individual care. Patient engagement has recently attracted increasing attention from the international community.[53-55] Defensive medical practices, although not always harmful, have switched the core value to the interest of care providers. Evidence shows that defensive practices often involve excessive and sometimes harmful interventions, exacerbating distrust and poor cooperation between patients and care providers.[56-58] A profit-driven management culture often favors clinical interventions and disease treatment, leaving public health under-resourced, which will eventually lead to consequences in patient safety.[46 47]

Similar to findings of other studies,[43 59 60] both health workers and patients emphasized the importance of individual competency and tended to endorse a punitive strategy for improving patient safety, for improving patient safety. This runs in counter with a systems strategy, which places a strong emphasis on 'upstream' systemic factors.[43] Although it is fundamental to address system flaws for achieving sustainable safety outcomes,[61 62] blaming individuals is often emotionally more satisfying.[43 59 60] Knowledge of errors may help individuals thwart some systemic failures.[63]

Challenges for nurturing PSC

The concept of PSC reflects the philosophy of patient-centered health care. In reality, however, the concerns of health workers may not always be aligned with those of the patients. There may exist cognitive conflicts and interest conflicts between health workers and patients. This study involved managers, care providers and patients as participants. We found that patients are more likely to focus on financial security, psychological safety assurance, and engagement in decision making; whereas, health workers are more concerned about the organization of technical services. This may impose serious barriers for health workers to communicate with patients effectively and involve patients in clinical decisions in a meaningful way. Interest conflicts between patients and providers make the situation even worse, fueling defensive behaviors from both sides. Cognitive and interest conflicts threaten mutual understanding, trust and cooperation between patients and health workers, and thereby damage the safety and quality of patient care.[64-68]

Poor PSC can also be shaped by broad policy and social environments. Health workers have to consider the interests of their employers and follow policy and regulatory requirements. Over the past few decades, MCH institutions in China have been exposed to intense market competitions. The low salary and high bonus system encourages health workers to increase services, but sometimes at the cost of sacrificing patient interests. The distrust of patients in health services is prevalent. In extreme cases, this has been transformed into medical violence. The legal system and the public media have played a small role, if at all, in the improvement of social environments.[69-74]

Limitations and further studies

This study was conducted in six MCH institutions and the results are context specific. Caution needs to be taken in relation to the generalization of the results. The study provides a high-level classification of patient safety, which should not be treated as an operational taxonomy to be used directly in practices.

The PSC framework was developed through a qualitative study. Further studies are needed to quantify the reliability and validity of the instrument. There is also a need to verify the association between

PSC and patient care outcomes.

Conclusion

This study developed a 12-dimensional framework for PSC in MCH institutions in China. Despite general similarities between this instrument and existing instruments measuring PSC in hospitals, there are some features which are specific to MCH institutions. Three additional dimensions (patient engagement, defensive medical practices, and competing interest between public health and individual care) are included. The focus of our instrument is more about "health" rather than "diseases". Adverse events arising from MCH services as well as health consequences as a result of the absence of needed services (e.g. preventive care) are considered equally important in relation to patient safety.

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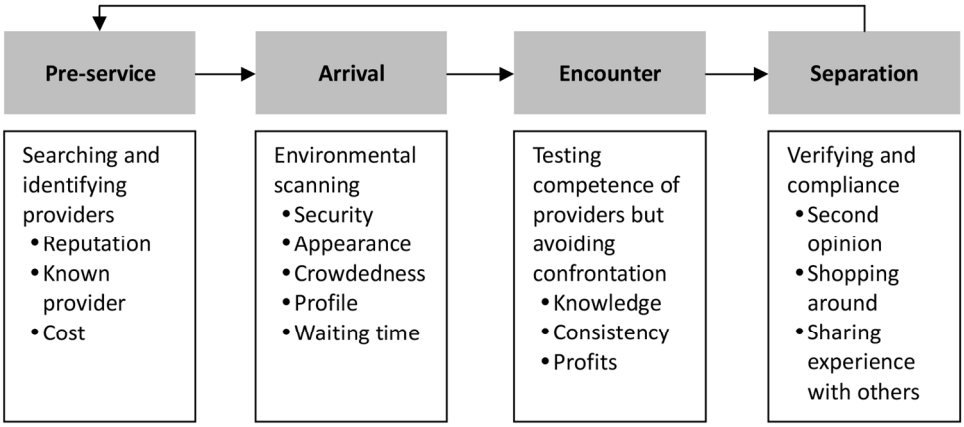

Figure 1 How patients make decisions when seeking health services

Figure 1 How patients make decisions when seeking health services

146x82mm (300 x 300 DPI)

Appendix Table 1 The general characteristics of six MCH institutions

Province	MCH institution	Number of				
		Staff	Beds	Outpatients (*1000per year)	Hospitalized (*1000 per year)	Deliveries (*1000 per year)
Hebei	SJZ	1022	450	520	21	16
	MC	90	40	15	1.6	1
	XH	110	60	120	2	1
Beijing	HD	729	460	740	20	14
	CY	443	125	280	6	4
	FT	362	120	280	3.5	2.2

**Rough data provided by administrative managers of those MCH institutions.*

Appendix Table 2 The general characteristics of 118 participants

Characteristics		Health workers (n1=79)		Patients (n4=39)	Total (N=118)
		Managers (n2=20)	Care providers (n3=59)		
Sex	Male	5(25.0%)	3(5.1%)	13(33.3%)	21(17.8%)
	Female	15(75.0%)	56(94.9%)	26(66.7%)	97(82.2%)
Age	20-29 years	0(0.0%)	8(13.6%)	16(41.0%)	24(20.3%)
	30-39 years	7(35.0%)	33(55.9%)	13(33.3%)	53(44.9%)
	40-49 years	9(45.0%)	16(27.1%)	1(2.6%)	26(22.0%)
	50-59 years	3(15.0%)	1(1.7%)	4(10.3%)	8(6.8%)
	60 years or above	1(5.0%)	1(1.7%)	0(0.0%)	2(1.7%)
	Missing	0(0.0%)	0(0.0%)	5(12.8%)	5(4.2%)
Education	Primaryorunder	0(0.0%)	0(0.0%)	4(10.3%)	4(3.4%)
	Secondary	0(0.0%)	0(0.0%)	7(17.9%)	7(5.9%)
	Juniorcollege	3(15.0%)	23(39.0%)	6(15.4%)	32(27.1%)
	Undergraduate	10(50.0%)	25(42.4%)	6(15.4%)	41(34.7%)
	Masterorabove	2(10.0%)	9(15.3%)	2(5.1%)	13(11.0%)
	Missing	5(25.0%)	2(3.4%)	14(35.9%)	21(17.8%)

Appendix Table 3 Other general characteristics of 79 health workers

Characteristics		Managers (n2=20)	Care providers (n3=59)	Total (n1=79)
Working years	0-4 years	0(0.0%)	3(5.1%)	3(3.8%)
	5-9 years	3(15.0%)	14(23.7%)	17(21.5%)
	10 years or above	17(85.0%)	42(71.2%)	59(74.7%)
Professional title*	Clinicians	7(35.0%)	14(23.7%)	21(26.6%)
	Public health	2(10.0%)	15(25.4%)	17(21.5%)
	Nurses	5(25.0%)	21(35.6%)	26(32.9%)
	Administrative	6(30.0%)	0(0.0%)	6(7.6%)
	Others	0(0.0%)	9(15.3%)	9(11.4%)

**Professional title is a qualification authenticated by health administrative bureaus, which qualifies medical professionals' specialty legally. Most administrative managers of medical institutions in China had been promoted from frontline staff rather than specialized administrative managers.*

Appendix Table 4 Dimensions and items of patient safety culture in MCH institutions

Dimensions/items	Health workers (n1=79)		Patients (n4=39)	Total (N=118)
	Managers (n2=20)	Care providers (n3=59)		
1. Management support	**19(95.0%)**	**53(89.8%)**	**17(43.6%)**	**89(75.4%)**
1.1 Management gives priority to PS, considering other goals like profits or reputations.	10(50.0%)	14(23.7%)	3(7.7%)	27(22.9%)
1.2 Management is committed to continuous improvement of PS.	13(65.0%)	27(45.8%)	2(5.1%)	42(35.6%)
1.3 Management is committed to create a good working atmosphere.	1(5.0%)	1(1.7%)	0(0.0%)	2(1.7%)
1.4 Management provides adequate allocation of resources to the department where I work.	2(10.0%)	15(25.4%)	0(0.0%)	17(14.4%)
1.5 Management thinks highly of improving organizational environments and medical facilities.	16(80.0%)	38(64.4%)	14(35.9%)	68(57.6%)
1.6 Management pays more attention to profit-making departments than others.	6(30.0%)	11(18.6%)	0(0.0%)	17(14.4%)
2.Regulation and procedure	**19(95.0%)**	**54(91.5%)**	**13(33.3%)**	**86(72.9%)**
2.1Innovations of regulations and procedures are rigorous and flexible.	6(30.0%)	10(16.9%)	1(2.6%)	17(14.4%)
2.2Motivatemechanism of the organization is fair and feasible.	9(45.0%)	30(50.8%)	0(0.0%)	39(33.1%)

2.3 Some regulations and procedures are unreasonable and lead to inconveniences, barriers or risks.	14(70.0%)	37(62.7%)	13(33.3%)	64(54.2%)
2.4Frontlines can obey regulations and procedures in the organization.	16(80.0%)	26(44.1%)	2(5.1%)	44(37.3%)
2.5Risk preventing and responding mechanism has been introduced to reduce or avoid errors.	6(30.0%)	15(25.4%)	0(0.0%)	21(17.8%)
2.6 Frontline staff can be able to involve in decision-making.	3(15.0%)	10(16.9%)	0(0.0%)	13(11.0%)
3.Staffing	**16(80.0%)**	**52(88.1%)**	**16(41.0%)**	**84(71.2%)**
3.1I often feel busy too much.	3(15.0%)	9(15.3%)	4(10.3%)	16(13.6%)
3.2Staffing is far from sufficient to deal with workload.	13(65.0%)	41(69.5%)	11(28.2%)	65(55.1%)
3.3 Because of overload working, we cannot provide patients the best services as we could.	13(65.0%)	48(81.4%)	10(25.6%)	71(60.2%)
4.Teamwork	**13(65.0%)**	**47(79.7%)**	**5(12.8%)**	**65(55.1%)**
4.1Referrals between the organization and other institutions are efficient to ensure PS.	5(25.0%)	9(15.3%)	3(7.7%)	17(14.4%)
4.2 Cross-department teamwork in the organization is not satisfying.	9(45.0%)	34(57.6%)	1(2.6%)	44(37.3%)
4.3Communication is not pleasant between supervisors and subordinates.	3(15.0%)	3(5.1%)	0(0.0%)	6(5.1%)
4.4Handoffs are handled seriously and carefully.	1(5.0%)	8(13.6%)	0(0.0%)	9(7.6%)
4.5 Teamwork is satisfying in the department where I work.	8(40.0%)	31(52.5%)	1(2.6%)	40(33.9%)
5.Non-punitive response to adverse events	**17(85.0%)**	**42(71.2%)**	**6(15.4%)**	**65(55.1%)**
5.1Frontlines might not report adverse events happened due to worries about punishments.	4(20.0%)	4(6.8%)	0(0.0%)	8(6.8%)
5.2 Frontlines are encouraged to report adverse events.	5(25.0%)	17(28.8%)	0(0.0%)	22(18.6%)
5.3 Adverse events are mostly attributed to individuals in the organization.	2(10.0%)	2(3.4%)	6(15.4%)	10(8.5%)
5.4 Feedback of adverse events reported is delivered in time.	3(15.0%)	7(11.9%)	0(0.0%)	10(8.5%)
5.5Effortsare much engaged in preventing adverse events to reoccur.	2(10.0%)	18(30.5%)	0(0.0%)	20(16.9%)
5.6 In the organization, it is preferred to learn from adverse events than blame or punish individuals.	17(85.0%)	41(69.5%)	0(0.0%)	58(49.2%)
6.Openness to adverse events	**10(50.0%)**	**38(64.4%)**	**0(0.0%)**	**48(40.7%)**
6.1If adverse event happen and might harm patients, I will report it.	8(40.0%)	21(35.6%)	0(0.0%)	29(24.6%)
6.2 If adverse event happen but nearly not harm patients, I will report it as well.	10(50.0%)	22(37.3%)	0(0.0%)	32(27.1%)
6.3 If adverse event happen to colleagues, I will report it as well.	5(25.0%)	20(33.9%)	0(0.0%)	25(21.2%)
6.4 If adverse event happen, individuals involved will be regarded by colleagues not as usual.	1(5.0%)	7(11.9%)	0(0.0%)	8(6.8%)

6.5 It is not superstitious to discuss adverse events among colleagues.	5(25.0%)	25(42.4%)	0(0.0%)	30(25.4%)
6.6 I am not worried about discussing my errors.	2(10.0%)	4(6.8%)	0(0.0%)	6(5.1%)
6.7 If adverse event happen and is not found by patient, he/she will be not informed to avoid dispute.	3(15.0%)	12(20.3%)	0(0.0%)	15(12.7%)
6.8 If adverse event happen, patient will be comforted to relieve feelings of unsafety.	5(25.0%)	6(10.2%)	0(0.0%)	11(9.3%)
7.Risk awareness and warning	**15(75.0%)**	**44(74.6%)**	**13(33.3%)**	**72(61.0%)**
7.1 Besides incidents, management pay much attention to errors or potential risks as well.	3(15.0%)	6(10.2%)	0(0.0%)	9(7.6%)
7.2 If potential risks emerge, efforts will be much engaged to avoid reoccurring.	7(35.0%)	17(28.8%)	0(0.0%)	24(20.3%)
7.3 I cannot ignore errors and potential risks in work.	1(5.0%)	5(8.5%)	0(0.0%)	6(5.1%)
7.4 I agree that most of errors are preventable.	6(30.0%)	16(27.1%)	2(5.1%)	24(20.3%)
7.5 I agree that 'to err is human'.	6(30.0%)	17(28.8%)	6(15.4%)	29(24.6%)
7.6 I consider my work as part of PS.	11(55.0%)	26(44.1%)	2(5.1%)	39(33.1%)
8.Continuous learning	**19(95.0%)**	**55(93.2%)**	**20(51.3%)**	**94(79.7%)**
8.1 Continuous learning is considered as an important thing in the organization.	15(75.0%)	40(67.8%)	4(10.3%)	59(50.0%)
8.2Colleagues always discuss how to improve work.	7(35.0%)	30(50.8%)	0(0.0%)	37(31.4%)
8.3 I am competent to handle my job.	16(80.0%)	39(66.1%)	19(48.7%)	74(62.7%)
8.4 I need to learn continuously.	12(60.0%)	35(59.3%)	2(5.1%)	49(41.5%)
8.5 New employees are trained enough to be acquainted with regulations and procedures.	7(35.0%)	17(28.8%)	0(0.0%)	24(20.3%)
8.6 Staff is trained enough (not limited to knowledge and skills).	10(50.0%)	40(67.8%)	1(2.6%)	51(43.2%)
9.Working perception	**20(100.0%)**	**54(91.5%)**	**37(94.9%)**	**111(94.1%)**
9.1 I have a sense of satisfaction and accomplishment in my work.	9(45.0%)	21(35.6%)	0(0.0%)	30(25.4%)
9.2 I feel tired of my work.	13(65.0%)	22(37.3%)	2(5.1%)	37(31.4%)
9.3 I can receive patients with compassion and empathy.	13(65.0%)	30(50.8%)	14(35.9%)	57(48.3%)
9.4 I can perform patience and kind attitudes in my work.	14(70.0%)	41(69.5%)	37(94.9%)	92(78.0%)
9.5 I work seriously and responsibly.	12(60.0%)	36(61.0%)	13(33.3%)	61(51.7%)
10.Providers' defensive behaviors	**9(45.0%)**	**22(37.3%)**	**9(23.1%)**	**40(33.9%)**
10.1 To avoid high risk, we might refuse patients who we are able to treat in fact.	2(10.0%)	9(15.3%)	0(0.0%)	11(9.3%)

10.2 To avoid dispute, I might yield to patient, rather than adhere to rules and guidelines.	5(25.0%)	15(25.4%)	2(5.1%)	22(18.6%)
10.3 To avoid dispute, we have to do massive informed consents in writing or orally to protect ourselves.	4(20.0%)	7(11.9%)	3(7.7%)	14(11.9%)
10.4Unnecessary interventions exist in the organization.	3(15.0%)	2(3.4%)	5(12.8%)	10(8.5%)
11.Patient involvement	**15(75.0%)**	**44(74.6%)**	**34(87.2%)**	**93(78.8%)**
11.1I inform patients (like alternative plans and risks) as enough as I can.	13(65.0%)	42(71.2%)	34(87.2%)	89(75.4%)
11.2I response to any question of patients.	0(0.0%)	9(15.3%)	13(33.3%)	22(18.6%)
11.3 We often take advice from patients.	7(35.0%)	13(22.0%)	12(30.8%)	32(27.1%)
11.4 We emphasize health education to patients.	5(25.0%)	19(32.2%)	7(17.9%)	31(26.3%)
11.5 I respect patient's willing and rights.	4(20.0%)	21(35.6%)	7(17.9%)	32(27.1%)
11.6 Patients are encouraged to participate in risk management in the organization.	4(20.0%)	13(22.0%)	9(23.1%)	26(22.0%)
12.MCH specific	**6(30.0%)**	**6(10.2%)**	**0(0.0%)**	**12(10.2%)**
12.1 Management doesn't support to complete all of public health tasks.	8(40.0%)	14(23.7%)	0(0.0%)	22(18.6%)
12.2 Staffing allocated on public health is insufficient.	4(20.0%)	7(11.9%)	0(0.0%)	11(9.3%)
12.3 Staffing allocation make priority to clinic departments rather than public health departments.	1(5.0%)	1(1.7%)	0(0.0%)	2(1.7%)
12.4Our cooperation with other MCH institutions is satisfying.	4(20.0%)	13(22.0%)	1(2.6%)	18(15.3%)
12.5 I agree that public health is very important and necessary part of a MCH institution.	6(30.0%)	4(6.8%)	0(0.0%)	10(8.5%)
12.6 I agree that public health should be given more attentions than is now.	3(15.0%)	1(1.7%)	0(0.0%)	4(3.4%)
12.7 Public health workers are neglected frequently.	0(0.0%)	1(1.7%)	0(0.0%)	1(0.8%)
12.8 Public health departments are prejudiced as 'special' in the organization.	0(0.0%)	3(5.1%)	0(0.0%)	3(2.5%)

Original codes		Operational codes	Final codes
Researcher A	*Researcher B*		
Concept of PS	Concept of PS	Concept of PS	Concept of PS
Patient factors	Environmental factors	Environmental factors	Management support
Medical industry			Regulation and procedure
Policies and regulations	Management support	Organizational structures	Staffing
Legal	Working atmosphere	Working atmosphere	Teamwork
social	Individual factors	Individual factors	Non-punitive
	Providers' defensive behaviors →	Providers' defensive behaviors →	Openness to adverse events
Organizational goals			Risk awareness and warning
Organizational structures	Patients' defensive behaviors	Patients' defensive behaviors	Continuous learning
Organizational environment and facilities			Working perception
Individual perceptions, attitudes, behaviors			Providers' defensive behaviors
			Patient involvement
			MCH specific
			Environmental factors
			Patients' defensive behaviors

Appendix Figure 1 The modifying process of main dimensions coded by two parallel researchers

**Not showing specific sub-dimensions and items in each main dimension, and some dimensions of final codes came from sub-dimensions of operational codes.*

Appendix Table 5 The coding reliability of 12 re-test cases

No. of cases	Group	Consistency reliability between researchers	Re-test reliability
1	Manager	85.0%	68.2%
2	Manager	68.8%	66.7%
3	Care provider	79.4%	62.2%
4	Care provider	85.0%	73.9%
5	Care provider	66.7%	69.2%
6	Care provider	63.3%	66.1%
7	Care provider	75.6%	76.1%
8	Care provider	82.9%	82.5%
9	Patient	100.0%	66.7%
10	Patient	88.2%	73.7%
11	Patient	92.9%	62.5%
12	Patient	75.0%	63.9%

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No	Item	Guide questions/description	
Domain 1: Research team and reflexivity			
Personal Characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	Page 4
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*	Page1,4
3.	Occupation	What was their occupation at the time of the study?	Page 1,3
4.	Gender	Was the researcher male or female?	Page 3
5.	Experience and training	What experience or training did the researcher have?	Page 1,3,4
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	Page 4
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research*	Page 4
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*	Page 1,3,4
Domain 2: Study design			
Theoretical framework			
10.	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*	Page 4
11.	Method of approach	How were participants approached? e.g. *face-to-face, telephone, mail, email*	Page 4
12.	Sample size	How many participants were in the study?	Page 4
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	Page 4
Setting			
14.	Setting of data collection	Where was the data collected? e.g. *home, clinic, workplace*	Page 4
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	Page 4,14
16.	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*	Page 4
Data collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 4
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	Page 4
19.	Audio/visual	Did the research use audio or visual recording to	Page 4

	recording	collect the data?	
20.	Field notes	Were field notes made during and/or after the interview or focus group?	Page 4
21.	Duration	What was the duration of the interviews or focus group?	Page 4
22.	Data saturation	Was data saturation discussed?	Page 4
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No, because we did not keep contact details of the participants.
Domain 3: Analysis and findings			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	Page 5
25.	Description of the coding tree	Did authors provide a description of the coding tree?	Page 4-5
26.	Derivation of themes	Were themes identified in advance or derived from the data?	Page 4-5
27.	Software	What software, if applicable, was used to manage the data?	Page 4
28.	Participant checking	Did participants provide feedback on the findings?	No, because we did not keep contact details of the participants.
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number*	Page 6-12
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	Page 4-5, 12-14
31.	Clarity of major themes	Were major themes clearly presented in the findings?	Page 5-12
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Page 5-12