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Comparing quality of primary healthcare between public and private providers in China: study protocol of a cross-sectional study using unannounced standardised patients in seven provinces of China

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ABSTRACT

Introduction The Chinese government has encouraged the development of private sector in delivering healthcare, including primary healthcare (PHC) in the new round of national health reform since 2009. However, the debate about the role of the private sector in achieving universal health coverage continues with poor support from theories and empirical evidence. This study intends to compare the quality of PHC services between the private and public providers in seven provinces in China, using unannounced standardised patients (USPs).

Methods We are developing and validating 13 USP cases most commonly observed in the PHC setting. Six domains of quality will be assessed by the USP: effectiveness, safety, patient centredness, efficiency, timeliness and equity. The USP will make 2200 visits to 705 public and 521 private PHC institutions across seven provinces, following a multistage clustered sample design. Using each USP-provider encounter as the analytical unit, we will first descriptively compare the raw differences in quality between the private and public providers and then analyse the association of ownership types and quality, using propensity score weighting.

Ethics and dissemination The study was primarily funded by the National Natural Science Foundation of China (#71974211, #71874116 and # 72074163) and was also supported by the China Medical Board (#16-260, #18-300 and #18-301), and have received ethical approval from Sun Yat-sen University (#2019–024). The validated USP tool and the data collected in this study will be freely available for the public after the primary analysis of the study.

Trial registration number Chinese Clinical Trial Registry: #ChiCTR2000032773.

Strengths and limitations of this study

- Use of the unannounced standardised patients to facilitate a fair comparison of quality between the private and public institutions in primary healthcare.
- Based on a large representative sample of primary healthcare providers across seven provinces of China.
- Theory-guided and framework-guided data collection and analyses.
- Systematic approach to identify confounders and mediators.
- Inability to determine the causal relation between ownership types of the primary healthcare facilities and quality due to the cross-sectional design.

INTRODUCTION

The year of 2019 marked the 10th anniversary of China's national health reform announced in 2009.[1] The reform has achieved impressive progress in expanding insurances and public health coverage, but it has not yet fundamentally changed its health delivery system and both the quality and efficiency of care are highly variable, if not suboptimal.[1 2] Since 2011, the government has encouraged private investment in healthcare delivery partly to promote reforms in the public sectors by creating competition from the private sector and partly to satisfy rising demands for quality of care as the population's socioeconomic conditions improve.[3] Consequently, the government has gradually relaxed restrictions on private engagement in health delivery in terms of health regional planning, public subsidy, health insurance contracting, taxation and price-setting.[4] As a result, the private share of total hospital numbers increased from 30.8% in 2009 to 57.2% in 2017.[5] In 2016, China released Healthy China 2030—setting a vision to promote primary healthcare (PHC) as the

cornerstone of national health development.[6] In other low and middle income countries (LMICs) the private sector provides a large share of PHC as well: almost half of the outpatient consultations were provided by the private sector in an analysis of 39 low-income countries.[7] Thus, the global goal of universal health coverage (UHC) seems to depend on PHC from both the public and private sectors.

However, despite the high visibility of the private PHC providers, the fierce debate continues concerning the role of the private sector in achieving UHC in China and other LMICs. The debate centres on the quality of care delivery by the private sector relative to the public sector.[8 9] Theoretically, the opponent of the private sector postulates that due to information asymmetry between providers and customers, the profit-driven private providers are willing and able to manipulate services that maximise profits rather than quality,[10 11] whereas a competing theory argues that private providers can use more up-to-date and flexible management to improve quality to compete with public providers.[12] Empirically, there is insufficient and conflicting evidence comparing the quality of private versus public providers in China and internationally.[13–16] We have identified four systematic reviews in this subject. Two earlier reviews of 80 studies[17] and 102 studies,[18] respectively, came to completely opposite conclusions regarding the relative quality of the two sectors; and the other two reviews (including the latest 2017 review) added no certainty to the debate.[15 19]

Part of the puzzle of this debate related to the challenges in assessing and comparing the quality of care. In order to accurately and fairly compare the quality of PHC delivered between the public and private providers, we must at least address three critical hurdles: a clear definition of quality, accurate measurement of quality and sufficient adjustment for case mix before the fair comparison. Popular quality frameworks include the WHO Framework, the Donabedian Framework, the Bamako Initiative and the Institute of Medicine (IOM) quality initiative.[20–24] For this study, we adopted the IOM framework that defines quality in six domains: effectiveness (avoiding underuse and misuse), safety (avoiding harm), patient centredness (respectful of and responsive to individual preferences), timeliness, efficiency (avoiding waste) and equity of care (no variance in quality because of personal characteristics).[20] Furthermore, we propose to compare the quality of PHC between the private and public providers by using unannounced standardised patients (USPs) so that we can accurately measure quality and control case mix. The traditional methods of measuring quality include chart abstraction, patient rating of care and using a clinical vignette to test clinician knowledge.[25] Those methods depend on indirect information that may not accurately and adequately represent the actual practice. This study instead will use USP, who is a healthy person trained to 'consistently' simulate the medical history, physical symptoms and emotional characteristics of a real patient. The measurement using USPs can (1) control case mix to enable cross-provider comparison because the 'same patient' is presented to all providers; (2) eliminate 'Hawthorne effect' due to the nature of unannounced visit; and (3) reduce recall bias as the trained SP generally reports data right after each clinician encounter.[26–28]

The use of USP controls sufficiently for the patient-level variations and enables a valid and objective comparison between providers. Furthermore, for the policy-makers who are considering the role of the private sector, in addition to understanding the quality differences as they are, they also need evidence on the effect of the intrinsic nature of the ownership on quality of care: will private ownership inherently lead to poorer (or better) quality of PHC? Because of lack of a randomised controlled study, we intend to explore this question by studying the association of ownership types of health facilities to the quality of PHC. The study of the association will require adequate control for not only the patient-level confounding factors (which will be achieved by the use of USP) but also the facility and environmental confounders.

This is one of a series of studies (ACACIA (Primary heAlth Care quAlity Cohort In chinA) study: https://www.researchgate.net/project/ACACIA-Study) using USPs and smartphone-based virtual patients in assessing and understanding the quality of PHC in a random sample of primary care facilities in seven provinces of China.[29 30] In this particular study, our purpose is to explore the association of the ownership types of the providers to the quality of PHC, which includes two steps: (1) raw comparison of the quality of care between the private and public PHC providers using USPs so as to expose any objective quality differences between the two groups and (2) comparison after adjusting for potential confounding so as to isolate the relations between the intrinsic natures of the private ownership to quality of PHC.

STUDY SITES AND PERIOD

We have drawn a representative sample of those eligible facilities from the seven provinces using a multi-stage, clustered sample design. We selected seven provinces of China—Gansu, Guizhou, Hunan, Inner Mongolia, Shaanxi, Sichuan and Guangdong—by purposive sampling to represent different health, socioeconomic, geographic and ethnic conditions across the country. Then, all the medical institutions that satisfied our criteria of PHC facilities were selected from the medical institutions' database provided by China's National Health Commission. This list of eligible institutions formed our sampling frame. Then we divided the sample into seven strata, one province per stratum. The seven provinces have been purposely selected to represent the overall landscape of China's different health development (judging from expected life expectancy at the provincial level, etc) and geographies (representing different geographic areas as China's geo-locations often is closely linked with social and economic development status).

The USP survey work is planned to be conducted from June 2020 to August 2020.

METHODS AND ANALYSIS

Study design

The study protocol for the umbrella study was published elsewhere.[29] This is a cross-sectional study using USP to compare the quality of care and further using propensity score weighting (PSW) to investigate the association between the ownership types (ie, private vs public ownership) of PHC facilities/practices and their quality of care.

Setting, participants and sampling

For the purpose of this study, we take a working definition of PHC settings (ie, the inclusion criteria for our participating facilities in our study) to include (1) outpatient services of the departments of internal medicine, obstetrics/gynaecology and paediatrics at level 1 and level 2 hospitals (hospitals are classified into three levels in China with increasing focus on specialty care; most rural/county hospitals are level 2 hospitals) and (2) outpatient services of community health centres, community health stations, and clinics at the urban setting and township health centres and village clinics at the rural settings. We exclude level 3 hospitals, the hospitals not yet designated a level (normally new institutions with unstable operations), and any other specialty care hospitals and specialty care clinics like those practicing solely in dentistry and ophthalmology. Our research subjects only include licensed physicians and assistant physicians and village doctors (village doctors in China may not have a formal license but have a Village Practice Certificate) working in the institutions that meet the aforementioned criteria of PHC institutions. The included clinicians must practice in the area of general practice, internal medicine, surgery, obstetrics and gynaecology, or paediatrics, excluding other specialties such as cardiology and endocrinology.

For cost consideration and also to prevent small medical institutions (such as village clinics) from detecting the possible multiple visits of the USPs, the institutions with geographical proximity were combined into pseudo-sampling clusters at each stratum in a way that each pseudo-cluster contained no less than 66 doctors who met our aforementioned criteria. Using probability proportional to size systematic sampling, we drew a total of 100 pseudo-clusters from the seven provinces. Finally, 22 doctors were selected from each pseudo-cluster by systematic sampling and each sampled doctor corresponded to a USP visit. The medical institutions corresponding to the doctors sampled were included in our study sample. According to the above method, we sampled 1226 medical institutions, of which 705 were public and 521 were private. These medical institutions will receive a total of 2200 USP visits. As the current sampling assumed the use of 11 USP cases, the final sample may be further adjusted according to the final number of USP cases to be selected for the field implementation (see more details in the following section of Development and validation of USPs). Figure 1 summarises the sampling procedure. Figures 2 and 3 described our sample characteristics.

Theoretical framework

Our data collection and statistical analysis will be guided by our theoretical framework for ownership and quality (figure 4). We developed this framework based on the literature review of several health systems,[31] quality of care[32 33] and implementation science frameworks[34 35] and our own expert consultation understanding. In this framework, quality of care delivered by a health provider is determined by outside environmental factors (policies, regulations, etc) and inside factors (facility, doctor and patient). Those outside and inside factors are theoretically or empirically indicated as the determinants of quality of care in prior studies. Different ownerships may correspond to different governance structures, profit

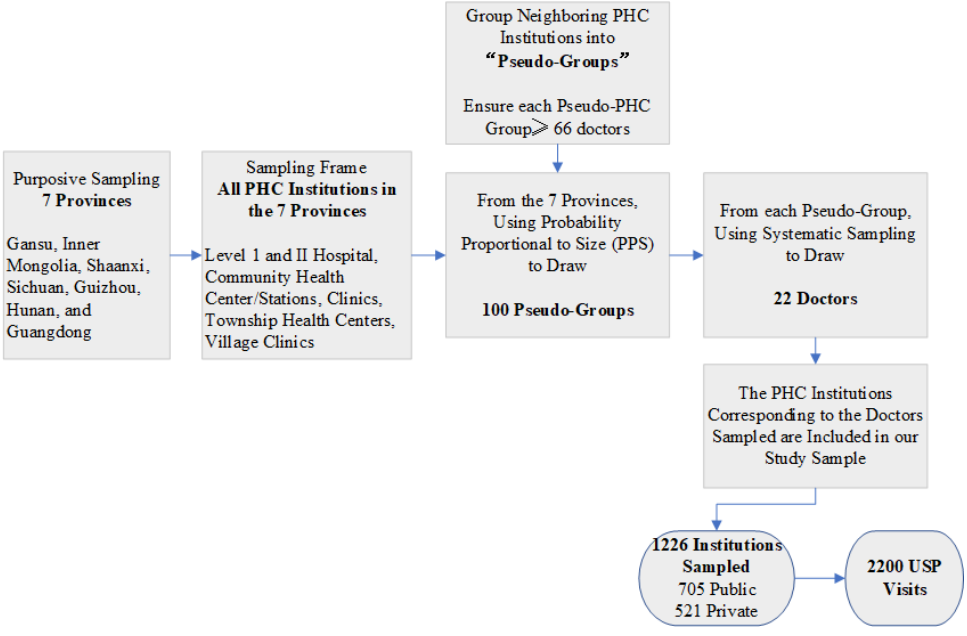

Figure 1 Sampling procedures. PHC, primary healthcare; USP, unannounced standardised patient.

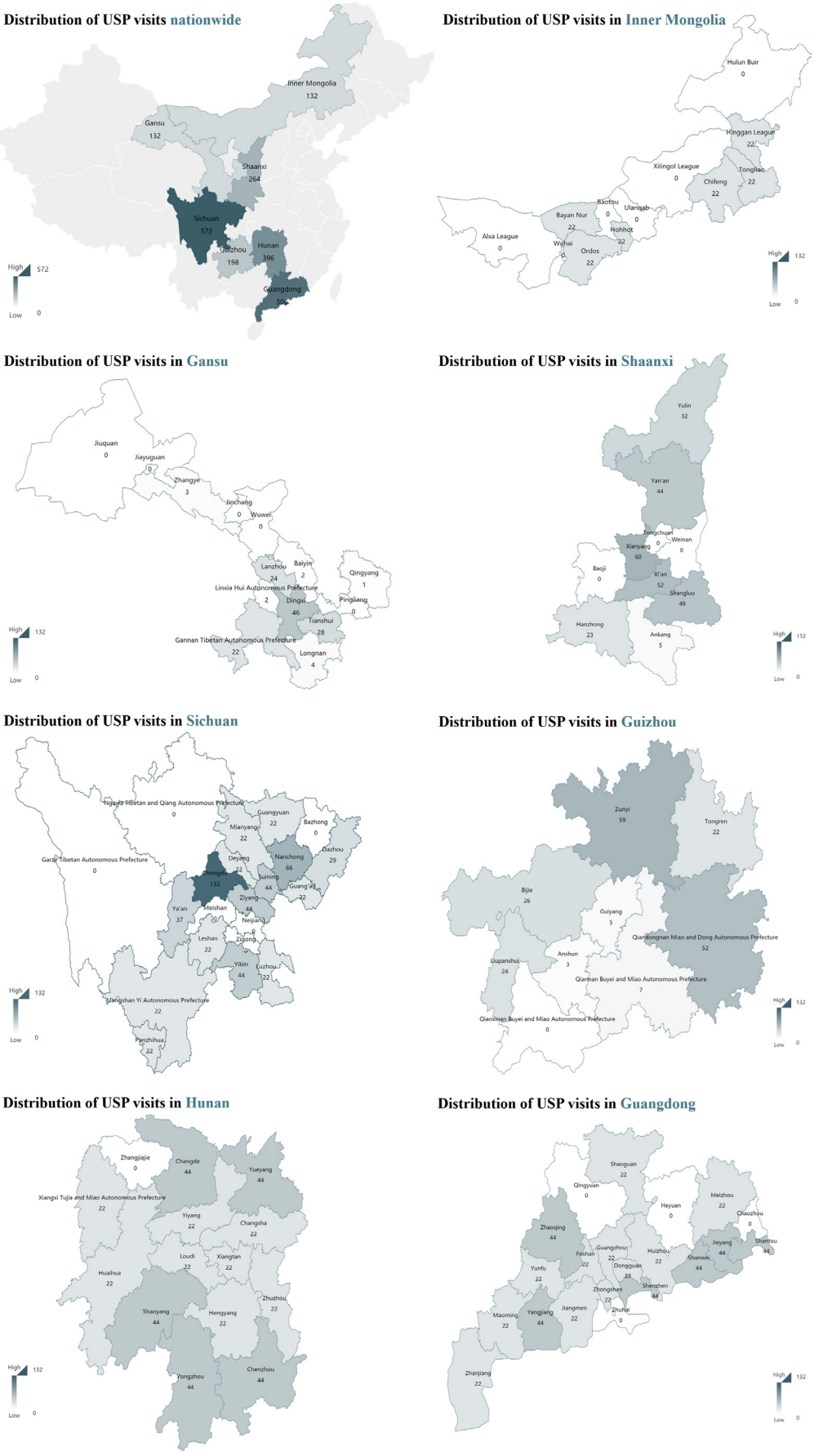

Figure 2 Distribution of USP–clinician visits of the study sample. USP, unannounced standardised patient.

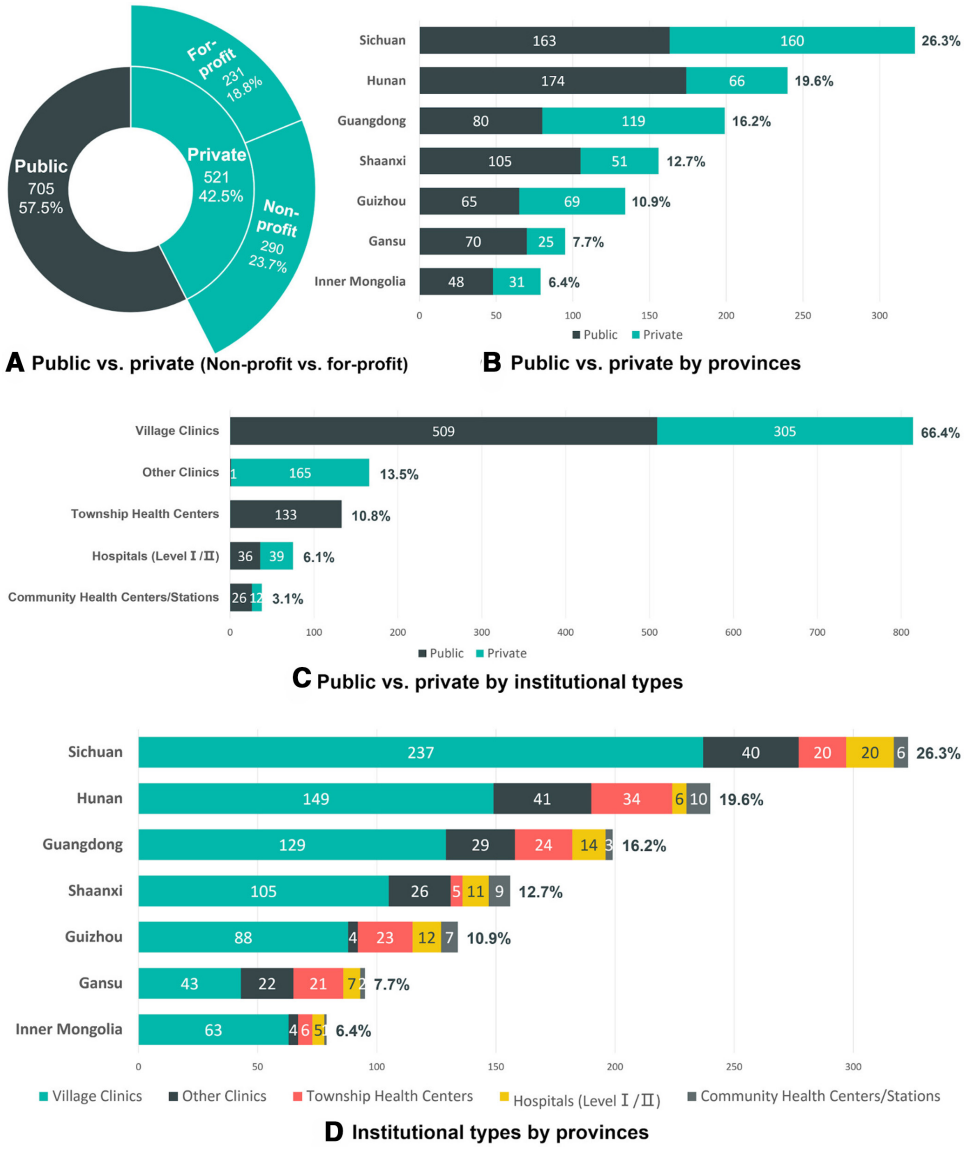

Figure 3 Distribution of sampled primary healthcare institutions.

orientation and presumed efficiency that affect various inside factors. The outside environmental factors, the external policies and incentives may be differentially applied to the health institutions of different ownerships and thus affect the behaviour of the facility and the individuals involved. In this quality framework, the patient factors have all been fixed through the use of our USPs. We will continue to improve this framework and will publish an updated version on our project website prior to any analysis of the study data.

Development and validation of USPs

Our USP case typically includes (1) a clinical scenario (with five domains—history, physical examinations, laboratory and imaging studies, diagnosis and management plan), (2) a patient clinical and socio-demographic profile, (3) scripts that match the clinical scenario for the SP to use during the clinical encounter, (4) a disguise plan to provide a cover for the faked identity of the SP, (5) an evidence-based quality checklist to score the technical quality of the encounter and (6) a survey form for patient-centred care. Details of the development and validation process of the USPs of this study have been published elsewhere.[29 30] Briefly, we selected 15 common PHC conditions based on two national surveys that include diabetes, hypertension, common cold, headache, postnatal depression, asthma, angina, lower back pain, gastritis, diarrhoea, fall, stroke, dementia, stress urinary incontinence and TB. Multidisciplinary teams of clinicians, public health professionals and health system researchers developed the USP cases and the quality criteria (the checklist) for those conditions, using the same development template. The cases are currently undergoing validation for content validity (ie, expert review), face validity (particularly to assess the ratio of USP being detected by the clinician under assessment and the accuracy of USP performing the case), criterion validity (ie, concordance of the quality scores given by the USP and a clinical expert on a same voice recording of a USP–clinician encounter) and test–retest

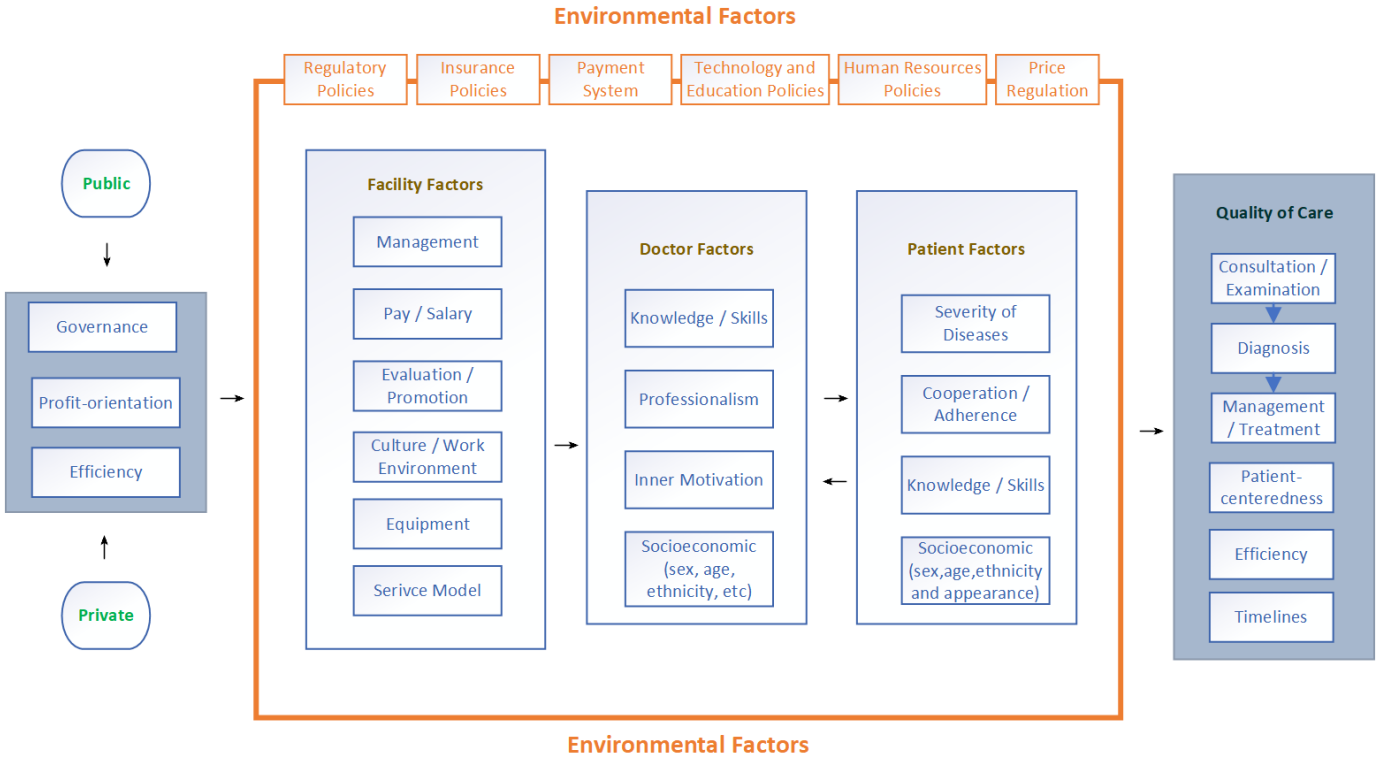

Figure 4 Theoretical framework for quality of care.

(ie, the same SP to score his own voice-recorded USP–clinician encounter two times) and inter-rater reliability (ie, concordance of two SPs score the same recorded USP–clinician encounter). We expect to use 8–11 cases for the final field implementation, depending on the validity of the developed cases.

Variables and measurements

The variable of primary interest is the ownership (ie, public vs private) of the PHC facility. There is no universal standard of classifying private versus public institutions.[36] Based on their comprehensive review of this typology, Perry and Rainey propose a public–private distinction based on the ownership, funding source and external social controls (primarily exercised through governmental authorities as opposed to market exchange) of the organisation.[36] As virtually all healthcare organisations in China are subject to heavy governmental controls and receive both public and private funding, we distinguish public versus private PHC facilities in this study through their ownership types. Public PHC facilities refer to the facilities that registered as state-owned facilities (Guo You or 国有) or collectively owned facilities (Ji Ti Suo You or 集体所有), and private facilities include all other types of facilities (like those owned by private businesses, state or private enterprises, or other social organisations/non-profit organisations). The private facilities can be non-profit or for-profit organisations.

The outcome variables of the study are various aspects of the quality of care as assessed by the USP with the IOM quality framework (table 1). Right after each USP–clinician encounter, the USP will complete (1) a case-specific technical quality checklist (effectiveness and safety), (2) a Patient Perceived Patient-Centeredness Rating Scale, which we are currently validating its Chinese version, and (3) a clinical encounter log that records costs of care and time of consultation. The primary outcome will be the technical quality (percentage of recommended questions asked and exams performed, the diagnostic accuracy and the appropriateness of the management based on the checklist), and the secondary outcomes include patient-centredness score, timeliness and efficiency (table 1).

Other explanatory variables related to the clinicians and their affiliated facilities as well as the regional socioeconomic characteristics will be collected. The clinician-specific information includes their socio-demographic profiles, qualification and services (table 1). The SP will take screenshots or phone pictures of the biosketches of the clinicians that the facilities often post on their website or the facility wall posters. The accuracy of physician-specific information will be checked later against the health department physician database. The facility-specific information will be obtained from the government's Health Facility Reporting System, including information on the facility type and size (table 1). The regional socioeconomic information will be collected from the local annual yearbook, including economic development (Gross Domestic Product (GDP) per capita) and urbanisation. Those variables will be updated and we will post the final version of the variables along with our final specification of our statistical analytical

Table 1 Variables and their definitions

Variables		Definitions	Nature	Data source	Data collection
Outcome variables					
	Effective and safe	*Per cent of items completed for clinical-guideline stipulated consultation and examinations *Accuracy of diagnosis *Accuracy of treatment plan	Primary Outcomes	Quality checklist	USP
	Patient centred	4 domains: illness experiences, seeking common ground, understanding the whole person and doctor–patient relationship	Outcomes	Patient Perspective Patient-Centeredness Rating Scale	USP
	Timely	Facility opening hours and wait time	Outcomes		USP
	Efficiency	Total and category expenditure	Outcomes	Expenditure form	USP
Exposure					
	Ownership type	*Private and public *For-profit and not-for-profit		Facility annual report	Routine reporting
Possible influencing factors of quality					
Environmental factors	Governance	Designated levels of health facilities	Confounders	Facility annual report	Routine reporting
	Health insurance	Health insurance contracting; payment methods	Confounders	Facility annual report	Routine reporting
	Pricing regulation	Pricing regulation of health services and products	Confounders	Local regulation	Policy review
	Human resources policies	Government policies on professional titles and promotion	Confounders	Local regulation	Policy review
	Science and technology policies	Regulations on qualifications for clinical clerkship, resident training and research grants	Confounders	National regulation	Policy review
Facility factors	Management	Use scale of business as proxies for management: volume of outpatient visits, hospitalisation and beds; and utilisation ratio of beds	Mediators	Facility annual report	Routine reporting
	Incentives and evaluation	Salary level and model of salary distribution and promotion mechanism	Mediators	Self-developed instrument	Smartphone-based virtual patient
	Work environment	Crowdedness and comforts of the clinics	Mediators	USP clinic and doctor form	USP
	Equipment	# of medical equipment valued over RMB 10 000; and information system	Mediators	Facility annual report	Routine reporting
	Service model	Member of medical corporate group, medical alliance, university affiliation, etc	Mediators	Facility annual report	Routine reporting

Continued

Table 1 Continued

Variables		Definitions	Nature	Data source	Data collection
Clinician factors	Knowledge and skills	*Medical competent *Medical education and training	Mediators	*National Health Human Resources Reporting *Virtual patients	*Routine reporting *USP
	Professionalism	Clinician professionalism	Mediators	Self-developed instrument	Smartphone-based virtual patient
	Motivation	Clinician motivation	Mediators	Self-developed instrument	Smartphone-based virtual patient
	Socio-demographics information	Age, sex, ethnicity and education	Mediators	*National Health Human Resources Reporting *USP clinic and doctor form	*Routine reporting *USP
Patient factors	Disease severity	Disease duration, comorbidity and complications	Confounders	Already controlled due to use of USP	
	Cooperation		Confounders		
	Knowledge and skills	Patient knowledge of the medical conditions	Confounders		
	Socio-demographics information	Age, sex, ethnicity and education	Confounders		

Source: authors.
USP, unannounced standardised patient.

model on our project website prior to any analysis of the study data.

Research Electronic Data Capture (REDCap) and its smartphone application[37] hosted at Sun Yat-sen Global Health Institute of Sun Yat-sen University will be used for data management and field data capturing (filling out checklist, 'photocopying' clinician laboratory orders, prescriptions and receipts for the purchase of drugs, recording times of consultation, voice-recording the clinical visit (during the case validation phase only) and taking Global Positioning System (GPS) coordinates of the facility).

Sample size calculation

The unit of analysis in this study is each USP–clinician encounter. In the sample size calculation, we chose the type I error (both sides) of 0.05 and assumed the maximum population of clinicians between private and public facilities to be 50 000. To account for the effect of multi-stage sampling and the collinearity between the predictor of interest (ie, the ownership of the facility) and other confounders, we conservatively assumed the intracluster correlation coefficient (ICC)[38] to be 0.2 and the squared multiple correlation coefficients between ownership and the other confounders to be 0.3, meaning that 30% of the variance in the ownership is assumed to be explained by the other confounders. The assumed ICC of 0.2 coupled with sampling cluster size of 22 gives the design effect of 5.2 and the assumed squared multiple correlation coefficient of 0.3 translates to the variance inflation factor of 1.43.[39] For the binary primary outcomes of diagnostic and management accuracy, we further assumed the accuracy rates in the public and private facility to be 85% and 70%, respectively. Under all the aforementioned assumptions, we calculated that a sample of 1518 USP–clinician encounters could achieve a power of 80% to detect a minimum effect size of 10% difference in the rates of diagnostic and management accuracy between private and public facilities. As for the continuous primary outcome of percentage of required items in the clinical guideline completed, we assumed the mean percentage in private and public facilities to be 50% and 65%, respectively, and the margin of error at 5%. Under these assumptions, we calculated that a sample of 593 USP–clinician encounters is required to achieve a power of 80% to detect a 1% point difference in the percentage of guideline-required items completed between private and public facilities. The sample size calculation was conducted using R package, samplesize4surveys (the ss4dpH and ss4dmH command).[40] As we decided to inherit the sample from the umbrella ACACIA study, its sample size of 2200 USP–clinician encounters (figure 2) should be more than enough for the purpose of this study.

Statistical method

Different statistical methods will be employed to address the two research questions we have put forward.

Raw comparison of PHC quality: private versus public

As the USP has controlled for confounding factors on the patient side (particularly the patient risk level and case mix), we will only perform simple descriptive analysis for the comparison between the private and public PHC providers. We will tabulate the sample characteristics for both clinicians and facilities. The standardised difference of those characteristics between public and private providers will be provided.[41] T-test/Wilcoxon test or χ^2 test will be employed to compare the clinicians and facilities between public and private providers. Then the various aspects of quality will be compared between private and public facilities without adjusting for any confounding. The purpose of this step is to show whether there are any objective differences in quality between the two types of facilities. All analysis for these comparisons will be conducted accounting for the complex survey design features of this sample.

Association of ownership type to quality

This part of the analysis intends to explore whether the intrinsic nature of the ownership type is associated with the quality of PHC. The intrinsic nature refers to the factors that inherently and inseparably embed with the ownership types. Given that we are using survey data without randomisation on public and private facilities, to compensate for potential confounding effects and reduce potential bias, a PSW approach will be used. Two analytical methods—PSW analysis and the traditional regression analysis—will be used for the same purpose of exploring the association of the ownership types to quality. The propensity score analysis will be the method of choice in this study, while the regression analysis will serve as the 'sensitivity analysis', to be used to see whether the results are sensitive to the analytical methods selected. Regardless of the analytical methods, a key challenge is to distinguish mediators and confounders during the analyses. Mediators lie in the inherent causal chain, thus should not be controlled for during the analysis (in other words, mediators belong to the 'intrinsic nature' of the ownership type aforementioned). On the contrary, confounders relate to both variables of interests and outcome variables but are not on the inherent causal chain and should be controlled to reduce bias. As the distinction between a mediator and confounder can be subtle, we will use the following systematic way to identify a list of confounders. We will first develop a candidate list of confounders and mediators, to be guided by relevant theories and empirical evidence on the relationship between the types of ownership and quality. We have already conducted a preliminary literature review and expert consultation, which resulted in the theoretical framework between ownership types and quality of care (figure 4). This framework will guide our work of identifying candidate confounders and mediators. Then an expert panel will review the candidate list and decide on the final list through consensus, using a Delphi iterate process. The panel will consist of policy-makers, researchers, hospital

managers, patients and clinicians who have deep knowledge of the public and private practice in China. This list of confounders and mediators will be published on the project website (https://www.researchgate.net/project/ACACIA-Study) prior to our regression and PSW analysis to minimise the risk of data manipulation during the analysis phase. We will also share our project and project data on Open Science Framework (https://osf.io/). In line with this approach, we have developed a preliminary list of variables of mediators and confounders and their data sources (table 1).

For the regression analysis in the sensitivity analysis, due to the correlations among the USP–clinician encounters from the same facility, generalised linear mixed-effects models (GLMMs), which is capable of addressing the correlations between outcomes of observations from the same facility, will be employed to assess the relationship between the quality of care and hospital ownership with potential confounders controlled. Different link functions will be used based on the type of outcome. For the process quality (with a continuous quality score), an identity link will be applied; while for whether the diagnosis is accurate and whether treatment is appropriate, a logit link will be applied instead. In addition to the variable of interest (ie, the ownership type of the PHC facilities), the potential confounders as aforedescribed will be included in the models. All models will be performed accounting for complex survey design features.

For the propensity score analysis, in addition to the confounders adjusted in the aforementioned regression analysis, other variables strongly associated with outcomes (Strong predictors of outcomes) but not a mediator will also be included in the development of the propensity score. The analysis will be based on PSW. The analytical unit will be each SP–clinician encounter. The propensity score in this study is the probability of SP–clinician visit being 'assigned' to a private facility (the exposure), conditional on a wide range of variables that may affect the quality (predictors of the outcome) or that may affect both the quality and the assignment (the confounding factors). Therefore, subjects with balanced propensity scores are balanced in covariates included in the propensity score model. Among other methods using the propensity score such as stratification on the propensity score, propensity score matching and covariate adjustment using the propensity score, we will use PSW as it not only provides a tool to balance two groups (private ownership vs public ownership of PHC facilities) but is also easier to address the clustering effect of the observations (USP–clinician encounter) in the same PHC facility. Below the detailed procedure of the PSW analysis is provided.

First, we will estimate the propensity score. Since the observations from the same facility are correlated, instead of applying a simple logistic regression model, we will need to apply the GLMM to estimate the propensity score for each SP–clinician encounter, with the correlation being taken into account. The 'facility ownership type' will be regressed on the afore-discussed confounders and strong predictors of the quality outcomes (see a preliminary list in table 1).[42 43] In the GLMM model, a random intercept will be included. The propensity score then will be estimated based on the fitted GLMM model. Per recommendations of Dugoff *et al*,[44] the propensity score model will be unweighted, given that we are not interested in making inference about the population when estimating propensity scores. Survey weight will be added as a covariate in the model. This is because the weight may capture relevant factors, for example, respondents' demographic characteristics and variables related to probability to respond to the survey.[44–46] After fitting the propensity model, we will then assess propensity score's balance across treatment and comparison groups. Second, after the propensity scores are estimated for each SP–clinician encounter, we will conduct weighted GLMM with the quality of care as the outcome and the ownership as the primary variable of interest to assess the association between the ownership and the quality of care. Again, by employing the weighted GLMM model, the correlations among the observations from the same facility are taken into account. Since the purpose is to make inference to the entire population, the analysis will take full account of the survey design features. Survey strata and cluster variables will be specified in our analysis. The weights are multiplications of the survey weights and the propensity score weights. The latter is the inverse of the estimated assignment probability in each ownership type. In weighted GLMM, SP–clinician encounters with similar background information will be weighted similarly. In such a way, the SP–clinician encounters are balanced between the two groups (private ownership vs public ownership) in the weighted GLMM model. Based on the type of outcomes, different link functions will be applied in weighted GLMM. As the covariates are already balanced in the propensity score, we will not include covariates in the weighted GLMM model in order to increase power. In the weighted GLMM analysis, the clustering effect is considered not only in estimating propensity score but also in the GLMM model and it should provide a valid estimate of the association between the ownership and the quality of care.[47]

For-profit versus non-profit

Our analysis will focus on the distinction between private versus public facilities, as our prior studies (unpublished yet) suggest no differences in quality and expenditure between the private for-profit and non-profit hospitals. However, we will conduct subgroup analysis to explore the performance differences between private for-profit and non-profit PHC facilities, following the same analytical principles for the regression and propensity scores aforementioned.

Patient and public involvement

Patient-centred care is a core element of our measurement of care quality in our study. We have engaged patients in the development of our standardised patient

cases such as selecting the cases that are most relevant to the patients, developing the scripts and deciding on the quality criteria that matter to the patients. In particular, we involved the patients' views on the development and validation of the Chinese version of the Patient Perspective of Patient-Centred Care instrument that the standardised patient will use during the field survey.

Ethics and dissemination

The project has been approved by the institutional review board of the School of Public Health of Sun Yat-sen University (#2019–024). We have obtained a waiver for obtaining clinician informed consent in this study as the process may lead to self-selection. Observing clinician unwittingly raises ethical concerns. We have discussed in more detail the unique ethical issues related to the USP in the study protocol of the umbrella ACACIA study. In summary, a USP study may meet the ethical standards if (1) it conducts de-identified and aggregated analysis only (not violating physician privacy), (2) it uses non-emergency settings only (not wasting scarce resources) and (3) the 'deception' of the USPs is necessary to prevent 'priming' the research subject.[48] The validated USP tool and the data collected in this study will be freely available for the public after the primary analysis of the study.

DISCUSSION

In this study, we compare the quality of private and public PHC providers as assessed by USP, using the IOM quality framework of six domains of quality. We will conduct two related analyses, each of which addresses a slightly different research question. The comparison of the quality between the private and public facilities addresses the question of whether there are any quality differences at all between those two groups (without addressing any confounding); then we will investigate whether the intrinsic nature of the private providers may be associated with worse (or better) quality of care. The information may provide much-needed empirical evidence to aid policy-makers in deciding on policies regarding the development of private sectors in the delivery of PHC and also the role of the private sector in achieving UHC in LMICs.

This proposed study may have several strengths. Although previous studies have suggested that in general, the quality of PHC is poor in China and other LMICs, quality studies have rarely been based on large random samples, sufficient numbers of tracer conditions and 'gold standard' assessment tools. Cashing in on our umbrella ACACIA study, we will be able to conduct a more thorough and valid comparison between the private and public providers with an adequately powered and representative sample of providers across seven provinces in China and a dozen or so representative tracer USP cases. Another strength of the proposal is that we intend to maintain complete transparency throughout the study with the pre-specified programme and analytical plans to improve research reproducibility. The last strength is that whenever possible we use theory-based programme development and data analyses. The study, however, is expected to have several limitations. Most noteworthy is that we cannot determine the causal relations between ownership types and quality of care despite our best effort to distinguish confounders from mediators in a systematic approach and to control confounding with PSW. Due to the cross-sectional nature of our study, we will never be able to fully control all confounding factors. However, the method of PSW at least separates our analyses into two steps. In the first step, we produce two groups by their ownership type based on the propensity scores and can test the balance of covariate distribution between the two groups; once we have achieved a balance between the two groups, we can then move into the second step of comparing the quality outcomes between the two groups. In this two-step approach, we can minimise the risk of the data-driven analysis as the first 'objective' step does not have the outcome data insight.

This is part of the ACACIA study. ACACIA study intends to survey the quality of PHC in the 7 provinces of China every 5 years. The first survey is scheduled for June–August 2020. The project website (https://www.researchgate.net/project/ACACIA-Study) contains more information on other related research and publication. The USP cases we developed and the data collected will be made available to other researchers after a protective time for the data analysis of the original research team so that international comparison may be conducted in the future.

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