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Development and validation of smartphone-based virtual patients to assess the quality of primary health care in rural areas: a study protocol

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ABSTRACT

Introduction: Valid, low cost and easy-to-implement tools for evaluating care quality are not readily available. While the Unannounced Standardized Patient (USP) is recommended as the gold standard for assessing quality, its use is restricted by the limited range of medical conditions that can be studied and a high implementation cost. Clinical vignettes provide a low-cost alternative; however, their lack of realism have brought their validity into question. Computerized virtual patients (VPs) can create high-fidelity, visualized and interactive simulations of doctor-patient encounters closely replicating clinical complexity that can be easily implemented via smartphone, at low marginal cost. Our study aims to develop and validate smartphone-based VP against USP as a quality assessment tool that can be used for research purposes and routinely applied to evaluate the quality of primary health care provided by primary health centers (PHCs) in rural areas.

Methods and analysis: The study will be implemented in outpatient settings of rural PHCs in seven Chinese provinces, and physicians practicing at township health centers and village clinics will be our study population. The development of VPs will involve three steps: (1) identifying 10 VP cases that can best represent rural PHCs' work, (2) designing each case by a case-specific development team, and (3) developing corresponding quality scoring criteria. After being externally reviewed for content validation, these VP cases will be implemented on a smartphone-based platform and will be tested for feasibility and face validity. This smartphone-based VP tool will then be validated for its criterion validity against USP and its reliability (i.e., internal

consistency and stability), with 1260 VP/USP-clinician encounters across the seven study provinces for all 10 VP cases.

Ethics and dissemination: Sun Yat-sen University: No. 2017-007. Study findings will be published and the tools developed will be freely available to low- and middle-income countries for research purposes.

Strengths and limitations of this study

- Developing and validating smartphone-based VP as a quality assessment tool for research and routine use in rural primary health care centers.
- Following an evidence-based approach to develop VP cases and scoring criteria.
- Systematically validating the VP assessment tool via a cross-national multicenter study
- The extent to which the VP assessment can reflect practitioners' real clinical practice needs to be verified.

Key words: Quality in health care, primary care, care quality assessment tool

INTRODUCTION

Universal health coverage (UHC) is a paramount goal of health system development for countries at all income levels.[1] The achievement of UHC is not possible without primary health care services,[1] which ensure integrated care close to the population they serve and link to health-related sustainable development goals.[2] However, service coverage alone cannot improve health outcomes if the quality of care is poor. Despite the fact that much attention has been shifted to enhance health care services, a dearth of scientific evidence exists on the quality of primary health care in resource-poor settings, particularly of low- and middle- income countries (LMICs).[3-5]

This scarcity of evidence may partially result from the limited availability of valid, low cost, and easy-to-implement quality assessment tools. As defined by Donabedian's framework for health care quality, quality can be evaluated by the *structure* of care (e.g., staff, equipment), the *process* of care delivery (e.g., doctor-patient interactions), and health *outcomes* (e.g., death or complications).[6] Process measures have been increasingly adopted, considering the benefits of frequent and timely evaluation, and the usefulness in improving practice.[7 8] The 'gold standard' of assessing process is the unannounced standardized patient (USP), namely a trained actor who simulates the symptoms, signs, and emotions of a real patient in a standardized fashion and presents him- or herself unannounced to clinics to assess care quality.[9] USP can reduce recall bias better than patient exit interviews, minimize the Hawthorne effect that inevitably occurs in direct observation, and allow for comparisons between users as case- and patient-mix are controlled.[3 7 10] Nonetheless,

the USP can only portray a limited number of conditions without obvious physiological symptoms and risk of invasive examinations. Also, training and implementation of USP can require substantial personnel and resources, making USP impractical for large-scale and routine quality assessment.[11 12]

On the other hand, clinical vignettes or case simulations have been widely used as a low-cost and convenient alternative to assess care quality.[7 13] Vignettes have been implemented in a paper-and-pencil form,[7] presented by an enumerator,[5] and streamlined by a computer.[13] The validity of the vignette in assessing the quality of patient care has gotten mixed reports. Some studies showed that vignettes only reflect clinicians' competency (know-how) rather than their actual behaviors and can cause overestimation of clinical performance.[7 14] By contrast, other studies found that vignette-based results, particularly those streamlined by computer, are quite close to the USP-based assessment.[13 15] The enumerator-administered vignette is similar to the announced standardized patient and thus is expensive and difficult to implement.[5] A computerized vignette can be interactive and can better represent the realistic complexity of a clinical encounter.[13] As a further improvement on computerized vignettes,[13] smartphone virtual patients (VPs) create high-fidelity, visualized, and interactive simulations that replicate clinical complexity and can be easily implemented at only marginal cost.[16] Although VPs cannot remove the Hawthorne effect, their advanced features may reduce the measurement gap between competency and real practice.[8 13] While VPs have been used in medical education to train and test clinical skills such as clinical reasoning, making diagnoses, and therapeutic

decisions,[17] the relative validity of their use as a measure for the quality of care has yet to be studied. Strengths and limitations of the abovementioned three methods are compared in Table 1.

In the present study, we propose to adapt smartphone-based VP for medical education as a quality-of-care assessment tool, given its advantages in 1) **standardization** (VPs are highly standardized, ensuring consistent assessments across users), 2) **flexibility** (Assessments can be delivered by smartphones for multiple users at anytime, anywhere, providing the data connectivity is available), 3) **scalability** (VPs can be modified to demonstrate and assess almost any clinical conditions with low marginal cost), and 4) **training** (VPs can further be used as a training tool to improve health care quality and thus to address the 'so what' question after quality assessment). These characteristics may especially benefit quality assessment and improvement in primary care of rural communities which are geographically scattered and difficult to reach and manage.

Therefore, our study aims to develop and validate **smartphone-based VPs** against USPs as a quality assessment tool that can not only be used for research purposes but also routinely applied to evaluate the quality of primary health care provided by primary health centers (PHCs) in rural areas. To maximize its validity,[13] we will properly construct high-fidelity VP cases to reflect clinical complexity in rural PHC contexts with real-time patient-doctor interactions and temporal constraints, as well as use evidence-based quality care scoring criteria; additionally, we will make the VP-based test anonymous to minimize the Hawthorne effect. The initial phase of

the study will mainly focus on rural China, while the ultimate goal is to develop and validate tools that can have a broad application in other LMICs.

METHODS AND ANALYSIS

Study setting

The validation study will be implemented in the outpatient setting of rural PHCs (i.e., township health centers and village clinics) in seven Chinese provinces (Guizhou, Sichuan, Gansu, Inner Mongolia, Shaanxi, Hunan, and Guangdong). We are selecting these provinces not only to reflect the five strata of low-to-high life-expectancies and various burden-of-disease patterns in China,[18] but also to contrast geographic regions with ethnic diversities, from southwest mountainous regions, to the northern plateau, middle inland region, and southeast coastal areas (**Error! Reference source not found.**). Our study targets township health centers and village clinics because they provide most primary health care in rural China.[19] At township health centers, primary health care is delivered by a workforce including licensed/unlicensed physicians, licensed/unlicensed assistant physicians, and registered nurses; while at village clinics, services are mainly delivered by one full- or part-time 'village doctor' who is a clinician with rudimentary medical training.[19-21] The outpatient setting is chosen due to the few inpatient cases in township health centers and village clinics.

VP case development

VP case selection

We intend to select 10 cases that can best represent the work of rural PHCs. The selection of the VP cases will be based on the following criteria: 1) high frequency of

clinical encounters in the primary care settings in rural areas, and/or 2) association with significant disease burden; 3) representation of the major areas of work of PHCs in rural China overall (e.g., public health service delivery, chronic disease management, infectious disease control, health education, and patient-centered care); and 4) suitability with USP methodology (e.g., no obvious physiological signs, low risk for invasive tests) for the sake of criterion validation in the current study. A case selection committee will be comprised of stakeholders, including physicians, public health practitioners, policy-makers, and members of the research team. Based on the literature review, the research team will prepare a list of the 30 most frequently seen conditions in township health centers and village clinics reported by either community dwellers[22] or the rural PHC clinicians (Appendix1) for the committee to rate and select.

VP case design

The 10 selected VP cases will then be constructed individually by 10 case-specific development teams (Figure 2). These teams consist of one *condition expert* in the relevant specialties of a tertiary teaching hospital who will be responsible for drafting the VP case; an *evidence-synthesis group* involving epidemiologists and evidence-based researchers who will search and synthesize evidence of the selected condition for the condition expert to work on; a *clinical consensus group* which consists of several condition-related clinical experts who will review the corresponding case from a scientific perspective; an overall all-condition shared *context-expert panel,* which includes clinicians and health managers from community health centers, township health centers, and village clinics, who will review the

contextual appropriateness of the cases in the rural PHC setting; and a *case coordinator* who will coordinate development of each case.

Each VP case will be structured into five domains—medical history, physical examination, laboratory and imaging studies, diagnosis, and management and treatment plan —to simulate real-life clinical scenarios. [10 17] The structured VP cases will have the ability to evaluate the examinee's performance by each domain and to aggregate performance scores across conditions. Besides these five condition-related domains, another practice contextual adjustor will be built into each case to consider medical resource constraints in rural practices (e.g., availability of basic medical equipment and medicines).

Scoring criteria

Corresponding to each VP case, care quality scoring criteria will be developed. These criteria include *process quality,* the *accuracy of diagnosis, and* the *appropriateness of the treatment and management plan*.[3 4] Process quality will be evaluated in reference to a clinical process checklist (to be detailed later) including all necessary questions that should be asked and physical examinations that should be performed by clinicians, alongside redundant or even potentially harmful practices. Diagnoses will be rated as correct, partially correct, or incorrect based on predetermined standards. The treatment & management plan will be considered appropriate if the clinician prescribes any of the correct medications or refers the patient to an upper level physician depending on the VP cases.

In addition, *cost of care* and *time-spent per encounter* will also be recorded.

Patient costs will cover medication fees and clinic fees charged per case. In order to recode clinicians' reaction time to each domain and to impose temporal constraints as in real clinical practices, the entire clinician-VP interaction process will be timed. This will include time spent on taking history, conducting physical examinations, prescribing drugs and treatments, and any interruptions)

As for the development of the aforementioned checklist for the predetermined standards of correctness regarding appropriateness of the treatment and management plan, a systematic evidence-based approach will be adopted (Appendix 2). Briefly, the evidence-synthesis group will systematically search and extract condition-specific checklist items and standards from clinical guidelines, reputable textbooks, and systematic reviews, etc., in that order, whereas the quality of the evidence will then be rated by the Appraisal of Guidelines for Research & Evaluation II (AGREE II)[23] or the revised Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) according to its type.[24] Afterwards, the clinical consensus group and the contextual-expert panel will review and revise initial standards using a Delphi process.[25]

VP case external review

To validate the content of VP cases, an independent expert panel of physicians, general practitioners, and rural PHC clinicians who otherwise are not involved in the study, will be convened to review the cases for content accuracy and appropriateness. The content validation involves qualitative and quantitative phases. In the qualitative phase, the expert panel will be required to evaluate the cases with respect to the

following: overarching assessment goal, representativeness of the goal and test items to each domain, the logical relationship of the content tested, and the appropriate wording, grammar, understandability, and relatedness to the rural PHC context. The panel will also mention their suggestions, if any, next to each item. Modified VP cases will then be given back to the expert panel for quantitative evaluation with respect to their adjustments for simplicity and clarity, as well as necessity and relevance to the assessment, using a four-point Likert scale ranging from 1 (the lowest) to 4 (the highest). The content validity index (CVI) will be computed for each domain and for the entirety of VP cases.[26]

Technical implementation

Revised VP cases will be implemented on *CureFUN*, an existing smartphone- based training platform using VPs with special customizations and set-ups to suit the assessment purpose. A live demonstration of a simplified VP can be accessed from http://www.curefun.com/zhiqu_front/www/experience/experience.html#/caseList and is also illustrated in Appendix 3. The smartphone-based VP assessment tool will not only present interactive clinical scenarios, but also automatically record each examinee's diagnosis pathway and grade it against the scoring criteria (Figure 33).

Feasibility study

Before a full-scale validation study, a feasibility study with 30% of the validation study sample (see study sample section) will be conducted to test the VP assessment tool's usability, accessibility, and stability, particularly in remote village clinics with weak phone connectivity. Selected clinicians will be instructed to individually attempt

two random VP cases within a given time, using their own smartphone devices from their workplace. Clinicians without a smartphone will be given a temporary one installed with the customized *CureFUN* applications. Clinicians' willingness to participate and adherence to the VP-based tests (e.g., percentage completing VP cases, score of the assessment, and number of attempts made at each case per person) will be automatically recorded. Upon completion of the cases, participants will be asked to fill in a five-point Likert-scale questionnaire regarding their subjective attitude toward the simulator VP experience (with 1 being the most negative response and 5 being the most positive), regarding ease of use, experienced assessment process and outcome, realism, device competence, accessibility, and other general comments. These results will be used to determine VP cases' face validity, whereby a satisfying score equals frequency (%) multiplied by positive evaluations; and scores no less than 1.5 are considered acceptable.[27]

Validation of VP as a quality assessment tool

Study design

The prospective validation study is a nationwide multicenter study with two main functions. This study will 1) assess the criterion validity of the VP-tool in assessing the quality of primary health care, by analyzing its measurement concordance against the standard USP measure, and 2) test the reliability of the VP tool, by examining its internal consistency and the stability of repeated VP assessments on the same examinees.

Study sample

From each of our seven sample provinces, two counties will be selected with sufficient variations in socio-economic conditions, demographics, and disease burdens between them while also approximating the provincial condition in general. Within each county, the government registry of all township health centers and village clinics will serve as our sampling frame, which will include 1) licensed practicing physicians, 2) clinicians who have not been licensed but are providing clinical services under the supervision of licensed physicians at township health centers, as well as 3) full- or part-time village clinicians. Temporarily-visiting clinicians (often senior clinicians sent by higher level medical institutions to support the development of township health centers), nurses, and allied health workers without prescription privileges will be excluded.

The sample size calculation is based on individual VP/USP-clinician encounter, and ensures sufficient power to detect variations at individual case level per county. For village clinics, one VP/USP case will be examined per time to minimize the detection of USPs. Assuming a 5% type I error and 80% power, to determine whether a moderate concordance correlation coefficient[28] of 0.90 [29] between VP and USP differs from zero, seven paired VP/USP-clinician encounters will be required for each of the 10 cases per county. As a stratified sampling strategy will be deployed that first samples townships and then villages from each township, the design effect should be taken into consideration when calculating the sample size. Assuming an intra-class correlation of 0.05 and 6 village clinics per township, then 9 paired VP/USP-clinician

encounters is needed. These nine paired VP/USP-clinician encounters will be assigned to 3 township health centers and 6 village clinics using probability proportional to size (PPS) method. These 9 paired VP/USP-clinician encounters will be assigned to township health centers and village clinics based on the ratio of the total number of clinicians at township health centers over the total number of village clinicians for each county. There are 1260 VP/USP-clinician encounters across our seven study provinces for all 10 VP cases. Figure 4 shows the sampling process and study flow for one VP case using Guizhou Province (Danzhai County) as a demonstration.

Criterion validity

Criterion validity[30] of the VP to assess quality of care will be evaluated mainly by its measurement concordance against the USP measure as the recognized gold standard[31] for assessing quality of care in real practice. The USPs will be developed in a related study, sharing the development teams for VP and a similar development process. The method of fielding USPs in rural China will follow approaches similar to those of the previous USP study in rural China.[3] Identical quality scoring criteria, described above, will be applied to scores. Each selected clinician will first see a USP (to avoid the practice effect due to the USP's unannounced feature), and then complete a smartphone-based VP assessment of the same condition. The clinician to be assessed will be randomly selected onsite by the USP from any on-duty clinicians on the day of the USP visit to the sampled township health center and village clinics. This situation would especially apply to township health centers, as most village clinics have only one clinician (note: Chinese patients normally see their primary care clinicians as a

walk-in patient and appointments are seldom needed). To record USP-clinician interactions, USPs will complete checklists immediately after their visit, as well as retain the medication prescription and the fee charge slips by the clinician. A week after the USP clinic visit, clinicians will be assigned a smartphone-based VP assessment. The VP-clinician interactions, drugs dispensed, and fees charged will all be recorded automatically by the online assessment system.

The concordance of the two assessments between USPs and VPs will then be analyzed by Lin's concordance correlation coefficient (r_c)[28] for continuous *process quality* scores, *fees charged* (yuan), and *time spent* (min),and the Kappa statistic[32] for dichotomous *diagnoses* and *treatment & management* measures. r_c evaluates how close pairs of observation fell on a 45° line (the perfect concordance line) through the origin in addition to their correlation. Kappa measures agreement in assessment beyond what is expected by chance alone. In addition, for continuous measures, a Bland-Altman plot will also be used to visualize the concordance.[33 34] For dichotomous measures, we will analyze their sensitivity (i.e., strength to detect correct diagnosis, treatment plan, etc.) and specificity (i.e., strength to detect incorrect diagnosis, treatment plan, etc.) using USP as the reference.

Reliability

To establish *test-retest reliability*, clinicians previously being assessed by VPs will be instructed to retake the same VP tests four weeks after their last assessment. The second VP test is set one month later than the first to reduce the practice effect,[35] assuming the clinician's general medical knowledge remains constant.[30] The

concordance of the two repeated tests indicate the stability of the VP assessment tool.[30] Similar concordance measures (i.e., r_c for continuous and Kappa for dichotomous measures) as described above will be used. The *internal consistency,* the intercorrelation of scores for process quality indicators, will be computed by Cronbach's alpha coefficients (α),[36] with $\alpha > 0.7$ representing acceptable reliability.[37] Table 2 summarizes the validity, reliability, and feasibility measures that will be examined in our study.

ETHICS AND DISSEMINATION

The study has been approved by the Institutional Review Board of the School of Public Health (IRB), Sun Yat-sen University (No. 2017-007). Informed consent will be obtained from all participating clinicians of VP tests. However, to reduce participation bias due to self-selection,[38] our IRB has approved the implementation of USP without prior informed consent from the individual participants, on the condition that involved clinicians will be fully de-identified and all analyses will only be conducted at the population level.[38] Study data will be securely stored and only de-identified information will be used for analysis. We will seek peer-reviewed publications for study findings and produce reports to inform health authorities. The tools and technology developed in this study will be freely available to other LMICs for research purposes.

DISCUSSION

To the best of our knowledge, this is the first study validating VP as a quality assessment tool in rural primary health care centers. This study follows an

evidence-based approach to develop VP cases and scoring criteria, implements them on a widely accessible platform (i.e., a smartphone), and systematically validates the VP assessment tool via a cross-national multicenter study representing rural PHCs over a wide range of geographic areas with distinct life expectancies and economic development levels. The VP assessment tool's accessibility, flexibility and scalability give it good potential to be easily adapted to other LMICs.

Nevertheless, it is to be noted that given its simulated nature, the VP-test theoretically may never completely bridge the 'competency-practice' gap. The validation study is thus essential to quantify the concordance/discordance between VP- and USP-based quality assessments. Our study will generate firsthand empirical evidence contributing to the understanding of the 'know-do gap',[5 39] and further shed light on circumstances that cannot be tested by USPs.

A limitation of the study, however, is that, in order to test the validity of VP against USP as the reference standard, we restrict the selection of VP cases to those that can be simulated by USP as well. Thus, the present study may not fully exhibit the potential of the VP in assessing quality of care. Further, the two purposely-selected counties for each province may not represent the provincial conditions entirely, although we will make every effort to consider provincial representation when selecting counties. Third, while the validation study is exclusively conducted on PHCs in rural China, the extent to which the VP assessment tool can be transported to other LMICs remains to be evaluated. Even so, the selected provinces from the 'five-Chinas' may improve the generalizability of our study

considering the comparable life expectancies of LMICs and these provinces.

Author's contributions

All authors contributed to the conceptualization and design of the study. DX, JL, and YYC conceived the initial study design, analytical methods, and composition of the team. JL was responsible for the study concept, initial draft, and revisions. DX was responsible for the study concept and revising the draft. YLC and XHW were responsible for the development of the scoring criteria. SS, HW, JNW, ZLZ, ZN, WJG, JP, CXT and WZ provided critical review and revision to the study design. All authors read and approved the final revision.

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Competing interests

The development of the VP assessment tool is a joint project of the Sun Yat-sen University Global Health Institute (SGHI) (representing the seven universities in China), and *CureFUN*. However, the VP cases will be independently developed and the validation studies will be rigorously conducted by the research team from SGHI and the seven universities, whereas CureFun will technically implement the cases on smartphones and have no influence over the study design and analysis.

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Figure 1. Seven sample provinces in China referencing countries of equivalent life expectancy in parentheses.

Figure 2. VP case development team role and responsibilities.

Figure 3. Main components of smartphone-based VP program.

Figure 4. Sampling and study process for one VP case in Danzhai County, Guizhou Province (THC: township health center; VC: village clinic)

Table 1. The strengths and limitations of methods to assess care quality.

Process Measure of Quality	Strengths	Limitations	Assessment Level
Unannounced Standardized Patient (USP)	Standardized, controlling for case-mix and patient-mix; Unannounced, no Hawthorne effect (if not be detected); Reduced recall bias	Expensive Limited medical conditions First-visit bias Selection bias if informed consent is required	**Action** (Do) **Gold standard**
Clinical Vignettes	Cost-effective; Suitable for large scale and cross-system comparison; Covering all illnesses; Accounting for case-mix and patient-mix.	Hawthorne effect Selection bias	**Competence** (Know how) **Over-estimating** care quality (best answers) or similar
Virtual Patients (VP)	Interactive Real-time response & automatic record Highly standardized Scalability & low marginal cost Efficient delivery: anytime, anywhere Suitable for large scale study	Hawthorne effect Selection bias High cost in initial development	**Performance** (Show how) **?**

Table 2. Main validation domains of the study.

Domain	Indicator	Data collection		Statistical analysis
		Phase	Method	
Content validity	Content validity index (CVI)	VP case review	Evaluations by an expert panel after reviewing VP cases, measured by a 4-point Likert scale (1=lowest, 4=highest).	CVI for VP case and for specific VP domain will be computed, where CVI = number of raters giving a rating of 3 or 4/total number of raters.
Feasibility	Willingness to participate; Adherence rate	Feasibility study	The subsample of clinicians' interactions with the 2 VP cases will be recorded by the online assessment	Willingness to participate = clinicians taking the VP tests/clinician being selected % Adherence rate = clinicians completed 2 VP cases/clinicians taking the VP tests %
Face validity	Satisfying score		Clinicians' subjective attitude toward the VP test experience measured by a 5-point Likert scale (1=most negative, 5=most positive).	Satisfying score for VP case and for specific aspects (e.g., usability, accessibility, etc.) will be computed, where satisfying score = frequency (%)* positive evaluations (3 to 5), and scores≥1.5 are considered acceptable.
Criterion validity	Concordance correlation coefficient (r_c); Kappa statistic	Validation study	The same clinician receives a USP visit and a VP test for a matching condition. The USP-clinician interaction is evaluated by the USP using the checklist, including fees and time per visit; while VP-clinician interaction is graded by the system.	The concordance of VP-test scores against USP-test score (gold standard) or two-repeated VP-tests will be examined by r_c for continuous process quality scores, fees charged (yuan), and time spent (min); and Kappa for dichotomous diagnoses and treatment & management measures.
Test-retest Reliability			Repeat VP-tests on the same clinician in a month	
Internal consistency	Cronbach's alpha coefficient (α)		VP-test scores on a single occasion	Intercorrelation of scores for process quality indicators with alpha >0.7 is acceptable.

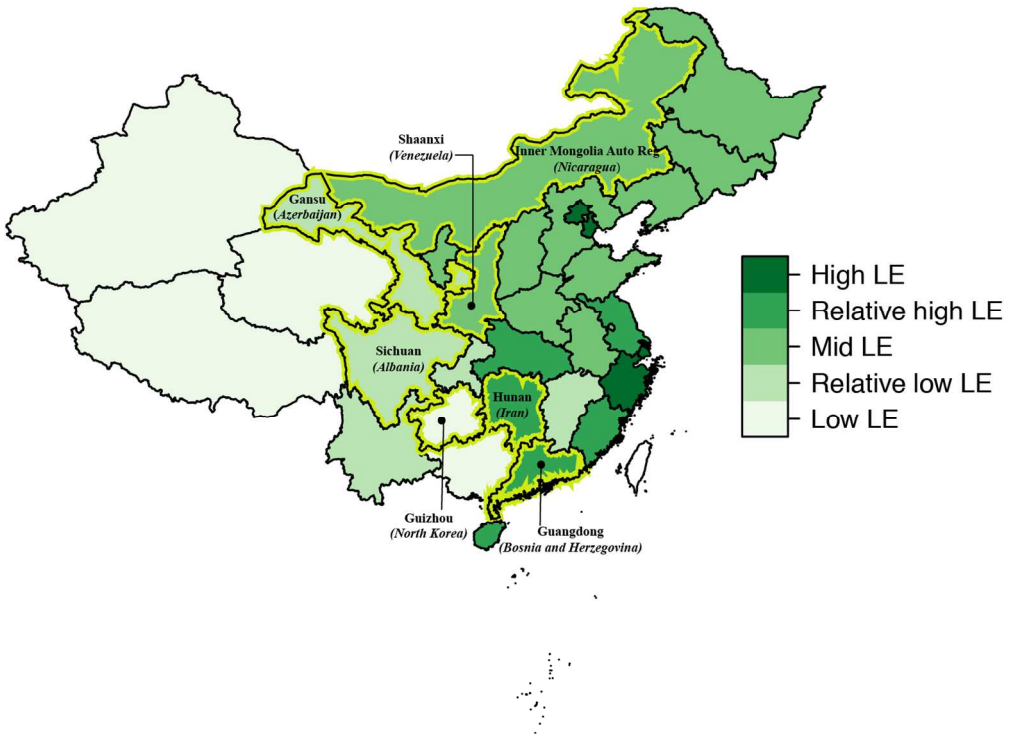

Figure 1. Seven sample provinces in China referencing countries of equivalent life expectancy in parentheses.

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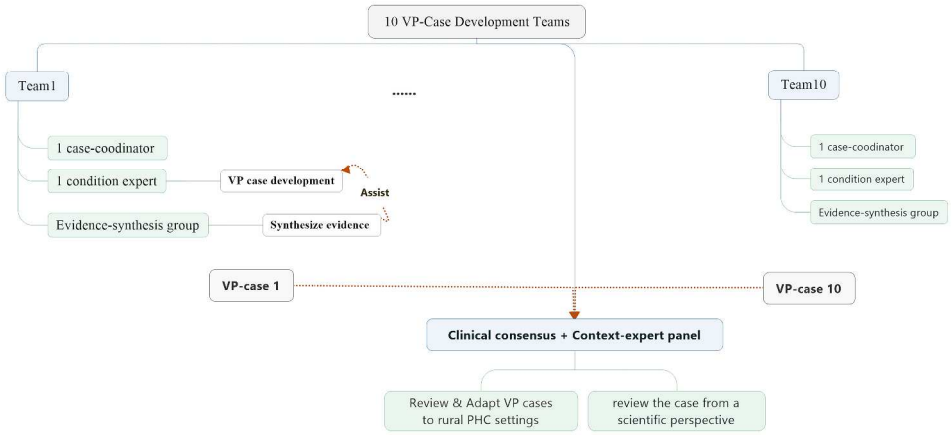

Figure 2. VP case development team role and responsibilities.

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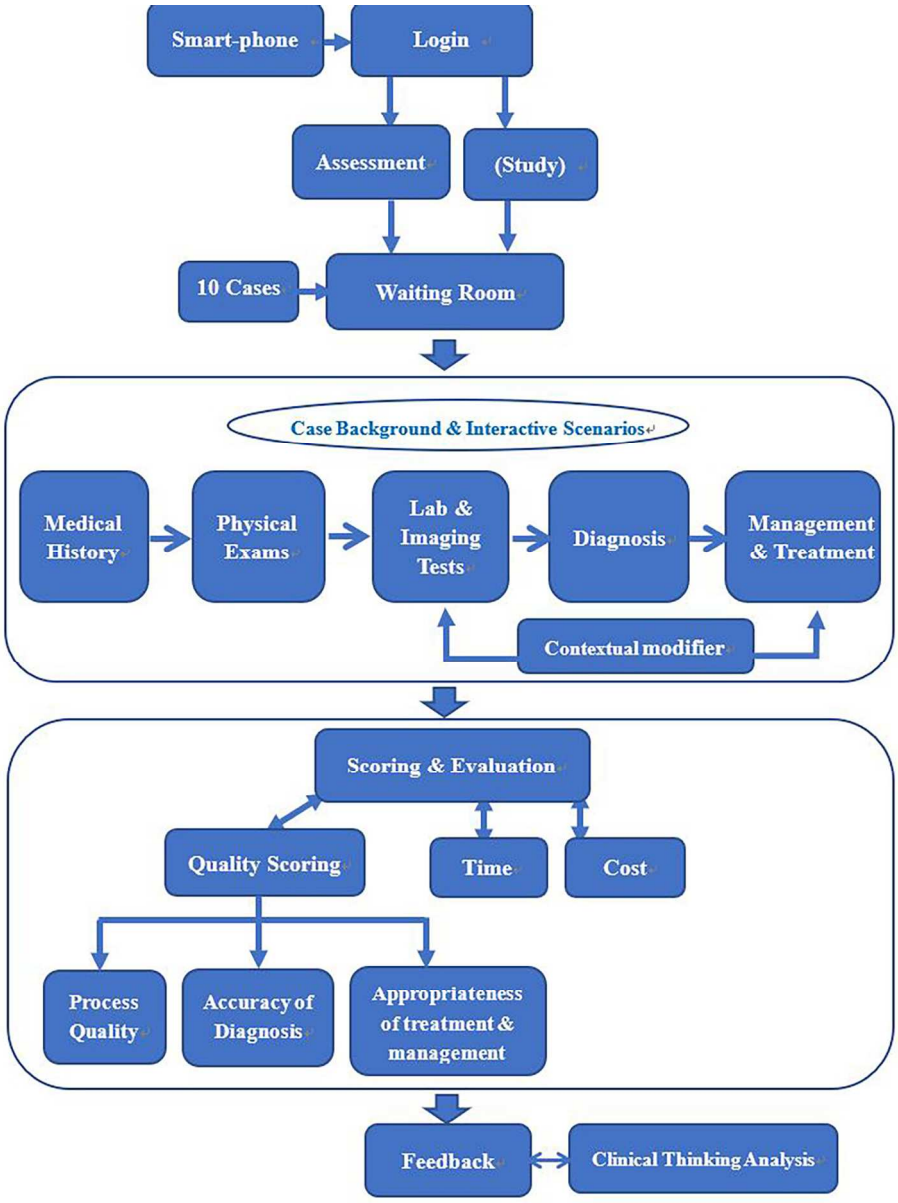

Figure 3. Main components of smartphone-based VP program. (VP: virtual patient)

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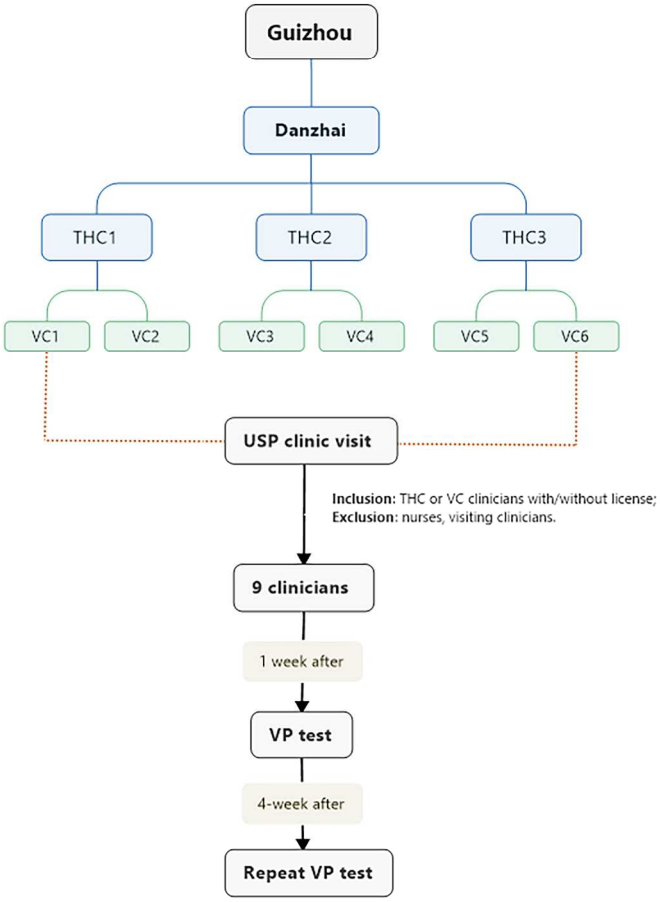

Sampling and study process for one VP case in Danzhai County, Guizhou Province (THC: township health center; VC: village clinic)

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Appendix 1. Top 30 conditions of high-frequency clinical encounters in primary health care settings in rural China.

Clinical condition	Two-week consultation constituent ratio[1]		Township health center[2]		Village clinics[2]	
	RANK	%	RANK	%	RANK	%
Cold	**1**	28	**1**	13.60	**1**	19.50
Hypertension	**2**	21.8	**4**	7.90	**6**	9.80
Diabetes mellitus	**4**	3.9	**7**	4.60	**8**	4.60
Chronic tracheitis	**8**	2	**2**	9.50	**4**	10.50
Acute tracheitis			**3**	9.00	**3**	10.70
Gastritis	**3**	5.5	**5**	7.50	**5**	10.30
Diarrhea			**6**	5.30	**2**	11.70
Urinary tract infection			**8**	4.50	**9**	2.90
Osteoarthritis	**7**	2.30	**17**	2.40	**18**	0.50
Low back pain	**5**	3.10	**16**	2.50	**15**	0.80
Psoatic strain			**14**	2.60	**14**	0.80
Peptic ulcer			**11**	2.90	**11**	1.70
General trauma			**10**	3.10	**13**	1.10
Sciatica			**19**	1.80	**22**	0.30
Child dyspepsia			**9**	3.20	**7**	7.00
Pelvic inflammatory disease			**12**	2.70	**16**	0.60
Vaginitis			**13**	2.70	**17**	0.50
Dysmenorrhoea			**18**	2.30	**19**	0.50
Cholecystitis			**15**	2.60	**12**	1.60
Toothache	**10**	1.30	**22**	1.30	**10**	2.70
Menopausal syndrome			**21**	1.40	**27**	0.10
Cholelithiasis			**20**	1.60	**20**	0.40
Idiopathic headache	**6**	2.50	**25**	0.60	**25**	0.20
Hemorrhoids			**23**	1.10	**21**	0.40
Asthma			**28**	0.60	**26**	0.20
Chronic dermatitis			**29**	0.20	**29**	0.10
Tympanitis			**24**	0.70	**24**	0.20
Conjunctivitis			**27**	0.60	**28**	0.10
Sinusitis			**26**	0.60	**23**	0.30
Ischemic heart disease	**9**	1.5				

[1.] Self-reported two-week consultation constituent ratio by community dwellers, information from the 2013 National Health Service Survey in China.

[2.] Clinicians reported common clinical conditions in primary health care centers by centers' type.

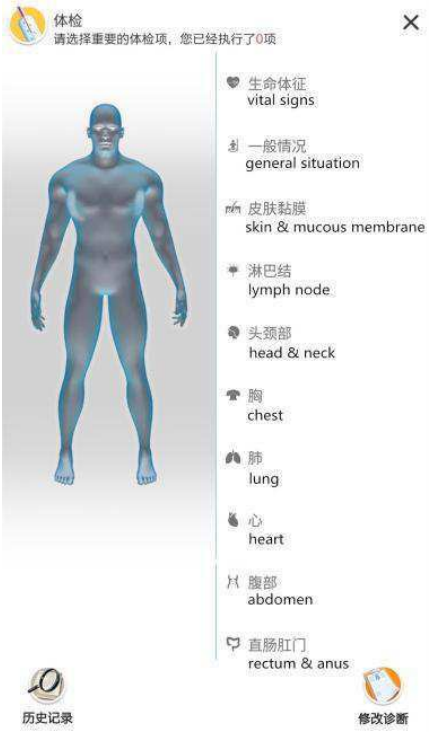
Appendix 2. Methods for checklist and standards development

To evaluate the quality of care in primary health care institutions, key diagnosis and treatment points of common and frequently-occurring diseases will be developed. The *WHO Handbook for Guideline Development* and evidence-based evaluation principles will be adopted. The main procedures are comprised in the following six steps that will be implemented.

1. Expert group recruitment: Convene a multidisciplinary group consisting of experts in public health, evidence-based medicine/document retrieval, as well as clinical physicians.
2. Data retrieval and literature evaluation: Employ a 5S model to retrieve and incorporate clinical practice guidelines, textbooks, systematic reviews, meta-analysis, and important literature reviews. Retrieve literature from Wanfang, Medlive, MEDLINE, National Guideline Clearinghouse (NGC), National Institute for Health and Care Excellence (NICE), World Health Organization (WHO), DynaMed, and UpToDate. Evaluate the literature using AGREE II, AMSTAR, and QUADAS-2 for the included clinical practice guidelines, systematic reviews, and diagnostic tests, respectively.
3. Preliminary items pool development: Extract essential diagnostic and treatment procedures from the high-quality literature attained.
4. Clinical expert consensus: Apply a 2- to 3-round Delphi method to achieve consensus for diagnosis and treatment. The importance, necessity, and feasibility of the items should be considered in the process of Delphi, and additional medical information must be supplemented in terms of the clinical practice. Furthermore, all items should be classified as: necessary (3 points), selective (2 points), irrelevant (1 points), and erroneous (0 points).
5. Pilot and revise: Conduct a pilot test among 2~3 primary health care settings using the preliminary items. Revise the items and finalize the key diagnosis and treatment point evaluation items.

6. Script development: Develop the script of the target disease based on key diagnosis and treatment point evaluation items before conducting the quality of service evaluation in primary health care institutions.

Appendix 3. Demonstrations of *Cure-Fun* smartphone-based platform current configurations of interview, physical exam and lab texts, and treatment.



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Using smartphone-based virtual patients to assess the quality of primary health care in rural China: protocol for a prospective multicenter study

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Using smartphone-based virtual patients to assess the quality of primary health care in rural China: protocol for a prospective multicenter study

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ABSTRACT

Introduction: Valid and low-cost quality assessment tools are not readily available. The Unannounced Standardized Patient (USP), the gold standard for assessing quality, is restricted by a high implementation cost; while clinical vignettes, as a low-cost alternative, have been questioned by their validity. Computerized virtual patients (VPs) create high-fidelity and interactive simulations of doctor-patient encounters which can be easily implemented via smartphone at low marginal cost. Our study thus aims develop and validate smartphone-based VP as a quality assessment tool for primary care, compared to USP.

Methods and analysis: The study will be implemented in outpatient settings of primary health centers (PHCs) in rural areas of seven Chinese provinces, and physicians practicing at township health centers and village clinics will be our study population. The development of VPs will involve three steps: (1) identifying 10 VP cases that can best represent rural PHCs' work, (2) designing each case by a case-specific development team, and (3) developing corresponding quality scoring criteria. After being externally reviewed for content validation, these VP cases will be implemented on a smartphone-based platform and will be tested for feasibility and face validity. This smartphone-based VP tool will then be validated for its criterion validity against USP and its reliability (i.e., internal consistency and stability), with 1260 VP/USP-clinician encounters across the seven study provinces for all 10 VP cases.

Ethics and dissemination: Sun Yat-sen University: No. 2017-007. Study findings will be published and the tools developed will be freely available to low- and

middle-income countries for research purposes.

Strengths and limitations of this study

- Developing and validating smartphone-based VP as a quality assessment tool for research and routine use in rural primary health care centers.
- Following an evidence-based approach to develop VP cases and scoring criteria.
- Systematically validating the VP assessment tool via a cross-national multicenter study
- The extent to which the VP assessment can reflect practitioners' real clinical practice needs to be verified.

Key words: Quality in health care, primary care, care quality assessment tool

INTRODUCTION

Universal health coverage (UHC) is a paramount goal of health system development for countries at all income levels.[1] The achievement of UHC is not possible without primary health care services,[1] which ensure integrated care close to the population they serve and link to health-related sustainable development goals.[2] However, service coverage alone cannot improve health outcomes if the quality of care is poor. Despite the fact that great emphasis has been made to enhance health care services, a dearth of scientific evidence exists on the quality of primary health care in resource-poor settings, particularly of low- and middle- income countries (LMICs).[3-6]

This scarcity of evidence may partially result from the limited availability of valid, low cost, and easy-to-implement quality assessment tools[7]. As defined by Donabedian's framework for health care quality, quality can be evaluated by the *structure* of care (e.g., staff, equipment), the *process* of care delivery (e.g., doctor-patient interactions), and health *outcomes* (e.g., death or complications).[8] Process measures have been increasingly adopted, considering the benefits of frequent and timely evaluation, and the usefulness in improving practice.[9 10] The 'gold standard' of assessing process is the unannounced standardized patient (USP), namely a trained actor who simulates the symptoms, signs, and emotions of a real patient in a standardized fashion and presents him- or herself unannounced to clinics to assess care quality.[11] USP can reduce recall bias better than patient exit interviews, minimize the Hawthorne effect that inevitably occurs in direct observation, and allow for comparisons between users as case- and patient-mix are controlled.[3 9 11] Nonetheless,

the USP can only portray a limited number of conditions without obvious physiological symptoms and risk of invasive examinations. Also, training and implementation of USP can require substantial personnel and resources, making USP impractical for large-scale and routine quality assessment.[12 13]

On the other hand, clinical vignettes or case simulations have been widely used as a low-cost and convenient alternative to assess care quality.[9 14] Vignettes have been implemented in a paper-and-pencil form,[9] presented by an enumerator,[5] and streamlined by a computer.[14] The validity of the vignette in assessing the quality of patient care has gotten mixed reports. Some studies showed that vignettes only reflect clinicians' competency (know-how) rather than their actual behaviors and can cause overestimation of clinical performance.[9 15] By contrast, other studies found that vignette-based results, particularly those streamlined by computer, are quite close to the USP-based assessment.[14 16] The enumerator-administered vignette is similar to the announced standardized patient and thus is expensive and difficult to implement.[5] A computerized vignette can be interactive and can better represent the realistic complexity of a clinical encounter.[14] As a further improvement on computerized vignettes,[14] smartphone virtual patients (VPs) create high-fidelity, visualized, and interactive simulations that replicate clinical complexity and can be easily implemented at only marginal cost.[17] Although VPs cannot remove the Hawthorne effect, their advanced features may reduce the measurement gap between competency and real practice.[10 14] While VPs have been used in medical education to train and test clinical skills such as clinical reasoning, making diagnoses, and therapeutic

decisions,[18] the relative validity of their use as a measure for the quality of care has yet to be studied. Strengths and limitations of the abovementioned three methods are compared in Table 1.

In the present study, we propose to adapt smartphone-based VP for medical education as a quality-of-care assessment tool, given its advantages in 1) **standardization** (VPs are highly standardized, ensuring consistent assessments across users), 2) **flexibility** (Assessments can be delivered by smartphones for multiple users at anytime, anywhere, providing the data connectivity is available), 3) **scalability** (VPs can be modified to demonstrate and assess almost any clinical conditions with low marginal cost), and 4) **training** (VPs can further be used as a training tool to improve health care quality and thus to address the 'so what' question after quality assessment). These characteristics may especially benefit quality assessment and improvement in primary care of rural communities which are geographically scattered and difficult to reach and manage.

Therefore, our study aims to develop and validate **smartphone-based VPs** against USPs as a quality assessment tool that can not only be used for research purposes but also routinely applied to evaluate the quality of primary health care provided by primary health centers (PHCs) in rural areas. To maximize its validity,[14] we will properly construct high-fidelity VP cases to reflect clinical complexity in rural PHC contexts with real-time patient-doctor interactions and temporal constraints, as well as use evidence-based quality care scoring criteria; additionally, we will make the VP-based test anonymous to minimize the Hawthorne effect. The initial phase of

the study will mainly focus on rural China, while the ultimate goal is to develop and validate tools that can have a broad application in other LMICs.

METHODS AND ANALYSIS

Study setting

The validation study will be implemented in the outpatient setting of rural PHCs (i.e., township health centers and village clinics) in seven Chinese provinces (Guizhou, Sichuan, Gansu, Inner Mongolia, Shaanxi, Hunan, and Guangdong). We are selecting these provinces not only to reflect the five strata of low-to-high life-expectancies and various burden-of-disease patterns in China,[19] but also to contrast geographic regions with ethnic diversities, from southwest mountainous regions, to the northern plateau, middle inland region, and southeast coastal areas (**Error! Reference source not found.**). Our study targets township health centers and village clinics because they provide most primary health care in rural China.[20 21] At township health centers, primary health care is delivered by a workforce including licensed/unlicensed physicians, licensed/unlicensed assistant physicians, and registered nurses; while at village clinics, services are mainly delivered by one full- or part-time 'village doctor' who is a clinician with rudimentary medical training.[20 22 23] The outpatient setting is chosen due to the few inpatient cases in township health centers and village clinics. The study recruitment is expected to start from April 2018.

VP case development

VP case selection

We intend to select 10 cases that can best represent the work of rural PHCs. The

selection of the VP cases will be based on the following criteria: 1) high frequency of clinical encounters in the primary care settings in rural areas, and/or 2) association with significant disease burden; 3) representation of the major areas of work of PHCs in rural China overall (e.g., public health service delivery, chronic disease management, infectious disease control, health education, and patient-centered care); and 4) suitability with USP methodology (e.g., no obvious physiological signs, low risk for invasive tests) for the sake of criterion validation in the current study. A case selection committee will be comprised of stakeholders, including physicians, public health practitioners, policy-makers, and members of the research team. Based on the literature review, the research team will prepare a list of the 30 most frequently seen conditions in township health centers and village clinics reported by either community dwellers[24] or the rural PHC clinicians (Appendix1) for the committee to rate and select.

VP case design

The 10 selected VP cases will then be constructed individually by 10 case-specific development teams (Figure 2). These teams consist of one *condition expert* in the relevant specialties of a tertiary teaching hospital who will be responsible for drafting the VP case; an *evidence-synthesis group* involving epidemiologists and evidence-based researchers who will search and synthesize evidence of the selected condition for the condition expert to work on; a *clinical consensus group* which consists of several condition-related clinical experts who will review the corresponding case from a scientific perspective; an overall all-condition shared *context-expert panel,* which includes clinicians and health managers from community

health centers, township health centers, and village clinics, who will review the contextual appropriateness of the cases in the rural PHC setting; and a *case coordinator* who will coordinate development of each case.

Each VP case will be structured into five domains—medical history, physical examination, laboratory and imaging studies, diagnosis, and management and treatment plan —to simulate real-life clinical scenarios. [11 18] The structured VP cases will have the ability to evaluate the examinee's performance by each domain and to aggregate performance scores across conditions. Besides these five condition-related domains, another practice contextual adjustor will be built into each case to consider medical resource constraints in rural practices (e.g., availability of basic medical equipment and medicines).

Scoring criteria

Corresponding to each VP case, care quality scoring criteria will be developed. These criteria include *process quality,* the *accuracy of diagnosis, and* the *appropriateness of the treatment and management plan*.[3 4] Process quality will be evaluated in reference to a clinical process checklist (to be detailed later) including all necessary questions that should be asked and physical examinations that should be performed by clinicians, alongside redundant or even potentially harmful practices. Diagnoses will be rated as correct, partially correct, or incorrect based on predetermined standards. The treatment & management plan will be considered appropriate if the clinician prescribes any of the correct medications or refers the patient to an upper level physician depending on the VP cases.

In addition, *cost of care* and *time-spent per encounter* will also be recorded. Patient costs will cover medication fees and clinic fees charged per case. In order to recode clinicians' reaction time to each domain and to impose temporal constraints as in real clinical practices, the entire clinician-VP interaction process will be timed. This will include time spent on taking history, conducting physical examinations, prescribing drugs and treatments, and any interruptions)

As for the development of the aforementioned checklist for the predetermined standards of correctness regarding appropriateness of the treatment and management plan, a systematic evidence-based approach will be adopted (Appendix 2). Briefly, the evidence-synthesis group will systematically search and extract condition-specific checklist items and standards from clinical guidelines, reputable textbooks, and systematic reviews, etc., in that order, whereas the quality of the evidence will then be rated by the Appraisal of Guidelines for Research & Evaluation II (AGREE II)[25] or the revised Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) according to its type.[26] Afterwards, the clinical consensus group and the contextual-expert panel will review and revise initial standards using a Delphi process.[27]

VP case external review

To validate the content of VP cases, an independent expert panel of physicians, general practitioners, and rural PHC clinicians who otherwise are not involved in the study, will be convened to review the cases for content accuracy and appropriateness. The content validation involves qualitative and quantitative phases. In the qualitative

phase, the expert panel will be required to evaluate the cases with respect to the following: overarching assessment goal, representativeness of the goal and test items to each domain, the logical relationship of the content tested, and the appropriate wording, grammar, understandability, and relatedness to the rural PHC context. The panel will also mention their suggestions, if any, next to each item. Modified VP cases will then be given back to the expert panel for quantitative evaluation with respect to their adjustments for simplicity and clarity, as well as necessity and relevance to the assessment, using a four-point Likert scale ranging from 1 (the lowest) to 4 (the highest). The content validity index (CVI) will be computed for each domain and for the entirety of VP cases.[28]

Technical implementation

Revised VP cases will be implemented on *CureFUN*, an existing smartphone- based training platform using VPs with special customizations and set-ups to suit the assessment purpose. A live demonstration of a simplified VP can be accessed from http://www.curefun.com/zhiqu_front/www/experience/experience.html#/caseList and is also illustrated in Appendix 3. The smartphone-based VP assessment tool will not only present interactive clinical scenarios, but also automatically record each examinee's diagnosis pathway and grade it against the scoring criteria (Figure 33).

Feasibility study

Before a full-scale validation study, a feasibility study with 30% of the validation study sample (see study sample section) will be conducted to test the VP assessment tool's usability, accessibility, and stability, particularly in remote village clinics with

weak phone connectivity. Selected clinicians will be instructed to individually attempt two random VP cases within a given time, using their own smartphone devices from their workplace. Clinicians without a smartphone will be given a temporary one installed with the customized *CureFUN* applications. Clinicians' willingness to participate and adherence to the VP-based tests (e.g., percentage completing VP cases, score of the assessment, and number of attempts made at each case per person) will be automatically recorded. Upon completion of the cases, participants will be asked to fill in a five-point Likert-scale questionnaire regarding their subjective attitude toward the simulator VP experience (with 1 being the most negative response and 5 being the most positive), regarding ease of use, experienced assessment process and outcome, realism, device competence, accessibility, and other general comments. These results will be used to determine VP cases' face validity, whereby a satisfying score equals frequency (%) multiplied by positive evaluations; and scores no less than 1.5 are considered acceptable.[29]

Validation of VP as a quality assessment tool

Study design

The prospective validation study is a nationwide multicenter study with two main functions. This study will 1) assess the criterion validity of the VP-tool in assessing the quality of primary health care, by analyzing its measurement concordance against the standard USP measure, and 2) test the reliability of the VP tool, by examining its internal consistency and the stability of repeated VP assessments on the same examinees.

Study sample

From each of our seven sample provinces, two counties will be selected with sufficient variations in socio-economic conditions, demographics, and disease burdens between them while also approximating the provincial condition in general. Within each county, the government registry of all township health centers and village clinics will serve as our sampling frame, which will include 1) licensed practicing physicians, 2) clinicians who have not been licensed but are providing clinical services under the supervision of licensed physicians at township health centers, as well as 3) full- or part-time village clinicians. Temporarily-visiting clinicians (often senior clinicians sent by higher level medical institutions to support the development of township health centers), nurses, and allied health workers without prescription privileges will be excluded.

The sample size calculation is based on individual VP/USP-clinician encounter, and ensures sufficient power to detect variations at individual case level per county. For village clinics, one VP/USP case will be examined per time to minimize the detection of USPs. Assuming a 5% type I error and 80% power, to determine whether a moderate concordance correlation coefficient[30] of 0.90 [31] between VP and USP differs from zero, seven paired VP/USP-clinician encounters will be required for each of the 10 cases per county. As a stratified sampling strategy will be deployed that first samples townships and then villages from each township, the design effect should be taken into consideration when calculating the sample size. Assuming an intra-class correlation of 0.05 and 6 village clinics per township, then 9 paired VP/USP-clinician

encounters is needed. These nine paired VP/USP-clinician encounters will be assigned to 3 township health centers and 6 village clinics using probability proportional to size (PPS) method. These 9 paired VP/USP-clinician encounters will be assigned to township health centers and village clinics based on the ratio of the total number of clinicians at township health centers over the total number of village clinicians for each county. There are 1260 VP/USP-clinician encounters across our seven study provinces for all 10 VP cases. Figure 4 shows the sampling process and study flow for one VP case using Guizhou Province (Danzhai County) as a demonstration.

Criterion validity

Criterion validity[32] of the VP to assess quality of care will be evaluated mainly by its measurement concordance against the USP measure as the recognized gold standard[33] for assessing quality of care in real practice. The USPs will be developed in a related study, sharing the development teams for VP and a similar development process. The method of fielding USPs in rural China will follow approaches similar to those of the previous USP study in rural China.[3] Identical quality scoring criteria, described above, will be applied to scores. Each selected clinician will first see a USP (to avoid the practice effect due to the USP's unannounced feature), and then complete a smartphone-based VP assessment of the same condition. The clinician to be assessed will be randomly selected onsite by the USP from any on-duty clinicians on the day of the USP visit to the sampled township health center and village clinics. This situation would especially apply to township health centers, as most village clinics have only one clinician (note: Chinese patients normally see their primary care clinicians as a

walk-in patient and appointments are seldom needed). To record USP-clinician interactions, USPs will complete checklists immediately after their visit, as well as retain the medication prescription and the fee charge slips by the clinician. A week after the USP clinic visit, clinicians will be assigned a smartphone-based VP assessment, which will consist of a demonstration VP case to allow the clinician getting familiar with the operation system, and the examination VP case of the same USP condition. The VP-clinician interactions, drugs dispensed, and fees charged will all be recorded automatically by the online assessment system.

The concordance of the two assessments between USPs and VPs will then be analyzed by Lin's concordance correlation coefficient (r_c)[30] for continuous *process quality* scores, *fees charged* (yuan), and *time spent* (min),and the Kappa statistic[34] for dichotomous *diagnoses* and *treatment & management* measures. r_c evaluates how close pairs of observation fell on a 45° line (the perfect concordance line) through the origin in addition to their correlation. Kappa measures agreement in assessment beyond what is expected by chance alone. In addition, for continuous measures, a Bland-Altman plot will also be used to visualize the concordance.[35 36] For dichotomous measures, we will analyze their sensitivity (i.e., strength to detect correct diagnosis, treatment plan, etc.) and specificity (i.e., strength to detect incorrect diagnosis, treatment plan, etc.) using USP as the reference.

Reliability

To establish *test-retest reliability*, clinicians previously being assessed by VPs will be instructed to retake the same VP tests four weeks after their last assessment. The

second VP test is set one month later than the first to reduce the practice effect,[37] assuming the clinician's general medical knowledge remains constant.[32] The concordance of the two repeated tests indicate the stability of the VP assessment tool.[32] Similar concordance measures (i.e., r_c for continuous and Kappa for dichotomous measures) as described above will be used. The *internal consistency,* the intercorrelation of scores for process quality indicators, will be computed by Cronbach's alpha coefficients (α),[38] with $\alpha > 0.7$ representing acceptable reliability.[39] Table 2 summarizes the validity, reliability, and feasibility measures that will be examined in our study.

Patient and public involvement

We will seek feedback from clinicians and patient representatives in the feasibility study and use their feedback to refine the VP cases. Our USPs are also lay people trained to portray patients and assess care quality based on their interactions with clinicians. Our scoring criteria thus are also patient centered. Furthermore, all participants will be acknowledged for their involvement in the study and will be provided with a final summary report of the study outcomes, as well as have free access to the VP training website. All published results will be publicly available.

ETHICS AND DISSEMINATION

The study has been approved by the Institutional Review Board of the School of Public Health (IRB), Sun Yat-sen University (No. 2017-007). Informed consent will be obtained from all participating clinicians of VP tests. However, to reduce participation bias due to self-selection,[40] our IRB has approved the implementation of

USP without prior informed consent from the individual participants, on the condition that involved clinicians will be fully de-identified and all analyses will only be conducted at the population level.[40] Study data will be securely stored and only de-identified information will be used for analysis. We will seek peer-reviewed publications for study findings and produce reports to inform health authorities. The tools and technology developed in this study will be freely available to other LMICs for research purposes.

DISCUSSION

To the best of our knowledge, this is the first study validating VP as a quality assessment tool in rural primary health care centers. This study follows an evidence-based approach to develop VP cases and scoring criteria, implements them on a widely accessible platform (i.e., a smartphone), and systematically validates the VP assessment tool via a cross-national multicenter study representing rural PHCs over a wide range of geographic areas with distinct life expectancies and economic development levels. The VP assessment tool's accessibility, flexibility and scalability give it good potential to be easily adapted to other LMICs.

VP has mainly been used in medical education to train and test critical thinking[18] [41 42], and only till recently few studies start to extend its usage into practice setting to change health provider behavior and improve care quality.[43 44] As a further extension, our study proposes to validate VP as a quality assessment tool via widely accessible smartphones. Nevertheless, it is to be noted that given its simulated nature, the VP-test theoretically may never completely bridge the 'competency-practice' gap. The

validation study is thus essential to quantify the concordance/discordance between VP- and USP-based quality assessments. Our study will generate firsthand empirical evidence contributing to the understanding of the 'know-do gap',[5 45] and further shed light on circumstances that cannot be tested by USPs.

A limitation of the study, however, is that, in order to test the validity of VP against USP as the reference standard, we restrict the selection of VP cases to those that can be simulated by USP as well. This conservative first step will nevertheless allow us to examine the extent to which VP can reflect care quality, and follow-up study will then explore the full potential of the VP in assessing quality of care. Further, the two purposely-selected counties for each province may not represent the provincial conditions entirely, although we will make every effort to consider provincial representation when selecting counties. Third, while the validation study is exclusively conducted on PHCs in rural China, the extent to which the VP assessment tool can be transported to other LMICs remains to be evaluated. Even so, the selected provinces from the 'five-Chinas' may improve the generalizability of our study considering the comparable life expectancies of LMICs and these provinces.

Author's contributions

All authors contributed to the conceptualization and design of the study. DX, JL, and YYC conceived the initial study design, analytical methods, and composition of the team. JL was responsible for the study concept, initial draft, and revisions. DX was responsible for the study concept and revising the draft. YLC and XHW were responsible for the development of the scoring criteria. SS, KH, HW, JNW, ZLZ, ZN,

WJG, JP, CXT and WZ provided critical review and revision to the study design. All authors read and approved the final revision.

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Competing interests

The development of the VP assessment tool is a joint project of the Sun Yat-sen University Global Health Institute (SGHI) (representing the seven universities in China), and *CureFUN*. However, the VP cases will be independently developed and the validation studies will be rigorously conducted by the research team from SGHI and the seven universities, whereas CureFun will technically implement the cases on smartphones and have no influence over the study design and analysis.

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Figure 1. Seven sample provinces in China referencing countries of equivalent life expectancy in parentheses. (LE: life expectancy)

Figure 2. VP case development team role and responsibilities. (VP: virtual patient)

Figure 3. Main components of smartphone-based VP program. (VP: virtual patient)

Figure 4. Sampling and study process for one VP case in Danzhai County, Guizhou Province (THC: township health center; VC: village clinic)

Table 1. The strengths and limitations of methods to assess care quality.

Process Measure of Quality	Strengths	Limitations	Assessment Level
Unannounced Standardized Patient (USP)	Standardized, controlling for case-mix and patient-mix; Unannounced, no Hawthorne effect (if not be detected); Reduced recall bias	Expensive Limited medical conditions First-visit bias Selection bias if informed consent is required	**Action** (Do) **Gold standard**
Clinical Vignettes	Cost-effective; Suitable for large scale and cross-system comparison; Covering all illnesses; Accounting for case-mix and patient-mix.	Hawthorne effect Selection bias	**Competence** (Know how) **Over-estimating** care quality (best answers) or similar
Virtual Patients (VP)	Interactive Real-time response & automatic record Highly standardized Scalability & low marginal cost Efficient delivery: anytime, anywhere Suitable for large scale study	Hawthorne effect Selection bias High cost in initial development	**Performance** (Show how) **?**

Table 2. Main validation domains of the study.

Domain	Indicator	Data collection		Statistical analysis
		Phase	Method	
Content validity	Content validity index (CVI)	VP case review	Evaluations by an expert panel after reviewing VP cases, measured by a 4-point Likert scale (1=lowest, 4=highest).	CVI for VP case and for specific VP domain will be computed, where CVI = number of raters giving a rating of 3 or 4 divided by the total number of raters.
Feasibility	Willingness to participate; Adherence rate	Feasibility study	The subsample of clinicians' interactions with the 2 VP cases will be recorded by the online assessment	Willingness to participate = clinicians taking the VP tests divided by the percentage of clinician selected Adherence rate = clinicians completed 2 VP cases divided by the percentage of clinicians taking VP tests
Face validity	Satisfying score		Clinicians' subjective attitude toward the VP test experience measured by a 5-point Likert scale (1=most negative, 5=most positive).	Satisfying score for VP case and for specific aspects (e.g., usability, accessibility, etc.) will be computed, where satisfying score = frequency multiply by positive evaluations (3 to 5), and scores≥1.5 are considered acceptable.
Criterion validity	Concordance correlation coefficient (r_c); Kappa statistic	Validation study	The same clinician receives a USP visit and a VP test for a matching condition. The USP-clinician interaction is evaluated by the USP using the checklist, including fees and time per visit; while VP-clinician interaction is graded by the system.	The concordance of VP-test scores against USP-test score (gold standard) or two-repeated VP-tests will be examined by r_c for continuous process quality scores, fees charged (yuan), and time spent (min); and Kappa for dichotomous diagnoses and treatment & management measures.
Test-retest Reliability			Repeat VP-tests on the same clinician in a month	
Internal consistency	Cronbach's alpha coefficient (α)		VP-test scores on a single occasion	Intercorrelation of scores for process quality indicators with alpha >0.7 is acceptable.

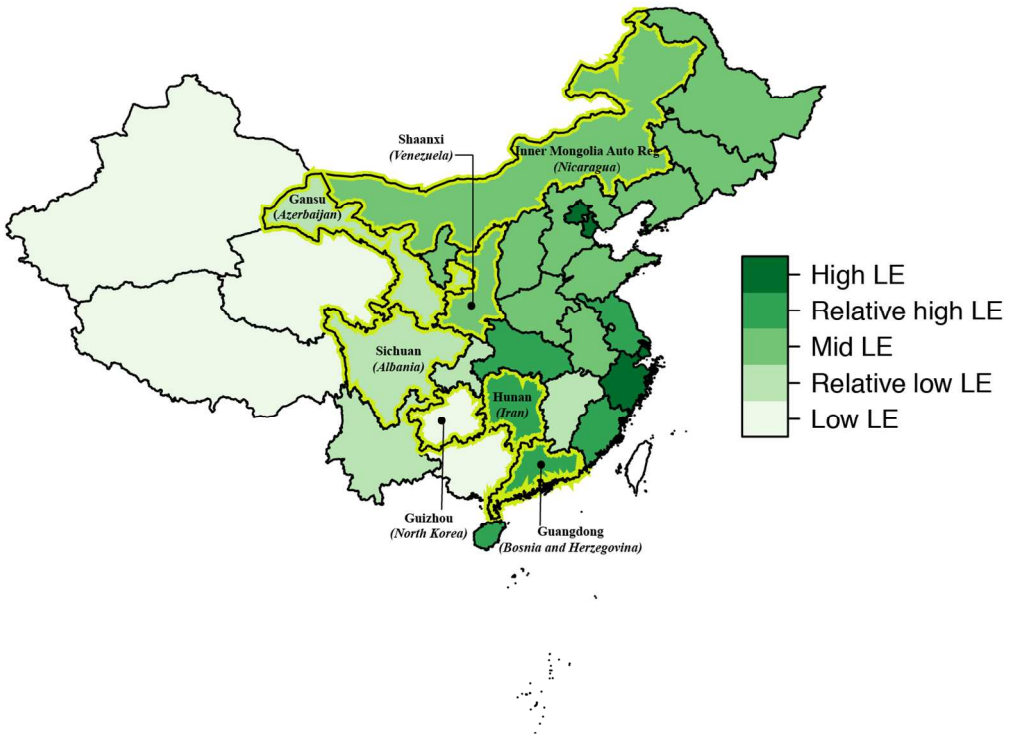

Figure 1. Seven sample provinces in China referencing countries of equivalent life expectancy in parentheses.

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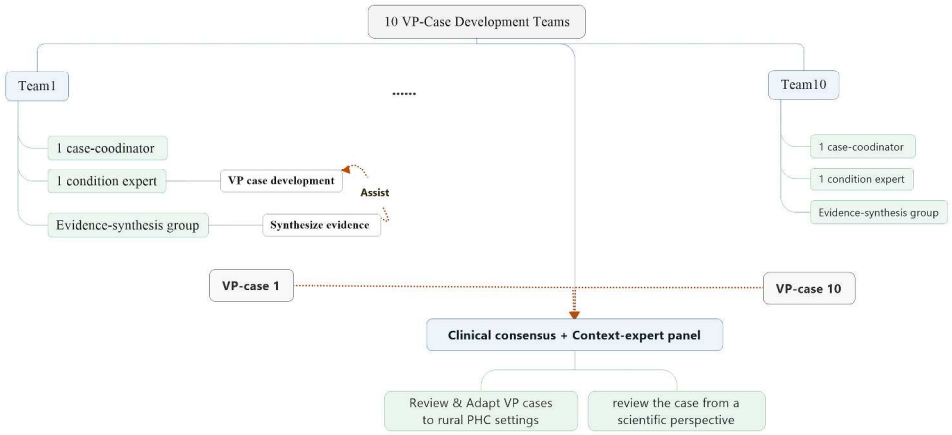

Figure 2. VP case development team role and responsibilities.

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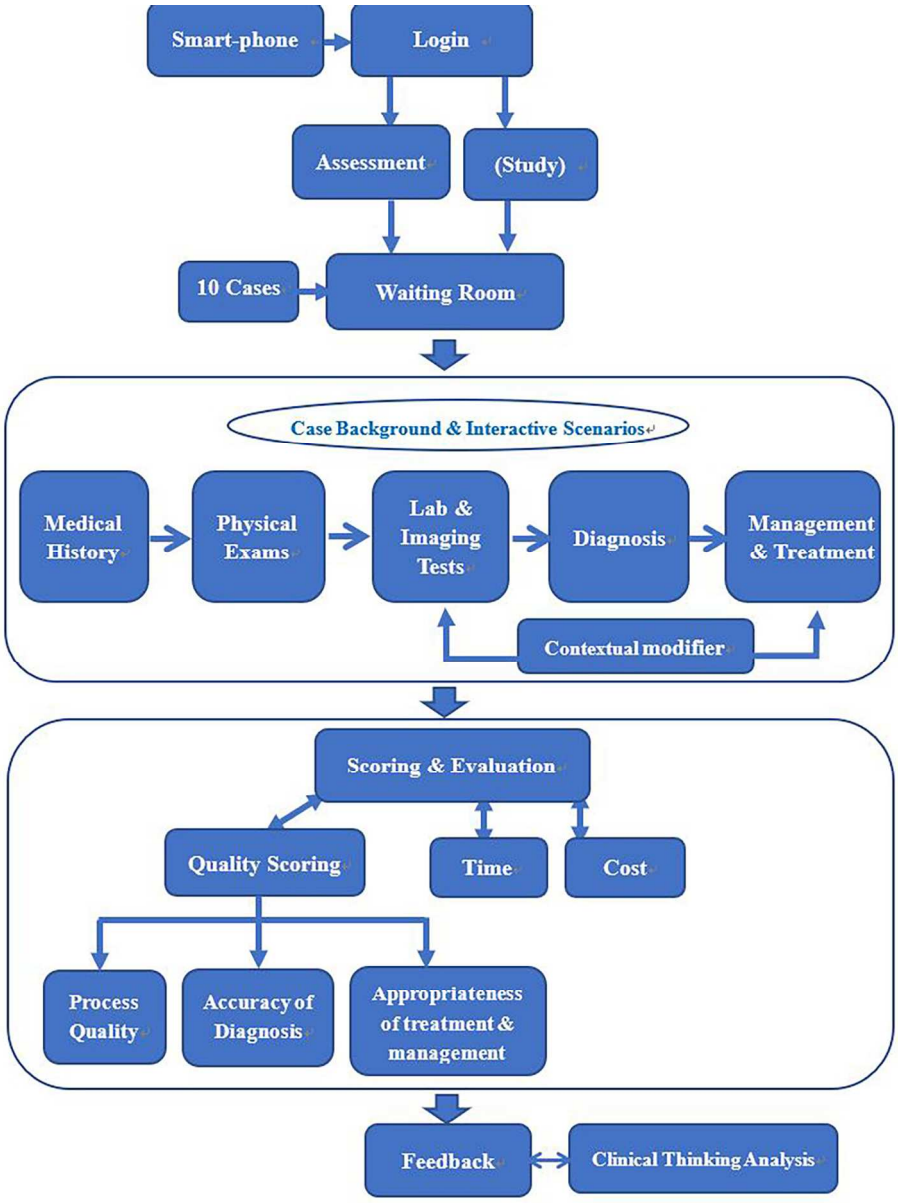

Figure 3. Main components of smartphone-based VP program. (VP: virtual patient)

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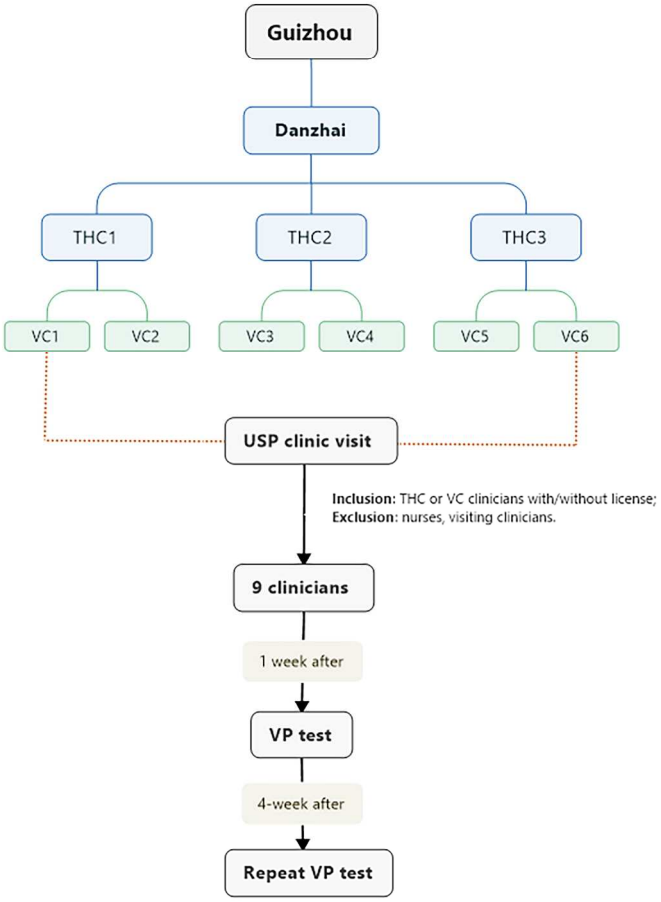


Figure 4. Sampling and study process for one VP case in Danzhai County, Guizhou Province (THC: township health center; VC: village clinic)

275x269mm (300 x 300 DPI)

Appendix 1. Top 30 conditions of high-frequency clinical encounters in primary health care settings in rural China.

Clinical condition	Two-week consultation constituent ratio[1]		Township health center[2]		Village clinics[2]	
	RANK	%	RANK	%	RANK	%
Cold	**1**	28	**1**	13.60	**1**	19.50
Hypertension	**2**	21.8	**4**	7.90	**6**	9.80
Diabetes mellitus	**4**	3.9	**7**	4.60	**8**	4.60
Chronic tracheitis	**8**	2	**2**	9.50	**4**	10.50
Acute tracheitis			**3**	9.00	**3**	10.70
Gastritis	**3**	5.5	**5**	7.50	**5**	10.30
Diarrhea			**6**	5.30	**2**	11.70
Urinary tract infection			**8**	4.50	**9**	2.90
Osteoarthritis	**7**	2.30	**17**	2.40	**18**	0.50
Low back pain	**5**	3.10	**16**	2.50	**15**	0.80
Psoatic strain			**14**	2.60	**14**	0.80
Peptic ulcer			**11**	2.90	**11**	1.70
General trauma			**10**	3.10	**13**	1.10
Sciatica			**19**	1.80	**22**	0.30
Child dyspepsia			**9**	3.20	**7**	7.00
Pelvic inflammatory disease			**12**	2.70	**16**	0.60
Vaginitis			**13**	2.70	**17**	0.50
Dysmenorrhoea			**18**	2.30	**19**	0.50
Cholecystitis			**15**	2.60	**12**	1.60
Toothache	**10**	1.30	**22**	1.30	**10**	2.70
Menopausal syndrome			**21**	1.40	**27**	0.10
Cholelithiasis			**20**	1.60	**20**	0.40
Idiopathic headache	**6**	2.50	**25**	0.60	**25**	0.20
Hemorrhoids			**23**	1.10	**21**	0.40
Asthma			**28**	0.60	**26**	0.20
Chronic dermatitis			**29**	0.20	**29**	0.10
Tympanitis			**24**	0.70	**24**	0.20
Conjunctivitis			**27**	0.60	**28**	0.10
Sinusitis			**26**	0.60	**23**	0.30
Ischemic heart disease	**9**	1.5				

[1.] Self-reported two-week consultation constituent ratio by community dwellers, information from the 2013 National Health Service Survey in China.

[2.] Clinicians reported common clinical conditions in primary health care centers by centers' type.

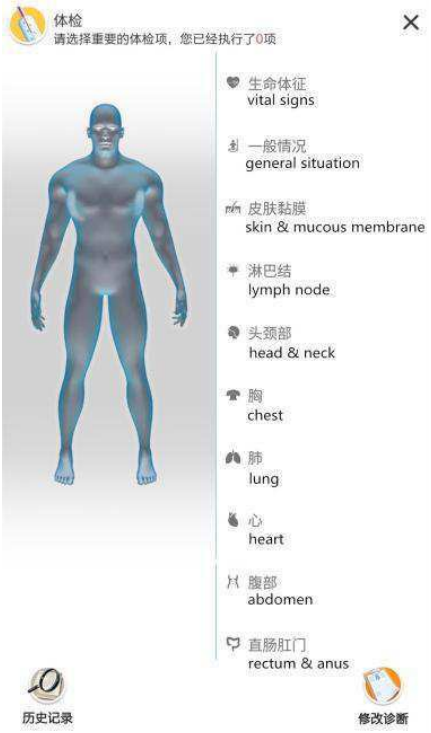
Appendix 2. Methods for checklist and standards development

To evaluate the quality of care in primary health care institutions, key diagnosis and treatment points of common and frequently-occurring diseases will be developed. The *WHO Handbook for Guideline Development* and evidence-based evaluation principles will be adopted. The main procedures are comprised in the following six steps that will be implemented.

1. Expert group recruitment: Convene a multidisciplinary group consisting of experts in public health, evidence-based medicine/document retrieval, as well as clinical physicians.
2. Data retrieval and literature evaluation: Employ a 5S model to retrieve and incorporate clinical practice guidelines, textbooks, systematic reviews, meta-analysis, and important literature reviews. Retrieve literature from Wanfang, Medlive, MEDLINE, National Guideline Clearinghouse (NGC), National Institute for Health and Care Excellence (NICE), World Health Organization (WHO), DynaMed, and UpToDate. Evaluate the literature using AGREE II, AMSTAR, and QUADAS-2 for the included clinical practice guidelines, systematic reviews, and diagnostic tests, respectively.
3. Preliminary items pool development: Extract essential diagnostic and treatment procedures from the high-quality literature attained.
4. Clinical expert consensus: Apply a 2- to 3-round Delphi method to achieve consensus for diagnosis and treatment. The importance, necessity, and feasibility of the items should be considered in the process of Delphi, and additional medical information must be supplemented in terms of the clinical practice. Furthermore, all items should be classified as: necessary (3 points), selective (2 points), irrelevant (1 points), and erroneous (0 points).
5. Pilot and revise: Conduct a pilot test among 2~3 primary health care settings using the preliminary items. Revise the items and finalize the key diagnosis and treatment point evaluation items.

6. Script development: Develop the script of the target disease based on key diagnosis and treatment point evaluation items before conducting the quality of service evaluation in primary health care institutions.

Appendix 3. Demonstrations of *Cure-Fun* smartphone-based platform current configurations of interview, physical exam and lab texts, and treatment.



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Using smartphone-based virtual patients to assess the quality of primary health care in rural China: protocol for a prospective multicenter study

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Using smartphone-based virtual patients to assess the quality of primary health care in rural China: protocol for a prospective multicenter study

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ABSTRACT

Introduction: Valid and low-cost quality assessment tools examining care quality are not readily available. The Unannounced Standardized Patient (USP), the gold standard for assessing quality, is costly to implement while the validity of clinical vignettes, as a low-cost alternative, has been challenged. Computerized virtual patients (VPs) create high-fidelity and interactive simulations of doctor-patient encounters which can be easily implemented via smartphone at low marginal cost. Our study aims to develop and validate smartphone-based VP as a quality assessment tool for primary care, compared to USP.

Methods and analysis: The study will be implemented in primary health centres (PHCs) in rural areas of seven Chinese provinces, and physicians practicing at township health centers and village clinics will be our study population. The development of VPs involves three steps: (1) identifying 10 VP cases that can best represent rural PHCs' work, (2) designing each case by a case-specific development team, and (3) developing corresponding quality scoring criteria. After being externally reviewed for content validity, these VP cases will be implemented on a smartphone-based platform and will be tested for feasibility and face validity. This smartphone-based VP tool will then be validated for its criterion validity against USP and its reliability (i.e., internal consistency and stability), with 1260 VP/USP-clinician encounters across the seven study provinces for all 10 VP cases.

Ethics and dissemination: Sun Yat-sen University: No. 2017-007. Study findings will be published and tools developed will be freely available to low- and middle-income

countries for research purposes.

Strengths and limitations of this study

- Developing and validating smartphone-based VP as a quality assessment tool for research and routine use in rural primary health care centers.
- Following an evidence-based approach to develop VP cases and scoring criteria.
- Systematically validating the VP assessment tool via a cross-national multicenter study
- The extent to which the VP assessment will reflect practitioners' real clinical practice needs to be verified.

Key words: Quality in health care, primary care, care quality assessment tool

INTRODUCTION

Universal health coverage (UHC) is a paramount goal of health system development for countries at all income levels.[1] The achievement of UHC is not possible without primary health care services,[1] which ensure integrated care close to the population they serve and link to the health-related sustainable development goals.[2] However, service coverage alone cannot improve health outcomes if the quality of care is poor. Despite efforts devoted to improving health care services, there is a lack of scientific evidence on the quality of primary health care in resource-poor settings, particularly of low- and middle- income countries (LMICs).[3-6]

This scarcity of evidence may partially result from the limited availability of valid, low cost, and easy-to-implement quality assessment tools[7]. As defined by Donabedian's framework, health care quality can be evaluated by the *structure* of care (e.g., staff, equipment), the *process* of care delivery (e.g., doctor-patient interactions), and health *outcomes* (e.g., death or complications).[8] Increasingly, process measures are being used, because of their advantages in terms of frequent and timely evaluation, and the usefulness in improving practice.[9 10] The 'gold standard' of assessing process is the unannounced standardized patient (USP), namely a trained actor who simulates the symptoms, signs, and emotions of a real patient in a standardized fashion and presents him- or herself unannounced to clinics to assess care quality.[11] USP can reduce recall bias better than patient exit interviews, minimize the Hawthorne effect that inevitably occurs in direct observation, and allow for comparisons between users as case- and patient-mix are controlled.[3 9 11] Nonetheless, the USP can only portray a

limited number of conditions without obvious physiological symptoms and risk of invasive examinations. Also, training and implementation of USP can require substantial personnel and resources, making USP impractical for large-scale and routine quality assessment.[12 13]

As an alternative, clinical vignettes or case simulations have been widely used as a low-cost and convenient method for assessing care quality.[9 14] Vignettes have been implemented in a paper-and-pencil form,[9] presented by an enumerator,[5] and streamlined by a computer.[14] Evidence of the validity of vignettes in assessing the quality of patient care is mixed. Some studies showed that vignettes reflect clinicians' competency (know-how) rather than their actual behaviors and can lead to overestimation of clinical performance.[9 15] By contrast, other studies found that vignette-based results, particularly those streamlined by computer, are quite close to the USP-based assessment.[14 16] The enumerator-administered vignette is similar to the announced standardized patient and thus is expensive and difficult to implement.[5] A computerized vignette can be interactive and can more realistically represent the complexity of a clinical encounter.[14] As a further improvement on computerized vignettes,[14] smartphone virtual patients (VPs) create high-fidelity, visualized, and interactive simulations that replicate clinical complexity and can be easily implemented at a low marginal cost.[17] Although VPs cannot remove the Hawthorne effect, their advanced features may reduce the measurement gap between competency and actual practice.[10 14] While VPs have been used in medical education to train and test clinical skills such as clinical reasoning, diagnosis and therapeutic decisions,[18]

their relative validity as a measure of quality of care has yet to be studied. Strengths and limitations of the abovementioned three methods are compared in Table 1.

In the present study, we propose to adapt smartphone-based VP for medical education as a quality-of-care assessment tool, given its advantages in 1) **standardization** (VPs are highly standardized, ensuring consistent assessments across users), 2) **flexibility** (Assessments can be delivered by smartphones for multiple users at any time, anywhere, providing data connectivity is available), 3) **scalability** (VPs can be modified to demonstrate and assess almost any clinical conditions with low marginal cost), and 4) **training** (VPs can also be used as a training tool to improve health care quality and thus to address the 'so what' question after quality assessment). These characteristics may especially benefit quality assessment and improvement in rural primary care settings, where communities are geographically scattered and difficult to reach and manage.

Therefore, our study aims to develop and validate **smartphone-based VPs** against USPs as a quality assessment tool that can be used both for research purposes and for routine evaluation of quality of primary health care provided by primary health centers (PHCs) in rural areas. To maximize its validity,[14] we will systematically construct high-fidelity VP cases to reflect clinical complexity in rural PHC contexts with real-time patient-doctor interactions and temporal constraints, and use evidence-based quality scoring criteria; additionally, we will make the VP-based test anonymous to minimize the Hawthorne effect. The initial phase of the study will mainly focus on rural China, while the ultimate goal is to develop and validate tools

that can have a broad application in other LMICs.

METHODS AND ANALYSIS

Study setting

The validation study will be implemented in the outpatient setting of rural PHCs (i.e., township health centers and village clinics) in seven Chinese provinces (Guizhou, Sichuan, Gansu, Inner Mongolia, Shaanxi, Hunan, and Guangdong). We are selecting these provinces not only to reflect the five strata of low-to-high life-expectancies and various burden-of-disease patterns in China,[19] but also to contrast geographic regions with diverse ethnic composition, including southwest mountainous regions, the northern plateau, the middle inland region, and southeast coastal areas (**Error! Reference source not found.**). Our study targets township health centers and village clinics because they provide the majority of primary health care in rural China.[20 21] At township health centers, primary health care is delivered by a workforce including licensed/unlicensed physicians, licensed/unlicensed assistant physicians, and registered nurses; while at village clinics, services are mainly delivered by one full- or part-time 'village doctor' who is a clinician with rudimentary medical training.[20 22 23] The outpatient setting is chosen due to the small number of inpatient cases in township health centers and village clinics. Study recruitment is expected to start from June 2018.

VP case development

VP case selection

We intend to select 10 cases that together can represent the work of rural PHCs. The

selection of the VP cases will be based on the following criteria: 1) high frequency of clinical encounters in the primary care settings in rural areas, and/or 2) association with significant disease burden; 3) representation of the major areas of work of PHCs in rural China overall (e.g., public health service delivery, chronic disease management, infectious disease control, health education, and patient-centered care); and 4) suitability for the USP methodology (e.g., no obvious physiological signs, low risk for invasive tests) for the sake of criterion validation in the current study. A case selection committee will be comprised of a range of stakeholders, including physicians, public health practitioners, policy-makers, and members of the research team. Based on the literature review, the research team will prepare a shortlist of the 30 most frequently seen conditions in township health centers and village clinics reported by either community dwellers[24] or rural PHC clinicians (Appendix1) from which the committee will select.

VP case design

The 10 selected VP cases will then be constructed individually by 10 case-specific development teams (Figure 2). These teams consist of one *condition expert* from the relevant specialty of a tertiary teaching hospital who will be responsible for drafting the VP case; an *evidence-synthesis group* involving epidemiologists and evidence-based researchers who will search and synthesize evidence about the selected condition for the condition expert to work on; a *clinical consensus group* which consists of several condition-related clinical experts who will review the corresponding case from a scientific perspective; an overall all-condition shared

context-expert panel, which includes clinicians and health managers from community health centers, township health centers, and village clinics, who will review the contextual appropriateness of the cases for the rural PHC setting; and a *case coordinator* who will coordinate development of each case.

Each VP case will be structured into five domains—medical history, physical examination, laboratory and imaging studies, diagnosis, and management and treatment plan —to simulate real-life clinical scenarios.[11 18] The structured VP cases will permit the examinee's performance in each domain to be evaluated, and for performance scores to be aggregated across conditions. In addition to these five condition-related domains, another practice contextual adjustment will be built into each case to consider medical resource constraints in rural practices (e.g., availability of basic medical equipment and medicines).

Scoring criteria

Care quality scoring criteria will be developed for each VP case. These criteria include *process quality,* the *accuracy of diagnosis, and* the *appropriateness of the treatment and management plan*.[3 4] Process quality will be evaluated in reference to a clinical process checklist (to be detailed later) including all necessary questions that should be asked and physical examinations that should be performed by clinicians, together with redundant or even potentially harmful practices. Diagnoses will be rated as correct, partially correct, or incorrect based on predetermined standards. The treatment and management plan will be considered appropriate if the clinician prescribes any of the correct medications or refers the patient to a higher-level

physician depending on the VP case.

In addition, *cost of care* and *time-spent per encounter* will also be recorded. Patient costs will cover medication fees and clinic fees charged per case. In order to link clinician reaction time to each domain and to impose the temporal constraints seen in real clinical practices, the entire clinician-VP interaction process will be timed. This will include time spent on taking history, conducting physical examinations, prescribing drugs and treatments, and any interruptions.

A systematic evidence-based approach will be adopted to developing the scoring checklist for the treatment and management plan, (Appendix 2). Briefly, the evidence-synthesis group will systematically search and extract condition-specific checklist items and standards from clinical guidelines, reputable textbooks, and systematic reviews, etc., in that order. The quality of the evidence will then be rated by the Appraisal of Guidelines for Research & Evaluation II (AGREE II)[25] or the revised Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) according to its type.[26] Afterwards, the clinical consensus group and the contextual-expert panel will review and revise initial standards using a Delphi process.[27]

VP case external review

To validate the content of VP cases, an independent expert panel of physicians, general practitioners, and rural PHC clinicians who otherwise are not involved in the study, will be convened to review the cases for content accuracy and appropriateness. The content validation involves qualitative and quantitative phases. In the qualitative phase, the expert panel will be required to evaluate the cases with respect to the

following: overarching assessment goal, representativeness of the goal and test items to each domain, the logical relationship of the content tested, and the appropriate wording, grammar, understandability, and relevance to the rural PHC context. The panel will also record their suggestions, if any, next to each item. Modified VP cases will then be given back to the expert panel for quantitative evaluation. They will be asked to assess the cases for simplicity and clarity, as well as necessity and relevance to the assessment, using a four-point Likert scale ranging from 1 (the lowest) to 4 (the highest). The content validity index (CVI) will be computed for each domain and for the entirety of VP cases.[28]

Technical implementation

Revised VP cases will be implemented on *CureFUN*, an existing smartphone-based training platform using VPs with special customizations and set-up to suit the assessment purpose. A live demonstration of a simplified VP can be accessed from http://www.curefun.com/zhiqu_front/www/experience/experience.html#/caseList and is also illustrated in Appendix 3. The smartphone-based VP assessment tool will not only present interactive clinical scenarios but will also automatically record each examinee's diagnosis pathway and grade it against the scoring criteria (Figure 33).

Feasibility study

Before a full-scale validation study, a feasibility study with 30% of the validation study sample (see study sample section) will be conducted to test the VP assessment tool's usability, accessibility, and stability, particularly in remote village clinics with weak phone connectivity. Selected clinicians will be instructed to individually attempt

two random VP cases within a given time, using their own smartphone devices from their workplace. Clinicians without a smartphone will be given a temporary device on which the customized *CureFUN* applications will be pre-installed. Clinicians' willingness to participate and adherence to the VP-based tests (e.g., percentage completing VP cases, score of the assessment, and number of attempts made at each case per person) will be automatically recorded. Upon completion of the cases, participants will be asked to fill in a five-point Likert-scale questionnaire regarding their subjective attitude toward the simulator VP experience (with 1 being the most negative response and 5 being the most positive), regarding ease of use, their experience of the assessment process and outcome, realism, device competence, accessibility, and other general comments. These results will be used to determine the face validity of the VP cases, with scores calculated by multiplying frequency (%) by positive evaluations (3 to 5); and scores no less than 1.5 are considered acceptable.[29]

Validation of VP as a quality assessment tool

Study design

The prospective validation study is a nationwide multicenter study with two main purposes: 1) to assess the criterion validity of the VP-tool in assessing the quality of primary health care, by analyzing its measurement concordance against the standard USP measure, and 2) to test the reliability of the VP tool, by examining its internal consistency and the stability of repeated VP assessments on the same subjects.

Study sample

From each of our seven sample provinces, two counties will be selected with

sufficient variations in socio-economic conditions, demographics, and disease burdens between them while also approximating the provincial condition in general. Within each county, the government registry of all township health centers and village clinics will serve as our sampling frame, which will include 1) licensed practicing physicians, 2) clinicians who have not been licensed but are providing clinical services under the supervision of licensed physicians at township health centers, as well as 3) full- or part-time village clinicians. Clinicians visiting on a temporary basis (often senior clinicians sent by higher level medical institutions to support the development of township health centers), nurses, and allied health workers without prescription privileges will be excluded.

The sample size calculation is based on individual VP/USP-clinician encounter and ensures sufficient power to detect variations at individual case level per county. For village clinics, one VP/USP case will be examined at a time to minimize the detection of USPs. Assuming a 5% type I error and 80% power, to determine whether a moderate concordance correlation coefficient[30] of 0.90 [31] between VP and USP differs from zero, seven paired VP/USP-clinician encounters will be required for each of the 10 cases per county. As a stratified sampling strategy will be deployed that first samples townships and then villages from each township, sample size calculations need to take into account the design effect. Assuming an intra-class correlation of 0.05 and 6 village clinics per township, then 9 paired VP/USP-clinician encounters is needed. These nine paired VP/USP-clinician encounters will be assigned to 3 township health centers and 6 village clinics using probability proportional to size

(PPS). These 9 paired VP/USP-clinician encounters will be assigned to township health centers and village clinics based on the ratio of the total number of clinicians at township health centers to the total number of village clinicians for each county. There are 1260 VP/USP-clinician encounters across our seven study provinces for all 10 VP cases. Figure 4 shows the sampling process and study flow for one VP case using Guizhou Province (Danzhai County) as an example.

Criterion validity

Criterion validity[32] of the VP to assess quality of care will be evaluated primarily by its measurement concordance against the USP measure as the recognized gold standard[33] for assessing quality of care in practice. The USPs will be developed in a related study, sharing the development teams for VP and a similar development process. The method of fielding USPs in rural China will follow a similar approach to those of the previous USP study in rural China.[3] Identical quality scoring criteria, described above, will be applied to scores. Each selected clinician will first see a USP (to avoid the practice effect due to the USP's unannounced feature), and then complete a smartphone-based VP assessment of the same condition. The clinician to be assessed will be randomly selected onsite by the USP from any on-duty clinicians on the day of the USP visit to the sampled township health center and village clinics. This situation would especially apply to township health centers, as most village clinics have only one clinician (note: Chinese patients normally see their primary care clinicians as a walk-in patient and appointments are seldom needed). To record USP-clinician interactions, USPs will complete checklists immediately after their visit,

and retain their prescription and the fee charge slips provided by the clinician. A week after the USP clinic visit, clinicians will be assigned a smartphone-based VP assessment, which will consist of an initial demonstration VP case to allow the clinician to familiarize themselves with how the system operates and then the test VP case of the same USP condition. The VP-clinician interactions, drugs dispensed, and fees charged will all be recorded automatically by the online assessment system.

The concordance of the two USP and VP assessments will then be analyzed by Lin's concordance correlation coefficient (r_c)[30] for continuous *process quality* scores, *fees charged* (yuan), and *time spent* (min),and the Kappa statistic[34] for dichotomous *diagnoses* and *treatment & management* measures. r_c evaluates how close pairs of observation fell on a 45° line (the perfect concordance line) through the origin in addition to their correlation. Kappa measures agreement in assessment beyond what is expected by chance alone. In addition, for continuous measures, a Bland-Altman plot will also be used to visualize the concordance.[35 36] For dichotomous measures, we will analyze their sensitivity (i.e., strength to detect correct diagnosis, treatment plan, etc.) and specificity (i.e., strength to detect incorrect diagnosis, treatment plan, etc.) using USP as the reference.

Reliability

To establish *test-retest reliability*, clinicians previously being assessed by VPs will be instructed to retake the same VP tests four weeks after their last assessment. The second VP test is set one month later than the first to reduce the practice effect,[37] assuming the clinician's general medical knowledge remains constant.[32] The

concordance of the two repeated tests indicates the stability of the VP assessment tool.[32] Similar concordance measures (i.e., r_c for continuous and Kappa for dichotomous measures) as described above will be used. *Internal consistency,* the intercorrelation of scores for process quality indicators, will be computed by Cronbach's alpha coefficients (α),[38] with $\alpha > 0.7$ representing acceptable reliability.[39] Table 2 summarizes the validity, reliability, and feasibility measures that will be examined in our study.

Patient and public involvement

We will seek feedback from clinicians and patient representatives in the feasibility study and use their feedback to refine the VP cases. Our USPs will be lay people trained to portray patients and assess care quality based on their interactions with clinicians. Our scoring criteria thus are also patient centered. Furthermore, all participants will be acknowledged for their involvement in the study and will be provided with a final summary report of the study outcomes and will have free access to the VP training website. All published results will be publicly available.

ETHICS AND DISSEMINATION

The study has been approved by the Institutional Review Board of the School of Public Health (IRB), Sun Yat-sen University (No. 2017-007). Informed consent will be obtained from all clinicians participating in the VP tests. However, to reduce participation bias due to self-selection,[40] our IRB has approved the implementation of USP without prior informed consent from the individual participants, on the condition that involved clinicians will be fully de-identified and all analyses will only be

conducted at the population level.[40] Study data will be securely stored and only de-identified information will be used for analysis. We will seek to publish study findings in peer-reviewed journals and produce reports to inform health authorities. The tools and technology developed in this study will be freely available to other LMICs for research purposes.

DISCUSSION

To the best of our knowledge, this is the first study validating VP as a quality assessment tool in rural primary health care centers. This study follows an evidence-based approach to develop VP cases and scoring criteria, implements them on a widely accessible platform (i.e., a smartphone), and systematically validates the VP assessment tool via a cross-national multicenter study representing rural PHCs over a wide range of geographic areas with distinct life expectancies and economic development levels. The VP assessment tool's accessibility, flexibility and scalability give it good potential to be easily adapted to other LMICs.

VP has mainly been used in medical education to train and test critical thinking[18] [41 42], and until recently few studies have applied the method in a practice setting to influence health provider behavior and improve care quality.[43 44] As an extension, we propose to validate VP as a quality assessment tool delivered via widely accessible smartphones. Nevertheless, it is to be noted that given its simulated nature, the VP-test theoretically may never completely bridge the 'know-do' gap. The validation study is thus essential to quantify the concordance/discordance between VP- and USP-based quality assessments. Our study will generate firsthand empirical evidence

contributing to the understanding of the 'know-do gap',[5 45] and shed light on circumstances that cannot be tested by USPs.

A limitation of the study, however, is that, in order to test the validity of VP against USP as the reference standard, we restrict the selection of VP cases to those that can be simulated by USP. This conservative first step will nevertheless allow us to examine the extent to which VP can reflect care quality, and a follow-up study will then explore the full potential of the VP in assessing quality of care. Further, the two purposely-selected counties for each province may not represent the provincial conditions entirely, although we will make every effort to consider provincial representation when selecting counties. Third, while the validation study is exclusively conducted on PHCs in rural China, the extent to which the VP assessment tool can be transported to other LMICs remains to be evaluated. Nonetheless, by implementing the study in a diverse set of Chinese provinces may improve the generalizability of our study considering the comparable life expectancies of LMICs and these provinces.

Author's contributions

All authors contributed to the conceptualization and design of the study. DX, JL, and YYC conceived the initial study design, analytical methods, and composition of the team. JL was responsible for the study concept, initial draft, and revisions. DX was responsible for the study concept and revising the draft. YLC and XHW were responsible for the development of the scoring criteria. SS, KH, HW, JNW, ZLZ, ZN, WJG, JP, CXT and WZ provided critical review and revision to the study design. All

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Competing interests

The development of the VP assessment tool is a joint project of the Sun Yat-sen University Global Health Institute (SGHI) (representing the seven universities in China), and *CureFUN*. However, the VP cases will be independently developed and the validation studies will be rigorously conducted by the research team from SGHI and the seven universities, whereas CureFun will technically implement the cases on smartphones and have no influence over the study design and analysis.

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Figure 1. Seven sample provinces in China referencing countries of equivalent life expectancy in parentheses.

Figure 2. Virtual patient case development team role and responsibilities.

Figure 3. Main components of smartphone-based virtual patient program.

Figure 4. Sampling and study process for one VP case in Danzhai County, Guizhou Province.

Table 1. Strengths and limitations of quality assessment measures.

Process Measure of Quality	Strengths	Limitations	Assessment Level
Unannounced Standardized Patient (USP)	Standardized, controlling for case-mix and patient-mix; Unannounced, no Hawthorne effect (if not be detected); Reduced recall bias	Expensive Limited medical conditions First-visit bias Selection bias if informed consent is required	**Action** (Do) **Gold standard**
Clinical Vignettes	Cost-effective; Suitable for large scale and cross-system comparison; Covering all illnesses; Accounting for case-mix and patient-mix.	Hawthorne effect Selection bias	**Competence** (Know how) **Over-estimating** care quality (best answers) or similar
Virtual Patients (VP)	Interactive Real-time response & automatic record Highly standardized Scalability & low marginal cost Efficient delivery: anytime, anywhere Suitable for large scale study	Hawthorne effect Selection bias High cost in initial development	**Performance** (Show how) **?**

Table 2. Main validation domains of the study.

Domain	Indicator	Data collection		Statistical analysis
		Phase	Method	
Content validity	Content validity index (CVI)	VP case review	Evaluations by an expert panel after reviewing VP cases, measured by a 4-point Likert scale (1=lowest, 4=highest).	CVI for VP case and for specific VP domain will be computed, where CVI = number of raters giving a rating of 3 or 4 divided by the total number of raters.
Feasibility	Willingness to participate; Adherence rate	Feasibility study	The subsample of clinicians' interactions with the 2 VP cases will be recorded by the online assessment	Willingness to participate = clinicians taking the VP tests divided by the percentage of clinician selected Adherence rate = clinicians completed 2 VP cases divided by the percentage of clinicians taking VP tests
Face validity	Satisfying score		Clinicians' subjective attitude toward the VP test experience measured by a 5-point Likert scale (1=most negative, 5=most positive).	Satisfying score for VP case and for specific aspects (e.g., usability, accessibility, etc.) will be computed, where satisfying score = frequency multiply by positive evaluations (3 to 5), and scores≥1.5 are considered acceptable.
Criterion validity	Concordance correlation coefficient (r_c); Kappa statistic	Validation study	The same clinician receives a USP visit and a VP test for a matching condition. The USP-clinician interaction is evaluated by the USP using the checklist, including fees and time per visit; while VP-clinician interaction is graded by the system.	The concordance of VP-test scores against USP-test score (gold standard) or two-repeated VP-tests will be examined by r_c for continuous process quality scores, fees charged (yuan), and time spent (min); and Kappa for dichotomous diagnoses and treatment & management measures.
Test-retest Reliability			Repeat VP-tests on the same clinician in a month	
Internal consistency	Cronbach's alpha coefficient (α)		VP-test scores on a single occasion	Intercorrelation of scores for process quality indicators with alpha >0.7 is acceptable.

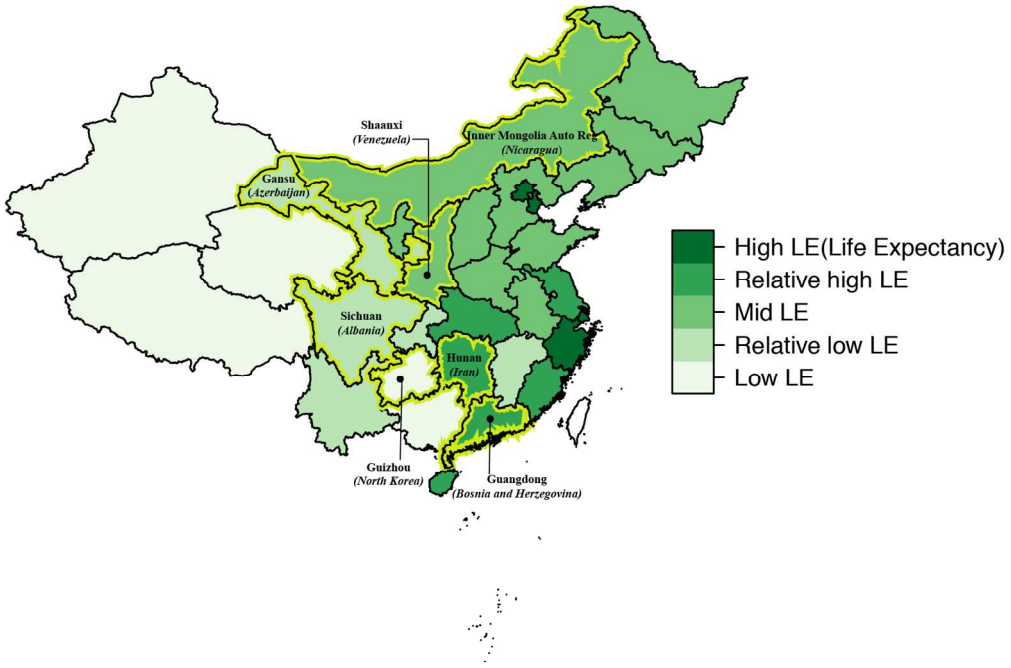

Figure 1. Seven sample provinces in China referencing countries of equivalent life expectancy in parentheses.

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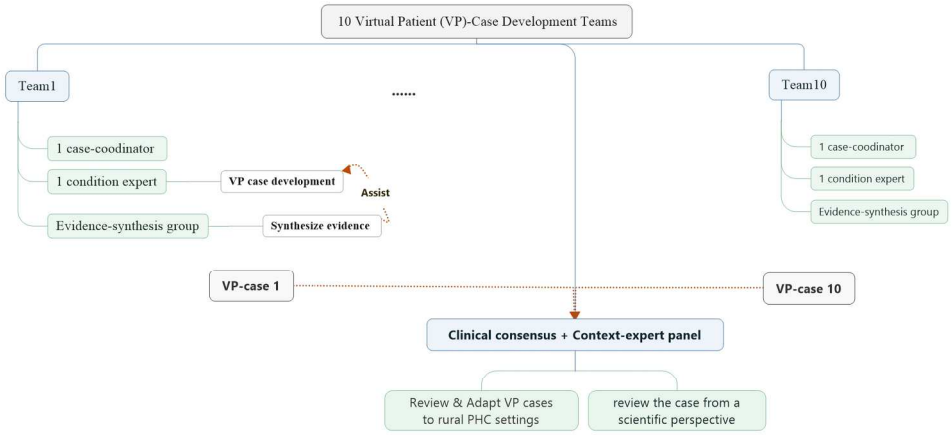

Figure 2. Virtual patient case development team role and responsibilities.

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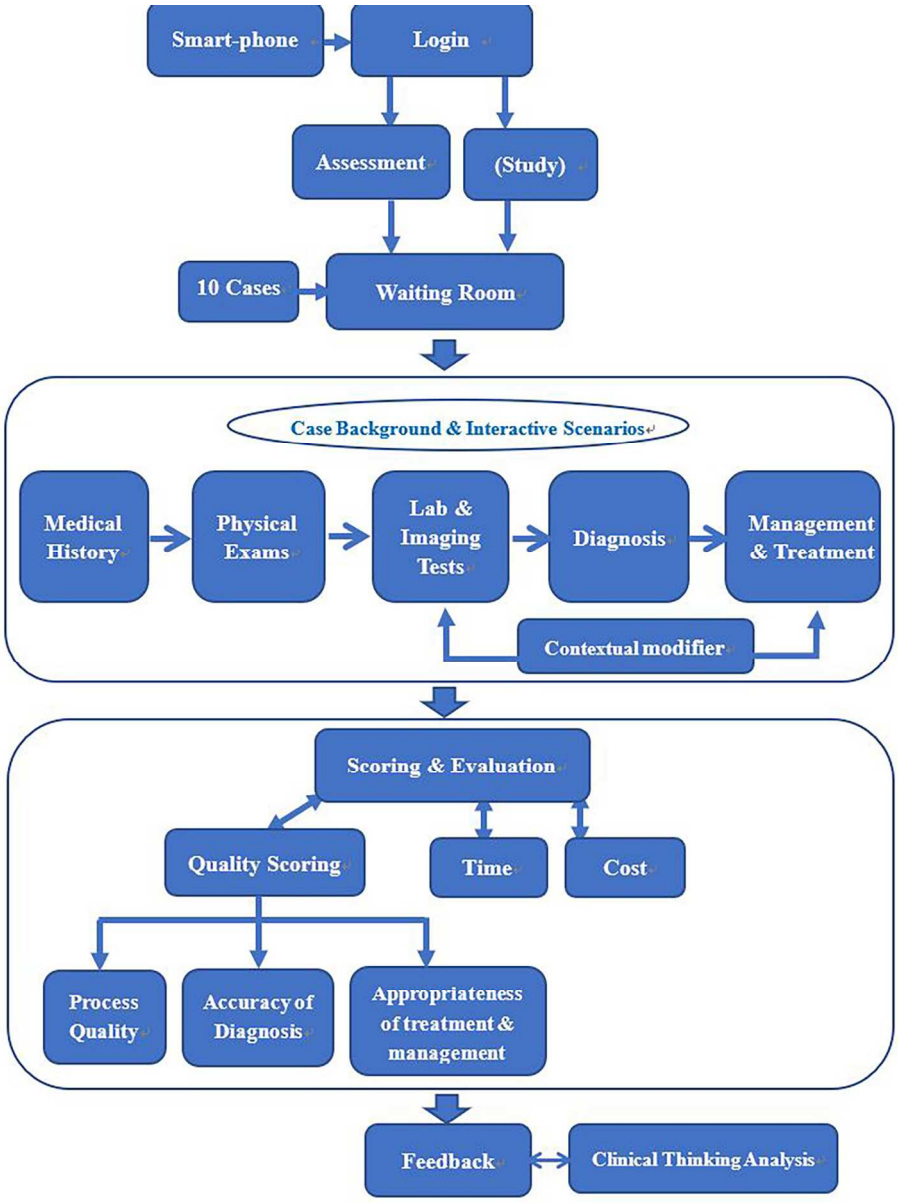

Figure 3. Main components of smartphone-based virtual patient program.

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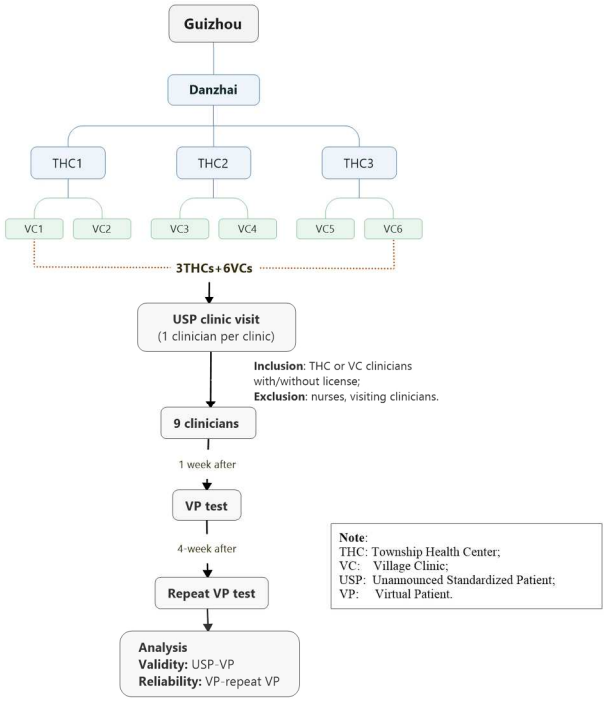

Figure 4. Sampling and study process for one VP case in Danzhai County, Guizhou Province.

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Appendix 1. Top 30 conditions of high-frequency clinical encounters in primary health care settings in rural China.

Clinical condition	Two-week consultation constituent ratio[1]		Township health center[2]		Village clinics[2]	
	RANK	%	RANK	%	RANK	%
Cold	**1**	28	**1**	13.60	**1**	19.50
Hypertension	**2**	21.8	**4**	7.90	**6**	9.80
Diabetes mellitus	**4**	3.9	**7**	4.60	**8**	4.60
Chronic tracheitis	**8**	2	**2**	9.50	**4**	10.50
Acute tracheitis			**3**	9.00	**3**	10.70
Gastritis	**3**	5.5	**5**	7.50	**5**	10.30
Diarrhea			**6**	5.30	**2**	11.70
Urinary tract infection			**8**	4.50	**9**	2.90
Osteoarthritis	**7**	2.30	**17**	2.40	**18**	0.50
Low back pain	**5**	3.10	**16**	2.50	**15**	0.80
Psoatic strain			**14**	2.60	**14**	0.80
Peptic ulcer			**11**	2.90	**11**	1.70
General trauma			**10**	3.10	**13**	1.10
Sciatica			**19**	1.80	**22**	0.30
Child dyspepsia			**9**	3.20	**7**	7.00
Pelvic inflammatory disease			**12**	2.70	**16**	0.60
Vaginitis			**13**	2.70	**17**	0.50
Dysmenorrhoea			**18**	2.30	**19**	0.50
Cholecystitis			**15**	2.60	**12**	1.60
Toothache	**10**	1.30	**22**	1.30	**10**	2.70
Menopausal syndrome			**21**	1.40	**27**	0.10
Cholelithiasis			**20**	1.60	**20**	0.40
Idiopathic headache	**6**	2.50	**25**	0.60	**25**	0.20
Hemorrhoids			**23**	1.10	**21**	0.40
Asthma			**28**	0.60	**26**	0.20
Chronic dermatitis			**29**	0.20	**29**	0.10
Tympanitis			**24**	0.70	**24**	0.20
Conjunctivitis			**27**	0.60	**28**	0.10
Sinusitis			**26**	0.60	**23**	0.30
Ischemic heart disease	**9**	1.5				

[1.] Self-reported two-week consultation constituent ratio by community dwellers, information from the 2013 National Health Service Survey in China.

[2.] Clinicians reported common clinical conditions in primary health care centers by centers' type.

Appendix 2. Methods for checklist and standards development

To evaluate the quality of care in primary health care institutions, key diagnosis and treatment points of common and frequently-occurring diseases will be developed. The *WHO Handbook for Guideline Development* and evidence-based evaluation principles will be adopted. The main procedures are comprised in the following six steps that will be implemented.

1. Expert group recruitment: Convene a multidisciplinary group consisting of experts in public health, evidence-based medicine/document retrieval, as well as clinical physicians.
2. Data retrieval and literature evaluation: Employ a 5S model to retrieve and incorporate clinical practice guidelines, textbooks, systematic reviews, meta-analysis, and important literature reviews. Retrieve literature from Wanfang, Medlive, MEDLINE, National Guideline Clearinghouse (NGC), National Institute for Health and Care Excellence (NICE), World Health Organization (WHO), DynaMed, and UpToDate. Evaluate the literature using AGREE II, AMSTAR, and QUADAS-2 for the included clinical practice guidelines, systematic reviews, and diagnostic tests, respectively.
3. Preliminary items pool development: Extract essential diagnostic and treatment procedures from the high-quality literature attained.
4. Clinical expert consensus: Apply a 2- to 3-round Delphi method to achieve consensus for diagnosis and treatment. The importance, necessity, and feasibility of the items should be considered in the process of Delphi, and additional medical information must be supplemented in terms of the clinical practice. Furthermore, all items should be classified as: necessary (3 points), selective (2 points), irrelevant (1 points), and erroneous (0 points).
5. Pilot and revise: Conduct a pilot test among 2~3 primary health care settings using the preliminary items. Revise the items and finalize the key diagnosis and treatment point evaluation items.

6. Script development: Develop the script of the target disease based on key diagnosis and treatment point evaluation items before conducting the quality of service evaluation in primary health care institutions.

Appendix 3. Demonstrations of *Cure-Fun* smartphone-based platform current configurations of interview, physical exam and lab texts, and treatment.