BMJ Open How to strengthen clinical research in Shenzhen, China: qualitative study

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ABSTRACT

Objectives To better understand the strengths and weaknesses, and to propose policy recommendations, regarding conducting high-quality clinical research in Shenzhen, China.

Design A qualitative study conducted from August to November 2016 using a semistructured interview format involving both focus group interviews and individual interviews.

Setting Shenzhen, China.

Participants Stratified purposive and convenience sampling were used. Thirty individuals experienced in conducting and managing clinical research were selected from key stakeholder groups, comprising 11 from local hospitals, 14 from pharmaceutical/medical device companies and 5 from government agencies.

Methods A semistructured interview guide was developed by the study group and used by experienced interviewers in focus group discussions and individual interviews. The interviewees were encouraged to share their opinions freely and discuss their own topics of interest during the interviews. Thematic analysis was used for analysis and all data were coded and extracted using NVivo V.11.0 software.

Results Favourable driving factors for clinical research in Shenzhen identified by all stakeholders included the recent trend of increased governmental funding for clinical research, supportive governmental policies, wide recognition of the value of clinical research and high demands from local industry. The major challenges include a lack of technical infrastructure, weak human research subject protection and a lack of capable research resources.

Conclusions Despite the established strengths, Shenzhen still needs to develop suitable technical platforms, human resources training programmes and strong human research subject protection programmes pertaining to clinical research. This would facilitate the establishment of a functional system that can be expected to lead to increased medical research innovation in Shenzhen.

BACKGROUND

Clinical research is broadly defined as human-oriented research for which an investigator directly interacts with human subjects.¹ It serves as the bridge connecting innovation from bench to bedside and hence determines the fate of newly developed medical products.

Strengths and limitations of this study

- A qualitative study was used to explore the strengths and weaknesses that Shenzhen has in terms of developing a high-quality clinical research programme, which would be difficult to discern using quantitative methods.
- To our knowledge, it is the first study to involve all key clinical research stakeholder groups, that is, policy-makers, health product developers and healthcare professionals, in the same geographical area.
- Data extraction and analyses were carried out with computerised software to avoid subjectivity.
- The limitations of the study include the convenient sampling and focusing on just one city in China; caution should be taken when generalising the conclusions to other areas of the country or other countries.

China has become the second largest consumer of medicines. However, China continues to be a country that uses more medical evidence than it contributes, owing to a lack of solid clinical research data.^{2 3} Most clinical practice recommendations used in China have been derived from low-level evidence, such as expert opinion, or knowledge generated by other countries.^{4 5} China has been ranked as the ninth country for clinical research capability according to an evaluation based on clinical trials and papers published in leading clinical research journals between 2014 and 2016.⁶ The Chinese government has been committed to promoting clinical research and medical innovation since 2012. Currently, 32 national clinical research centres have been established. They have assumed leading roles and made great achievements in major disease fields by building wide collaborative networks of knowledge generation, translation and application of clinical practice. In 2016, the National Health Commission of China, together with the Ministry of Science and Technology and other key regulators, advocated for the enhancement of clinical

research capabilities. This has created a more favourable environment and better policies to support medical research nationally. In addition, China's vast geography and population also offer unprecedented opportunities to conduct medical research.⁷ The significant geographical variations in diet, climate, culture, health systems, and so on, offer the potential for many questions regarding disease aetiology and the best medical practice to be answered.

As China's first 'Special Economic Zone', Shenzhen has become a large metropolitan city with a total population of over 20 million and a mean gross domestic product of US\$27 000 per capita. It is now widely known as a 'City of Innovation'. It has played a role as a pioneer innovator, spreading new ideas across China. Shenzhen's bioindustry is developing at a mean annual growth rate of 20%. Shenzhen is in the first batch of Chinese biological industrial bases, with particularly large investments in stem cell research, immunology and gene therapy. However, the number of clinical studies conducted in Shenzhen remains relatively low. The city must improve both its clinical research capability and systems. Our previous study found that knowledge and training regarding clinical research design and research ethics for medical professionals in public hospitals in Shenzhen are inadequate, and improved training is urgently needed.⁸

To better understand the strengths and weaknesses regarding conducting high-quality clinical research in Shenzhen, China, in order to inform a strategic plan with policy recommendations, the Health Commission of Shenzhen and the Peking University (PKU) Clinical Research Institute (PUCRI) (Shenzhen) designed and conducted the present study.

METHODS

Research design and study team

A qualitative research study involving focus groups supplemented by individual interviews was deemed appropriate to meet the study aim. The study was designed and conducted by our study group, which has expertise in relevant areas (PJ, female, MD, PhD, over 10 years of experience in managing clinical research studies; PxX, male, MD, PhD, over 30 years of experience in clinical practice and over 20 years of experience in research administration in a tertiary hospital; YW1, female, PhD, MHSc, over 10 years of experience in designing and implementing qualitative research; YW2, male, MD, PhD, senior investigator with over 30 years of experience in leading large clinical studies, including qualitative studies). The focus group and individual interviews were coordinated by CZ and ML (two experienced research administrators) and LZ (an experienced government officer responsible for health research). PJ, HC (female, PhD, an experienced researcher in qualitative study design, implementation and reporting) and HW (male, PhD, a health researcher with a strong background in epidemiology and clinical research) performed all analyses.

Setting

The focus group interviews were all conducted at the PKU Clinical Research Institute (Shenzhen), under the Shenzhen-PKU Shenzhen-Hong Kong University of Science and Technology Medical Center, China. All the individual interviews were conducted in the private offices of the interviewees at their own institutions.

Study sample

We purposively selected a convenience sample of participants from research hospitals, pharmaceutical and medical device companies, and the government agencies in charge of funding and managing health research in Shenzhen. Participants were required to meet the following inclusion criteria: (1) having sufficient experience in either conducting clinical research or managing clinical research programmes; (2) currently working at a research hospital, industrial organisation with a medical product development programme, or government agency responsible for health research funding and administration; (3) being able to express themselves with well-articulated stories and to deeply reflect on their stories; and (4) being willing to participate in the study.

We contacted 36 potential participants and 30 responded. Among the respondents, 11 were directors or representative senior staff from research management offices in research hospitals, 14 were from research and development departments of pharmaceutical and medical device companies, and 5 were regulators and administrators from relevant government agencies. Each participant was informed about the study procedures and was free to withdraw from the research. All participants provided written informed consent to participate in the study, which included permission to audiotape and transcribe the interviews. Potentially identifying information was removed from each transcript.

Data collection and reflexivity

A semistructured interview guide was developed (table 1) based on a group discussion involving the study team, and it was employed in both the focus group and individual interviews. The guide included questions around three themes: (1) current status of clinical research implementation, (2) current status of training pertaining to clinical research, and (3) strengths, weaknesses, opportunities and barriers to conducting clinical research in Shenzhen.

For both focus group and individual interviews, the interviewer gave a brief introduction about why and how the interview would be conducted at the beginning, followed by each participant signing the consent form. During each interview, specific questions were allowed for some flexibility, depending on how new ideas emerged during the interviews. The interviewees were encouraged to share their opinions freely and discuss their own questions of interest. However, the interviewer made sure that all questions listed in the interview guide were covered before ending the interviews. Each focus group interview lasted for 60–90 min. Each individual interview lasted for

Table 1 Semistructured interview guide used in the study, by interviewees' career field

Theme	Interviewee's career field		
	Academia	Industry	Government
Current status of clinical research in Shenzhen	<ol style="list-style-type: none"> 1. Type, number and annual funding of investigator-initiated clinical studies in your hospital in recent years 2. Type, number and annual funding of sponsor-initiated clinical studies in your hospital in recent years 	<ol style="list-style-type: none"> 1. Type, number and annual funding of clinical trials in your company in recent years 2. Sites of your studies and percentage participated in or led by hospitals in Shenzhen 	<ol style="list-style-type: none"> 1. Type and number of clinical research projects funded annually by your agency and total annual funding supplied for clinical research 2. Funding mechanism
Strengths, weaknesses, opportunities and barriers to conducting clinical research in Shenzhen		Same questions to all interviewees on strengths, weaknesses, opportunities and barriers	
Current status of training pertaining to clinical research in Shenzhen	<ol style="list-style-type: none"> 1. Type of training programmes (knowledge/skills/ethics) attended by your clinical researchers, or your training plan. 2. Your evaluation of the training programmes 3. Problems you encountered and your views on the reasons underlying these problems 4. Your suggestions for improvement 	<ol style="list-style-type: none"> 1. Type of training programmes (knowledge/skills) attended by your clinical development staff 2. Your evaluation of the training programmes 3. Problems you encountered and your views on the reasons underlying these problems 4. Your suggestions for improvement 	<ol style="list-style-type: none"> 1. Policies for clinical research training 2. Type of training programmes (knowledge/skills/ethics) provided by your agency 3. Your evaluation of the training programmes 4. Problems you encountered and your views on the reasons underlying these problems 5. Your suggestions for improvement

40–60 min. The individual interviews were conducted in a private office, free of interruptions, in each participant's institution for convenience. PJ made field notes during the interviews and focus group interviews. All interviews were audio recorded and transcribed verbatim in Chinese. Data collection was considered complete after three focus group interviews and 11 in-depth individual interviews were complete, at which point saturation of the themes was achieved.

Recruitment

Participants did not know about this study before they were invited to participate. They were contacted based on the candidate list specifically put together for this study by the Health Commission of Shenzhen and the Food and Drug Administration of Shenzhen. Contact was first made by a research coordinator (CZ) via telephone and email to arrange a face-to-face group or individual interview. He briefly introduced the study aim and requested participation by staff who were engaged in the clinical research process for appointments, respectively.

Data analysis

The transcribed data were analysed using thematic analysis with an inductive approach. NVivo V.11 software was used for analysis of the data. Two researchers (PJ and CH) independently coded and analysed the transcripts by selecting the units of analysis, making sense of the transcribed data, developing codes, categorising the data and abstracting. The analysis was focused on text from the three themes, but it also used related information from other topics that were brought up during interviews. After reviewing all the

interviews, the two researchers discussed and came to an agreement on the coding and categorisation. The two researchers then independently coded the transcripts of all the interviews using the agreed on coding and categorisation. Differences between the two researchers were minimal. After completing the initial analyses, the team confirmed the findings by checking them with the interview transcripts. To explore the validity of the results, the results were shared with all interviewers by email.

No objections or new considerations were raised, and all interviewers agreed with the findings.

The findings of the study were presented by listing the illustrative quotes from the respective interviews. The researchers who conducted the data collection and analysis translated the quotes selected for this article into English. Original quotes are available on request.

Patient and public involvement statement

The study was not designed to answer clinical questions. Thus, patients were not directly involved in the study. However, the study focused on capability building in clinical research, which will indirectly influence improvements in clinical practice.

RESULTS

The 30 participants had diverse backgrounds (tables 2 and 3). They were engaged in different aspects of clinical research and came from research hospitals (n=11), pharmaceutical and medical device companies (n=14), and relevant government agencies (n=5).

Table 2 Characteristics of the participants in the three focus groups

Participant characteristic	Focus group 1	Focus group 2	Focus group 3
Number	6	6	7
Career field	Academia	Industry—pharmaceutical company	Industry—medical device company
Role	Directors or senior officers of research management offices; principal investigators; staff of clinical trial offices	General managers; medical directors; clinical research associates	General managers; medical directors; clinical research associates

Based on our analysis, we refined the strengths and weaknesses of clinical research in Shenzhen and proposed strategies to strengthen clinical research activity in the city. The findings are supported by quoted comments of the research participants.

Strengths of current clinical research

Trend of increased funding for clinical research from government

An interviewee from government officers commented as follows: ‘To keep pace with the rapid growth of national clinical research and enhance clinical research capability, the establishment of the ‘Shenzhen Clinical Research Center’ and ‘Special Funds for Clinical Research’ has been considered by the Health Commission of Shenzhen’. Another participant from the research management office of one hospital said, ‘Research funds are sufficient. Special attention has been paid to research funding in the past several years. Our hospital has received 90 million RMB in research funds from the government over the past 5 years. The other two hospitals may receive over 1 billion RMB in support’.

Recognition of the value of clinical research

One interviewee from a hospital research management office commented, ‘The leadership and key persons in hospitals have realized the value of, and emphasized the recognition of, clinical research’.

Another participant from a hospital opined, ‘Our principal investigators have been interested in clinical research, because they would be left behind, regardless of their involvement in academia or clinical practice, if they do not participate in research activities’. A participant from a clinical trial office of a hospital stated, ‘More clinical trials and investigator-initiated large-scale studies have taken place at our hospitals within the last few years’.

In addition, Shenzhen is regarded as an immigrant metropolis, with unique features of population structure and patient specialties at the hospitals. One official from a hospital management bureau remarked, ‘We

should make good use of our patient resources, instead of dealing with animals or samples in the lab’. This official went on to state that ‘special attention should be paid to research in children and female patients, and food and nutrition fields, taking 2 million children (Shenzhen) into consideration, which is comparable to the patient pool of Beijing and Shanghai. It is possible to lead vital and high-impact clinical research projects in those fields with enriched patient resources.’

Implementation of policy to attract clinical research professionals

As there is a high demand for talented professionals, all hospitals have implemented special policies to attract such talent. Many professionals with master’s and doctoral degrees have been recruited. The director of the research management office of one hospital stated that ‘currently, most hospitals are recruiting post-doctoral students. In addition to the salary of 80 000–240 000 RMB per year for each post-doctoral researcher at every hospital, 120,000 RMB per year is also provided by the government as subsidies. One of those hospitals has established the goal of recruiting 100 post-doctoral researchers’.

The ‘Peacock Talent Project’ was launched in 2011 to bring in international high-tech experts and research teams. Most Peacock teams specialise in high-tech research fields such as digital information biomedicine and new-energy technology. The government provides each team with 15–80 million RMB.

In addition, in 2014, the ‘Sanming Project of Medicine’ in Shenzhen was introduced as an initiative to attract first-class international and national medical experts to come to Shenzhen to help to enhance capacities in clinical practice, medical education and research in local hospitals. Each project is funded by 8–15 million RMB over 5 years.

A senior officer at the Health Commission said, ‘Obviously, the ‘Peacock Talent Project’ and ‘Sanming Project

Table 3 Characteristics of the participants in individual interviews

Career field	Academia	Industry	Government
Number	5	1	5
Role	Directors or senior officers of research management offices in hospitals	General managers of pharmaceutical companies	Senior officers at the Health Commission, the Food and Drug Administration and the Hospital Management Bureau of Shenzhen

of Medicine' have had a positive impact on attracting talent to the local healthcare system'.

High demands from industry

At present, Shenzhen is an important innovation base for the development of large precision medical instruments. Interviewees from hospitals also mentioned the rapid development of medical devices, which accounts for the majority of clinical trials in local hospitals, for example: 'We have conducted about 130 registered clinical trials since 2010; most of them were focused on medical devices and diagnostic reagents, which are reflective of the characteristics of enterprises in Shenzhen'.

In addition, pharmaceutical companies hope to enhance the cooperation between hospitals and enterprises, including the set-up of phase I clinical trial institutions as research platforms to support the growing needs regarding clinical trials in Shenzhen. Interviewees from industry commented:

Shenzhen plays a key role in China's medical device industry, with more than 1000 pharmaceutical and medical device companies. And these companies are backed up by Shenzhen's advanced industry with innovation and modern technology.

There are many device and testing agent enterprises in Shenzhen. In fact, we are willing to fund the establishment of a hospital research platform that can solve the problems of enterprises, save costs, and increase efficiency in Shenzhen.

Weaknesses of current clinical research

Lack of infrastructure to support clinical research

Infrastructure for research was cited by some interviewees from hospitals as a major issue, because the national funding allocation model has resulted in potential researchers being deterred from the pursuit of clinical research. Interviewees from hospitals stated the following:

Whether the project is funded by the National Natural Science Foundation, provincial funds, or the local Scientific and Technological Innovation Committee of Shenzhen, most of this funding is directed toward basic research. In addition, major expenses are expected for equipment, rather than personnel, according to the current funding policy.

It is difficult for clinicians to carry out clinical research successfully because of insufficient support, in terms of study design, implementation of data collection, analysis, and interpretation of study data. Currently, we do not have study coordinators in most research projects.

We attempted to establish a research institute for women and children several years ago. However, it failed to make a significant impact, owing to a lack of support from leadership; inadequate funding or funding policy, in which funds were spent for equipment only, rather than human resources; and a lack

of research time allocated for physicians, because of their heavy workload and clinical duties etc.

The interviewees from industry presented major concerns regarding the fact that existing businesses and regulatory management systems are inefficient and the process for initiating and conducting clinical trials is unclear. Several factors influence companies' interest in cooperation with hospitals in Shenzhen. First, the time-consuming contract approval process, especially concerning industry protocols, was identified as the number one area of concern and discontent. The entire approval process varies widely in duration (from 1 month to 1 year) and by unit and hospital, including for trials conducted at China Food and Drug Administration-certified clinical trial sites. Second, the ethical review application and approval processes are also a source of frustration, due to the lack of standard requirements and procedures. The full process from submission to approval is also time consuming.

Insufficient number of qualified investigators in clinical research

Most interviewees from both hospitals and industry listed the lack of qualified and well-trained personnel as a big obstacle. Participants from hospitals remarked:

For instance, no qualified staff can be assigned to work on the research project, even though we obtained the funding.

Few graduate students are available, because most hospitals in Shenzhen are not university-affiliated.

The investigator-initiated studies might not be properly designed and conducted, as there is a lack of methodology knowledge and training.

In addition, interviewees from industry mentioned:

Owing to the lack of experienced and skilled research teams in Shenzhen, the methodology, design, and implementation of clinical research, and application of ethical regulations are compromised. Thus, we have had to cooperate with investigators from Beijing or Shanghai.

Most research management staff members in hospitals, including study coordinators, are employed on a part-time basis, and feel overwhelmed by their workload. Without adequate training and appropriate preparation, it is difficult for them to carry out their jobs properly.

Suggestions on how to strengthen clinical research in Shenzhen

Interviewees proposed suggestions regarding the enhancement of clinical research activity in Shenzhen.

Several interviewees from hospitals alluded to a lack of knowledge and skills, especially in terms of methodology. A training model involving combined systematic theory and practice would be ideal. One interviewee stated, 'The provision of systematic and continuous training

is urgently needed for those who are managing and conducting research on human subjects. A theory and practice combination training model is preferred during the process of conducting clinical research'. In addition, a greater number of clinicians should be attracted to, and supported in, clinical research, as another interviewee pointed out, 'In addition, it is important to motivate clinicians to conduct clinical research rather than basic research, with the support of favorable policies, such as more refined promotion and incentive criteria. Basic research tends to be more easily published. Publication is necessary for the promotion of clinical doctors'.

The network for clinical research was also addressed. One interviewee stated, 'It would be nice if we could initiate a 'Clinical Research Symposium' in Shenzhen, as this would definitely create a conducive atmosphere and establish a communication platform for doctors to share experiences across disciplines'.

It has been noted that the government has paid special attention to medical research innovation, with a series of policies aimed at attracting talent and platform building. For instance, interviewees remarked, 'Our leadership is committed to clinical research as a strategic growth opportunity for research innovation in Shenzhen. Specifically, how can we conduct a greater number of clinical research studies, more efficiently, at a higher quality?' and 'We have made budget plans for the development of a thoroughly integrated clinical research information technology system, with current centralized electronic medical records'.

Interviewees from industry proposed recommendations to enhance clinical research collaborations with hospitals, including: (1) setting up an efficient platform in hospitals to deal with contract and regulatory processes; and (2) recruiting qualified research staff. The industry interviewees stated the following:

Partnering is ever-increasing among pharmaceutical and biotechnology companies, and medical practices. Regarding industry protocols, it is important to expedite contract and regulatory processes. We desire increased transparency and efficiency in the contracting process.

We are hoping to fund a Clinical Research platform that can act as an entry point at hospitals, for access to specific consultation and support services, such as the assignment of trained coordinators.

It would be better if hospitals could recruit qualified study coordinators for allocation on an as-needed basis.

DISCUSSION

Our study revealed the obstacles and favourable factors associated with conducting clinical research in Shenzhen. To our knowledge, this was the first qualitative study to integrate comments and suggestions from all key stakeholder groups to evaluate the strengths and

weaknesses of conducting clinical research in China. A wide gap exists between the limited research capabilities in Shenzhen and the many unmet demands of medical research. We identified several favourable driving factors, including supportive policies, increased funding for clinical research from the government, and wide recognition of the value of clinical research by all stakeholders. However, the major barriers include a lack of supportive technical and administrative infrastructure, weak human research subject protection and a lack of capable research personnel.

Strategies were proposed based on the interview findings in the following areas:

Establishment of a technical support platform

Interviewees expressed concern about the lack of support in terms of study design, and actually conducting the study through to data analysis. The clinical research model has tended to be complex, with multicentre, large-scale, long-term follow-up design features. Furthermore, increased interest in a greater number of registries and longitudinal cohort studies has been noted since the introduction of the concepts of real-world evidence and precision medicine. This has been facilitated by the growth of information technologies and use of electronic medical records.⁹ Based on the increased complexity of administrative and regulatory processes, funding agencies and scientists are calling for 'systematic improvement in the infrastructure and workforce for clinical research.'^{3 4}

However, many hospitals do not have a well-developed, integrated platform.² Thus, in addition to offering funding and incentives for specific projects, government investment should also include funding for platforms by which the following may be achieved: provision of long-term support³; establishment of a structured electronic database system and regional data centre at a health authority's premises^{9 10}; securing protected research time for investigators^{2 3}; cultivation of an environment of innovation and cooperation^{3 9}; and quality and risk management. Such platforms should provide the technical support required for the design, implementation, quality control, data management, statistical analyses and other aspects of clinical research projects.

In addition, the government should aim to support study investigators by creating a central pool of study coordinators with specific expertise in a variety of areas (along with standard job descriptions) who can be recruited for individual projects on an as-needed basis and by providing opportunities for training.

Industry-sponsored clinical trials would also benefit from such centralised platforms, by creating a single means by which the processes of approval and initiation of a study, its progress, and successful and compliant operations may all be streamlined. Thus, these platforms should include a continuous quality assurance mechanism. It would be useful to additionally consider the integration of medical practice management systems and research systems to facilitate clinical research.

Upgrading human research subject protection programmes

Considering the weak capacities regarding ethical review and approval in hospitals in Shenzhen, and the high levels of unmet need in the biopharmaceutical industry, it would not be possible to enhance the review capacity in all major research hospitals at the same time and in a short period due to the lack of locally available qualified human resources. Instead, a regional ethics committee (involving individuals with the best expertise in Shenzhen) was proposed to provide ethical review services that meet the international quality standards required for high-quality multicentre clinical studies, avoid duplication of reviews and expedite the entire process; a single IRB approach has also been recommended in the USA.^{11 12} The use of a central regional IRB for multisite trials has been encouraged in the updated regulations of China. In this way, the limited funding resources available could be used for a practical capacity building programme that involves using external expertise to rapidly bring local capacity up to international standards. Thus, Shenzhen could develop a qualified human research subject protection programme in a short time, which would serve all ethical approval applicants across the whole city. This resource could further be used to provide ethical training to all local medical researchers (to increase research integrity), develop capacity building programmes for local IRBs and, as a long-term goal, enhance the ethical review capacity in all hospitals in Shenzhen. Our previous survey indicated that the need for greater awareness of ethical issues in research is obvious and that the availability of ethical training is insufficient.⁸

Implementation of a clinical research capability training programme

Based on our interviews, our current research staff are evidently considered generally inexperienced and insufficiently trained to manage research involving human subjects. The researchers tend to lack basic concepts and skills regarding clinical research methodology, design, implementation and ethical regulations. Our previous survey also reported on the lack of clinical research training in Shenzhen.⁸ Many Chinese doctors and nurses reportedly do not currently have the skills and knowledge to meet the scientific, ethical and feasibility multisector management requirements.^{13 14} Thus, research competency-based training programmes should be developed and offered by the various research institutions.

Clinical research training differs from that of basic science education. Therefore, different training courses, in terms of content and target audience, should be designed and offered to ethical committee review members, principal investigators and study coordinators, among others.

According to the previous survey of Shenzhen hospital staff, most of them underwent training at academic seminars and forums in specific therapeutic fields. PUCRI has established a branch in Shenzhen as the first support platform for facilitating clinical research in Shenzhen. PUCRI

(Shenzhen) started providing various training courses in 2016, including training on clinical research ethics and regulations, protocol design, project management and quality control, and so on. In addition, hospitals should take responsibility for ensuring proper research training before project initiation.⁸

LIMITATIONS

A potential limitation of this study was the use of convenience sampling to select participants in fields related to clinical research. This can lead to the collection of biased information. However, our data analysis process showed that the sample reached satisfactory saturation of information. Thus, we deem that the sampling method had little impact on our findings.

In addition, the study was conducted in just one city of China and caution should be taken when generalising the conclusion to other parts of the country or other countries. In the other major cities of China, such as Beijing, Shanghai and Guangzhou, there are more human resource expertise regarding clinical research. However, many other cities in China and across the world are facing a similar situation as in Shenzhen: high demands but few resources to conduct clinical research. Our study findings should help to inform how to establish a strong system for the development of high-quality clinical research, which in turn would bring about healthcare innovation.

CONCLUSIONS

This study outlined the current strengths, weaknesses and opportunities associated with the improvement of clinical research, and it developed an action plan for response to a dynamic environment. While acknowledging the relevant strengths of clinical research in Shenzhen, the study found that the city still needs to develop high-quality technical platforms, highly trained research personnel and an independent human research subject protection programme. This would facilitate the establishment of a functional system for increased innovation in medical research. The challenges associated with conducting clinical research in Shenzhen are evidently not location specific, and are reflective of the situation in other major cities and regions in China. Only with the implementation of effective and sustainable governance policies and a well-established system can Shenzhen achieve its potential to become a fertile field for healthcare innovation.

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Contributors YW, YW, Px and PJ conducted the interviews. CZ, ML and LZ contacted the participants and coordinated the study activities. HC, PJ and HW performed all analyses. PJ and HC wrote the first draft of the manuscript and rewrote new drafts based on input from all coauthors; they contributed equally to this paper. YW provided extensive input on the structure of the manuscript, and revisions to the manuscript drafts. All authors read and approved the final manuscript.

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Data sharing statement Original quotes and audio data from the interviews are available on request by emailing the corresponding author. The data presented were anonymous and the risk of identification is low.

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REFERENCES

1. National Institutes of Health. Glossary [EB/OL]. 2018 <https://humansubjects.nih.gov/glossary> (Accessed 26th Oct 2018).
2. Wang C, Liu Q. A turning point for clinical research in China? *Lancet* 2013;382:835–6.
3. Zhang J, Huang H, Shen X. Cultivating and investing in clinical research in China. *Lancet* 2015;386:1506–8.
4. Jiang L, Krumholz HM, Li X, *et al.* Achieving best outcomes for patients with cardiovascular disease in China by enhancing the quality of medical care and establishing a learning health-care system. *Lancet* 2015;386:1493–505.
5. Chen Y, Wang C, Shang H, *et al.* Clinical practice guidelines in China. *BMJ* 2018;360:j5158.
6. EB/OL. China Association of Enterprises with Foreign Investment R&D-based pharmaceutical association committee. deepening the drug innovation ecosystem reform—a plan to design and build china's clinical research system [in Chinese]. 2018 <http://www.rdpac.org/Upload/UploadFileDir/201801/18/201801181018241482.pdf> (Accessed 30th Oct 2018).
7. Wu Y, Yin D, Abbasi K. China's medical research revolution. *BMJ* 2018;360:k547.
8. Ji P, Wang H, Zhang C, *et al.* A survey on clinical research training status and needs in public hospitals from Shenzhen. *J Educ Train Stud* 2017;5:73–7.
9. Sun X, Tan J, Tang L, *et al.* Real world evidence: experience and lessons from China. *BMJ* 2018;360:j5262.
10. Zhang L, Wang H, Li Q, *et al.* Big data and medical research in China. *BMJ* 2018;360:j5910.
11. National Institutes of Health. Final NIH policy on the use of a single institutional review board for multi-site research [EB/OL]. 2016 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html> (Accessed 13th Feb 2018).
12. Clinical Trials Transformation Initiative. Use of single IRBs for multi-center clinical trials [EB/OL]. 2013 <https://www.ctti-clinicaltrials.org/projects/single-irb> (Accessed 13th Jun 2018).
13. Hu Y, Huang Y, Ding J, *et al.* Status of clinical research in China. *Lancet* 2011;377:124–5.
14. Shao P, Gwenth RW, Wang J. Probe into study on training of clinical research nurses in China [in Chinese]. *Chinese Nursing Research* 2015;29:2026–7.