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Socio-technical barriers affecting large-scale deployment of AI-enabled wearable medical devices among the ageing population in China

Fei Xing a, Guochao Peng a,*, Bingqian Zhang a, Shuyang Li b, Xinting Liang a

a School of Information Management, Sun Yat-sen University, Guangzhou 510006, China

b Management School, University of Sheffield, Sheffield, UK

Abstract

In order to provide better health and caring services to its rapidly growing ageing population, China has turned to new digital innovations empowered by Internet of Things (IoT) and artificial intelligence (AI) technologies, e.g. wearable medical devices (WMDs). This paper reports on an exploratory study that investigated socio-technical barriers and challenges affecting large-scale deployment of AI-enabled WMDs amongst Chinese old people. Nine focus groups were done to collect in-depth insights and comprehensive viewpoints respectively from Chinese families, local device providers, and public healthcare organisations. The qualitative data collected was analysed by using a thematic analysis approach. The results showed a set of 16 crucial barriers related to diverse technological, managerial, clinical, financial, legal and personal aspects. amongst these, lack of collaboration between WMD providers and public health organizations was identified to be the most critical barrier. This challenge was triggered by a range of clinical, financial, legal, managerial, and technical reasons, and would substantially prevent large-scale deployment and usage of AI-enabled wearable medical devices in the Chinese context.

1. Introduction

According to the United Nations (2019), the world's elderly population (i.e. people at the age of 65 or above) reached 703 million in 2019, and is predicted to double to 1.5 billion in 2050. Such phenomenon of population ageing has become one of the most significant global grand challenges. In China, official statistics showed that by the end of 2019, China's population surpassed 1.4 billion, and accounted for nearly 18.5% of the world's total. At the same time, China's elderly population has been growing rapidly and reached 176 million by the end of 2019, representing 12.6% of the total of the country. It is widely acknowledged that China's increasingly ageing population is attributed to its one-child policy, which has substantially changed the country's fertility rates and led to the 4-2-1 structure of Chinese families (i.e. each family has four grandparents, two parents, and one child) (Jiang and Sánchez-Barricarte, 2011; Zhan, 2005). As a consequence, many Chinese families are nowadays facing difficulties in taking care of their elder members (Peng et al., 2016). These phenomena are also generating increasing pressure to the national health and welfare systems as well as the whole Chinese society and economy (Fan et al., 2016; Peng et al., 2016). Faced with challenges raised by the ageing population, China has been trying to seek for new digital innovations to provide better health and caring services to the elder people (Fan et al., 2016). This is one of the key objectives involved in the country's national health plan, called "Health China 2030" launched in 2016.

Under this national background, and also with recent development of Internet of Things (IoT) and artificial intelligence (AI) technologies, wearable medical devices (WMD) emerge to be one of the most efficient digital means to relieve healthcare pressure caused by the ageing population in the world in general (Baig et al., 2017) and in China in particular (Peng et al., 2016). WMDs are lightweight and portable devices with embedded IoT sensors to monitor elder people's health status, movement and vital signs (e.g. temperature, heart rates, blood pressure, etc) in a constant and real-time manner over distance (Baig et al., 2017; Peng et al., 2016). Apart from these monitoring functions, AI technologies and applications equip WMDs with strong power to prevent, detect and manage chronic diseases of elderly people (Baig et al., 2017; Bolous et al., 2019). The data analytical results, predictions and alerts generated by the system can be automatically sent to predefined family members and healthcare organisations. In other words, this solution allows elderly people to stay at home but still be taken care of by their family members and health professionals remotely (Peng et al., 2016).

However, and despite strong market demand and substantial effort made by device providers, anecdotal evidence shows that AI-enabled WMDs have not been widely accepted by either the Chinese society or health professionals. There seems to be a range of severe barriers and challenges affecting large-scale deployment of these devices in the Chinese context. The current literature (e.g. Dupuy et al., 2016; Shin and Biocca, 2017; Baig et al., 2019) only shed light on a limited subset of these challenges (i.e. mainly from the perspective of elderly users with no exploration from the views of device providers and health professionals), which are not sufficient in understanding this complicated phenomenon in full. In order to fill this knowledge gap, the study reported in this paper attempted to seek answers for two research questions:

1) What barriers are currently affecting large-scale deployment of AI-enabled WMDs among China's ageing population, from the perspectives of local device providers, public health organisations, and elderly people?

2) How these barriers may be interrelated and influence each other?

In relation to these research questions, the study generally aims to obtain an in-depth understanding and holistic exploration on potential barriers and issues influencing large-scale deployment of AI-enabled WMDs in the Chinese context. A set of more specific research objectives was also established:

- To identify barriers and issues associated with the deployment of AI-enabled WMDs, respectively from the perspectives of local device providers, public health organisations, and elderly people in China;
- To compare the differences and similarities of barriers and challenges experienced by the three groups of stakeholders;
- To explore potential relationships among the identified barriers and so highlight the most influential ones.

The results of the study should be of interest to elderly people and their family members, and will be particularly important and useful to researchers, WMD manufacturers, public healthcare organisations, service companies, and policy makers who are keen to promote the usage and large-scale deployment of such digital innovation in China and worldwide.

2. An overview of literature on AI-enabled WMDs

In order to explore existing studies and literature related to the research topic, a systematic review was conducted. During this extensive review process, the researchers searched for adequate keywords (e.g. wearable technology, wearable device, Internet of things, AI, medical, health, care, ageing population, elderly people, and China) in a number of databases (e.g. Web of Science, ScienceDirect, Google Scholar, ResearchGate, and ProQuest), and also tracked suitable citations in the retrieved articles. This systematic review led to the identification of three WMD-related research streams, respectively concerning with hardware aspects, AI enhancements, and user engagement and deployment issues, as presented below.

2.1 Related studies on WMDs as IoT-based hardware

WMDs are in essence IoT-based wearable devices, which can take the form as remote body trackers, wristbands or smart watches (Kim and Shin, 2015; Lunney et al., 2016; Wang and Loh, 2017). As highlighted by researchers in the field, the most typical and basic functions of WMDs are to track movements and locations of users, and then generating analytical patterns about people's physical activities, like walking, running, swimming, and sleeping (Marakhimov and Joo, 2017; Mishra et al., 2016). With more advanced IoT sensors and technical elements (such as photoelectric and electrocardiogram measurement technologies), WMDs can be used to track vital signs (such as temperature, heart rate, blood oxygen, blood pressure, and so on) in real-time (Andreu-Perez et al., 2015; Pantelopoulos and Bourbakis, 2009), and so can be used by more vulnerable groups of people with caring needs (e.g. elderly people) for distance health monitoring, disease management, and rehabilitation (Azariadi et al., 2016; Kekade et al., 2018; Radder et al., 2019). It was identified from our systematic review that, the number of articles on WMD has been increasing rapidly in recent years. However, the majority of these studies focused on engineering and hardware aspects, such as improving the performance and measurement accuracy of built-in sensors of WMDs (Kamišalić et al., 2018; Papi et al., 2015), enhancing IoT and wireless data transmission efficiency (Lee et al., 2016; Schonle et al., 2017), and designing new hardware proof of concepts for specific caring needs (Malhi et al., 2012; Shen et al., 2012; Zhou and Dong, 2018). Although the study reported in this paper does not focus specifically on engineering and hardware aspects, previous research in this first stream still allows us to gain knowledge of technical features of WMDs and so better explore and understand technical issues identified in the empirical stage of the study.

2.2 Related studies on AI applications integrated with WMDs

Further to hardware aspects, researchers and industrial practitioners in recent years have been striving to couple WMDs with AI technologies, which were deemed to have the power to transform the healthcare sector substantially (Fagherazzia and Ravaud, 2019; Tran et al., 2019). Machine/deep learning, data mining, and natural language processing are fundamental methods forming the basis of AI (Boulos et al., 2019; Fagherazzia and Ravaud, 2019). Various AI applications and algorithms utilising data collected from thousands of WMD users are being developed and tested to perform automated diagnosis, predict patients' health trends, and generate analytical results and personalised alerts. WMDs empowered by AI will not just assist elderly people in managing their own health status more effectively (Price-Haywood et al., 2017; Shin and Biocca, 2017), but can also help caregivers and clinicians to select optimal treatments and proactive interventions for individual patients (Tran et al., 2019). In light of this AI wave, our extensive review of the literature identified an increasing number of articles that demonstrate new WMD prototypes containing a front-end IoT-based hardware and a back-end AI application with innovative deep learning algorithms (Chen et al., 2016; Inan et al., 2018; Lin et al., 2019; Jeyaraj and Nadar, 2019). Further to the hardware features discussed above, this second stream of research enables us to better understand potential use cases and scenarios where AI tools and applications can enhance the power of wearable medical devices.

2.3 Related studies on user engagement and deployment of AI-enabled WMDs

Despite potential benefits promised by AI-enabled WMDs, their real-world deployment and effectiveness are largely depending on the uptake and engagement of their intended users (Tran et al., 2019). Consequently, the third stream of research on WMDs attempts to understand potential factors that could influence the acceptance, usage and deployment of these devices (e.g. Dupuy et al., 2016; Kalantari, 2017; Papa et al., 2020; Baig et al., 2019). The study reported in this paper particularly contribute to this research stream.

Based on results of the systematic review, some of the identified factors affecting WMD users' acceptance attitudes and usage behaviours include perceived usefulness, perceived ease of use, perceived risks, level of comfort, personal innovativeness, health belief, self-efficacy, subjective norms and social influence (Dupuy et al., 2016; Chuah et al., 2016; Li et al., 2016; Yang et al., 2016; Marakhimov and Joo, 2017; Alaiad and Zhou, 2017; Chang et al., 2018). In general, these technology acceptance and adoption studies concluded that users were not entirely satisfied with their usage experience of WMDs and their continuance usage intention of such digital innovation might not always be high. Further studies identified additional empirical evidence to show case other important obstacles and challenges affecting the usage and deployment of WMDs. Among these, legal, ethical and regulatory issues (particularly data security and privacy threats) were often reported by researchers (Casselman et al., 2017; Pesapane et al., 2018), together with criticisms on a range of hardware problems, such as low battery capacity, inaccurate sensors, unstable performance, and poor data transmission quality (Dupuy et al., 2016; Piwek et al., 2016; Baig et al., 2017; Schall et al., 2018; Baig et al., 2019; Duignan et al., 2019).

Overall, these prior studies retrieved from the systematic review provided useful theoretical background and important early findings on the research topic and phenomena under investigation. However, when the amount of literature on technical aspects is very rich, our extensive review identified several knowledge gaps in the third research stream related to user engagement and deployment of AI-enabled WMDs:

- Most studies in this stream look into WMD acceptance and adoption issues merely from a user perspective, without considering the views of device providers and health professionals. In fact, device providers and health professionals are both fundamental entities of the wearable healthcare ecosystem. Health professionals can even become beneficiaries (or victims) of AI-enabled WMDs, when they need to make diagnosis and treatment decisions based on information and suggestions given by the system (Casselman et al., 2017). As such, the opinions and concerns of device suppliers and care professionals are crucial when investigating the uptake and large-scale deployment of WMDs.

- As mentioned above, AI technologies have offered greater power as well as new possibilities and use cases to WMDs. However, current studies in this stream focus primarily on issues affecting the acceptance and usage of the hardware device itself, without sufficient consideration and exploration of emerging problems associated with AI applications and functions embedded in WMDs.
- Many studies retrieved in this stream focus on the uptake and usage of WMDs by patients/users at different ages with diverse types of chronic diseases, without focusing specifically on elderly people. In addition, most of these studies were not done in the Chinese context. Given the fact that China's elderly population (i.e. 176 million) accounts for 25% of the world's total (i.e. 703 million) in 2019, there is an imperative need of further research to investigate large-scale WMD deployment issues among China's ageing population.

Consequently, the study reported in this paper attempts to fill the above knowledge gaps, and contributes to the research stream of technology acceptance, adoption and deployment of WMDs. To the best of our knowledge, this is by far the first study to investigate barriers and challenges affecting large-scale deployment of AI-enabled WMDs in the Chinese context by drawing on the perspectives of elderly people, device suppliers and health professionals.

3. Research methodology

3.1 Inductive and qualitative approach

Giving the scarcity of existing literature on the phenomena under studied (especially for the Chinese context), an exploratory and inductive approach was adopted in this research. In addition, and as discussed above, large-scale deployment of AI-enabled WMDs is not just depending on factors (e.g.

product quality) related to device manufactures, but is also affected by the attitudes and concerns of elderly people and health service providers. In order to generate holistic findings to answer the predefined research questions, the perspectives of users, device providers and public health organisations should all be taken into account. It was also expected that socio-technical barriers and challenges experienced by elderly people, WMD providers, and health organisations might be interwoven with each other, and so might not be identified and measured effectively by using quantitative methods. As a result, this inductive study also adopted a qualitative approach, with the aim to collect in-depth opinions and insights from the three types of stakeholders concerned.

3.2 Focus group as data collection method

Individual interview is a commonly used data collection method in qualitative research, but was considered less suitable for this study. In particular, elderly people may not hold sufficient knowledge and understanding on innovative tools like WMDs, and they will often turn to their younger family members for advice and support when purchasing and using these new devices. As such, it is not appropriate to seek opinions from elderly people individually without involving their family members. On the other hand, and for device providers and public health organisations, the standpoints of managerial staff towards large-scale deployment of WMDs may be better complemented and triangulated by the insights and feelings of technicians and clinicians.

As a results of these considerations, the research team selected focus group rather than individual interview as a better data collection method to suit the needs and context of this study. As highlighted by other qualitative researchers, focus group can provide a more natural environment for participants to discuss and interact with each other, and so can serve as an efficient tool for researchers to explore and obtain inner thoughts and feelings from a small group of stakeholders (Krueger and Casey, 2000; Morgan, 1996; Onwuegbuzie et al, 2009). In this study, focus group allowed the research team to involve both elderly and younger members in Chinese families (as well as, managerial staff and their technicians and clinicians in device providers and public health organisations) to have a dynamic and highly interactive discussion together.

Based on the theoretical background knowledge obtained from the systematic review, a focus group interview protocol was established (in Appendix). This interview protocol contains a set of main topics and questions applied to all participants, together with further sets of specific aspects to be explored respectively with users, device providers and health organisations. It is important to note that these topics and questions contained in the interview protocol were not set as 'stone', but could be modified according to actual conversations occurred in the focus group. We believe that such setting can lead to more fruitful conversation and data, and eventually generates more significant and meaningful findings that integrate the views and insights of different groups of stakeholders in different parties.

3.3 Focus group administration and profile of participants

9 focus groups were arranged and conducted respectively with five Chinese user families, two local WMD providers, and two public health organisations. The recruitment of participants followed our pre-defined criteria which requires the participating user families currently using WMD facilities for elderly family member(s). Regarding WMD providers and public healthcare organisations, the recruitment should meet the criteria that they both provide or are in charge of the WMD devices in the participating city. As shown in Table 1, 1-2 elderly people plus 2-3 family members were involved in each of the five focus groups with Chinese families. For each of the two WMD providers, 2-3 senior/middle managers plus 2 engineers participated in the study. The last two focus groups involved 2 managerial staff and 2-3 clinicians/caregivers from each public health organisation. Overall, a total of 38 stakeholders participated in the 9 focus groups. For convenience of the participants, focus

groups with the five Chinese families were conducted in their homes, and the remaining focus groups with WMD providers and health organisations took place in their workplaces, all with pre-booked appointments. With the researchers as moderators, each focus group lasted for 50 minutes to 1.5 hours, and was digital recorded with consent obtained from the participants. The digital records were transcribed by the researchers, who also sent the transcripts to relevant participants for validation.

Table 1. Summary of focus group participants

	Participants	Total
Focus Group 1/ Family A (FG1/F-A)	1 x elderly member* 2 x family members	3
Focus Group 2/ Family B (FG2/F-B)	2 x elderly member 2 x family members	4
Focus Group 3/ Family C (FG3/F-C)	2 x elderly member 2 x family members	4
Focus Group 4/ Family D (FG4/F-D)	2 x elderly members 3 x family members	5
Focus Group 5/ Family E (FG5/F-E)	1 x elderly members 3 x family members	4
Focus Group 6/ Device Provider A (FG6/DP-A)	1 x CEO 1 x sales manager 2 x technical engineers	4
Focus Group 7/ Device Provider B (FG7/DP-B)	2 x senior managers 1 x sales manager 1 x hardware engineer 1 x software engineer	5
Focus Group 8/ Health Organisation A (FG8/HO-A)	2 x managerial staff 2 x clinicians/caregivers	4
Focus Group 9/ Health Organisation B (FG9/HO-B)	2 x managerial staff 3 x clinicians/caregivers	5
	Total	38

* In the age of 60 or above

3.4 Data analysis

The focus group data collected was analysed by using a thematic analysis approach. Thematic analysis is one of the predominant and effective techniques for analysing qualitative data. Braun and Clarke (2006) defined thematic analysis as "*A method for identifying, analyzing and reporting patterns within data*". Thematic analysis provides a set of systematic procedures that can generate codes and themes from qualitative data (Nowell et al, 2017). A code is a concise label/phrase that captures the meaning of a chunk of original data relevant to the research questions, while a theme is a pattern obtained through thematic extraction and is composed of a set of codes shared a central concept (Clarke et al, 2015).

By following the guidelines given by Braun and Clarke (2006), the thematic analysis conducted in this study consisted of several steps. In particular, the analysis process started by reading and re-reading the transcripts with the aim to become familiar with the data collected from the nine focus groups. The second step involved an open coding process, from which an extensive list of codes was extracted from the dataset, together with corresponding quotations. We started the coding process with data collected from WMD providers (which proved to have better understanding of the whole WMD ecosystem), and continued the process with data obtained from user families and health organisations. The third step was concerned with rearranging and grouping the identified codes into 16 sub-themes (i.e. 16 critical barriers) and 6 themes (i.e. 6 barrier categories), as summarised in Table 2. Through this step, the main categories of barriers affecting large-scale deployment of WMDs started emerging, and the interrelations between the identified barriers also became clear. The fourth step was to re-examine and reassure that all codes assigned to the themes and sub-themes followed a coherent pattern. Finally, all identified themes and sub-themes together with selected codes and quotations were related back to the research questions, and served as the basis and evidence for reporting the findings in the following sections.

Table 2. Summary of themes and key codes emerged from the data

Main Themes	Sub Themes	Key Codes	Quotations From
Technological Barriers	T1: Difficult to maintain device accuracy, reliability & battery lifetime	T1a: Device performance T1b: Device size T1c: Battery recharge	Device Provider
	T2: Lack of efficient AI applications	T2a: AI functions T2b: Algorithm testing T2c: Low data volume	Device Provider
	T3: Lack of functional integration	T3a: Device diversity T3b: System fragmentation T3c: No fit-to-all device	User Family

Managerial Barriers	M1: Lack of top management support	M1a: Unknown brands M1b: Managerial concerns	Public Healthcare Organisation
	M2: Difficult to establish collaboration between device providers and public health organisations	M2a: Doctor concerns M2b: Bureaucratic system M2c: Internal regulations	Device Provider; Public Healthcare Organisation
Clinical Barriers	C1: Lack of evidence to prove clinical value of the device	C1a: Lack of clinical tests C1b: No authorised approval C1c: Insufficient user trial	Public Healthcare Organisation; User Family; Device Provider
	C2: Fear of undesirable changes in clinical workload	C2a: Workload difference C2b: Practical change C2c: Fear and pressure	Public Healthcare Organisation
Financial Barriers	F1: Dilemma between cost and benefits	F1a: R&D cost F1b: Selling price F1c: Buying power	Device Provider
	F2: Lack of sustainable business model	F2a: Insurance alliance F2b: Revenue source F2c: Service subscription	Device Provider; Public Healthcare Organisation
	F3: Insufficient public funding against huge public demand	F3a: Public fund F3b: Additional admin cost F3c: Finance sustainability	Device Provider; Public Healthcare Organisation
Legal Barriers	L1: Lack of efficient legislation to clarify responsibilities	L1a: Legal risk L1b: Local legislation L1c: Liability L1d: Image damage	Public Healthcare Organisation
	L2: Lack of data privacy	L2a: Data privacy L2b: Data security L2c: Lost data control	User Family
Personal Barriers	P1: Lack of user trust	P1a: Low user confidence P1b: Sense of unsafety	User Family
	P2: Difficult to meet complicated needs of elderly people	P2a: Diverse caring needs P2b: Individual differences	User Family
	P3: Lack of personalised data analytical services	P3a: Personalised service P3b: Customisation	User Family
	P4: Psychological resistance	P4a: Strange device design P4b: Social perception P4c: Psychological pressure	User Family

4. Results and findings

The results derived from the thematic analysis contained a set of crucial barriers (totally 16) divided into six categories, namely technological (3), managerial (2), clinical (2), financial (3), legal (2), and personal barriers (4). In order to highlight the links between these identified barriers and different groups of stakeholders, Figure 1 was developed. As shown in Figure 1 below, WMD providers, public health organisations, and user families, have very different concerns and difficulties, of which each can have essential impact on large-scale deployment of WMDs in China. The following subsections present and discuss these identified socio-technical barriers in detail.

4.1 Technological barriers

As discussed in section 2, most current literature on WMDs focused on technical and engineering aspects and issues. This in fact reflects severe technical difficulties and challenges associated with the design and development of AI-enabled WMDs, as also confirmed by the device manufacturers interviewed.

In particular, WMDs are typically designed in the form of small-size bracelets or watches. In such a rather small space, different kinds of IoT sensors will need to be inserted in order for the device to detect a range of physical variables and vital signs of users in a non-intrusive way. However, it is extremely hard to integrate various advanced sensors into a single device while keeping its small-size, accuracy and reasonable price: "*Our R&D department has been trying hard, but if we embed these sensors all together, the device will become too big and too heavy for elderly people to wear; if we compress the size of the device and sensors too much, their accuracy and stability will be affected […] there are some advanced sensors that are very small and accurate, but their prices will not be affordable to normal families*" (FG6/DP-A).

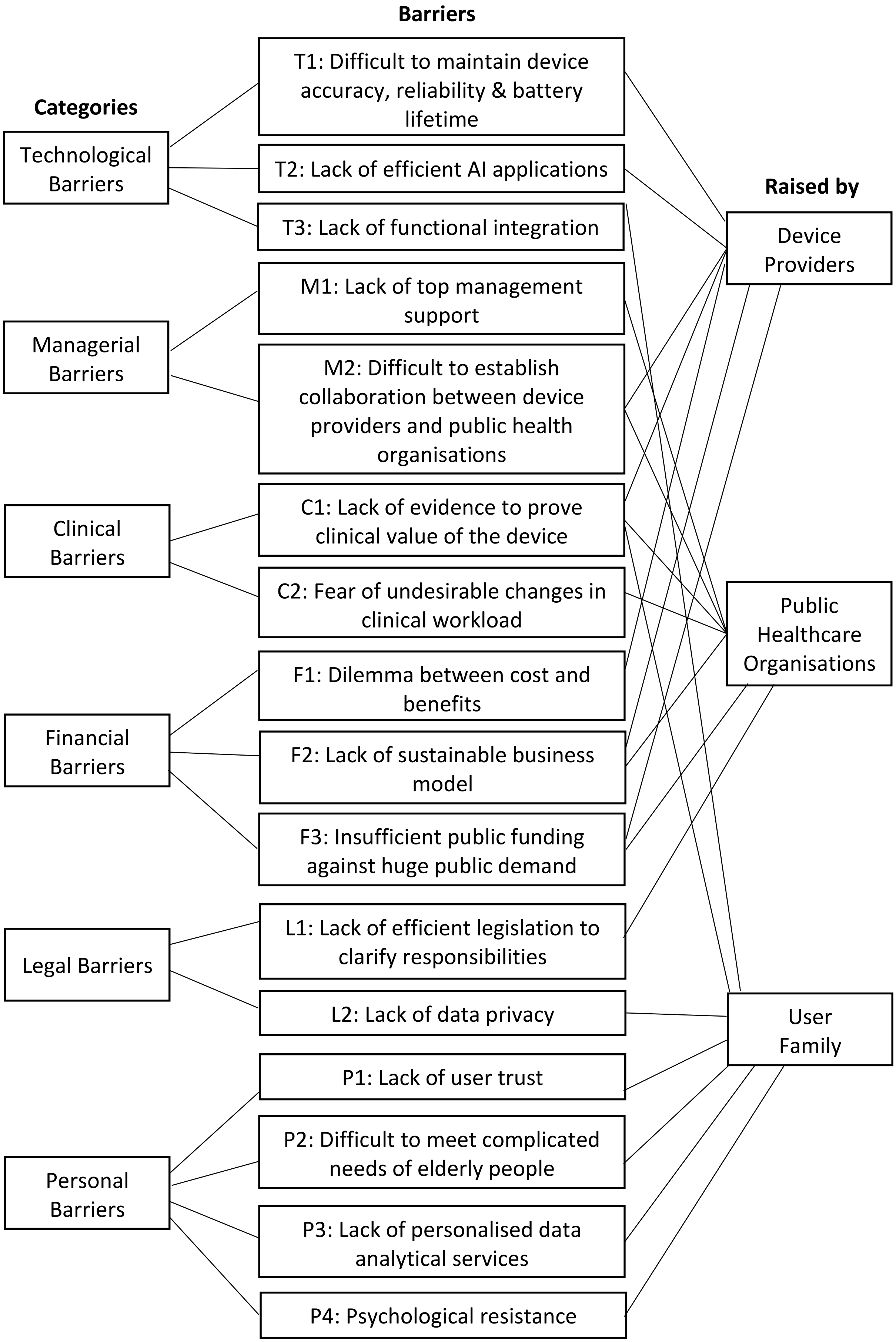

Figure 1. Socio-technical barriers affecting large-scale deployment of WMD in China

In addition, battery lifetime has been another long lasting issue of smart devices, including smart phones, tablets and smart watches. For WMDs, it is also a highly prioritised task for providers to maximise battery life of their devices, since elderly people (especially those with chronic diseases like dementia and amnesia) may be unwilling or even unable to recharge the device frequently. More importantly, "*if the battery in WMDs runs out too quickly, critical alerts may not be sent to caregivers on time, and this could lead to a fatal incident*" (FG7/DP-B). However, it is not easy to guarantee a long battery life of WMDs, especially "*when the device is embedded with too many sensors and functions, its battery will inevitably drain very fast*" (FG6/DP-A).

Consequently, and faced with these hardware challenges, the current solution adopted by WMD providers is to design and develop different types of devices to suit specialised usage needs, e.g. wearable blood pressure monitor (for those with heart issues), portable glucose wristwatch (for those with diabetes), and blood oxygen detector (for those with respiratory diseases). This however raises user concerns about functional integration of WMDs: "*Old people often have different chronic diseases like heart problem, diabetes or something else, but I am not aware of any clinically approved WMDs to integrate all the needed functions together and I feel inconvenient to wear a bunch of separate devices on my arm*" (FG2/F-B).

Moreover, and apart from IoT and hardware issues, WMD providers who are keen to develop new algorithms and AI applications to empower their devices will be confronted with further challenges: "*It is not just about how to develop a highly efficient algorithm based on machine learning, but also about how to test the algorithm and prove its clinical efficiency*" (FG6/DP-A). The other WMD provider interviewed reinforced that, "*these new algorithms will need to be repetitively tested and* *improved with real data of a considerable amount of elderly people, but we don't always have the needed data with the limited number of users for some devices*" (FG7/DP-B).

4.2 Managerial barriers

In recent years, many WMD startups have emerged in the healthcare market. However, these commercial device providers will not be able to build reputation and gain trust easily from elderly people and their families without support and recommendations from public health organisations: "*The WMD market is fairly new and immature, and there are many device startups like us nationally and globally […] consumers often know little about our brands or products, and they are more likely to trust their doctors and take the advice given by health institutions*" (FG6/DP-A).

However, top management teams of public health organisations may often be reluctant to give their support to WMD providers: "*Conceptually, WMDs will be much needed in the future. If elderly people purchase and use these devices in their own risk, then fine. But if we need to recommend or apply any of these devices and related AI applications officially to our patients, we are not ready to do so in either managerial or operational levels*" (FG9/HO-B). Further analysis of the focus group data identified that such lack of top management support from public health organisations is attributed to various financial and legal concerns (e.g. lack of sustainable business model, insufficient public funding, and lack of efficient legislations to clarify responsibilities). Apart from the top management view, doctors and clinicians of public health organisations also have reservations about formally adopting WMDs in clinical practices: "*I don't feel confident with these wearable devices, because many of them may only suit fitness purposes but cannot meet the high levels of accuracy and reliability required in a clinical environment […] More and more of these devices now have an AI label, but they may not be intelligent at all in reality. If anything goes wrong, who should be responsible for it:*

the WMD provider, health organisation, or doctors" (FG8/HO-A). These financial, legal and clinical barriers raised by public health organisations are further discussed below.

Consequently, and apart from some small pilot trials, it is currently very difficult for WMD providers to establish official collaborations with (and gain support from) public health organisations to promote their devices in the Chinese market: "*We have not been very successful in dealing with public health organisations, which have many complicated if not bureaucratic regulations and practical concerns. Without their support, it is hard for us to persuade our potential consumers, especially when we also have limited marketing budgets*" (FG7/DP-B).

4.3 Clinical barriers

During the focus group interviews, WMD providers, health organisations, and user families emphasised on fairly different issues from their own perspectives. But one critical concern highlighted by all the three parties was the lack of evidence to prove clinical value of current wearable medical devices. As discussed in the literature review, unlike normal IoT devices used for fitness purposes (e.g. Fitbit), AI-enabled WMDs are intended to be used by a rather vulnerable group of users (i.e. elderly people) for specific caring and clinical needs, and thus need to meet higher medical requirements. In the West, there is a small subset of innovative and high-quality WMDs that have obtained clinical approval from authorised bodies, e.g. an AI-enabled WMD offered by Current Health (a Scottish-based company) was approved by the U.S. Food and Drug Administration in April 2019 (Landi, 2019). But these Western products are rarely available in the Chinese market at the moment.

In China, many domestic WMD brands have emerged in recent years, but "*the majority of them cannot provide sufficient evidence to prove their clinical value, and also have not obtained any* *official approval from relevant medical authorities. This is why these devices and related AI applications cannot be accepted by public health organisations*" (FG8/HO-A). From the other side of the coin, the WMD providers interviewed acknowledged the current lack of clinical evidence associated with their products. In fact, the technical issues discussed above already presented severe challenges to maintain high-level clinical efficiency of WMDs. More importantly, conducting clinical tests and obtaining medical certification are not straightforward tasks that can merely be dependent on technical factors: "*To meet clinical standards, our IoT devices and associated mathematical algorithms will need to be iteratively tested, verified and improved with the involvement of a large number of elderly people. But it is very difficult for us to carry out such large-scale clinical tests without support and cooperation of public health organisations and patients*" (FG7/DP-B).

In addition, fear of undesirable changes in workload is another important clinical barrier raised by doctors and clinicians in public health organisations. In theory, WMDs can act as an alternative channel for doctors and caregivers to monitor health status of elderly people and provide patients with caring services remotely. This can potentially minimise the need of hospitalization and so reduce clinical workload and pressure. But in reality, clinicians and medical staff already have very tight daily schedules and so may neither be willing nor able to afford additional remote tasks: "*Imagining that I have a patient sitting in my consulting room and another one waiting on the other side of WMD, which one should be treated first? I also feel more stressful to make a diagnosis by just using data provided by WMDs over distance*" (FG8/HO-A). The situation will certainly become more chaotic if the device lacks clinical stability or provides misleading analytic results to doctors, as discussed earlier.

4.4 Financial barriers

Technical challenges on WMD design and development (as discussed above in section 4.1) and elderly people's high expectations on functionality and selling prices (as further discussed in section 4.6) raises an essential techno-financial dilemma to WMD providers: "*We understand the expectations of elderly people, but if we develop an ideal device meeting all hardware requirements and also with strong AI power, the costs and prices will be too high for both manufacturers and consumers to accept*" (FG7/DP-B).

In fact, the prices of wearable medical devices are never cheap (e.g. costing hundreds and even thousands of US dollars), especially given their high R&D and manufacturing costs. Device manufacturers worldwide have been trying to ally with insurance companies, mHealth application firms, and health service providers to develop new business models to make their hardware devices more affordable to the general public. For instance, some devices may come as part of a health insurance policy in the US. In such case, insurance companies will pay for the hardware for the insurant, who in turn needs to pay a reasonable monthly insurance fee (but for, e.g. 10 years) with other benefits. In another scene, WMD providers (like Biotricity based in the US) may divide their products into two parts, namely the hardware device and its AI application. Consumers may not need to pay for any upfront fee for the hardware, but will need to subscribe to its AI applications/services on a 12-month tariff. However, these emerging business models may not currently suit the Chinese market: "*The collaboration of WMD manufacturers and domestic insurance companies is in a very infant stage. This is not just because the market is new but is also due to the fact that insurance companies have doubts about clinical efficiency of existing devices and they even have plans to invent their own ones […] There are also too many free but low quality mHealth applications in China, so unless we can get clinical clearance from authorised health departments, consumers may not be willing to subscribe to our AI software tool*" (FG6/DP-A).

Instead of having consumers or private companies to digest the costs of WMDs, some Western countries have also tried to relieve the financial burden of patients by using public funding. For example, the UK launched its Whole System Demonstrator (WSD) programme in 2008 to try out the provision of free remote monitoring devices and services to 6191 patients with caring needs (UK Department of Health, 2011). Following the success of the WSD programme, the UK Department of Health initiated another campaign called "3millionlives" in 2012 with the aim of promoting and deploying similar remote health services to 3 million citizens with chronic diseases and healthcare needs (Car et al., 2012). However, for a developing country like China with 176 million of elderly people, public funding will never be sufficient to meet the huge public demand, as cogently concluded by a public health manager involved in the focus group: "*It is not realistic for any country with the size of China to provide free WMDs and related services to the society. In fact, there will also be new admin and staff costs occurred to hospitals and health centers. It is urgent to develop a feasible and sustainable financial model to support all parties involved*" (FG8/HO-A).

4.5 Legal barriers

Although WMD providers have made substantial efforts to reassure intended collaborators and consumers, public health organisations and elderly people still have strong concerns regarding potential legal risks associated with the deployment and usage of these devices.

In particular, and from the perspective of public health organisations, the clinical and managerial staff interviewed expressed their worries about existing legislations that might not be efficient in clarifying responsibilities when medical accidents occurred with WMD users. In fact, such unexpected medical accidents may be caused by various reasons, such as potential failures of the WMD device (e.g. inaccurate measurement of vital signs), pitfalls of associated AI applications (e.g. inefficient algorithm), misbehaviour of clinical and caring staff (e.g. fail to take appropriate actions when received alerts automatically sent by the system), and even mistakes made by elderly users (e.g. fail to wear the device properly or recharge it on time). As a result, if a medical accident occurs, it may not always be easy to identify clearly whether the event is caused by device, application or human factors and who should be responsible for it. The public health managers interviewed reinforced that "*the current legal system is not efficient enough to deal with such situations [...] this can put our clinical staff in a vulnerable position and also damage our public image and reputation*" (FG8/HO-A).

On the other hand, and from the perspective of users, elderly people and their family members are particularly concerned with potential breach of their data privacy. In fact, the nature of AI-enabled WMDs determines that these devices and related applications will not just collect personal information of elderly users, but more importantly also have the capacity to track real-time data on their health status, movements, locations, living styles, behaviours, preferences, and many more. The focus group participants had severe doubts about how their sensitive data might be treated and used by WMD providers: "*How providers can make sure our personal health profiles will not be accessed by unauthorised people? Will they track any additional data using the device without informing us or analyse our data in any unintended ways? Will they even sell our data to any third parties to gain commercial benefits?*" (FG2/F-B). A younger family member of another focus group even raised that "*it is increasingly heard from the media that some mobile service providers had breached clients' data privacy [...] I think the situation may be worse for AI-powered WMDs given the huge business value of the data collected*" (FG3/F-C).

4.6 Personal barriers

Last but not least, the analysis of the focus group data identified a further set of personal barriers from a user's angle. Some of these barriers have actually been covered in the above discussion as consequences of the identified technical, clinical and legal issues. Most notably, Chinese elderly people and their family members did not seem to trust WMD devices currently available in the market, and expressed particular concerns regarding their clinical efficiency and data protection provisions. Moreover, and as discussed in section 4.1, elderly people felt it difficult to find a highly integrated piece of WMD device to satisfy all their caring needs, especially when they had several chronic diseases. Apart from the hardware component, younger family members also felt disappointed in the lack of personalised data analytical services offered by WMD providers: "*it is common for providers to put an AI label on their products, but in fact these devices often just have the basic monitoring function with no real AI features or personalised services*" (FG5/F-E).

Beyond these issues, it was also identified that elderly people had psychological resistance toward using WMDs. Such resistance is partially caused by a lack of trust of the device. But more importantly, the elderly members interviewed repetitively mentioned that although they were becoming old, but they "*are still rather active and don't want to be looked differently*" (FG3/F-C). In fact, if WMD devices are simply designed as bracelets and watches, they may not achieve the best clinical performance. Some WMDs thus may have more specialised designs to suit clinical purposes. For example, a holter monitor is a well-known type of wearable device used by elderly people with heart diseases. It contains a set of electrodes to be placed on the chest of users and so constantly monitor their electrocardiogram (ECG). However, the elderly members interviewed worried that, wearing such WMD devices on the body might be perceived as a sign of being "*old, sick and abnormal*" (FG4/F-D).

5. Further discussion and propositions

Findings of this study extend the current understanding of WMD towards the embeddedness of cutting-edge AI technologies and the involvement of multiple stakeholders (i.e. device providers, public healthcare organisations and elderly people as end users). To facilitate the transformation process of digital healthcare systems as well as to promote the use and deployment of AI-enabled WMDs, an important step is to identify challenges and barriers influencing key stakeholders from all different levels. Based on the qualitative findings derived from this research, two key propositions can be put forward.

First, and as discussed above, the exploration of WMD usage and deployment barriers is limited or restricted to the views of intended users in the current literature and so are largely concerned with user-related issues. However, device providers, healthcare organisations, and end users are all 'intertwined pillars' involved in healthcare transformation enabled by AI-powered WMDs. As such, this study adds to the user view (as reported in the literature), by providing a more holistic picture that integrated the perspectives of device providers and public healthcare organisations.

As demonstrated in Figure 1 (in Section 4), our findings echoed the current literature (e.g. Tran et al., 2019; Baig et al., 2019; Dupuy et al., 2016; Shin and Biocca, 2017), by confirming a set of important barriers preventing elderly people from using AI-enabled WMDs, such as concerns about device performance and stability, functional deficiency, data privacy, failed to meet user needs, lack of personalised services, and psychological resistance. On the other hand, and for public healthcare organisations, clinical doubts and concerns appear to be the most critical barriers, together with managerial and regulatory issues. This echoes Baig et al. (2017)'s study from the perspective that clinical efficiency is critical in determining the value of wearable monitoring systems. Adding to Baig et al. (2017)'s finding of integrating more clinical functions into a single piece of WMD, the results of this study show that having sufficient evidence to prove the clinical value and efficiency of the integrated device is also extremely important. Moreover, and regarding device providers, continuous technological innovation is a typical challenge that they are facing. Although seamless functional integration and high system efficiency have been frequently stressed by users and other researchers (e.g. Baig et al., 2019; Duignan et al., 2019; Baig et al., 2017; Piwek et al., 2016), our findings show that these technical features are not easy to achieve practically from the view of WMD vendors. Additionally, compared to LeRouge and Garfield (2013)'s study that financial benefits are important in healthcare innovation, our findings also reveal the challenges of having inefficient business model and insufficient public funding to support this type of investment.

Proposition 1: Different groups of stakeholders have different concerns towards the deployment and usage of AI-enabled WMDs: public healthcare organisations have strong concerns about clinical, managerial and regulatory aspects; device providers are confronted with technological and financial challenges; elderly users emphasise more on personal and usage related issues.

Second, the thematic analysis has led to the exploration of complicated inter-relationships between the identified barriers as summarised in Figure 2, which contributes to the literature in addressing the shortage of framework providing key stakeholders with causal relationships of challenges in healthcare transformation (Gastaldi et al., 2018). From this network of inter-relationships, lack of collaboration between device providers and public health organizations emerged as the most problematic issue preventing large-scale deployment of wearable medical devices in the Chinese context. As clearly shown in Figure 2, this challenge is attributed to a range of clinical, financial, legal, managerial, and technical barriers, and so will be very difficult to resolve.

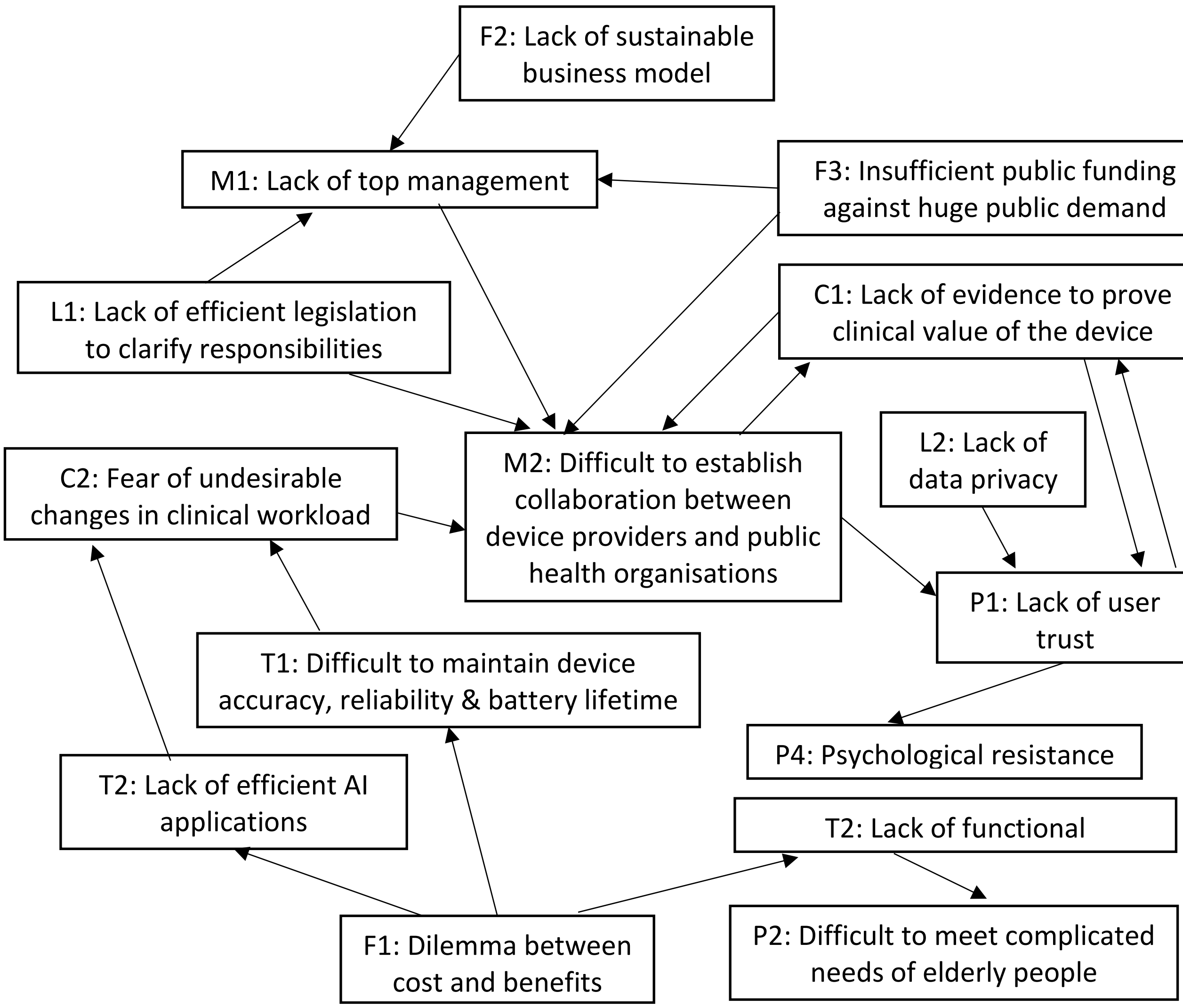

Figure 2. Inter-relationships between identified barriers

In fact, it was found in this study that "trustworthiness" and "collaboration" are two closely linked concepts that can essentially influence each other. This is consistent with findings in the current literature regarding user trust and advanced healthcare systems (e.g. Shareef et al., 2021; Papa et al., 2020). Absence of trust due to issues such as faulty design, inefficient functionality and privacy breach inhibits the adoption, implementation and widespread of advanced healthcare systems (Shareef et al., 2021). When there is a lack of trustworthiness and collaboration, the whole endeavour of WMD deployment in China currently seems to remain in a negative 'loop': due to a lack of collaboration between device providers and public health organisations, elderly people as end-users tend not to trust these vendors and their products and even have psychological resistance to use these devices; without sufficient support from public health organisations and engagement of elderly users, it is difficult for WMD providers to accumulate enough data and clinical evidence to prove the efficiency of either the device or related AI algorithms; finally, without sufficient clinical evidence to prove the value and efficiency of WMDs, public health organisations are reluctant to trust the device and establish collaboration with (and give support to) device providers.

Therefore, simply focusing on technological innovation may not break the ice. Given the current situation and the local regulatory system, Chinese WMD providers may firstly try to approach private caring centers (instead of public health organisations), which may be a better starting point to seek for health collaboration. With informed consent, devices can be provided for free to elderly patients of private health centers, but only for testing purposes (i.e. not depending on it to make clinical decisions). This can help WMD providers to recruit and engage a considerable number of elderly users in the early stage and collect the needed data to test and improve their products. Once device providers obtain clinical clearance, they will be in a better position to establish collaboration with public health organisations as well as to partner with other parties (such as insurance companies) to develop more sustainable business models, and eventually achieving large-scale deployment among the elderly population.

Proposition 2: It is more essential for device providers to work closely and establish effective collaboration with healthcare organisations than merely achieving technological innovation; this is currently affected by a wide range of reasons but is the key to gain user trust and drive large-scale deployment and usage of AI-enabled WMDs.

6. Theoretical and practical implications

This study brings novel and original contributions to the current body of knowledge, and yields several important theoretical implications. First, the findings of our paper demonstrate holistic understanding and integrative view of challenges and barriers for AI-enabled WMD deployment based on insights and experience of multiple groups of stakeholders (i.e. elderly people, device providers and health professionals). These findings add to the current literature on technology acceptance and adoption of WMDs – which were primarily done from a user perspective. Second, our study responds to the existing gap raised by Jiang and Cameron (2020) that there is a lack of research examining negative experiences and barriers to wearable devices, especially involving innovative functions such as AI-powered detection and management of chronic diseases. Another contribution emerges from this research is the complicated network of inter-relationships among the identified barriers. Our results clearly show that the identified barriers do not exist independently from each other and are closely interrelated. These barriers and inter-relationships provide a good theoretical foundation for conducting fellow research on this increasingly important research topic in both China and worldwide.

This study also has practical implications to different organisations, stakeholders and participants involved in the wearable healthcare transformation. For Chinese WMD providers, we hope our findings can make them better aware of current concerns and worries of both consumers and health professionals, and so possibly reshape their action plans and put their efforts and resources in the most urgent aspects (i.e. to gain trust from the public and health experts by improving clinical values of their products). For health organisations, our findings can let them better understand the demands of elderly people and challenges currently faced by WMD providers. We hope public health organisations can so rethink their roles in this digital transformation process, and try to provide more possible support to WMD providers. Moreover, and even for local authorities and policy decision makers, our findings show imperative needs for them to launch more public funding schemes as well as to improve local legislations, in order to build a healthier WMD deployment environment. In sum, large-scale deployment of AI-enabled WMDs requires a joint effort of WMD providers, health professionals, local governors and the general public. We hope our findings can be useful to all these parties in their future strategic planning and decision making processes. It is important to note that, by comparing our findings with those reported in the literature, we feel our results may not just be useful in the Chinese context, but may also be valuable to (and so should be considered by) Western counterparts.

7. Conclusions, limitations and future studies

This paper presents a range of critical socio-technical barriers affecting large-scale deployment of AI-enabled WMDs in China, by exploring and integrating the perspectives and insights of local device providers, public health organisations, and elderly people. It can be concluded that, challenges and barriers associated with WMD deployment are rather different across diverse parties. As such, our holistic set of findings derived from stakeholders in different parties is crucial to understand and potentially improve the *status quo*. Another important conclusion is that the identified barriers are not just complicated and but are also interrelated, and so cannot be resolved easily. However, lack of clinical trust and collaboration was found to be at the core of the entire network of barriers. Therefore, we would like to conclude that enhancing clinical trust by encouraging collaboration among all concerned parties will be the key to achieve large-scale deployment of WMDs in the future.

There are several limitations in this research. First, this study was conducted within the specific research setting of China and aimed at collecting qualitative data to explore in-depth insights of stakeholders within this context. Therefore, some identified barriers and interrelationships among them may be mainly applicable to China and countries with similar context. An interesting direction of future research is to validate and test these findings beyond the Chinese context, especially by using quantitative methods. Another limitation is related to the fact that AI-enabled WMD is an emerging and fast evolving topic. When the purpose of this study was to obtain current insights and experiences of relevant stakeholders, we did not consider how the wearable health ecosystem and related policies were changing over time and how these changes might affect WMD deployment and usage. Therefore, fellow researchers can consider to adopt a longitudinal approach to examine how the identified barriers and interrelationships may be changed alongside the evolution of the wearable healthcare ecosystem in the world in general and in China in particular in the long run.

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Appendix: Focus group interview protocol

[Main topics and questions to all]

In your view, what barriers can affect large-scale deployment and usage of AI-enabled WMDs among the ageing population in China?

What concerns do you have about the hardware device itself?

What concerns do you have about the software and AI functions associated with the device?
How do you think these mentioned barriers may influence each other, any examples to demonstrate your thoughts?

[Additional topics and questions to elderly people]
How do you feel about the actual clinical value of AI-enabled WMDs?
What do you hear from your caregivers and doctors about WMDs?
What should be done by WMD providers in order to enhance your willingness to adopt and use AI-enabled WMDs?

[Additional topics and questions to WMD providers]
What have you done to meet market demand and enhance users' willingness to adopt and use your products? What difficulties are you facing?
What have you done to build collaborations with local health organisations? What difficulties did you experience?

[Additional topics and questions to health organisations]
How do you feel about the actual clinical value of AI-enabled WMDs?
What internal resistance may prevent health professional from accepting AI-enabled WMDs, at both individual and organisational levels?
What types of collaboration have you (or your health organisation) established with WMD providers? What are the difficulties in building and maintaining such collaboration?