Politecnico di Torino
Dipartimento di Architettura e Design

Systemic Design for Chronic Disease Management in China

A Solution for the Self-Management of Knee Osteoarthritis in Shanghai

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Abstract

Chronic diseases present enormous challenges to every health system. In recent years, there is a growing consensus in the global health community that digital health technologies, such as wearable technology and artificial intelligence, can bring new opportunities to ensure better health and well-being for more people. It shows the potential of changing traditional doctor-patient relationships, communication methods, and patients' passive medical experience. Tech is changing the way of managing diseases and it is worth discussing how to use it to benefit patients and medical staff.

There is a large number of patients with chronic diseases in China. As China is aging rapidly, chronic disease prevention and treatment will become an increasingly important part of public health and medical services. However, China's primary care lacks enough suitable medical resources and has many other problems, making Chronic Disease Management difficult and inefficient.

When facing such a complex problem combining individuals, society, technology, and so on, adopting the systemic design approach might be a suitable and efficient way to analyze and solve the problem. Systemic design intends to take an overview of the complex healthcare problem in a macro vision; on the other hand, it also takes into consideration both objects and their relations in the system.

The thesis aims to discuss how systemic design approach can support the improvement of chronic disease management, especially when digital health begins to participate in disease management. A systemic design framework for chronic disease management is proposed and improved by a literature review and case analysis, and then adopted in the case study of the self-management of Knee Osteoarthritis (KOA) in Shanghai, in order to guide the design research and practice. The systemic solution and the concept of the product system including physical and digital parts is generated, intending to help the patient with early-stage KOA to avoid rapid deterioration and surgery, as well as make CDM at the primary care level effective.

Keywords

chronic disease management, digital health, systemic design, the self-management of Knee Osteoarthritis

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List of Abbreviations

CDM	Chronic Disease Management
CHC	Community Healthcare Center
DiGA	Digitale Gesundheitsanwendung (Digital Health Application)
DTx	Digital Therapeutics
FD	Family Doctor
GP	General Practitioner
ISPs	Independent Sector Health Care Providers
KOA	Knee Osteoarthritis
mHealth	Mobile Health
MSK	Musculoskeletal
NCDs	Non-communicable Diseases
NHS	National Health Service
OA	Osteoarthritis
PT	Physical Therapists
SHI	Statutory Health Insurance

01
Introduction

This chapter first introduces the research background of the thesis topic, including the CDM challenge that the majority of healthcare systems are facing, the opportunity coming from digital health, and systemic design methodology which is considered a suitable way of addressing the problem. It then proposes the research questions and research aim, hoping to answer the questions by focusing on the self-management of knee osteoarthritis in Shanghai, China.

1.1 Research Background

1.1.1 The Challenges of Chronic Diseases

Chronic diseases (also known as non-communicable diseases, NCDs) are diseases that persist for a long time. The World Health Organization (WHO) (2005) suggested the shared features of chronic disease in its report: (1) Take many years to become fully established; (2) Can be prevented in most cases; (3) Require a long-term and systematic treatment approach. The main types of NCD are cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes (World Health Organization, 2022), but there are many other chronic disease types threatening people's lives.

Nowadays, chronic diseases have become a challenge for all healthcare systems around the world. In 2019, the share of the global burden of disease from non-communicable diseases (chronic diseases) is 63.82% (Roser & Ritchie & Spooner, 2021). More than $30 trillion will be borne by the global economy due to NCDs over the period 2011-2030, which account for 48% of global GDP in 2010 (Bloom et al., 2012).

As chronic diseases are often caused by genetic, physiological, environmental, and behavioral factors, even cannot be prevented by vaccines or cured by medication, the traditional way of dealing with acute diseases is not effective when facing chronic diseases. Patients living with chronic diseases will decrease their quality of life gradually. When chronic conditions get worse, they have to face surgeries even the direct life threat.

Chronic Disease Management (CDM) can be defined as an integrated way to care or coordination of care among healthcare providers and other participatory, including patient education and monitoring patient outcomes data for the early detection of potential complications (Krumholz et al., 2006). There are many approaches included in chronic disease management, such as a conceptual framework called the chronic care model (CCM) developed by Wagner et.al (1998), and the disease management programme (DMP). The goal of CDM is to enhance the functional status, minimize distressing symptoms, prolong life through secondary prevention, and enhance the quality of life (World Health Organization, 2008).

Many countries have sought to create a good management way and framework to respond to chronic disease to enhance the care for people with chronic conditions. In some European countries that do well in CDM, the majority of approaches tend to focus on populations with defined conditions, and the general practitioner (GP) or family doctor (FD) tends to act as principal provider or ‘care coordinator’. But these countries also face the problem of considerable fragmentation between social (municipalities) and health care services, and the use of clinical information systems for chronic disease management tends to be less developed (Nolte et al., 2015).

Meanwhile, when more policies are implemented for the four main types of chronic disease, more chronic diseases need to be noticed. Some chronic diseases may not threaten patients' lives directly, but they lead to a decline in the quality of patients' lives and affect both their physical and mental health indirectly, including mental disorders, vision and hearing impairment, and musculoskeletal disorders (such as osteoarthritis). If only considering the disease burden coming from NCDs at a global level, in 2019 the top 3 large disease burden respectively comes from cardiovascular diseases (393 million, 15 %), cancers (251 million, 10%), and musculoskeletal disorders (150 million, 6%). These three NCDs have become the main causes of making the large burden of disease in many countries, such as China, Italy, and the United States (Roser & Ritchie & Spooner, 2021).

China hasn’t performed well in managing chronic diseases. In 2018, the number of chronic disease patients in China reached about 300 million, of which the burden of chronic disease among people under the age of 65 accounts for 50% (Wu et al., 2018). However, Chinese chronic disease management is not effective: From 2003 to 2017, the incidence of chronic diseases in Chinese residents increased from 123.3% to 245.2% (Huang et al., 2019).

Moreover, as China is aging rapidly and the probability of individuals suffering from chronic diseases will increase with age significantly, more elderly patients will require chronic disease management services in the future. The aging population may cause China's expenditure to increase rapidly (World Bank, 2019).

It has become a matter of great importance to discover the problems that existed in Chronic Disease Management (CDM) today and discuss how to make an effective, efficient, and sustainable result.

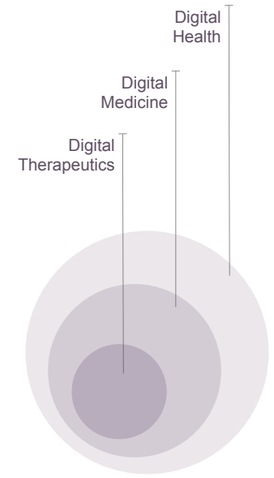
1.1.2 The Opportunity: Digital Health Help with Chronic Disease Management

When chronic disease management is facing the problems of fragmentation and discontinuity, the tech is transforming the way we treat and manage the disease.

In 2021, the Seventy-third World Health Assembly (WHA) endorsed the Global strategy on digital health 2020-2025, highlighting that digital health has great potential to protect and improve human health and welfare, as well as shape the future of global health (World Health Organization, 2021).

Digital Health is understood as “the field of knowledge and practice associated with the development and use of digital technologies to improve health” (World Health Organization, 2021). It consists of so many concepts such as mobile health (mHealth), telehealth (also known as telemedicine), smart wearable technology, and digital therapeutics (DTx).

The scope of digital health



Digital Health is considered to be an effective way of maximizing the use of medical resources. The information, exchanged among patients, different medical staff, and devices, makes patients with chronic diseases and community medical staff get medical resources much easier and improves the effectiveness of community medical treatment and chronic disease management greatly.

The smart wearable device refers to a type of device that can understand the wearer's own condition and its surrounding context, and give appropriate feedback through information prompts and early warnings (Pankajavalli & Karthick, 2019). In the field of digital health, wearable product systems, integrating wearable hardware products and digital platforms (including the mobile application), have promoted the development of mHealth, and have received more and more attention in the field of chronic disease management.

Patients can obtain their own behavioral data and physical conditions through smart devices constantly and continuously, which is of great significance to the self-management of chronic diseases. Doctors can learn about patients' daily behavioral data remotely and understand the patient's self-management situation. It helps formulate or adjust a personalized chronic disease management plan for patients and enhances the confidence of doctors in diagnosis (Yao, 2017).

In addition, using patient data for disease diagnosis under the premise of privacy protection and developing smart community medical care is one of the effective ways to achieve hierarchical diagnosis and treatment and improve the management of chronic diseases.

Digital health in the form of telehealth

Source: Image by tirachardz on Freepik

1.1.3 Adopting Systems Thinking and Systemic Design to Meet the Challenges

Healthcare is a huge socio-technical system with many participants and roles dedicated toward the recovery of individual and social health. In order to ensure quality and manage costs across the whole system, a holistic view of healthcare and design is necessary (Jones, 2013).

Chronic disease management, as a part of healthcare, also faces the issue of system complexity. The approach or model to Chronic Disease Management is the result of the local policy context and organizational characteristics, with regional and local individual characteristics (Rosen et al., 2007).

Systems thinking is thought of as an essential paradigm to deal with complex problems. Systems thinking is a kind of "contextual" thinking, which is the opposite of analytical thinking. It sees objects themselves as networks of relationships embedded in larger networks, both the objects and the relationships are important research objects (Capra & Luisi, 2014).

Systemic design originated from the systems thinking and system theories developed from the beginning of the 20th century through various methodologies, such as cybernetics and the complexity of systems, which is aimed at considering problems as systems and analyzing them in the complexity of the interactions among components (Bistagnino, 2011; Sposito & Faggian, 2013). When facing a complex problem combining individuals, society, technology, and so on, applying a systemic design approach might be a suitable and efficient way to analyze and try to solve the problem (Fiore et al., 2018).

1.2 Research Questions and Aim

This research aims to discuss how the systemic design approach can support the improvement of chronic disease management. To get the aim, it should take into account the features of CDM when adopting the systems thinking and systemic design methodology, combing them into a targeted systemic design process to guide the design work and come out with the design solution that can improve the situation of CDM in the end.

The majority of approaches to CDM tend to focus on populations with a certain disease and propose different managing ways depending on the type of disease, and there is wide variation in the CDM model between different regions. Therefore, this research decides to focus on one kind of chronic disease, Knee Osteoarthritis (KOA), and conduct a case study of Shanghai, to examine the design process and carry out the systemic design program.

There are several research questions should be answered:

- What are the characteristics of CDM that should be considered in systemic design?
- How to obtain a suitable design process/framework to guide the design research and practice? How to verify and improve the framework?
- What is the basic situation of the Chinese Health System and Chronic Disease Management?
- For the Case study of Shanghai, how to obtain effective information and analyze them?
- How to design a possible solution to solve problems in a systemic way?

1.3 Thesis Structure

The thesis consists of six chapters.

Chapter 1 is the introduction. It first introduces the research background of the thesis topic, including the challenges of CDM that the majority of health systems are facing, the opportunity coming from digital health, and the systemic design methodology which is considered suitable for dealing with the problem. It then proposes the research aim and research questions, hoping to answer the questions by carrying out a systemic design program for the self-management of knee osteoarthritis in Shanghai.

Chapter 2 is the study of Systemic Design methodology. It starts with a brief introduction to systems thinking, then the main system design principles are introduced. After that, the discussion focuses on how to adopt a systemic design approach to sustainable health and better chronic disease management. This chapter ends with a formation of the design framework based on the system design methodology, which is to be used to define and address the problems in chronic disease management.

Chapter 3 verifies and improves the design framework proposed in chapter 2 by analyzing three digital health products in three regions and counties (the United States, England, and Germany). One chronic disease, osteoarthritis (OA), is selected to narrow the research scope and bring detailed knowledge about its management.

Chapter 4 starts to carry out the systemic design project of the self-management of Knee Osteoarthritis in Shanghai. It first introduces the key information of the background of Shanghai based on desk research. Then, it conducts quantitative study and qualitative studies to investigate the current situation of KOA self-management.

Chapter 5 starts to design a systemic strategy according to what has been found in Chapter 4. Following the systemic strategy, some design practice work is conducted and tested to get the users' feedback and iterate.

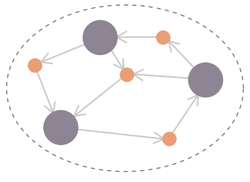
Chapter 6 is a Conclusion and Discussion. It discusses the research value points and the limitations that should be noticed.

02

Theoretical Study on Systemic Design

This chapter provides the study of the systemic design methodology. It starts from the general systems thinking from which systemic design originated. It then introduces the main system design principles. After that, the discussion focuses on how to adopt a systemic design approach to design for sustainable health and better chronic disease management. The chapter ends with a formation of the design framework based on the system design methodology, which is to be used to define and guide the next work of design research and design practice.

2.1 Systems Thinking and Systemic Design



System

Systems thinking is considered an essential paradigm for dealing with complex problems. The concept of systems thinking is developed since the beginning of the 20th century through various fields of system theories study, such as the General Systems Theory (GST), Cybernetics, and Complexity Science. Systems thinking stands for looking at the interactions of the elements that make up the whole problem or system, in order to come out with different conclusions or solutions, which cannot be achieved by using solely the traditional scientific paradigm (Sposito & Faggian, 2013).

Contrary to analytical thinking, systems thinking is a kind of "contextual" thinking. It notices the system's structure, sees objects themselves as networks of relationships embedded in larger networks, and both the objects and the relationships are important research objects (Capra & Luisi, 2014). Therefore, products can be considered sub-systems within a hierarchy of larger and larger contexts and larger and larger systems (Buchanan, 2019).

Systemic design is based on systems thinking. In general, systemic design is the process of using the theory and method of system science and advanced design methods to design a new system that can obtain anticipatory change and meet the target requirements to the greatest extent (Bistagnino, 2011; Fiore et al., 2018; Jones, 2020; Liu & Vrenna, 2021). As Systemic design absorbed the concepts coming from the GST and many other theories, it can be applied in many different fields, such as urban planning, architectural design, software development, and product service system design innovation.

The systemic design approach developed by professor Bistagnino (2011), first focused on the output and input of material and energy in a certain territory of the production processes. This design approach considers that one’s output (waste) can be the input (resource) for other ones, enabling to create of new products and services, thus generating a new economy and distributing wealth for the society, which is one of the keys for sustainable development (Bistagnino, 2011).

The key principles of this systemic design approach include: (i) Output (waste) becomes an input (resource); (ii) Notice the relations existing among components of the system; (iii) Increase the system's ability of resilience and autopoiesis; (iv) Act locally; (v) Human-centered design (Bistagnino, 2011).

Now there are some studies on the systemic design methods and methodology during these years and have developed into a comprehensive design methodology (Barbero, 2017; Battistoni & Giraldo & Barbero, 2019):

1) Holistic diagnosis (HD): Field and desk research on all main elements that build and influence the current system to understand the context of the project. Some visual tools can be used later in the stage, such as a system map.

2) Definition of problems and breakthroughs: Analyze all the data collected in the first stage to define the critical problems that existed in the current scenario and then try to find feasible breakthroughs. The visual map can indicate the problems related to the flow/relation and components of the system. The analysis of a range of best practices that tackle similar challenges of the project, or expert's advice would be helpful methods.

3) Design of a new system: Considering the relationships between processes and actors, as well as the different kind of flow, then integrate the design opportunities into a systemic solution. It is also recommended to use a visual map to show the new system and describe the solution.

4) Assessment of the outcome: Preliminary evaluation of the impact of the design solution and the new system from the aspect of environment, economy, society and so on.

5) Implementation: In this stage, designers do design practice in the real world according to the preliminary systemic solution. As Systemic Design Project is always complex and broad, it should be implemented step by step.

6) Analysis of the results and feedback: Collect real data about the potential benefits of the solution following the stage of implementation; adjust and iterate the design solution; keep finding the new opportunities.

When facing the sociotechnical systems, Jones (2014) proposed ten systemic design principles for sociotechnical design: (i) Idealization; (ii) Appreciating Complexity; (iii) Purpose Finding; (iv) Boundary Framing; (v) Requisite Variety; (vi) Feedback Coordination; (vii) System Ordering; (viii) Generative Emergence; (ix) Continuous Adaptation; (x) Self-organizing.

Based on the holistic diagnosis that characterises systemic design, Fiore et al. (2018) developed an approach to analyzing sociotechnical systems: (i) Identifying the main actors; (ii) Problem definition/framing/setting; (iii) Application domain (operating context) analysis; (iv) Identifying relationship among the different stakeholders of the system; (v) Requirement definition and prioritising; (vi) Collecting data with instrumented products.

In China, a systemic design approach was used to achieve a bottom-up sustainable development that integrates urban and rural resources and opportunities (Lou et al., 2010). The design approach integrated the methods with the concept of "acupuncture", a famous Chinese traditional treatment way. With the acupunctural design approach, it can facilitate the formation of innovative virtual/physical networks among different regions by implementing small and precise innovation hubs, just like the Acupoints to the Meridians. Therefore, the heritage and resources can be shared among various stakeholders through virtual & physical networks (Lou et al., 2010).

The topics applying systemic design approach vary from the agrifood sector to the study of interfaces, aimed to create systems that balance social, environmental, and economic aspects. At the same time, more new topics are being explored, such as the sustainability of healthcare (Barbero & Pallaro, 2017)..

2.2 Sustainable Healthcare and Systemic Design

2.2.1 The Concepts of Sustainable Healthcare

A health system “consists of all organizations, people and actions whose primary intent is to promote, restore or maintain health” (WHO, 2007). Healthcare is a series of activities delivered by practitioners, including diagnosis, treatment, and prevention of disease. There is a growing focus on how to build efficient, equitable and sustainable health systems and sustainable healthcare might be one part of a better health system.

Sustainability emerged in The Ecologist’s A Blueprint for Survival in 1972. The most common definition of "Sustainable" or "Sustainable Development" is: It meets the needs of the present without compromising the ability of future generations to meet their own needs (United Nations, 1987). There are three pillars or dimensions of Sustainability: Environmental Sustainability, Social Sustainability, and Economic Sustainability. For different topics, the framework of sustainability may change lightly, all three pillars link to each other in different ways.

Right now, it seems that there isn’t a certain common definition for Sustainable Healthcare, some researchers give various definitions from different aspects. Marimuthu and Paulose (2016) subdivide sustainability practices in hospitals’ operations into four categories: environment-orientated, customer-orientated, employee-orientated, and community-orientated. The Sweden's Innovation Agency, defined the concept of Sustainable Healthcare as consisting of sustainable hospitals, sustainable behaviours, and sustainable technologies (Eriksson et al., 2015). But the discussion on the topic of Sustainable Healthcare has involved all three pillars of sustainability.

According to the study conducted by Marimuthu and Paulose (2016), environmental sustainability in healthcare mainly consists of reducing and managing medical waste and pollution, and some other researchers and designers also focus on the energy consumption related to the hospital building and surrounding environment.

Economical sustainability in healthcare often refers to how to make the most efficient use of available resources, reduce the cost and make the service affordable for both the providers and the consumers (Marimuthu & Paulose,2016).

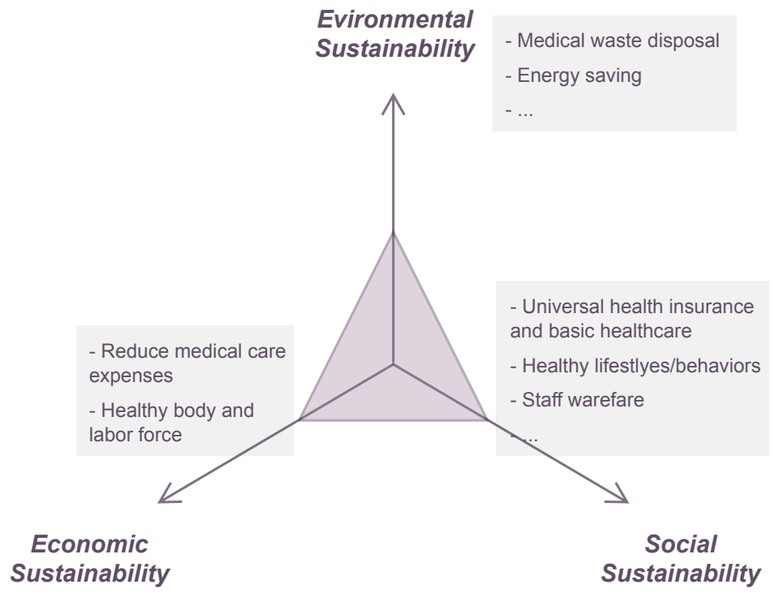
Social sustainability often refers to ensuring basic needs and access to opportunities and allocation of resources in an equal way. In the field of healthcare, social sustainability may consist of ensuring basic healthcare

accessibility and affordability, organization stability (such as employee welfare), and patient satisfaction (Marimuthu & Paulose, 2016). In the 2030 Agenda (WHO, 2015), the third sustainable development goal is about Good Health and Well-being, setting more specific goals for sustainable healthcare.

Apart from the definition, there are different actions recommended for promoting a better and sustainable health system: Taking into consideration all stakeholders; empowering patients' responsibility and self-efficacy; prioritizing disease prevention, health promotion, and public health services; increasing community resilience and promoting local assets; improving patients' trust; promoting innovative models of care; the usage of healthcare technologies (Marimuthu & Paulose, 2016; Tsekleves & Cooper, 2017; Eriksson et al., 2015; WHO, 2017).

In the case of the New Betio Hospital in Kiribati (Blanch & Anderson, 2021), a team of architects and health planners at Jacobs were engaged to improve the healthcare system and facilities across Kiribati. The team considered all three pillars of sustainability (economic, social and environmental), and added the fourth dimension to ensure a holistic and sustainable design, which is systems sustainability. In this case, systems sustainability includes things such as Staff retention, Technology, and Resiliency, in order to improve building performance, and in turn, health outcomes, care delivery and efficiency of operating systems.

Figure 2.1 Pillars and Requirements for Sustainable Healthcare



2.2.2 Linking Sustainable Healthcare with Systemic Design

As shown in the discussion and the concept of practice, the definition of Sustainable Healthcare is ambiguous and the approaches to promoting it are various. Nevertheless, the majority of researchers agree that the problems of Sustainable Healthcare are complex and comprehensive and balanced approaches should be taken to address the present and future obstacles coming from the aspect of the economy, society, environment, and others (Prada, 2012; Fischer, 2015; Marimuthu & Paulose, 2016; Barbero & Pallaro, 2017).

Systemic design approach is suitable to be adopted in designing healthcare in order to achieve a better and more sustainable system. Systemic design intends to take an overview of the complex healthcare context in a macro vision; on the other hand, it also takes into consideration among elements (such as the care seekers and care providers) and their relations in the certain system in a micro vision, focusing mainly on the sustainability of health treatments and the improvements in the interaction between doctor, patient, and cure (Barbero & Pallaro, 2017). Systemic design, as a merger of human-centred design and multi-stakeholder service system design, can adapt design practices to sociotechnical complexity and solve the wicked problems in the healthcare system (Jones, 2020).

When talking about what system types designers might face in designing for healthcare, Jones (2013) refers to the four system models defined by systems thinkers Ackoff and Gharajedaghi (1996), and gives examples of each system type in the field of healthcare respectively, within the single context of a large city.

1) The first type is ***deterministic system***, with neither the whole system nor its part having intentionality. For healthcare, the Electronic Health Record (EMR) system, Web apps, and the highly reliable medical equipments are considered to belong to this type, because they won't embody purpose without human intervention.

2) The second type is ***animate system*** that the whole system has intention while its parts haven't choices. This system type is often thought of as the organismic system, which can interact with the environment and make choices according to feedback. For healthcare, it can refer to human actors, such as patients and physicians.

3) The third type, ***social system***, according to Ackoff, is the only system type that both the whole system and its parts have intentionality. It is human-constructed, containing many subsystems with multiple purposes, highly interconnected networks of processes, activities, rules, and actors. Related examples include the university and the hospital.

   In addition, the sociotechnical system has become a more integrated way of considering organizations in the field of healthcare. It includes social subsystems and technological subsystems (information technology, work processes, work environment).

4) The fourth type is ***ecological system***, a more complex system that its parts

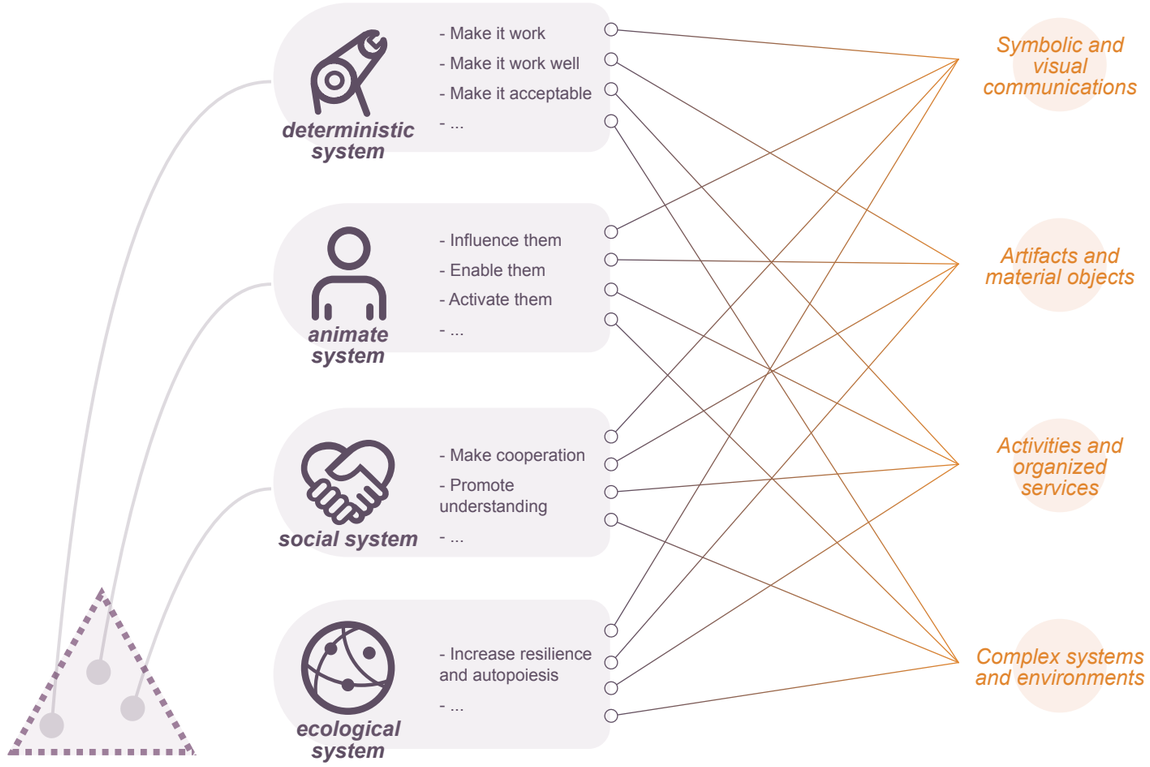
have intentionality while the whole system doesn't. It represents the city or geographic region that the healthcare services.

How does systemic design deal with these different system types? Jones (2020) mentioned Buchanan's "four orders of design" which is an influential schema for problem framing. The "four orders of design" include (Buchanan, 1992): (i) Symbolic and visual communications; (ii) Artifacts and material objects; (iii) Activities and organized services; (iv) Complex systems and environments. Designers can try to deal with complex problems by adopting placements as a whole strategy for creative invention (Buchanan, 1992).

These studies show that systemic design needs to consider the context, identify the design placement and boundaries, discuss and define the problem into different areas and aspects, and then use a combination of different design strategies to solve the problems in a system.

Figure 2.2 Ways of designing for different system types

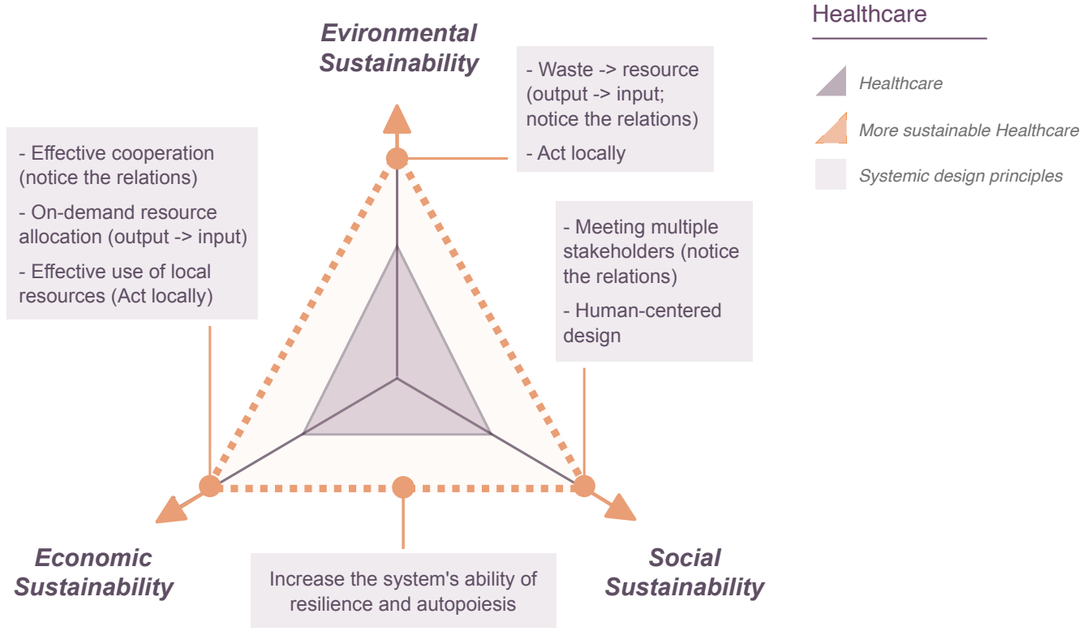
Note: With reference to the relevant discussion of Jones (2020) and Buchanan (1992)



On the other hand, in the field of healthcare, design practices that adopt systemic design and take into account the systemic design principles have expanded to product design, communication design, e-health/m-health, and product service system design (Barbero & Pallaro, 2017). Some studies have discussed more specific areas such as food safety and toxic chemistry problems (Savina et al., 2018), product service design on chronic hemodialysis (Pereno, 2017), and multi-stakeholder systems in healthcare (Pereno & Eriksson, 2020).

All these practices indicate that by adopting systemic design approach and systemic design principles, designers and researchers can promote the sustainability of healthcare together with other participators.

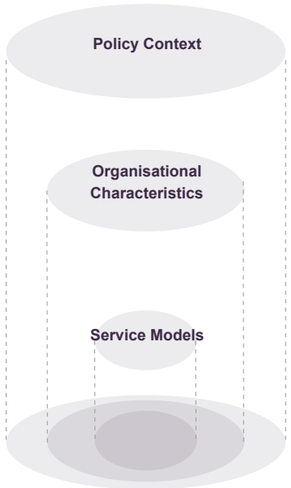
Figure 2.3 SD principles help Sustainable Healthcare



2.3 Systemic Design Framework for Chronic Disease Management

As mentioned in the previous chapter, the matter of managing chronic conditions is a big challenge for all health systems to achieve sustainable healthcare. Like the health system, the model of chronic disease management is diverse in different regions and locations.

According to Rosen et al. (2007), there are three tiers of Influence on the effectiveness of chronic disease service. Figure 2.4 presents these three tiers.



- The outermost tier Policy Context refers to the regulation and policy which sets the context in which chronic disease services operate, and defines the incentives that shape the responses of health care, which include payment and reimbursement mechanisms, quality indicators and performance targets, and accountability for services.
- The middle tier is the characteristics of the organizations which participate and provide chronic disease care. It consists of the scale of the organizations, continuity of relationships, it and data systems, local performance measurement
- The inside tier Service Model is a critical factor in determining whether chronic disease management programs succeed. It refers to how to provide patients with chronic conditions with front-line healthcare services that span multi-discipline teams and professional groups.

Figure 2.4 Tiers of Influence on the Effectiveness of Chronic Disease Services

Source: Adapted from Rosen et al. (2007)

For the specific topic of chronic disease management, how systemic design approach help on the operational level?

Systemic design can address the 'product system' characterized by a social, political, economic and cultural context, considering the actors/stakeholders and the relations among them, seeing processes as organized flows of resources and information (Fiore et al., 2018). Therefore, it is possible to set a hypothesis and adopt systemic design approach to form a design framework for the context of chronic disease management and guide the design research and practice in the next stage.

Taking into consideration the systems thinking, system types and systemic design approach, the design framework for chronic disease management is formed, trying to identify the content of design research or design practice by establishing different operating layers. Figure 2.6 presents the main content of the framework, and more content is introduced as follows.

The framework has been carried out into four levels with four steps. The four steps follow the systemic design approach (Barbero, 2017; Battistoni & Giraldo & Barbero, 2019), with the combination of researching and analyzing elements at different four levels, in order to obtain a systemic solution.

The first step Holistic Diagnosis is to use different methods to get all information about the program. The second step is Problem Definition, problems and concerns are expected put into different levels for better understanding and consideration. In the third step, the breakthrough and design solution are proposed for a better system, and in the fourth step, some design practice and iteration will be done.

The contents of four levels are initially defined, mainly considering the characteristics and influencing tiers of the model of chronic disease management, as well as the holistic approach concept that systemic design mentions:

- Level 4 -- Local context. Understanding the local context of CDM is an important premise. Different regions publish different policies that influence and shape the model of chronic disease management. At the same time, government policy and regulation are also related to the other aspects of the region, such as geography, demography, and economy. The holistic research should be conducted (Barbero, 2017).
- Level 3 -- Social (or sociotechnical) system for CDM. On this level, the elements and the relations in the system should be identified, as well as their aims and characteristics. A system map can be used to gather the information and analyze this level.
- Level 2 -- CDM process or organization workflow. If level 3 is to show the components of the system, level 2 is to reveal the way and process of how CDM happens in the system. Although a system often includes the process and rules that form the system, the process is taken alone in order to analyze the service model of CDM better. The process is driven and realized by different stakeholders who are involved at different times. The process can be visualized by design tools such as a service map or journey map (Pereno, 2017).
- Level 1 -- Specific product/service for patients. Apart from the human actors, there are non-human actors who participate in the CDM system, playing their roles and helping the system work well. The human-centered principle is often applied on this level (Jones, 2013).

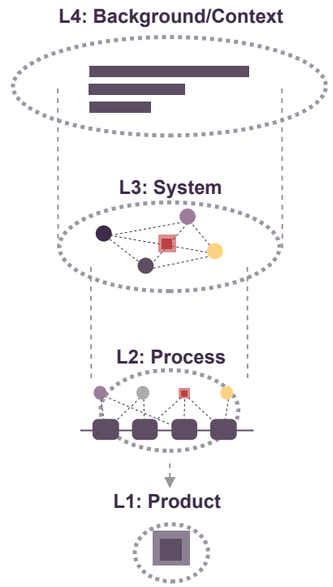
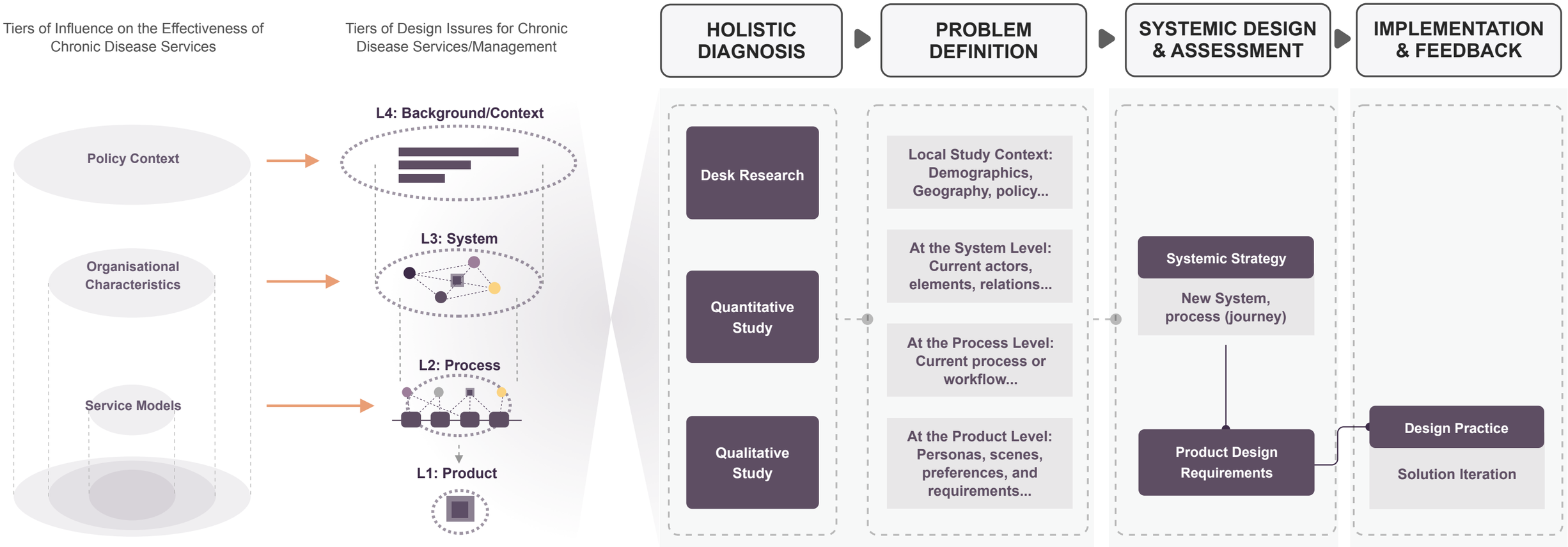


Figure 2.5 Four levels of the Design Framework for Chronic Disease Management

Figure 2.6 Design Framework for Chronic Disease Management



03

Osteoarthritis: Product Solutions for the Management

This chapter improves the design framework proposed in chapter 2 by analyzing three digital health products in three regions and counties (the United States, England, and Germany).

A specific chronic disease, osteoarthritis (OA), is selected to narrow the research scope and bring detailed knowledge about its management. All three product cases can provide digital health solutions to help patients manage their diseases. However, their focuses and operating model are different, influenced by many factors, which the analysis work in chapter 3 wants to find out.

3.1 Research on the Management of Osteoarthritis

3.1.1 Introduction to Osteoarthritis: Causes, Symptoms, and Effects

Osteoarthritis (OA) is a kind of musculoskeletal (MSK) disorders and the most common form of arthritis. It happens when the cartilage, the natural cushioning between joints, wears away, so it also known as wear-and-tear arthritis. It most commonly occurs on the hands, hips, and knees.

OA is the most prevalent joint disease, and one of the most common causes of disability worldwide (Collaborators, 2018). Although osteoarthritis is not a fatal disease, it affects the patient's physiology and psychology to different degrees, reduces the patient's quality of life, and also increases the risk of other diseases (such as cardiovascular disease).

Figure 3.1
Osteoarthritis occurs on the hand, hip, and knee

Sourece: Freepik.com
1. Image by Freepik
2. Image by jcomp on Freepik
3. Image by stefamerpik on Freepik

3.1.2 The Treatment and Management of Osteoarthritis

Categories of treatment and management of Osteoarthritis

According to international recommendations, there are three main categories for the treatment and management of OA: non-pharmacological, pharmacological, and surgical (Zhang et al., 2010). For different types, several international Clinical Practice Guidelines (CPGs) have been released to help physicians manage and treat their patients.

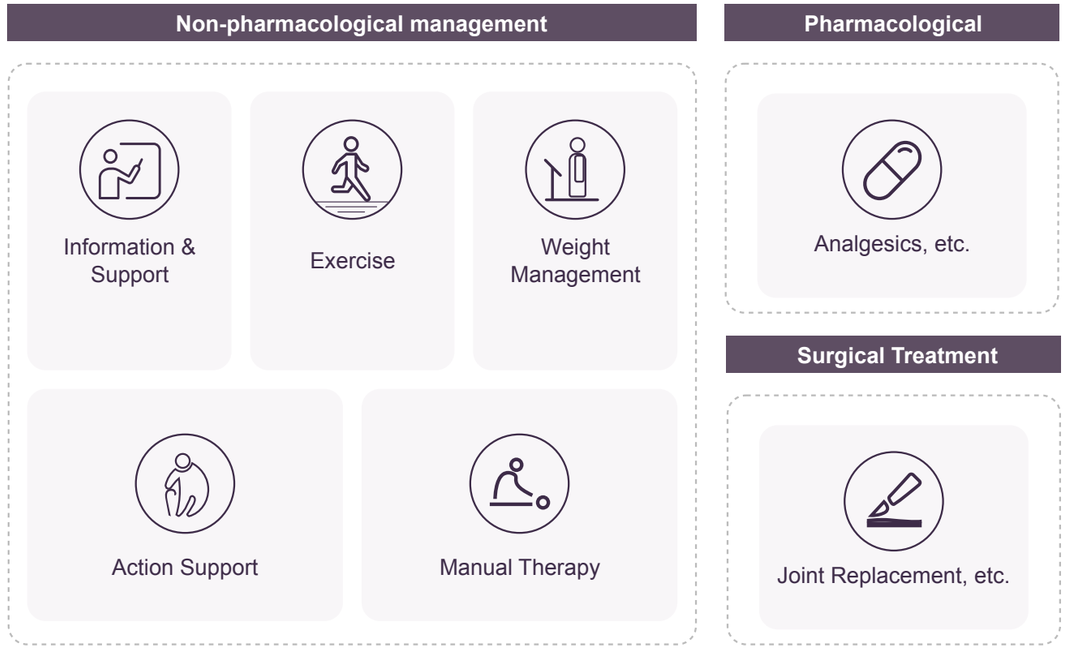
Patients in different stages of OA are recommended different combinations of management ways. For example, patients with early-stage symptoms only need non-pharmacological treatment and management, while patients with progressed OA need non-pharmacological treatment with additional pharmacological management. For patients with end-stage OA, surgical treatment such as joint replacement can improve the quality of life in the end.

During the past decade, much emphasis has been put on non-pharmacological management. The European League Against Rheumatism (EULAR) (2013) recommends nine topics for the non-pharmacological core management of hip and knee OA: assessment, general approach, patient information and education, lifestyle changes, exercise, weight loss, assistive technology and adaptations, footwear and work.

Patient arthritis education and structured therapeutic exercise programs (with or without dietary weight management) are topics belonging to the non-pharmacological core management of hip and knee OA, which are recommended by many professional institutes as the first-line interventions for their ability to reduce pain and disability, regardless of the severity of the disease (EULAR, 2013; Bannuru et al., 2019; National Institute for Health and Care, 2022). The National Institute for Health and Care Excellence (NICE) (2022) published guidelines for the Management of osteoarthritis, and give recommendations about exercise and information and support (see in figure 3.2).

Figure 3.2 Management ways of Osteoarthritis

Source: Partially adapted from National Institute for Health and Care, 2022



3.1.3 The Self-Management of Osteoarthritis

The words "chronic disease self-management" refers to the process that the individuals manage their symptoms, physical/mental health, and lifestyle changes caused by chronic diseases effectively, through their own abilities (Barlow et al., 2002), with the help of professional medical staff. Compared with the traditional medical model, the self-management model emphasizes the patient's initiative, as well as the establishment of self-efficacy, self-monitoring, goal setting and action planning, decision-making, problem-solving, self-adjustment, and cooperation between patients and professional medical staff (Osborne et al., 2004).

For aspects of osteoarthritis care, “self-management” means that a person can do for themselves with advice from the primary care team, such as the GP, nurse, physiotherapist, occupational therapist, and from information leaflets. Its advice includes traditional medical interventions such as education intervention, psychological intervention, and rehabilitation intervention.

The primary care team is supposed to agree with a patient with osteoarthritis on an individualized self-management strategy, to achieve target positive behavioral changes such as exercise, weight loss, use of appropriate footwear, and pacing. The core treatments of non-pharmacological treatments, especially exercise, emphasize recommended (NICE, 2008; OARSI, 2019).

Self-management can make patients become more active participants in managing their condition, improving adherence to the treatment offered and reducing reliance on medical interventions. Therefore, providing patients with a framework that encourages self-management is now considered an integral part of all long-term disease care (NICE, 2008).

However, the effectiveness of support is limited because of some restrictions. One reason is that some healthcare professionals hold a negative attitude towards the outcomes of self-management and seldom recommend it to patients, which leads to patients' access to readily accessible support and advice being generally poor. On the other hand, patients often cannot stick to self-management programs originally formulated due to different personal reasons (NICE, 2008; Yin & Xu & Zhou, 2020).

NICE (2008) suggested that healthcare systems must encourage greater self-management in order to face deeper aging and more medical resource consumption. There will be a range of providers, voluntary and independent sectors, offering self-managed programs to provide help for osteoarthritis patients in need of healthcare support.

3.2 Digital Health Products for the Self-Management of Osteoarthritis

Here, digital health can help solve some problems and engage better patient self-management.

Benefiting from its advantages such as information collection, real-time data exchange, and remote communication, the application of digital health has covered the whole stage of the majority of musculoskeletal (MSK) disorders (including osteoarthritis): Prevention, Acute injure, Chronic management, and Surgery. Use cases include patient engagement and education, health coaching, expert medical opinion, remote physical therapists, evidence-based assessment, and so on. It connects different players to improve healthcare outcomes.

In recent years, there are lots of digital health vendors on the market providing self-managed programs/plans to patients in need, and they called themselves digital MSK clinics, MSK platforms, etc. Some vendors have performed well with clear development paths such as Hinge Health, Kaia, and Sword, while some other newer and younger vendors in this field are just getting started according to the latest and constantly changing policy.

Not only depending on the one-sided information presentation towards the user, more and more vendors use technology like wearable technology and computer vision technology to collect data and set AI platforms, helping healthcare providers make decisions, providing patients with individual management plans and on-demand medical interventions. Overall, the tech is transforming the way we treat and manage disease.

Digital health products for different disease stages

3.3 Case Analysis of Digital Health Products

3.3.1 Selecting the Product Cases

In this section, 3 practice cases of digital health products for OA self-management will be selected for analysis in specific contexts.

The purpose of the analysis is to verify the effectiveness of the Systemic design framework for CDM and improve it, which can be divided into several aspects:

1) Are the form of products and services that function in disease management the result of other systems in which they operate?

2) If so, what factors of each level are at work; what are the key points to focus on when considering the influence coming from a certain level?

3) What are the relationships among different influencing factors of each level? What are the connections and constraints?

As mentioned before, the features of the same influence factors of CDM and health care system are often different by region. In order to understand whether the products or services are correspondingly unique under different policy backgrounds, organizational characteristics, and work processes, 3 representative products/services from different countries will be selected for analysis. The selected cases are shown in table 3.1.

Table 3.1 Basic information on cases selected

Product Name	Hinge Health	Phio	Orthopy Health
Logo	Hinge Health	Phio.	Orthopy
Company	Hinge Health, Inc	EQL Limited	Orthopy Health GmbH
Launched Year	2015	2019 (Phio Engage - 2021)	2020
Geographic Scope	The United States	England	Germany
Customers Serviced (Incomplete)	1,000 enterprise customers, now accessible to 21 million lives (Oct, 2022)	Has partnered with Medicash (available to over 240,00 corporate policyholders)	500+ Downloads in Google Play

3.3.2 Case One: Hinge Health

Product introduction

Founded in 2015, Hinge Health is a digital platform specifically designed to provide digital healthcare to those suffering from chronic musculoskeletal conditions such as back and joint pain (Hinge Health 2022). The platform basically offers physical therapy and behavioral health treatment services remotely by leveraging wearable sensors, an app, health guidance, and medical expert support. It received FDA 510(k) clearance in 2016.

The product system of Hinge Health is very simple. Patients who use the products will receive 2 motion sensor devices with IMU sensors in them, 2 bandages, and a Hinge Health app. When the sensor is fixed on different parts of the user's body, it can identify different body movements flexibly. In addition, Hinge Health has also begun to use machine vision technology to help patients perform full-body movement assessments.

Process and system introduction

The reason for Hinge Health's success is that it understands the importance of professional physicians in rehabilitation training. There is a complete clinical care team for personalized physical and behavioral support for patients. Apart from this, Hinge Health has developed a core technology platform integrating external electronic medical records (EMR) into Hinge Health's Digital MSK Clinic, enabling highly personalized care and robust coordination with external providers.

Another reason is about the right choice of business model. Hinge Health earns money from its digital healthcare plans purchased by employers and private health insurers. The platform and program are available through employer-sponsored healthcare plans. The program is covered by most insurance plans, so, for many employees and dependents, Hinge Health is completely free to use.

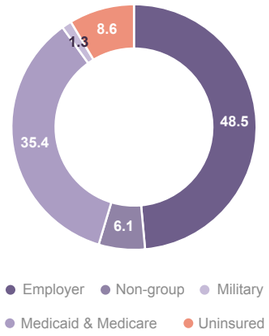
Context introduction

The US healthcare system does not provide universal health care coverage to the country's entire population, and can be defined as a mixed system, where publicly financed government Medicare and Medicaid health coverage coexists with privately financed (private health insurance plans) market coverage (Nishtar, 2007).

As of 2021, around 48% of American citizens received private insurance coverage through their employer (group insurance), 6% received private insurance through health insurance marketplaces (non-group insurance), 21% and 14% of citizens relied on Medicaid and Medicare (paid by state or federal govt.), and 1% on other public forms of insurance, leaving more than 8% of Americans uninsured (Health Insurance Coverage of the Total Population | KFF, 2021).

Meanwhile, one-fifth of the GDP in the U.S. is spent on healthcare, with a sixth of that figure occupied by orthopedics and musculoskeletal health. 80% of Americans suffer from some form of chronic back or joint pain. All of this information makes employers and private health insurers concerned about musculoskeletal disorders, and willing to try and pay for them.

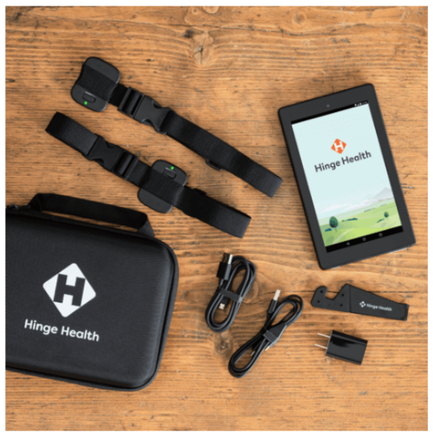
Health Insurance Coverage of the Total Population in the U.S.



Source: Data for Health Insurance Coverage of the Total Population | KFF, 2021

Main Components of Hinge Health

1. Wearable sensors for accuracy
2. Personalized exercise therapy
3.Unlimited 1-on-1 health coaching

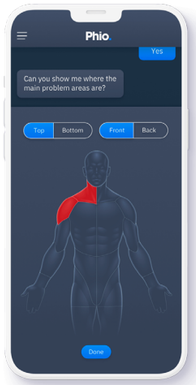


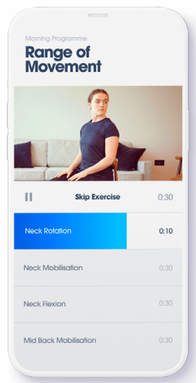
Source: Screenshot from the official website of Hinge Health (2022). https://www.hingehealth.com/for-individuals/

3.3.3 Case Two: Phio

Phio Platform

1. Phio Access
2. Phio Engage





Source: Images from EOL. (2022). https://www.eql.ai/phio

Product/service introduction

The Phio Platform, launched by an UK health technology business EQL, includes two digital products: Phio Access and Phio Engage (EQL, 2022).

- Phio Access is a clinically-led digital triage support tool designed to provide clinicians with efficient triage services and assist physicians in providing the appropriate treatment for each MSK case.
- Phio Engage is a self-care app for people needing musculoskeletal (MSK) care. It provides MSK care for people who have been identified by a qualified clinician as suitable for self-managed care, with oversight from clinicians as required.

The functions of Phio Engage consists of providing a tailored exercise programme, allowing people to control the intensity of that programme according to their needs, tracking exercise progress, and providing qualified clinical oversight and intervention through the app as needed.

Process introduction

First, efficient and accurate triage through Phio Access. Phio Access uses conversational AI for initial patient assessment, helping clinicians divide patients into those who need urgent help, those who can self-manage, and those who could benefit from in-person appointments.

If the patient is more suitable for self-management at this time, clinicians can recommend the patient to use Phio Engage, reducing the need for face-to-face treatment and empowering patients to self-manage their care.For self-managed patients (including recovered), they can use Phio Engage to do personal exercise anywhere and tracks their progress.

If the patient needs more intervention from a clinician, such as face-to-face communication with a physical therapist, Phio Access can provide clinicians with an in-depth patient history to make the first appointment efficiently.

System introduction

As the launcher of Phio, EQL works with different partners to provide products and services to patients in need. These partners include National Health Systems (NHS clinicians), insurers, private healthcare providers, employee benefits providers, and pharmaceutical companies.

The impact might be: On the one hand, the Phio platform may eliminate the need for more GP appointments related to MSK pain, and it can provide patients who are waiting for referring with basic management knowledge and guidance ahead of time to get rapid self-management support.

However, it seems that EQL hasn't worked with NHS directly. In terms of working with private healthcare providers, EQL has formed a partnership with Circle Health Group, the UK's independent hospital provider, providing Phio Engage as one of the products in its integrated care service, which will help in digital physiotherapy management and appointment (EQL, 2021).

Context

The UK has been implementing the National Health Service (NHS) since 1948, in order to provide everyone in the UK with healthcare based on one's needs, and not on one's ability to pay. The NHS is respected throughout the world for the standard of care that gives to patients. The UK operates primarily a tax-funded national health system, the same as Denmark and Italy (Nolte et al., 2015).

According to the regulation of NHS, a patient usually needs to see a GP in primary care before being referred to the NHS hospital's specialist department. This is the routine process that links primary care to elective care, which is planned, non-urgent specialist care.

However, the regulation also leads to delays in some patients' treatment access. To relieve the pressure of NHS staff shortages, since the early 2000s, some private health care companies (independent sector health care providers, ISPs) also undertake the delivery of NHS-funded elective care, covering the specialties such as ophthalmology and trauma and orthopaedics (Peytrignet et al., 2022). If patients are referred to these ISPs, all the costs of normal programs will be covered by the NHS. Some areas of the UK already allow Self-referral for NHS physiotherapy that is suitable for patients with relatively simple conditions such as joint pain or other injuries.

For digital health, the NHS App was developed by NHS Digital and NHS England and available since 2018. All GPs in England will be required to connect to it. It now recorded more than 28 million sign-ups, with over 16 million repeat prescriptions ordered and 1.3 million GP appointments booked in the last year (NHS Digital, 2022).

NHSX is a joint unit of NHS England and NHS Improvement and the Department for Health and Social Care, responsible for digitizing healthcare services. Apart from innovating alone, it also intends to buy technologies from third-party vendors and technology providers from the market. NHSX and NHS Digital will establish a single API platform for health and social care which can support APIs created by third parties, providing them with potential commercial models. NHSX will be procuring services that meet its requirements and can help achieve its goals. Some pre-existing procurement frameworks, such as G-Cloud, will be taken into account. It means that the products of third-party vendors might be procured by NHS and adopted by patients and NHS staff (NHS England - Transformation Directorate, 2021).

3.3.4 Case Three: Orthopy Health

Product/service Introduction

Orthopy Health is a digital application that helps users to do orthopedic therapies, exercises, progression analysis, and therapy planning. It mainly focuses on the patients who are before, during and after orthopedic treatment, such as meniscus damage and ankle sprain. Orthopy Health's goal is to offer therapy supplements for all acute orthopedic injuries.

According to the founder's interview content and the introduction on the official website, there are three main functions for users to help them go through their treatment (Orthopy, 2022).

- Understandable knowledge contributions: Relevant treatment information
- Individual therapy support: made training plans and exercises for home training
- Visible progress: Personal development as a motivational aid

Process and System Introduction

Orthopy Health meets its users after they are diagnosed by the doctor. In the first step, patients download the app and inform themselves about their injury and treatment path through patient education section. Then they do pre- and post-surgery exercise at home following the training plan and guidance on the application. The app can record the user's progress and analyze the training result.

According to the introduction of Orthopy Health, Orthopy Health is not supported by an active professional medical team or a team of physiotherapists, and all treatment requirements still need patients to ask their own doctor or physiotherapist face-to-face.

Orthopy Health hasn't conducted any way to motivate patients' real-life physicians or physical therapists to use the software with patients to evaluate the patient treatment, which means if the patient's physicians are not interested in using this product, it may not help.

However, the founder of Orthopy Health GmbH believes these problems are only phased. The product is currently being tested for free, and it is planning to obtain digital prescription certification in Germany in 2023. In the future, Orthopy Health can be prescribed by doctors as a digital prescription and reimbursed by the patient's health insurance company.

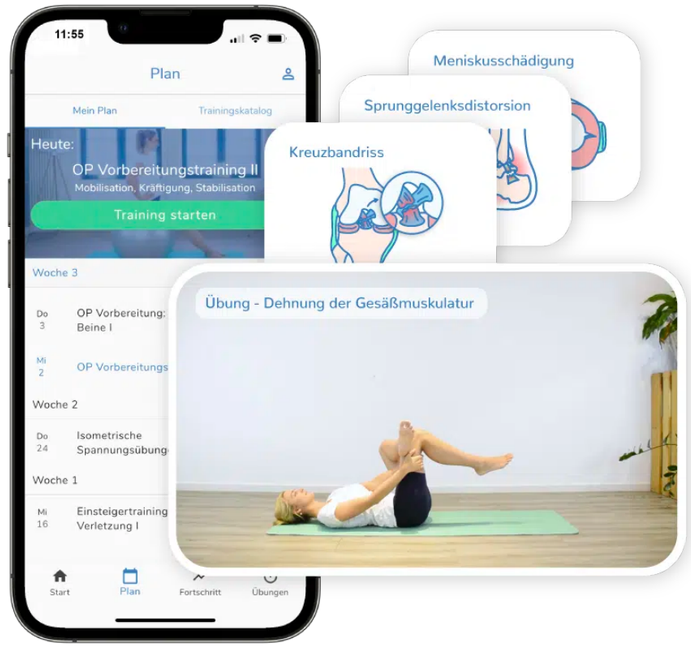
Context

The vision of Orthopy Health is related to an innovative and new legal foundation: The Digital Healthcare Act, developed by the German lawmakers and passed in December 2019.

The health care systems in Germany are primarily funded through statutory health insurance (SHI), which cover 73 million Germans (approximately 90% of the total population). Based on the new law, they are entitled to use DiGAs, only if they have a prescription or an attested diagnosis (The Medical Futurist, 2022).

DiGA stands for Digitale Gesundheitsanwendung or Digital Health Application in English. Simply speaking, DiGAs are "apps on prescription", which are approved by the regulatory body. DiGAs are digital health applications that can be prescribed by doctors for patient use for a variety of diagnoses. Statutory health insurers reimburse the associated DiGA costs in Germany, with prices negotiated in advance with the umbrella association of German health insurance companies.

Orthopy Health App



Source: Images from Digitale Unterstützung Bei Orthopädischen Therapien - Orthopy (2022). https://www.orthopy.de/ueber-orthopy/

3.4 Key Findings

3.4.1 From Four Levels

The above work completes the analysis of the three digital health product solutions, from the micro to macro background, the purpose is to verify and improve the systemic design framework for CDM proposed in the previous chapter. The figure briefly summarizes the relevant content of each case. More detailed discussion around several previous questions and findings is followed.

Product

The first thing can be determined is that as a system playing a role in a complex disease management system, the product/service must be affected by other systems, but there are also some independent stable parts among these cases which are not be affected. These common characteristics of product/service systems are related to patient's health needs and the basic treatment requirements of certain diseases (here, are MSK disorders).

For example, patient education, exercise therapy, progress tracking, and health reporting functions, all appear in the three product solutions, and should also appear in other product solutions related to musculoskeletal disease management. Then, around these basic functions, digital health exerts its unique advantages. Some methods related to evidence-based, patient motivation or user experience improving are more or less reflected in the product, helping to achieve better treatment and management effects.

Process

The involvement of the emerging product solution has an impact on the traditional management process, but the three solutions have different degrees of impact, which are related to regional or national policies, such as health insure system, reimbursement regulations, and digital health product criteria.

For Hinge Health in the United States, the cooperation way with commercial insurance companies and employers is very flexible, and the formed workflow is very likely not subject to the original medical treatment process. Just as the website of Hinge Health said, “take a short online questionnaire following the link below, telling us about your pain. No referral or diagnosis is needed from a doctor”.

Phio in England hopes to solve the problem of low referral efficiency in NHS, assisting or even replacing GPs to realize the triage of MSK diseases. However, this vision is subject to the GP gatekeeper system in the UK currently. Thus, the majority of its partners are private healthcare providers and insurers, and it still

lacks integration into NHS. But with the digitalization of the health care system, Phio is anticipated to connect to public health platform or procured by NHS.

Germany has become a leader in the digital healthcare space. The introduction of Digital Healthcare Act and DiGA Fast Track process let digital health product like Orthopy be able to integrate into the traditional treatment and management processes with less conflict.

System

The system level should define the main stakeholders/elements and clarify the relationship among them. Through case studies, the essential actors/elements of the system include the payer (such as governments or insurers), the healthcare providers (in primary care or hospitals), the patients, and the product.

It also found that the types of stakeholders/elements that need to be focused on in the system are determined by other multiple levels and aspects.

- The policy context often determines the type of payer (who pays for it) and cash flow.
- The treatment and management process of a certain disease identify the type of healthcare providers. In terms of OA, the process often includes physicians in primary care and specialists such as orthopedists, physiatrists, and PTs.
- Digital health products will become important participants in the system, becoming representatives of product companies and their service delivery teams.

In addition, some other participants may be added, depending on the functions with which the digital health product can provide its users.

Context

In terms of the local context, the policy context often reflects and tries to solve local problems. There are at least two policy-related contexts that need attention: (1) What the health insurance system looks like? (2) How can it integrate into the reimbursement system? (3) Relevant regulations, frameworks, and criteria of digital health products.

Providing universal health care coverage is beneficial to guarantee the health rights of the entire population, and it is also one of the SDGs. But it also means that when facing new concepts such as digital health or digital therapeutics (DTx), correct decision-making and strong promotion of national policies are required. Germany's digital health policy has pioneered a new approach, and other countries such as France are beginning to follow the path and create their own models.

3.4.2 Identify Key Concerns of Each Level

It can be found that the design of the product solution is a thoughtful decision, taking into account the care process in different stages of the disease and the health system (rules, policies) in which the solution is applied. According to the analysis of cases, the previous framework can be improved by clarifying the concerns of each level, as well as the connections and constraints between the levels.

1) The concerns of Product level. In this part, a patient-centered approach is worth promoting, focusing on user needs, the preferences of users, and use scenarios that are mainly related to the treatment and management requirements of a certain disease.

2) The concerns of Process level. Here, it needs to pay attention to the form of traditional processes of disease treatment and management. On the one hand, traditional processes should be taken into account or followed to ensure the science and feasibility of medical care. On the other hand, it needs to consider how the product solution intervenes and integrates into the old process and contributes to a new process. After all, a process guides the way how actors work together to manage diseases.

3) The concerns of System analysis. The level of system analysis is to identify the actors and other elements involved in the system, and what the relationships are among them. In all these case studies, new participants (companies or products) and relations are added, leading to the change of the original system.

4) The concerns of Context. Pay more attention to the related policy context, topics such as health system structure, health insurance, and digital health requirements.

04

Self-Management of Knee Osteoarthritis in Shanghai

Chapters 4 and 5 carry out an example of the management of knee osteoarthritis in Shanghai in China, following the design framework to conduct design research and design practice work, exploring the characteristics and particularities which should be noticed when designing digital health products in this regional context.

According to the design framework, this chapter consists of the main work of Holistic Diagnosis and Problem Definition.

4.1 Background Overview of Chronic Disease Management in China

4.1.1 China's Health Reform and Chronic Disease Management

Who pay for it?

China's old health reform started in 1985, and it made the Chinese health system face the battle between marketization and public welfare for more than 20 years. It also turned the Chinese health system into a "hospital-treatment-centered" operation model. In 2009, the Chinese government launched the "New Health Reform", and set "basic medical and health services for all" as the goal of this reform (State Council, 2009).

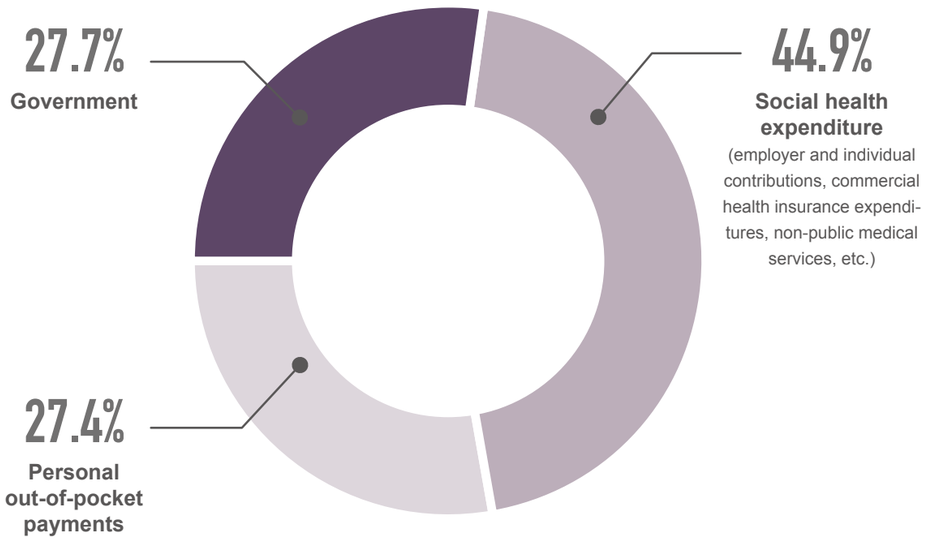
The new health reform is expected to bring the field of health that has been pushed to the market since the 1980s to the route of public welfare, to provide effective, convenient, and affordable healthcare services to the public. On the other hand, China gradually implements two kinds of basic health insurance systems: basic health insurance for employees and basic health insurance for urban and rural residents.

Nowadays, China has achieved nearly universal health insurance coverage. By the end of 2021, 1,364.24 million Chinese (more than 96% of the total population) participated in basic health insurance, including 354.22 million people with basic health insurance for employees, and 1,010.02 million people with basic health insurance for urban and rural residents (NHSA, 2022).

In 2021, China spent 6.5% of its GDP on healthcare expenditures. The national health expenditure mainly includes government expenditure (27.4%), social health expenditure (consists of employer and individual contributions, commercial health insurance expenditures, non-public medical services, etc., 44.9%), and personal out-of-pocket payments (27.7%) (NHC, 2022). As the part of social health expenditure, basic health insurance has become the main purchaser of healthcare services.

Figure 4.1 The Coverage of China's Basic Health Insurance (2021)

Figure 4.2 Sources of Funding for the Medical Expenditure (2021)



Health Reform (in Primary Care)

Health Reform and the Development of CDM in China

/1985
The Start of Marketization reform of Health System

In the 1980s, China's economic system reform started from the countryside and the Chinese model known as the "barefoot doctor" gradually faded out of the stage.

/2008
Explore Family Doctor Service Models

Zhoujiaqiao Community Health Care Service Center in Changning District in Shanghai, took the lead in launching the "responsible doctor" health management service model.

/2009
China's New Health Reform

China has set “basic medical and health services for all” the goal of health-care reform.
- Accelerate the construction of the basic health insurance system
- Preliminary establishment of national essential drug system
- Improving the grassroots medical and health service system
- Promote the gradual equalization of basic public health services
- Promoting pilot reforms in public hospitals

/2011
Propose qualified general practitioners

The document "Guidlines on Establishing a General Practitioner System" proposed for the first time there should be qualified general practitioners in primary care.

A family doctor training class at the Weifang Community Health Service Center, Shanghai

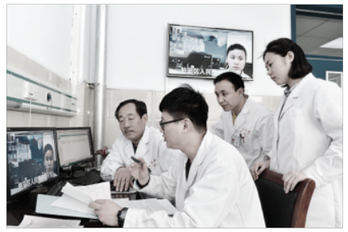
/2016
Extend Family Doctor System to the whole country

The "Notice on Printing and Distributing the Guiding Opinions on the Signing Service of Family Doctors" clarified that a family doctor is the first responsible person to provide residents with medical care in the form of signing service agreements.

/2018
"Internet + Medical Health"

Publishing the "Opinions on Promoting the Development of "Internet + Medical Health"

A family doctor training class at the Weifang Community Health Service Center, Shanghai



/Since the 1980s
Community-based CDM Pilot

Establish community-based comprehensive prevention and treatment demonstration sites for chronic diseases in Beijing, Tianjin, etc.

Family doctors can service at home

A family doctor is measuring blood pressure at the patient's home. (Changning district, Shanghai)

Community Health Service Centers for CDM

Accelerate the construction of an urban community health service network with community health service centers as the main body... Provide treatment services for chronic disease management, etc.

GPs should take responsible for CDM

General practitioners mainly undertake integrated services such as preventive health care, diagnosis and treatment and referral of common/frequently-occurring diseases, patient rehabilitation, chronic disease management, etc.

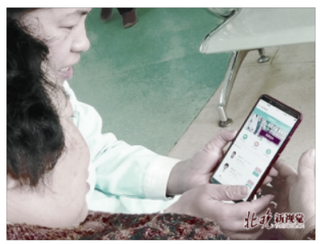
The GP in the health care service center is measuring blood pressure for the protection patient. (Changning Shanghai)

/2016
"Human-centered" health plan

"Healthy China 2030" Planning Outline pay attention to health influencing factors such as personal life and behavior, medical and health services and security, production and living environment

"Smart" family doctor

Optimize the "Internet +" family doctor contract service.



The "Smart family doctor" application was adopted in 14 community health service centers in Fengtai District,Beijing

Development of CDM

What does China's health care delivery system look like?

The figure shows the structure of China's health care delivery system. It consists of hospitals, primary health facilities, professional public health facilities, etc., covering urban and rural areas. Like some Western countries, China assigns different missions and functions to different types of healthcare institutions (State Office, 2015).

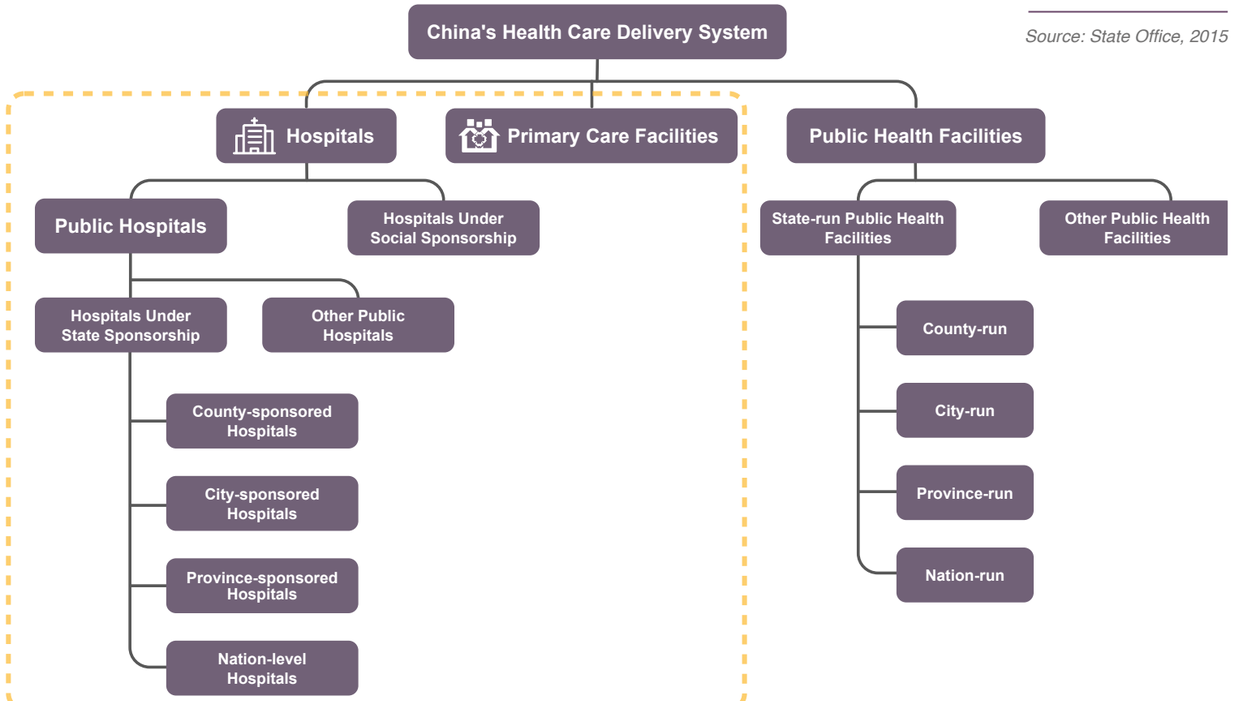
The Chinese government doesn't implement compulsory grassroots referral and people know less about the concept of Family Doctor before. Patients do not need to be first diagnosed and approved for referral by a primary care institution before they go to the hospital. On the contrary, Chinese patients can go directly to any level of hospital to see a specialist and the medical fee can be reimbursed prorated according to the expenditure.

The policy of hierarchical diagnosis and treatment has not been able to be implemented very well in China. Although this kind of regulation allows patients to seek medical treatment freely, it also causes a waste of medical resources. The mindset of "going to the hospital for serious and minor illnesses" has led to overcrowding in large hospitals, and fewer patients in primary medical institutions. In particular, it is not an effective behavior to manage chronic diseases which need long-term and continue interventions.

Faced with the pressures of an ageing population and continued growth in medical spending, China has been developing tiered diagnosis and treatment, such as setting higher reimbursement ratios for patients if they go the primary care.

Figure 4.3 China's health care delivery system

Source: State Office, 2015



Hospitals (public)

The public hospitals maintain public welfare and play important roles in the provision of basic healthcare services, diagnosis, and treatment of acute and critical illnesses and difficult diseases. Different levels of hospitals are responsible for residents' health in corresponding regions.

Primary Care Facilities

The primary care facilities provide basic public health services such as prevention and health education, as well as diagnosis and treatment for common diseases, as well as rehabilitation and nursing services for some diseases. The primary care facilities should referral patients to upper-level hospitals if the disease is out of their capability.

Public Health Facilities

The professional public health facilities often seldom provide direct service to the public. The Institutions provide professional public health services to their jurisdiction and undertake corresponding management work.

What is the model of CDM in China? Who are involved in it?

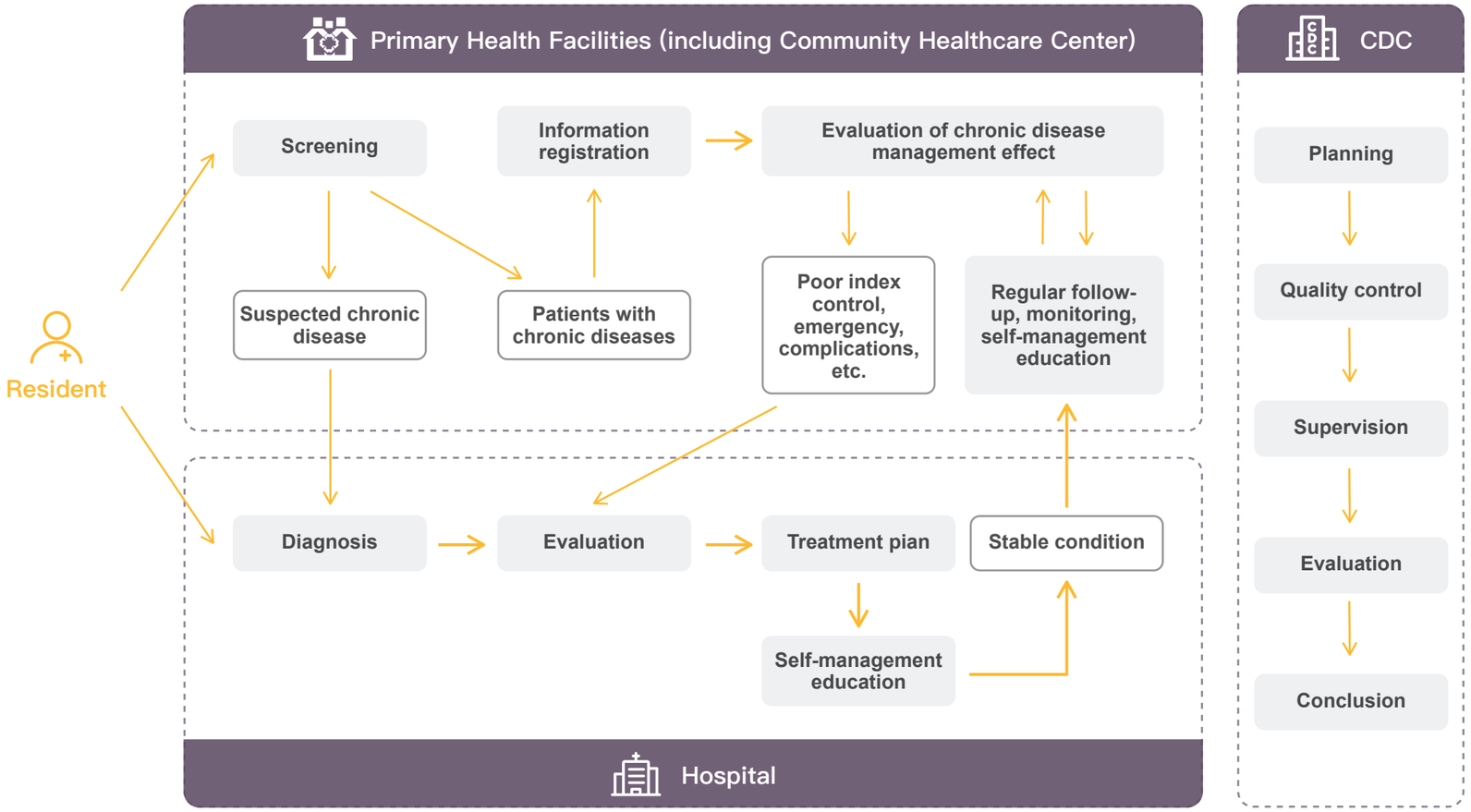
From 2009 to 2019, during the period of ten-year health reform, many suggestions and practices were put forward to explore the way of improving the health system. China's health reform goes through hardships but also gets some good outcomes. At the same time, some important policies have had a relatively important impact on the construction of the chronic disease management system, especially the policies regarding the establishment of primary care.

In practicing and planning new health reform, China has gradually formed a chronic disease management process based on the network of chronic disease prevention and control depending on the close cooperation between communities and medical service organizations (Lv & Deng, 2016). In this network, Community Healthcare Service Centers, hospitals, and the Centers for Disease Control and Prevention (CDC) carry out chronic disease prevention and treatment. The figure below shows the process (Lv & Deng, 2016):

- Primary health facilities should establish health records, screen suspected patients, pay attention to patients' conditions in daily life, and evaluate management effects.
- The doctor in the hospital diagnoses the chronic diseases for the first time, evaluates the patients introduced from the community with unstable conditions, formulates personalized treatment plans and self-management education, and then referrals patients with stable.
- The CDC manages and controls the entire chronic disease management process from a macro perspective, including formulating plans, conducting quality control, regular supervision and guidance, and later evaluation and summary.

Figure 4.4 The progress of chronic disease prevention and treatment in China

Source: Image partly adapted from Lv & Deng, 2016



The new role: General Practitioners as Family Doctors in primary care

According to the development and the policies published in history, it can be found that in the aspect of chronic disease management, several solutions have been proposed and will implement in the future:

1) Strengthen primary care, such as the implementation and promotion of the "family doctor system", GPs' education, and the suitable structure of the family doctor's team.

2) Regulate and improve the collaborative interaction between upper-level healthcare institutions (such as public hospitals) and institutions in primary care (such as community healthcare centers).

3) Use "Internet +" to connect the information between the patients and primary care, as well as primary care and the hospitals. Complete personal health records to realize care for the whole life.

China has shown its efforts of introducing the concept of General Practitioners (GPs) and Family Doctors (FDs) into its health system, making them important roles in primary care and in CDM gradually.

The concept of GPs and FDs originally came from the United Kingdom and they have been adopted in many European countries for years. The European Union defines the GPs/FDs as: "the specialist physicians trained in the principles of the discipline general practice or family medicine. They are personal doctors, primarily responsible for the provision of comprehensive and continuing care to every individual seeking medical care irrespective of age, sex, and illness. They care for individuals in the context of their family, community, and culture, always respecting the autonomy of their patients. They recognize they will also have a professional responsibility to their community" (Europe, 2002).

With the involvement of GPs and FDs, primary care/community healthcare is expected to take the main duty of CDM. In some cases, the transformation has shown great effects. For example, in Chang Ning District, Shanghai, patients with chronic disease management who have signed a contract with family doctors perform better than those who don't in terms of community consultation, chronic disease management and prevention, and medical cost control (Lu et al., 2016).

Now the relationship between Chronic Disease Management and Family Doctor System is strong. Chronic disease management is one of the important duties of family doctors. Li et al. (2017) found that the number of patients with managed hypertension or diabetes is the second important factor influencing family doctors' bonuses (nearly 35%), which may prompt doctors to sign and serve more patients with chronic diseases.

Figure 4.5 Chen Hua, a family doctor at the community health care center in Zhoujiaqiao Street, Changning District, Shanghai, is treating residents in the community.

Source: Photo by Ding Ting, published by Xinhua News Agency (January 22, 2013). http://www.gov.cn/jrzg/2013-01/22/content_2317914.htm

Figure 4.6 Chen Jun (right), a family doctor at the Community Health care Center of Pengpu Xincun Street, Jing'an District, Shanghai, is instructing resident Chen Sanhua on daily medication.

Source: Photo by reporter Pei Xin, Xinhua News Agency (April 28, 2016). http://www.gov.cn/xinwen/2016-06/07/content_5080139.htm

4.1.2 Problems of Disease Management in Primary Care

However, the institutions in primary care were ignored for a long time before the New Health Reform, while the development of primary care has been going slowly during the New Health Reform. There are several problems that should be noticed, and they may persist for a longer time.

Problem 1: Primary care still lacks enough, suitable, and qualified healthcare resources.

The first worrying issue is that there is a limited increase in the number of institutions in primary care and an insufficient number of GPs with matched medical education. From 2009 to 2019, the increasing situation of institutions in primary care is not as good as that of the hospital.

From 2011 to 2019, the increase in healthcare providers in hospitals and primary care shows that medical staff tends to work in the hospital rather than the community. In 2019, the number of GPs per 10,000 Chinese residents reached 2.2. Compared with the target of 5 qualified general practitioners per 10,000 residents in urban and rural areas in 2030, there is a gap of 100,000 GPs needed to be filled.

The doctors at work in institutions of primary care have less relevant education, probably because the promotion of specific education for general practitioners only happened several years ago. A survey on the training status and needs of general practitioners in three regions found that the theoretical knowledge that GPs needed the most includes the knowledge and management of common diseases (especially chronic diseases), rational drug use in the community, and first aid and health education (Zhao Yali, 2013).

In addition, primary care facilities also lack medicines, which leads to doctors in primary care facilities being unable to conduct routine screening to judge the condition and prescribe medicines that patients need (Lui et al., 2017).

Problem 2: Patients don't trust primary care very much.

Due to the short development time, insufficient manpower, limited resources, drug supply constraints, and other reasons, community health service institutions have not been favored by patients for a long time. At the same time, with the original advantage, the large hospitals developed rapidly and gain more medical resources in recent years.

Influenced by this long-term situation, Chinese patients have formed a mindset of "going to the hospital regardless of serious and minor illnesses". They don't trust the diagnosis and treatment plans provided by physicians in primary care facilities. This has resulted in the phenomenon of "overcrowded" in large hospitals and "fewer patients" in primary care facilities.

Problem 3: Chronic disease management needs more coherent and integrated support

Figure 4.7 Number of healthcare institutions in China, 2010-2019

Source: Data from China Statistical Yearbook. http://www.stats.gov.cn/english/Statisticaldata/AnnualData/

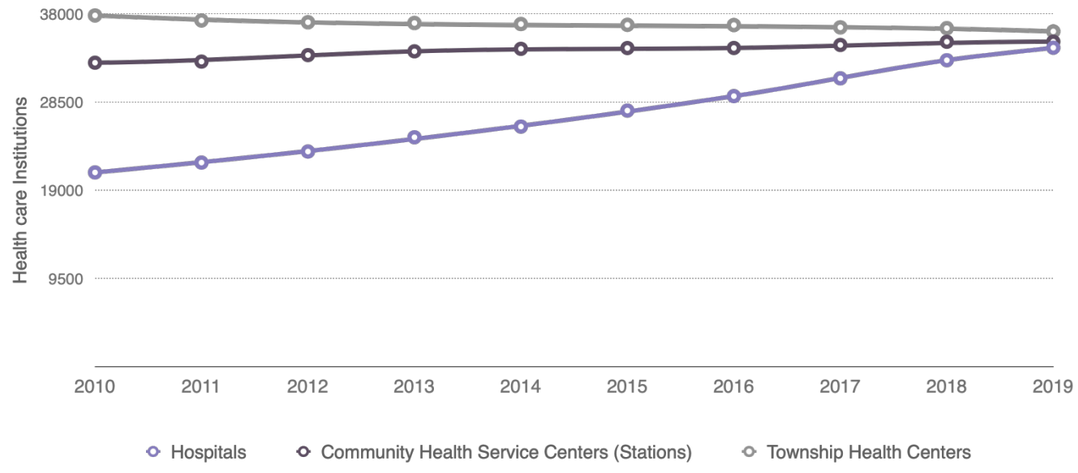
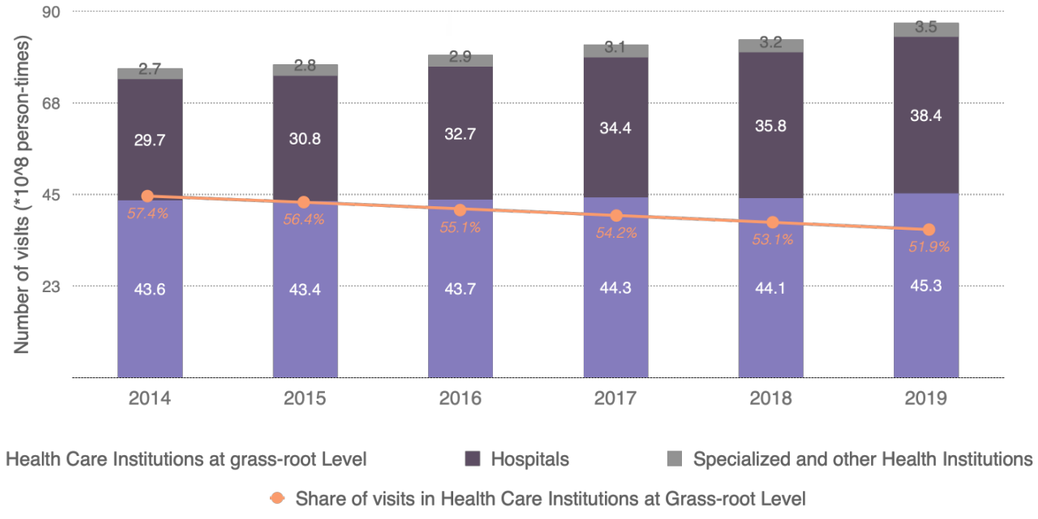


Figure 4.8 Number of visits in China, 2014-2019

Source: Data from China Statistical Yearbook. http://www.stats.gov.cn/english/Statisticaldata/AnnualData/



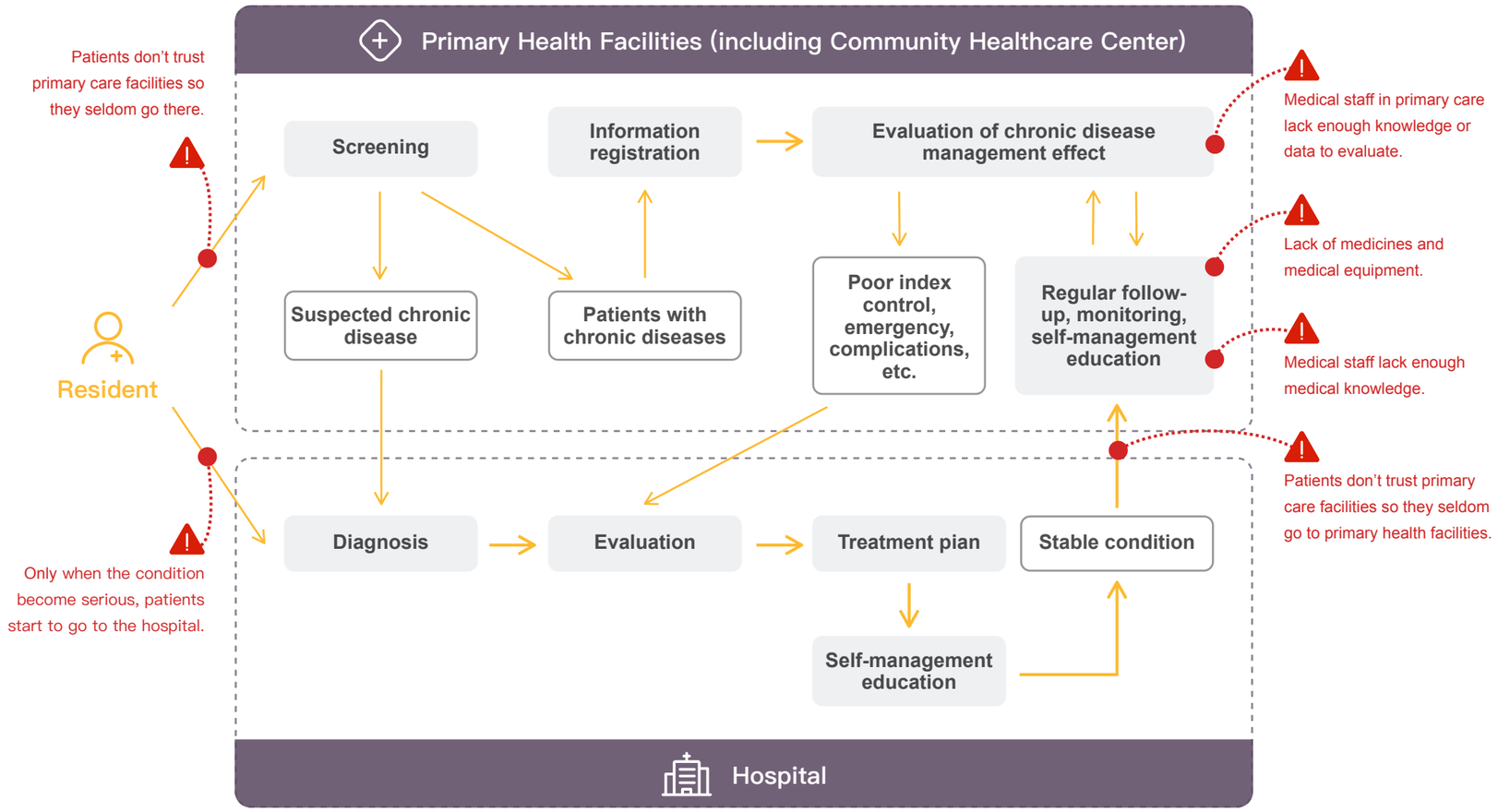
Chronic disease management is a long-term process with multi-level, multi-disciplinary healthcare providers participating to provide a continuum of care to patients. It is helpful if the patient's medical information transferred among different healthcare providers could be used efficiently.

However, in China, the majority of information technology (IT) systems for public health services are not integrated with the IT systems for clinical care. The application of IT is fragmented. That hinders the implementation of decision support based on the timely generation of evidence from everyday primary healthcare practice data (Li et al., 2017).

Thus, we can put these main problems together to see how these problems influence the whole process of chronic disease management in the figure below.

Figure 4.9 Problems that might exist in the process of Disease Management in China

Source:Image of the process partly adapted from Lv & Deng, 2016



4.1.3 Focus on the Self-Management of Knee Osteoarthritis in China

Why does the self-management of Osteoarthritis matter in China?

Osteoarthritis is becoming prevalent in china. The number of people suffering from OA in China rose from 261 million (1990) to 612 million (2017), greatly exceeding the growth of the total population (Long et al., 2020; Li et al., 2022). In addition, the prevalence of osteoarthritis in different joints is often considered to increase with age (Tang et al., 2016; Tie et al., 2018). With the acceleration of ageing and the increase in life expectancy in China, OA will become a more troublesome problem for healthcare (Li et al., 2022).

The main goal of the management of osteoarthritis is to relieve pain, and delay the progression of the disease, thereby safeguarding the patient's quality of life and delaying surgery. However, in China, the majority of CDM regulations are related to four types of chronic diseases that have the greatest impact on national health: cardiovascular disease, cancer, respiratory disease, and diabetes. Not only because these four chronic diseases affect a large number of people, but also because they would threaten the patient's life directly.

There has been a lack of a unified implementation consensus on the management of such chronic diseases like OA, resulting in blind spots in implementation and management. Patients with OA lack institutional and professional support in the face of disease management, and they have not formed sufficient awareness and ability for managing the disease by themselves. Therefore, the burden of OA would get worse if there is no action to be adopted.

The problems like osteoarthritis have received attention in recent years. "China's Medium- and Long-Term Plan for the Prevention and Treatment of Chronic Diseases (2017-2025)" has included the "Healthy Bones" special action into the Healthy Lifestyle Action Plan. It recommended that all regions should survey the bone health of residents, and conduct bone health knowledge publicity and free clinic activities, establish a management base in the community, provide services and support such as consultation, screening, and patient management (State Office, 2017).

Sun et al. (2019) suggest that based on the relatively high prevalence, the self-management and community-based management of OA should be considered, which are similar to the management of hypertension and diabetes.

One of the common Osteoarthritis: Knee Osteoarthritis

Knee Osteoarthritis (KOA) is one of the most common types of OA. The overall prevalence of KOA in the Chinese population over 40 years old was 17.0%, the male was 12.3% while the female was 22.2% (Tie et al., 2018).

Knee osteoarthritis will not have much impact on the patient's life in the early stage, but if neglecting the management in the early stage, it will lead to the deterioration of the disease to the middle and late stages. Patients with end-stage KOA will not only suffer from pain and mobility problems but also face the risk of major surgery if their ages are too old. Motion limitations and other problems affect physical and mental health, resulting in a significant decline in patients' quality of life. Treatment and surgery also impose huge health service costs on families and society. The thesis decides to focus on Osteoarthritis of the Knee (KOA), as a more specific example of the management of OA and chronic diseases.

There are so many factors that induce KOA. Aging, obesity, gender, and joint injury are the most prominent factors, which make this disease more common for elderly people and women are more likely to have KOA than men (Prieto-Alhambra et al., 2014).

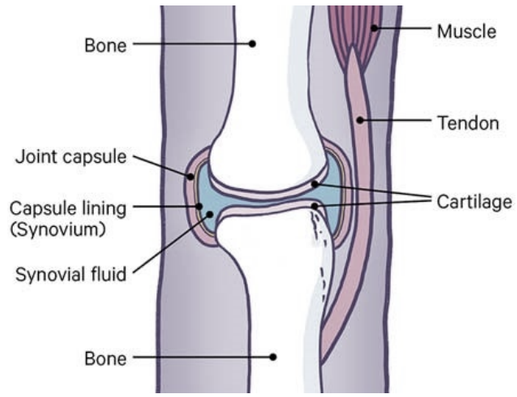


Figure 4.10 A healthy joint

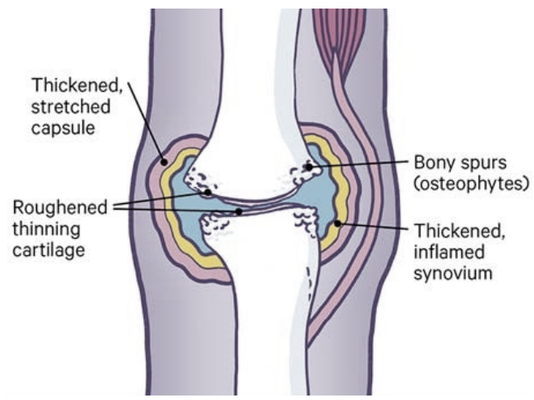


Figure 4.11 A joint affected by OA

Source: Versus Arthritis (n.d.). https://www.versusarthritis.org/about-arthritis/conditions/osteoarthritis-of-the-knee/)

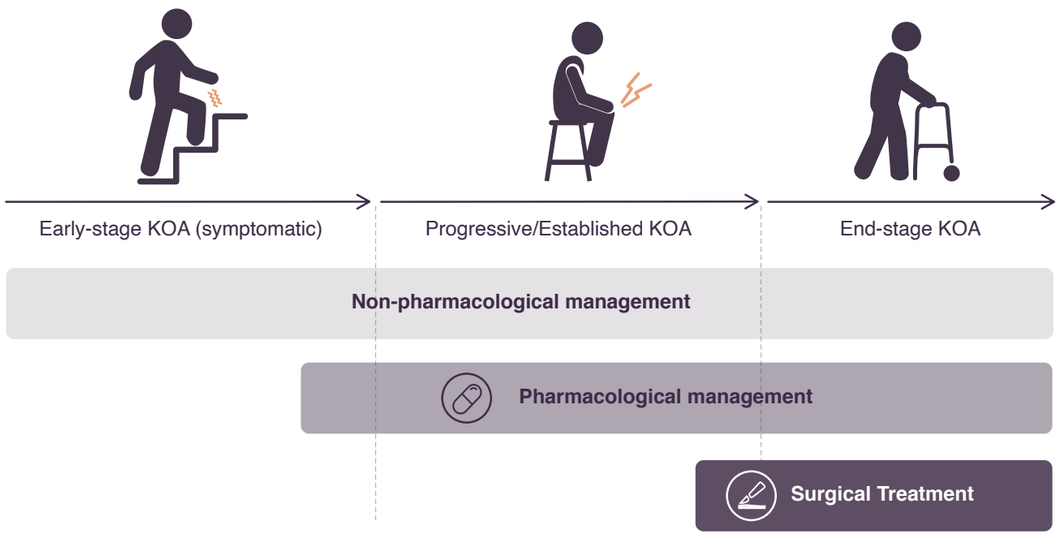
Although the discussion and consensus on the management and self-management of KOA are insufficient, the Chinese Orthopaedic Association (COA) released the "Expert Consensus on Step-by Treatment of Knee Osteoarthritis (2018 Edition)" (referred to as Expert Consensus), provides guidance and suggestions in the situation of China (Wang & Yu & Qian, 2019).

The Expert Consensus divides the course of KOA into 4 stages: early, mild, moderate, and severe/end-stage. The other general classification is to see KOA into 3 stages: early-stage, established/evident/progressive, and end-stage (Mahmoudian et al., 2021; Im, 2022). In this thesis, the classification follows the 3 stages (puts the "early stage" and the "mild stage" together called as early-stage).

When there is perceivable pain, patients are in the early stage. At this stage, there is a window of opportunities to address lifestyle-related risk factors for disease progression; during established/evident/progressive KOA, rapid progress might happen and develop into end-stage KOA, in which patients often face joint replacement surgery in end-stage KOA (Mahmoudian et al., 2021).

Like the treatment and management of OA, Expert Consensus recommended different combinations of treatments and management categories (non-pharmacological, pharmacological, and surgical) for patients at different stages (Wang & Yu & Qian, 2019). Figure 4.12 roughly shows the combination of types of treatment and management for patients with different stages of KOA.

Figure 4.12 Treatment and management for patients at different stages of KOA



Source: With reference to Mahmoudian et al., 2021; Wang & Yu & Qian, 2019

The process for the self-management of KOA

The Expert Consensus suggested that after patients are diagnosed by the doctors in the hospital, patients with light symptoms of KOA should be transferred to the primary healthcare institution and let primary healthcare physicians, such as GPs, continue the treatment. Primary healthcare physicians should provide basic treatment and guidance, and service to patients at this stage (Wang & Yu & Qian, 2019).

A self-efficacy and self-management program is strongly recommended for patients with knee, hip, and hand OA. Generally, the program usually takes the form of conferences (online or offline, 2 to 6 time weekly) provided by multidisciplinary teams. The program incorporates most elements of non-pharmacological treatment while paying attention to building patient self-efficacy, such as skill building (goal setting, positive thinking), disease and drug effects, joint protection measures, and fitness/exercise goals and methods (Kolasinski et al., 2020).

Although the Expert Consensus seldom mentions self-management, in fact, the work of primary healthcare physicians is mainly to help the majority of patients with daily self-management. Meanwhile, from the perspective of medical service providers, the content of KOA self-management is very similar to KOA conservative treatment in the Step-by treatment plan. It can be divided into two parts: "KOA-related knowledge and health education" and "Formulation and Implementation of the action plan" (Yin et al., 2020). At the specific implementation level, it also can break down into 4 stages (figure 4.13).

1) In the first step, the professional medical staff should provide patients with knee health education. It mainly includes KOA prevention and management, pain management, lifestyle modification, self-care strategies, nutritional pairings for weight management, and other ways to improve health-related quality of life. Effective patient education can strengthen patients' compliance with goals and action plans in the later stage, resulting in better disease management results.

2) In the second step, the medical staff should know clearly about the patient's condition and help formulate the KOA management goals and action plans. The focus of the plan is on exercise planning and weight management. The exercise program includes various types of exercise therapy, such as aerobic exercise, muscle strength exercise, joint ROM exercise, etc. When doctors develop exercise plans for patients, they need to choose the right types of exercise and set reasonable goals for each patient individually.

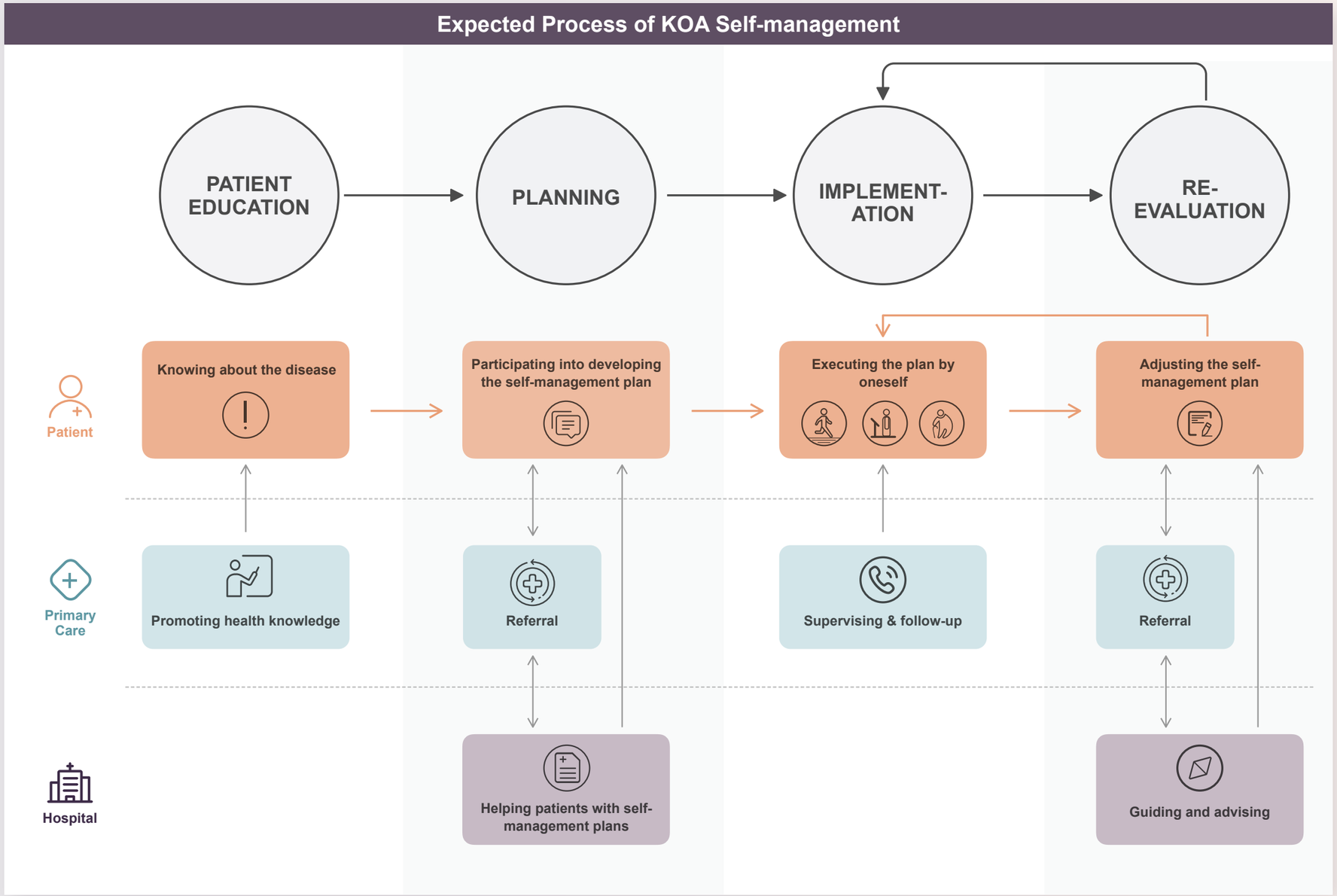
3) In the third step, medical staff often play the role of supervisors and assist patients with the process of KOA self-management. During the period, medical staff can follow up on patients' conditions regularly in the way of face-to-face group talks, follow-up visits, and telephone visits. Nowadays, with the development of the Internet and mHealth, medical staff are able to follow patients' conditions and give guidance online remotely, which avoids the trouble of long distances.

4) In the fourth step, the medical staff should re-evaluate the patient's condition

to see if the self-management plan can help the patient or not. The new plan is also an individual plan for each patient, considering their lifestyle and expectation.

Figure 4.13 Expected Process of KOA Self-management

Source: With reference to Yin et al. (2020)



Key Factors and problems of KOA self-management

The main factors affecting the self-management of patients with knee osteoarthritis are disease cognition, self-efficacy, emotion, and social support (Yin & Xu & Zhou, 2020). "Disease awareness" represents the patient's knowledge of the causes of disease and how to manage it; "self-efficacy" is the belief that one can control the disease and condition through actions; "emotion" refer to the patient's mental health; "social support" refers to whether there are people around the patient who can help and support them.

According to the research above, it seems like the ideal KOA self-management program takes into account all the four main influencing factors well and can help patients with KOA effectively. However, in fact, there are different problems on different factors.

Disease Awareness

1) Low disease awareness. A report shows that nearly 90% of patients with osteoarthritis lack understanding of related health knowledge, and even lack or misunderstand the severity of the disease at the end stage, such as disability. Patients at an early stage often do not realize that this is a “disease” that should be dealt with seriously. Therefore, they miss the opportunity to use effective methods for disease prevention and management, increasing the risk of surgery (Mylan, 2020).

Self-efficacy

2) Low Self-efficacy. Self-efficacy is still considered to be the core of self-management, and low self-efficacy and depression are the main precursors to increased pain and loss of function for patients with KOA (Yin & Xu & Zhou, 2020). However, 23% of patients had a negative attitude towards disease diagnosis and treatment, believing that it was a natural phenomenon of the "aging process", and did not take any measures to reduce joint discomfort. Among those over the age of 65, nearly 40% of patients chose to "accept their fate" and give up the treatment (Mylan, 2020).

Emotion

3) Bad Emotion. As the disease develops badly, it not only brings physical pain and hinders the patient's actions seriously, but also causes a huge psychological burden on the patient. 50% of patients with osteoarthritis said they were in a state of "extreme anxiety" for a long time, and 25% of patients often felt "frustration" (Mylan, 2020).

Social support

4) Less Social support. The study of He et al. (2013) shows that patients with osteoarthritis usually have less time for exercise and lower scores in cognitive symptom management practice and communication with doctors, which indicates that patients lack cognition and skills on exercise and emotion management, as well as the lack of professional support.

4.1.4 Requirements about Digital Health Products in China

From digital health to digital therapeutics, the development in China is still in its infancy. China has not yet clearly defined the definition, scope, and application scenarios of digital health or digital therapeutics, but it is gradually improving the rules and requirements to launch a digital health technology.

In December 2017, the China Food and Drug Administration (CFDA) published the "Guidelines for Technical Review of Mobile Medical Device Registration", clarifying that all mobile medical independent software or software + hardware used for patient management are medical devices, and their regulatory scope and requirements need to be clear.

In July 2021, the National Medical Products Administration (NMPA) issued the Guiding Principles for the Classification and Definition of Artificial Intelligence Medical Software Products, defining the classification of artificial intelligence (AI) medical devices, from Classification III (lower application maturity in the medical field) to Classification II.

In March 2022, NMPA issued the "Guiding Principles for the Registration and Review of Artificial Intelligence Medical Devices", which stipulated more detailed principles in different aspects.

However, there is still no relevant policy on whether or how digital products approved for medical device registration can be integrated with the existing health insurance reimbursement system. This leads to the need for related products to explore feasible operation modes in China.

For example, the Shukang app was the first digital therapeutics (Classification II) approved by the NMPA in November 2020 to assist clinicians in guiding patients to perform cardiopulmonary rehabilitation training. However, the main income of Shukang comes from overseas, and insurance is the payer. The cognitive function evaluation and training software Best Covered (Classification II) earned money mainly from cooperation with the government (to build a cognition-friendly community) and commercial insurance.

4.2 Study on the Self-Management of Knee Osteoarthritis in Shanghai

4.2.1 Objectives and Methods

Objectives

In the previous chapter, through the study of KOA management, it is clear to know the expected KOA self-management process and the responsibilities of community healthcare and the hospital during the process of KOA self-management.

However, it can also be found that patients' self-management of KOA always faces different obstacles in real life, the same as the common chronic disease management. Some obstacles may come from the patient's trust in primary care, and some may relate to the information, channel, or efficiency. In addition, there is less practice and procedures for KOA self-management compared with the four common chronic diseases. It needs more details to define the problems and find a breakthrough for the current system.

A smaller location should be focused on to get specific information, as China allows different regions to develop their own regulations about CDM based on the general policies and there are big differences among regions in China, from the aspect of geography, economy, population, etc.

This section will focus on the area of Shanghai city to get more detailed data for design research and design practice. Shanghai is a special and typical Chinese city that is facing a challenge from ageing and chronic disease.

Thus, the purpose of the study is divided into different objectives as follow:

- Learn about Shanghai's special situation, including population, geography, and regulations related to the healthcare system and chronic disease management.
- Determine on actors involved in KOA self-management, and how they work.
- Understand patients' cognition and attitude towards KOA and KOA self-management. Understand the patient's daily self-management condition, know the patient's behavior and attitudes about disease self-managemen.
- Figure out the real support that patients know or feel in the process of patient self-management: Who are the main helpers and what do they do? As well as the problems and expectations they faced before (including the support provided to patients by GPs and hospitals).
- Understand patients' acceptance and expectations of smart health products.

Methods

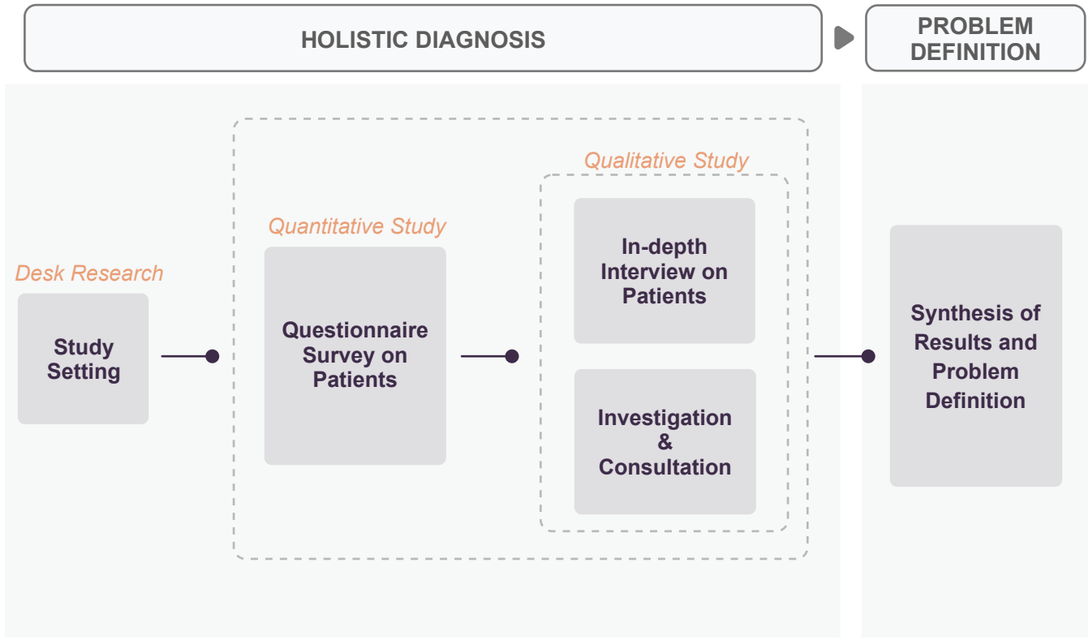
The study on the status quo of the self-management of KOA in Shanghai mainly applied these research methods: desk research, quantitative study (questionnaire survey) and qualitative study (interviews and observation). The implementation process is introduced as follows.

Firstly, conduct desk research to know about the context of CDM in Shanghai, including the aspects of population, geography, and regulations related to the healthcare system and chronic disease management.

Secondly, use the questionnaire survey to collect the overall situation of patients' knee health management, including basic information, disease conditions, self-management, healthcare resources understanding and use, assist products use, etc., to clarify research priorities for qualitative research.

After the survey, it enters qualitative research. Qualitative research mainly conducts interviews to obtain detailed information from the interviewee. According to desk research before, the interviewees may include KOA patients, community GPs, and related doctors in hospitals, all of which are important actors in the KOA self-management system and can uncover the situation.

Figure 4.14 Research path and methods



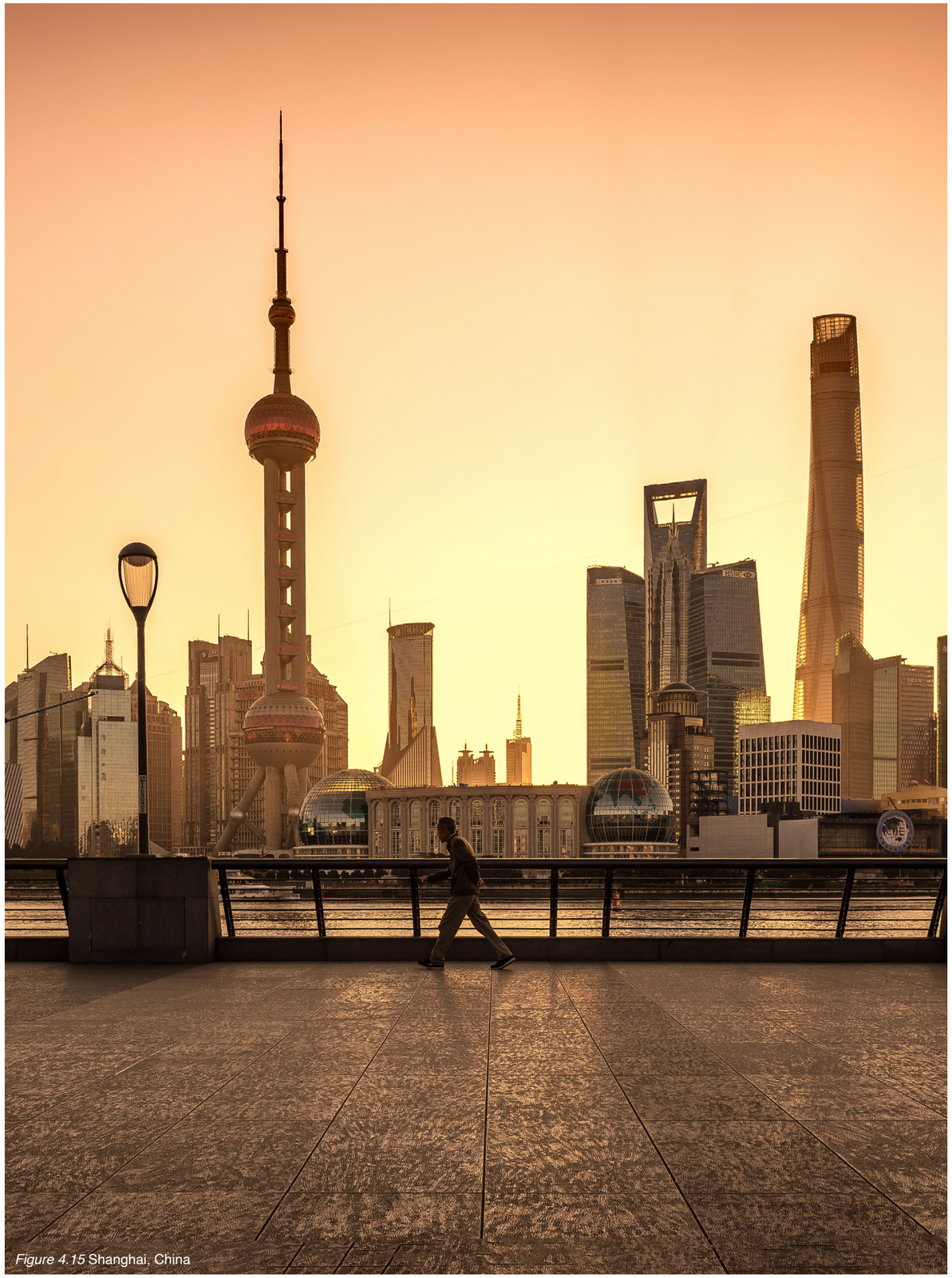


Figure 4.15 Shanghai, China

Source: Image by Nick M on flickr (2019, November). https://www.flickr.com/photos/thegrimfandango/49153927177/in/photostream/

Figure 4.16 A typical shikumen neighborhood in Shanghai
Source: Image by Yang Jian (2015, October 18). https://archive.shine.cn/sunday/Once-common-way-of-life-fades-away/

Figure 4.17 Shanghai Animal Street Life Hongkou

Source: Image by Dr. Matthias Ripp on flickr (2014, December 12). https://www.flickr.com/photos/56218409@N03/15817567137/in/photostream/

4.2.2 Desk Research

Population of Shanghai

Shanghai, one of the four direct-administered municipalities of China, is located in the eastern and coastal area of China. The city has 16 districts, with a total area of 6340.5 square kilometers. In 2020, there were 24.87 million residents in the city (Information Office of the Shanghai Municipal People's Government, 2022), making Shanghai the most populous urban area in China.

By the end of 2021, a total of 16.1343 million people (including retirees) participated in the basic medical insurance for employees, and 3.6505 million people participated in the basic medical insurance for urban and rural residents. The number of people who participate in long-term care insurance benefits was 381,000 (Shanghai Municipal Statistics Bureau, 2022).

Shanghai created so many great growing numbers and achievements, but it is also one of the earliest cities in China to enter the ageing society, as well as one of the cities with the deepest ageing degree. In 2020, residents aged 60 and above account for 23.4% of the total population and 16.3% are aged 65 and above (Information Office of the Shanghai Municipal People's Government, 2022). Moreover, according to forecasts, by 2030, 40% of the population with registered permanent residence in Shanghai will be aged 60 and above, and from 2040 to 2050, the share is expected to reach 44.5%, making Shanghai one of the most ageing cities in the world (Shanghai Observer, 2020). The ageing society will make severe challenges to the planning of the health system.

Medical resources in Shanghai

Shanghai has abundant medical resources. In 2021, the number of beds, the number of health technicians and the number of licensed (assistant) physicians in Shanghai will all be among the top three in China. By the end of 2021, there were 6317 health care institutions in Shanghai, consisting of 335 Community Health Service Centers, 432 hospitals, 1397 outpatient departments, and so on (Shanghai Municipal Bureau of Statistics, 2022).

However, facing a population of more than 20 million residents, Shanghai's medical resources per capita are not outstanding. According to the study (Souhu City, 2022), the number of beds in health institutions per thousand people is 6.49 (the national average is 6.77), the number of health technical personnel per thousand people is 9.62 (the national average is 7.95), and the number of licensed (assistant) physicians per thousand people is 3.34 (the national average is 3.02).

In addition, probably due to the provision of healthcare services for patients nationwide, Shanghai's medical resource load is high. In 2021, Shanghai is the city with the largest number of diagnosis and treatment visits, a total of 272 million. It is one of the two cities with more than 200 million visits.

Figure 4.18 Shanghai Geography and Population (2021)

Source: Data from Information Office of the Shanghai Municipal People's Government, 2022

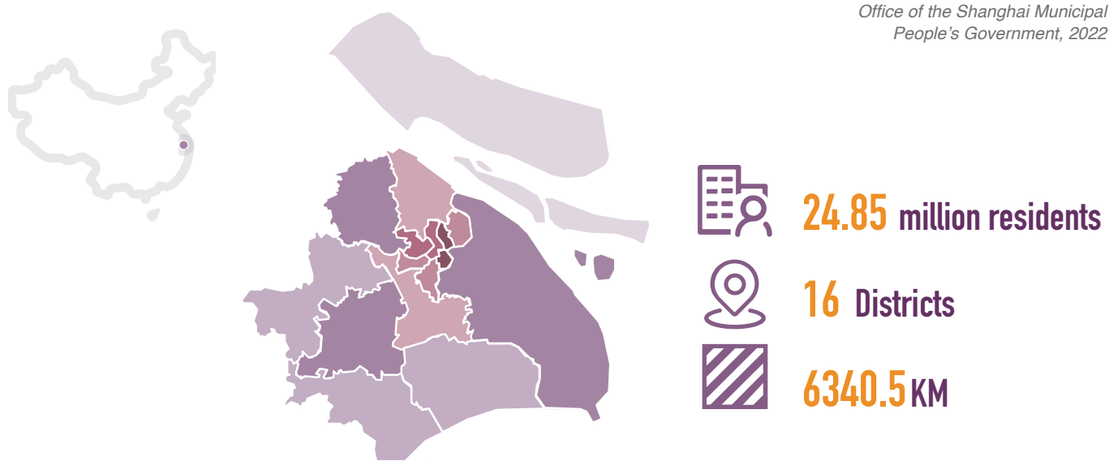
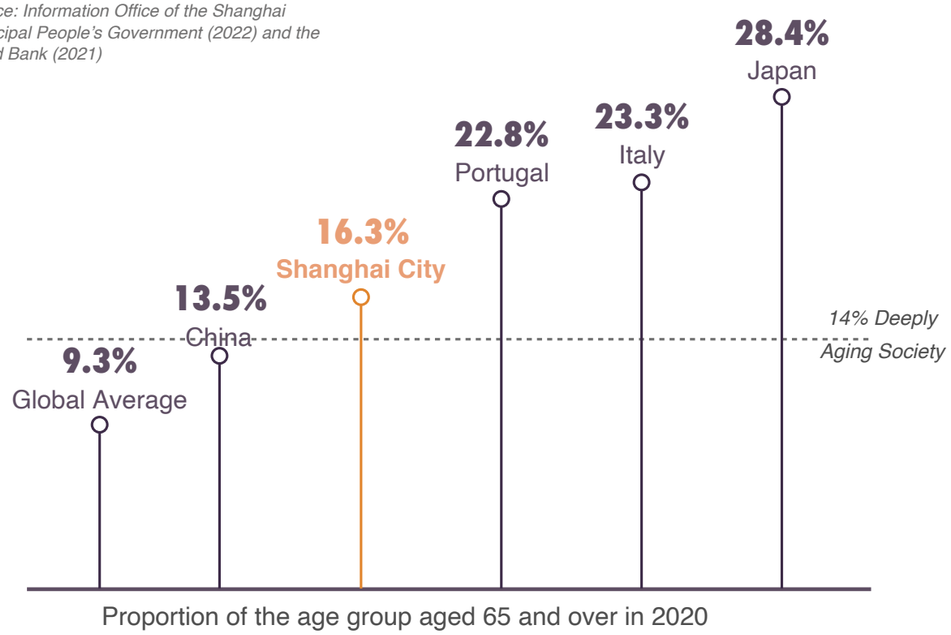


Figure 4.19 Proportion of the age group aged 65 and over in 2020

Source: Information Office of the Shanghai Municipal People's Government (2022) and the World Bank (2021)



Shanghai "1+1+1" Family Doctor Contracted Services

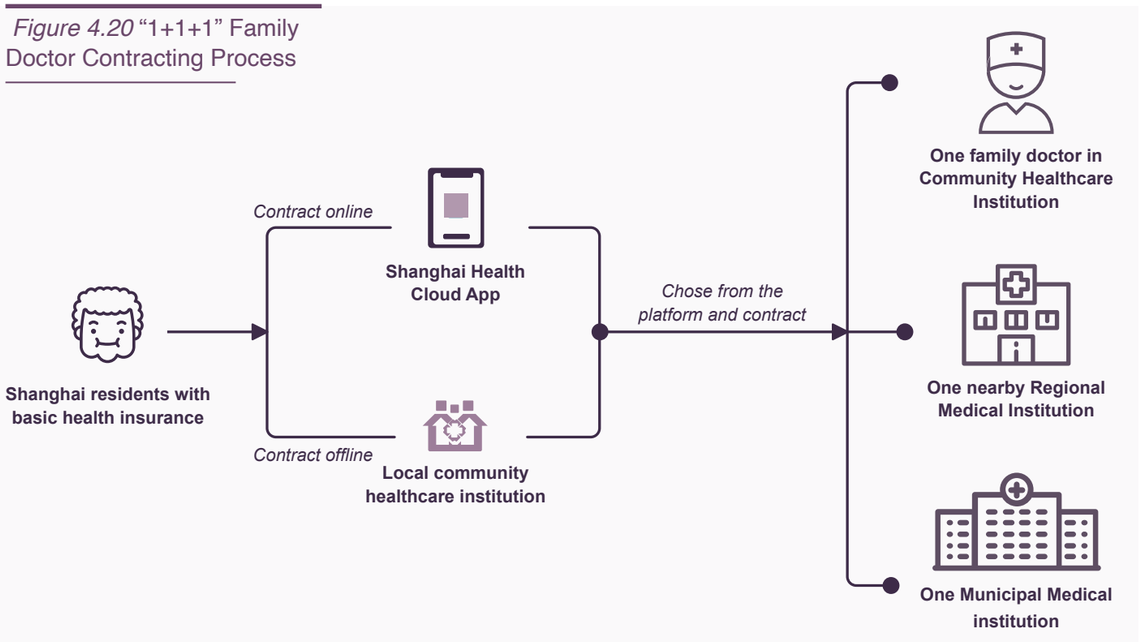
In 2016, the National Medical Reform Office released a document "Guiding Opinions on Promoting Family Doctor Contracted Services", proposing recommendations and guidance to FD contracted services. The specific implementation of FD contracted services varied among regions, cities, and hospitals.

As one of these pilot cities, the Shanghai municipal government implemented a new policy for '1+1+1' FD contracted services in June 2015 and promote the policy in the city in 2016. This policy allowed a resident with Shanghai basic medical insurance to sign with 1 family doctor in the Community Healthcare Institutions (including centers, sub-centers, service stations, and village clinics), as well as with 1 regional medical center and 1 municipal medical center (Shanghai Municipal Health Commission, 2020).

The three kinds of healthcare institutions undertake different duties and are devoted to providing thoughtful healthcare services to contracted residents together (Shanghai Municipal Health Commission, 2021).

- Municipal Medical Institutions are responsible for the diagnosis and treatment of critical and intractable diseases, specialist medical services in the city, and guiding the development of regional and primary healthcare institutions.
- Regional Medical Institutions provide residents in the region with basic medical service needs, such as outpatient, inpatient services, and emergency services for common diseases and frequently-occurring diseases.
- Health Care Institutions at Grassroot Level mainly consist of community healthcare centers (stations), village clinics, and outpatient departments. They undertake basic public health services such as preventive health care and health education, and medical services such as diagnosis and treatment, rehabilitation, and nursing of common and frequently-occurring diseases.

Figure 4.20 "1+1+1" Family Doctor Contracting Process



After the contract, the resident can see a doctor in any medical institution in 1+1+1, or be referred by a family doctor, and enjoy a series of preferential policies, including free examinations, two-month medication prescriptions for patients with NCDs, extended prescriptions, stay-home healthcare, and higher reimbursement (Shanghai Municipal Health Commission, 2020).

On December 29, 2021, the "Shanghai Internet + Family Doctor Contracting Service Platform" was launched and residents can use can log in to the "Shanghai Health Cloud APP" and sign a family doctor online. In addition, through the platform, contracted residents can conduct online health consultations with family doctors timely (Shanghai Release, 2021).

The family doctor must be a qualified general practitioner and always work in a family doctor team. Each team is equipped with at least one family doctor, one community nurse, one public health physician (full-time or part-time), and one rehabilitation therapist. Some other members can be taken into account such as physiatrists (rehabilitation physicians) and clinical pharmacists.

On the other hand, the salary structure of family doctors is different from that of traditional Chinese doctors. The contract signing fee for family doctors is a reflection of the value of the continuous health management service provided by the family doctor (team) to the contracted residents. As part of the income of the community health care institutions where the family doctor team is located, the contract signing fee can be used for staff salary distribution.

A study on the status of family doctor's salaries shows that the contracted service fees have a higher effect on the compensation of family doctors. According to the investigation of a community health care institution in Changning district, Shanghai. The contracted service fees accounted for 61% of the monthly income of family doctors in 2018, and for other team members in family doctor teams, the number was nearly 30% (TIAN et al., 2020).

By the end of 2021, the number of contracted residents is more than 8.64 million, with above 34% contracting rate. More than 4.39 million contracted residents were key groups (elderly people over 65s, pregnant women, children, patients with chronic diseases such as hypertensive and diabetes, patients the serious symptoms...), and the contracting rate reached 77%.

4.2.3 Questionnaire Survey on Patients

Questionnaire Design and Implementation

After taking an uncomplete overview of the related background, detailed research about the management of KOA will be conducted outside the regulations and policy documents.

The purpose of the questionnaire survey is to understand the knee health management of people with knee pain problems in daily life, define the target group and prioritize problems. In this survey, not all respondents were diagnosed with KOA. The reason for not limiting the investigation scope to patients diagnosed with KOA is that there are many "potential patients" who are with pre/early KOA while not going to the hospital to be diagnosed by a doctor.

The questionnaire includes the patient's basic demographic information, disease situation, self-management situation, understanding and use of medical resources, and use of related products, etc. (the complete questionnaire is in the appendix).

Two ways are used for the distribution of the questionnaire: "Online platform distribution" and "offline guidance to fill in". Through online channels, participants are between 45 and 60 years old. Therefore, the offline distribution mainly collects information on patients over 60 years old.

Online Collection

/Time:
2020/12/08 ~ 2021/03/04

/Place:
- Tencent Questionnair Platform

Offline Collection

/Time:
2021/12/07, 2021/12/11

/Place: (Yangpu District, Shanghai)
- Fuxin Lu Cmty. Good Neighbor Center
- Huangxin Park

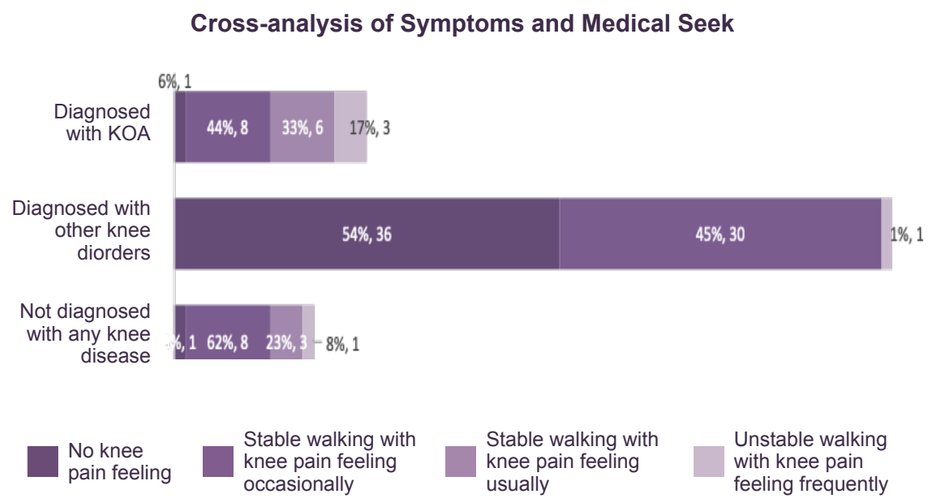
Sample Description and Results

There was a total of 98 persons who responded to the survey.

53% were male and 47% were female. The 50-65 age group accounted for 48%, the 40-50 age group 32%, and the 65-80 age group 12%. The main results of the questionnaire survey are summarized as follows.

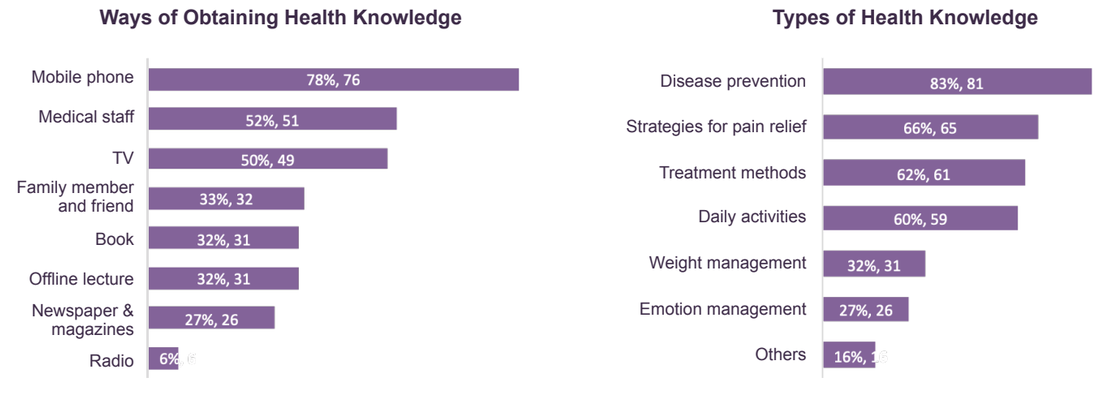
Figure 4.21 Sample Description

Figure 4.22 Symptoms and Medical Seek



The majority of respondents diagnosed with KOA or other knee problems were suffering from knee pain of different degrees. However, 45% of respondents without a diagnosis have occasional knee pain, which means they actually have the initial symptoms of the knee disease but did not seek medical help in time. It indicates that patients with light symptoms did not pay enough attention to managing the disease.

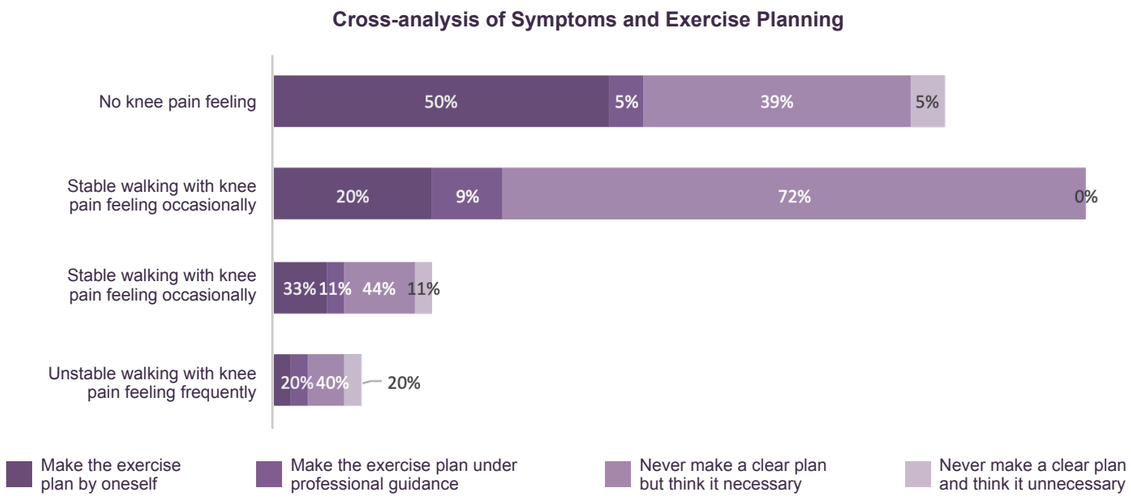
Figure 4.23 Health Knowledge



In terms of ways of acquiring health knowledge, "the mobile phone" is still the first medium for people of all age groups to choose to acquire health and medical knowledge, then followed by "consulting medical staff" and "watching TV".

When asked about the types of health knowledge wanted to acquire, the majority of respondents chose "disease prevention knowledge", "health strategies for pain relief" and "daily exercise advice"

Figure 4.24 Exercise Planning



When asked about their situation of exercise plan making, only 8% used to make an exercise plan under professional guidance. An exercise plan is defined as regular and targeted exercise behaviors, which include aerobic exercise, exercise therapy, etc. More than half (55%) of respondents stated that they "never make a clear exercise plan, but think it is necessary", and 33% of respondents said that they "make the exercise plan by themselves".

Additionally, respondents with early symptoms of KOA (who chose "stable walking with knee pain feeling occasionally") had the lowest rate of making an exercise plan, but the majority of them (72%) thought that a clear exercise plan is necessary.

Figure 4.25 Daily Exercise

Specific to the type of exercise that respondents have tried, 67% of them used to do "aerobic exercise (walking, swimming, etc.)" in their daily life. Nearly half (45%) of respondents did knee flexion and extension exercises before, and a few (29%) did muscle strength training.

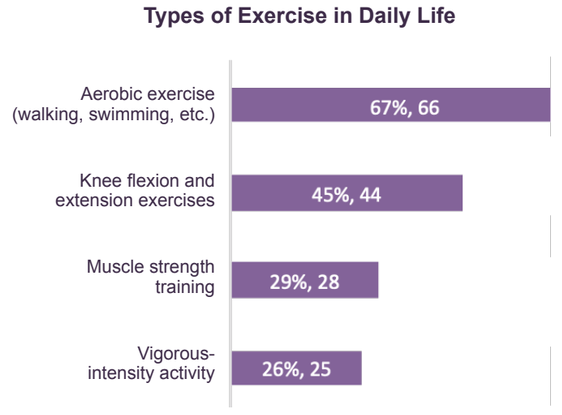


Figure 4.26 Unhealthy Behaviors

When it comes to the unhealthy behaviors in the respondents' daily life, "sedentary" is the most common unhealthy behavior, with 62% of respondents having the problem. Nearly half (48%) of the respondents thought they move in an incorrect and harmful way, while "vigorous activity" (40%) and "standing for a long time" (36%) are also common unhealthy behaviors for respondents.

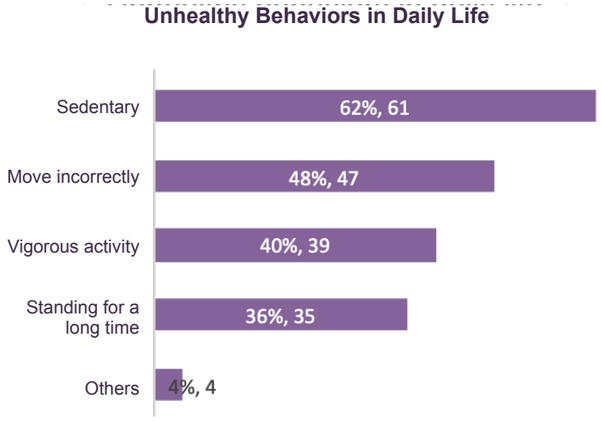


Figure 4.27 Helpful Persons

Most of the respondents believed that relatives and hospital doctors are the roles who can give more help in the process of disease management in daily life, 67 % compared to 64%. Half of them thought that friends also provide much help. Relatively, they seldom thought medical staff (GPs or other healthcare providers) in primary care could help them with KOA management.

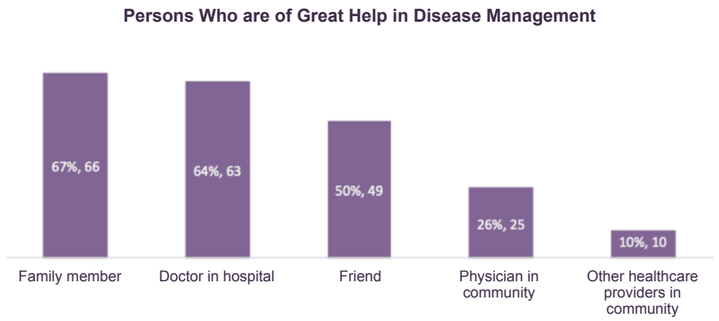


Figure 4.28 Duties of Community Healthcare

When asked what tasks they thought that healthcare providers in primary care could undertake in the KOA management, 70% of the respondents believed that the healthcare providers could carry out "health education", and nearly half of them chose “exercise guidance" (49%) and “assist in health management plan” (45%). Nearly one-third thought that primary care facilities could also help with "contact up-level hospitals, "diagnosis and treatment", and “supervision and reminder”.

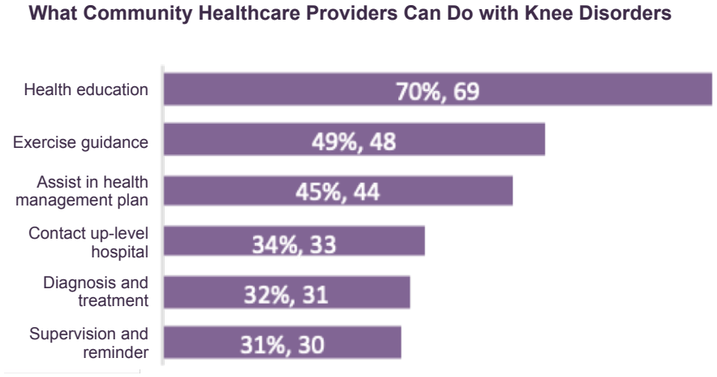
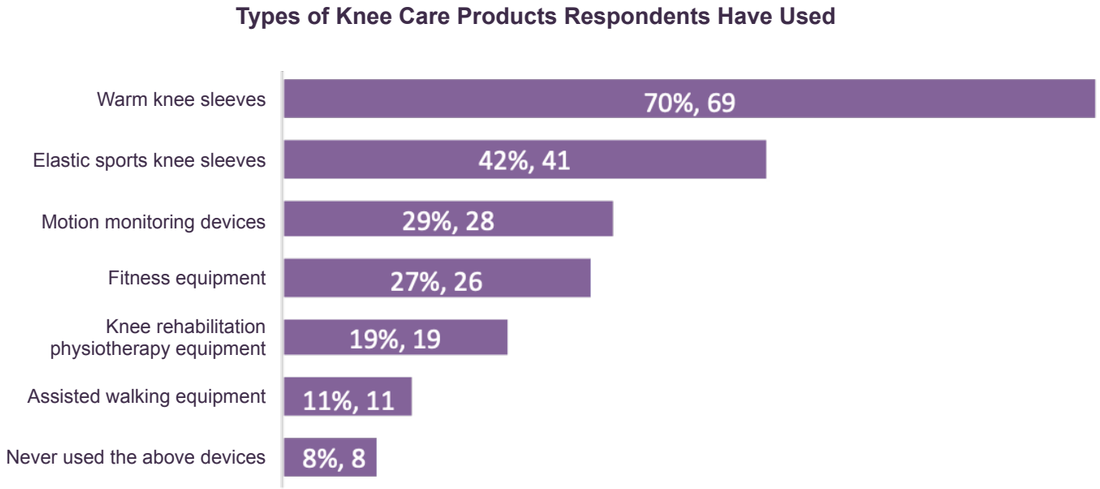
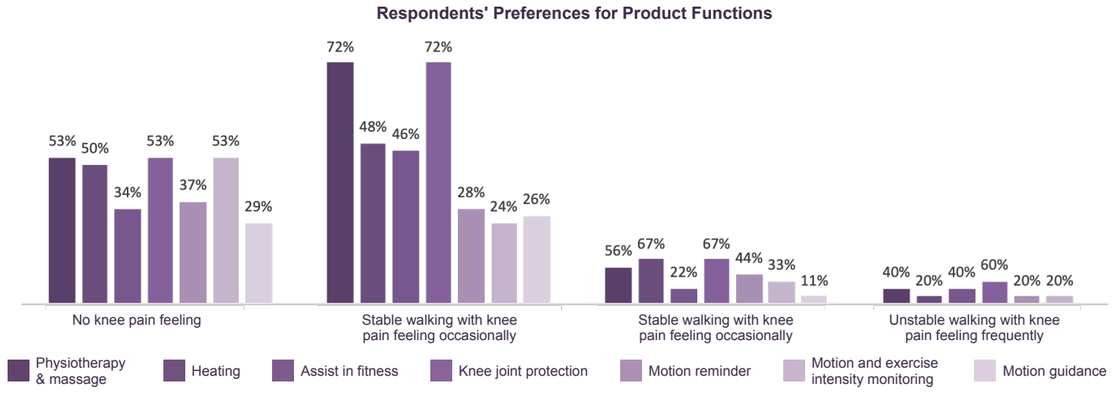


Figure 4.29 Knee Care Products



Regarding the related product, 70% of the respondents have used warm knee sleeves and 42% of them have used elastic sports knee sleeves for protection, indicating that the crowd has a high degree of acceptance of this type of product. In addition, younger respondents in 40-49 age group also used motion monitoring devices, such as smart bands.

Figure 4.30 Product Functions



In terms of product functional requirements, "knee joint protection" is the most needed function by all groups of respondents, followed by "physiotherapy & massage" and "heating". Respondents with occasional knee pain are more interested in the "assist in fitness" than other groups, while those who don't yet have knee pain are more interested in the "activity and motion monitoring" feature.

4.2.4 Qualitative Study on Key Actors

Sampling of Key Actors and Data collection

There were four types of key actors: patients with KOA, medical staff in primary care facilities, orthopedists, and physiatrists.

Two primary care facilities were selected for initial observation: One is a Community Healthcare Center, and another is a Community Healthcare Station. The two facilities were located in communities with more elderly residents, which means they are more likely to be in contact with (potential) patients with KOA. At the same time, a short interview with a GP (also a family doctor) at the Community Healthcare Station was conducted (the interview summary can be found in the appendix).

When investigating perspectives on KOA management from orthopedists in upper hospitals, two experienced orthopedists in tertiary hospitals are contacted through online platforms. Each investigation lasted for 15 minutes and was recorded for further research.

One physiatrist in a tertiary hospital in Shanghai was invited to provide professional knowledge about KOA management, and the situation of KOA patients' medical treatment conditions in the rehabilitation department of the hospital. A questionnaire was used to collect all information.

Patients with KOA are the main research subjects during design research, considering the patient-center design of the product level. 7 patients were recruited, ranging in age from 50 to 80 years old. Among them, 6 were diagnosed with different degrees of KOA, and 1 interviewee was undiagnosed but experienced mild knee pain.

The in-depth interview was one-on-one, and the time for each interview ranged from 30 mins to 90 mins. Patients can choose to participate in the interviews online or offline. Locations of the offline interviews included community activity centers and public parks.

Figure 4.31 Qualitative Study

Community Health Service Center	Doctor in Hospital	Patient with KOA
- Time - 2020/12/11 **- Place -** Chifeng Community Family Clinic; Quyang Subdistrict Community Health Service Center **- Research Methods -** Short Interview with a FD; Observation	**- Time -** 2020/ Dec.; 2021/ Sept. **- Place -** Online tele consulting to Orthopedist x2 Questionnaire survey to Phyisiatrist x1 **- Research Methods -** Short Interview; Questionnaire	**- Time -** 2020/12/07~ 2021/Jan. **- Place -** a. Online: Tele interview b. Offline: Fuxin Lu Cmty. Good Neighbor Center; Huangxin Park (Yangpu District, Shanghai) **- Research Methods -** Deep Interview

Figure 4.32 Interviewing a respondent

Place: Huanxing Park, Yangpu district, Shanghai
Time: 2020/12/11

Source: Author's own photograph

Figure 4.33 Photo of a community family clinic and its bulletin

Source: Author's own photograph

4.3 Synthesis of Results and Problem Definition

4.3.1 At the System Level: Current System Map

In the context of business and society, an Ecosystem refers to a network of interrelated elements, which provides the basis for resource integration and value co-creation for its participants in the way of mutual circulation of resources (Granstrand & Holgersson, 2020). Actors are considered as the basic resources and resource integrators in the system. The biggest difference between Actors and other elements or resource flows of the system is that an actor can manipulate other elements or different types of resource flows actively for their own purposes (Tronvoll, 2017).

An “Ecosystem map” is a visualized tool to present an ecosystem that includes all the key actors of the system, connected by different lines according to the type of value they exchange (Forlizzi, 2013).

Through the preliminary investigation of the current situation of KOA self-management, it is found that KOA patients are expected to be the main actors to take care of their own health while many other actors and elements work together in order to ensure the effectiveness of self-management. Therefore, in this section, the current situation of knee osteoarthritis self-management is summarized, from the perspective of a system or ecosystem. The results are presented in the form of an ecosystem diagram as follows.

Introducing to main entities of the KOA self-management system

According to the research, 7 actors and 2 important elements in the system were identified, and different types of resource flow between actors or elements were expressed through different lines (See figure 4.34).

1) Patients with (early/progressive) KOA: Patients are at the center of system resource flow and they are influenced by different kinds of entities during KOA Self-management. It should be noted that the flow between patients with early KOA and medical institutions is less because they rarely visit any medical institutions. (Because patients with end-stage KOA were not involved in the investigation, the group doesn’t show here.)

2) General Practitioners (in Community Health Care Institutions): General Practitioners (GPs) who work in Community Health Care Centers/Stations or Family Clinics are health gatekeepers for residents living in communities. In terms of KOA Self-management, they undertake the responsibilities of patient education, pre-screening, referral, and supervision in management. If the GP contracts with a patient and becomes a family doctor, the GP will take more responsibility for the contracted patient.

   During the investigation, it found that the capacity of the majority of GPs to diagnose and treat musculoskeletal diseases was limited (if they have no experience with these disease types), and they need more external support from other specialists. As general practitioners, family doctors without related knowledge usually have no confidence to provide exercise advice for patients, but they can contact rehabilitation specialists and ask for exercise advice for their contracted patients. Specialists may only visit the community health service institution several times a week for consultation. Some bigger community health care centers have set up inner rehabilitation departments and physiatrists.

3) Orthopedists: Orthopedists are doctors often in tier-2 or tier-3 medical institutions. They are professional to deal with patients' serious and emergency situations on bones or joints, getting used to using treatment methods, such as surgery and medication. However, when they first meet the patient, they may tend to think patients are at risk no matter what disease stage the patients are in.

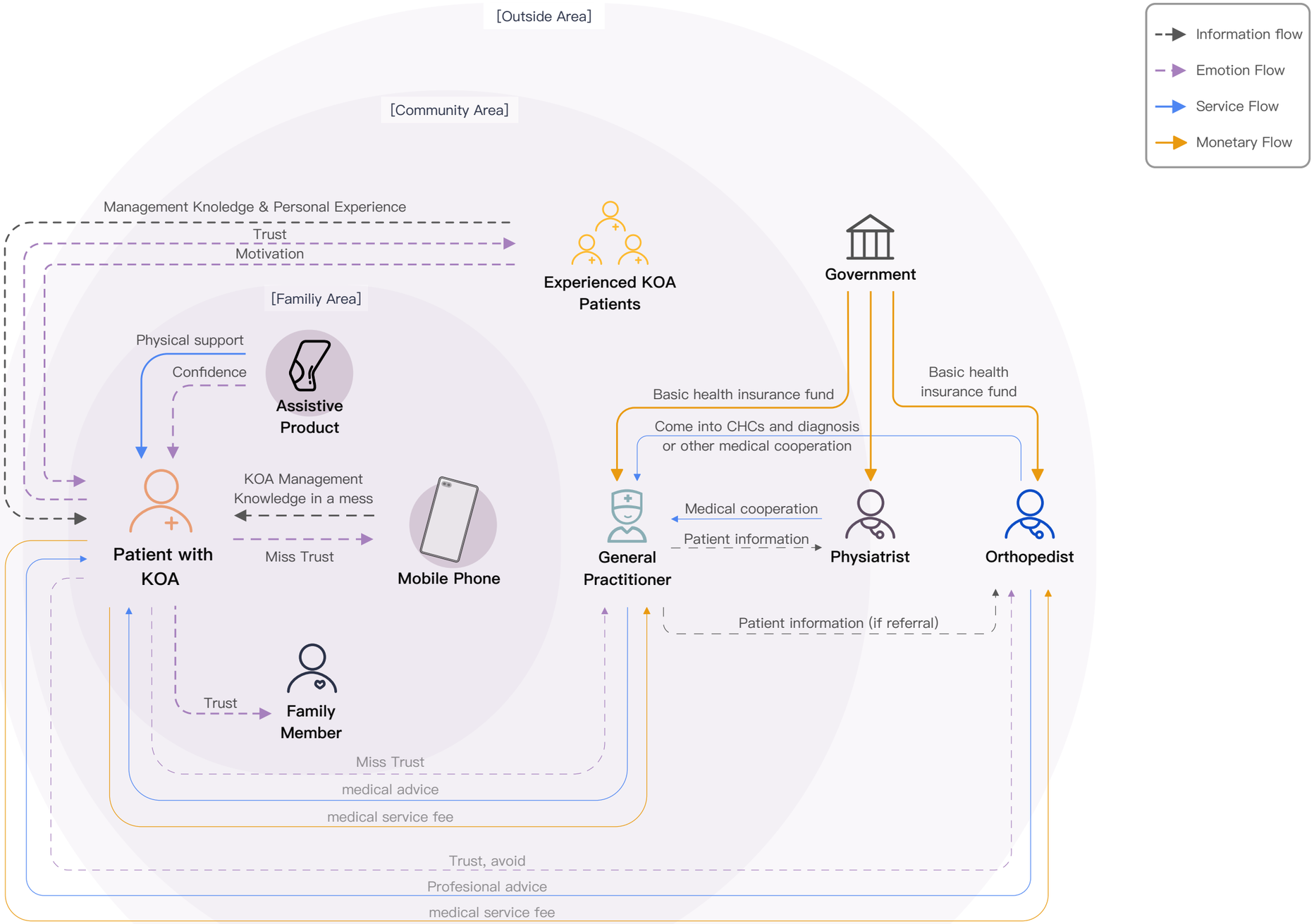
4) Physiatrists (rehabilitation physicians): Physiatrists focus on assisting the general improvement of functional recovery in disabled patients, but historically, physiatry originated from two different fields, physical medicine and rehabilitation, thus "health and welfare" is another field that they can help patients (Lee P. K., 2011). Physiatrists often have professional knowledge of conservative treatment and often work with other rehabilitation specialists including physical therapists (PTs), occupational therapists, and speech therapists. Compared with orthopedists, physiatrists can provide more help for patients during KOA self-management.

   On the other hand, physiatrists tend to have closer and more flexible cooperation with community healthcare centers. Physiatrists can work not only in upper-level hospitals but also work in communities. Some community health care centers have set up inner rehabilitation departments or even Community Rehabilitation Centers, letting physiatrists and their teams provide diagnosis and treatment services for patients in need nearby.

5) Family Members: During the investigation, it found that although family members seldom provide help for the patient’s daily disease management, they are often the most frequently mentioned people by the patient and are closely related to the patient. They have been with patients for the longest time and maintain a trustful and intimate relationship. At the same time, they are also concerned about the health of their patients and are willing to help when needed.

6) Experienced KOA Patients: Another type of role that affects the patient's daily disease management is patients' friends who have lived with KOA for a long time. They often have a better understanding of disease management. Similar situations and needs make patients and their friends often have

Figure 4.34 Current Ecosystem Map for KOA Self-management



disease-related chats, and experienced patients can often share their experiences, knowledge, and doctor's information, which is very helpful for patients with pre/early KOA.

7) Government (managing the basic health insurance fund): With the National Healthcare Security Administration and local healthcare security administration as the main relevant institutions, in charge of health insurance plan and medical service bidding and procurement, and is responsible for the supervision and management of health insurance funds.

In addition to the 7 actors, the system map also shows two important physical elements that many patients would use in daily life: assistive products and mobile devices.

Mobile Phone

According to the study, the main types of assistive products commonly used by patients are common knee sleeves (usually thick, soft, with warm keeping, some have the function of self-heating or even electric heating) and sports knee sleeves (light, thin, pressured sleeves, some with patella silicone ring). When the weather is cold or they feel knee pain, some patients will wear thick knee sleeves for warming at home or other places where they can sit and lie down without moving. On the other hand, when performing daily walking activities or more vigorous physical activities, some patients will wear sports knee sleeves intending to help with joint immobilization. From a professional medical point of view, some knee sleeves do can provide warmth or protection for a patient's knee health care.

Assistive Product

Mobile devices include smartphones, tablets, or wristbands. The patients who wear the smart band are younger. Tablets are used occasionally at home, and thus smartphones are still the device most patients carry with them the most of time. Patients usually use their mobile phones to contact others or to view information on the Internet such as news.

Another issue is that the two physical elements can be linked to more actors such as product suppliers, mobile phone manufacturers, and Internet companies. However, they will not be discussed in the current situation because of their limited impact on the system.

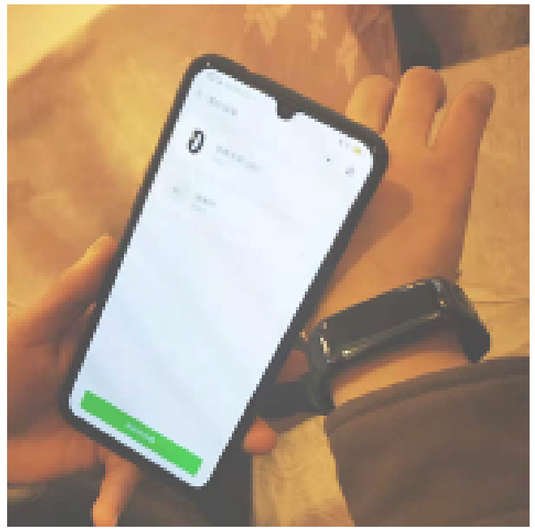


Figure 4.35 A respondent is showing her smart bracelets and related mobile app

Source: Author's own photograph

Figure 4.36 A respondent is showing his sports knee sleeve wearing during the daily life

Source: Author's own photograph

4.3.2 At the Process Level: Current Process and Order

By summarizing the system level of the current situation, the main elements and the relations among them of the current system are known. At the process level, it summarizes the way how these elements work together to realize the process of KOA self-management, and what the process looks like (compared to the expected process), concluding the specific problems.

In the case study of Shanghai, a typical patient's journey map of the KOA self-management process can be shown in figure 4.37. On the other hand, figure 4.38 highlights the explored problems of the journey and process. These problems are similar to what was mentioned in the general KOA self-management process according to desk research, but they also indicate the special local features of Shanghai.

Problem 1: Medical staff in primary care facilities tend to provide patients with passive support during KOA self-management.

It shows that patients' self-management ability has a lot to do with the activities that the medical staff participated in in the early stage.

As one of the primary care facilities, the Community Healthcare Centers (CHCs), as well as medical staff in CHCs, should play the role of good gatekeepers. They should make patients aware of the harm of the disease through patient education, and provide basic medical care and timely referral to delay the deterioration of the patient's disease as much as possible.

However, according to the interview with the family doctor, it was found that in the process of KOA self-management, some medical staff in primary care tend to provide medical services passively, which may make patients who need such medical services miss the opportunity to know about the disease and manage it. Take "Patient Education" as an example, the result of the patient survey shows that "the community healthcare centers never provide health education". However, the family doctor said that the center will hold this kind of activity, but patients need to contact the medical staff in the region first, to obtain promotional materials and activity arrangements. Apart from this, the family doctor also said that if patients don't ask, she won't provide her patients actively with services or advice like "pre-screening of KOA" and "contact rehab specialists".

On the other hand, medical staff in community healthcare center may live with a busy work day. According to the observation, it shows that most of the GPs were actually busy and had less free time. In the larger community healthcare center, patients were queuing to see a doctor, which is a bit different from the hypothesis of no patients. The "popular" situation of community healthcare centers may be a special phenomenon in several cities such as Shanghai. The main areas in which the fieldwork was carried out are Yangpu District and Hongkou District in Shanghai, where Aging is serious, the medical resources are sufficient, and the community healthcare is well developed relatively, causing more patients willing to go to primary care facilities for medical treatment.

> *Community doctors can't do much work. Some of them arrive at the community healthcare centers at 8:30 and leave work at 11:50, returning to the hospital in the afternoon. They usually only get off work for half a day and have no time at all. (R3)*
>
> *I signed a young family doctor before, but I only saw him once. It seems that he has two different working points, and I never see him every time I go to one point, so I simply don't go there anymore. (R6)*

Problem 2: Patients start to seek medical help only when it gets worse. They also know less about the different duties of specialist physicians on KOA management.

Information from the investigation on orthopedists and physiatrists shows that they are two types of doctors with very different capabilities and duties during KOA management, which makes them match patients in different disease stages. However, patients seldom know about the issue accurately and often cannot find suitable medical help for themselves.

Physiatrists are more suitable candidates for patients with pre/early KOA, due to their professional knowledge of conservative treatment. Physiatrists in the rehabilitation department usually treat patients with drug therapy, physical therapy, and exercise training. Compared with orthopedists, physiatrists are experts in Exercise plan formulation and guidance and they can help patients with the personalized management plan. Additionally, the physiatrist who responded to the survey said that the Rehabilitation Department will provide a one-time collective rehabilitation education for patients, explaining the specific home rehabilitation exercise training. Patients can take videos or photos and bring back the written pictures and text version materials.

However, in Chinese elderly patients' mindsets, the orthopedist in an upper-level hospital is the only doctor to deal with knee problems. This kind of thought may be relevant to their ways of going to the hospital. From most of the patients' perspectives, medical staff in primary care facilities do not have the expertise to treat KOA. And in the traditional Chinese people's point of view, hospitals are places that should be avoided.

> *I didn't go to the doctor, I only checked it online and found that there are quite a few people over 50 years old having the disease, so I didn't care. I didn't pay attention to it and I just took a health supplement when I was in pain. (R1)*
>
> *I have had a serious illness before, and I don't think this minor illness has anything that needs to be dealt with. (R4)*

In the early stages of KOA, patients generally do not pay attention to knee health because the symptom does not affect daily life. Therefore, most of the time, patients finally go the see a doctor only when they cannot bear knee pain or occur an early acute condition suddenly. It means that the disease has progressed to a more severe stage or needs acute intervention. In this period, orthopedists are thought of as their only choice. Even after the diagnosis, some patients do not take active ways to treat and manage their knee health. Some patients would finally know about physiatrists during their rehabilitation after the surgery.

Problem 3: Patients manage themselves without professional guidance or data-based evaluation, which may lead to ineffective or worse outcomes.

According to the interview, when patients with KOA find some problems with the knee joint (such as knee pain or difficulty in flexing/ extending), regardless of whether they go to a doctor or not, they will start to take care of knee health and adjust the behavior habits more or less, such as avoiding going upstairs and only doing the low intensive activities.

However, as indicated by the questionnaire survey, many patients lack professional guidance and knowledge in disease management, they adjust their daily exercise according to their feeling of physical conditions. But this kind of adjustment is more like a continued trial and error, lacking scientific guidance.

> *I cut down on activities that I think are unnecessary, such as going up and down stairs...I also don't climb mountains. I heard that walking 10,000 steps is not good. (R1)*
>
> *Now I can't do vigorous square dancing, I can't climb mountains or stairs. I can walk on flat ground, but I can't exercise vigorously, I can exercise a little. (R2)*
>
> *For a normal person, how much he eats and how much he consumes should keep in balance. If I feel uncomfortable, I won't exercise more even if I do less in a day. (R3)*

Meanwhile, patients also don't know the pros and cons that one motion could bring accurately, which is not good for them to evaluate themselves, adjust daily exercise plans, and persist for a long time.

Figure 4.37 Current process of the self-management of KOA

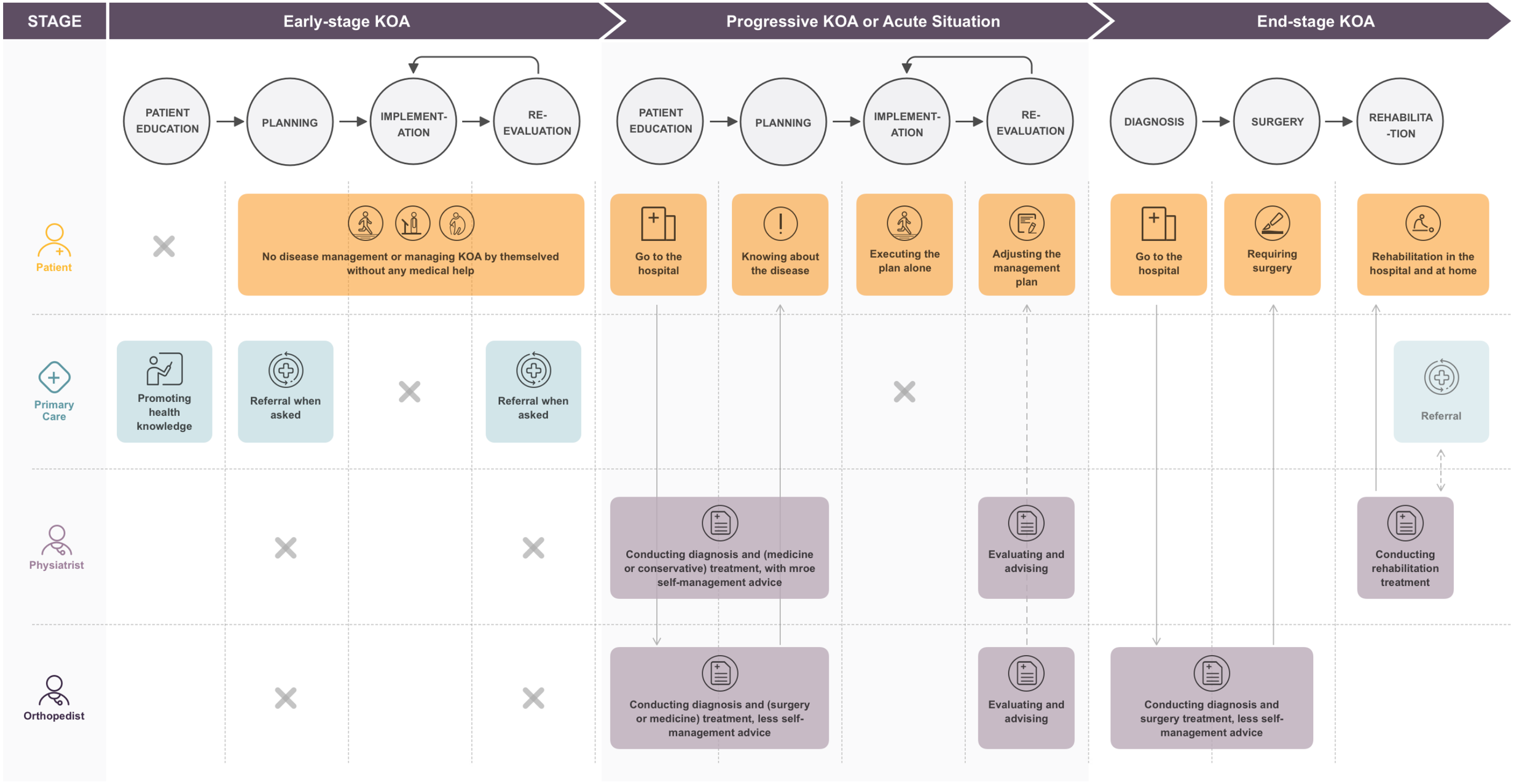
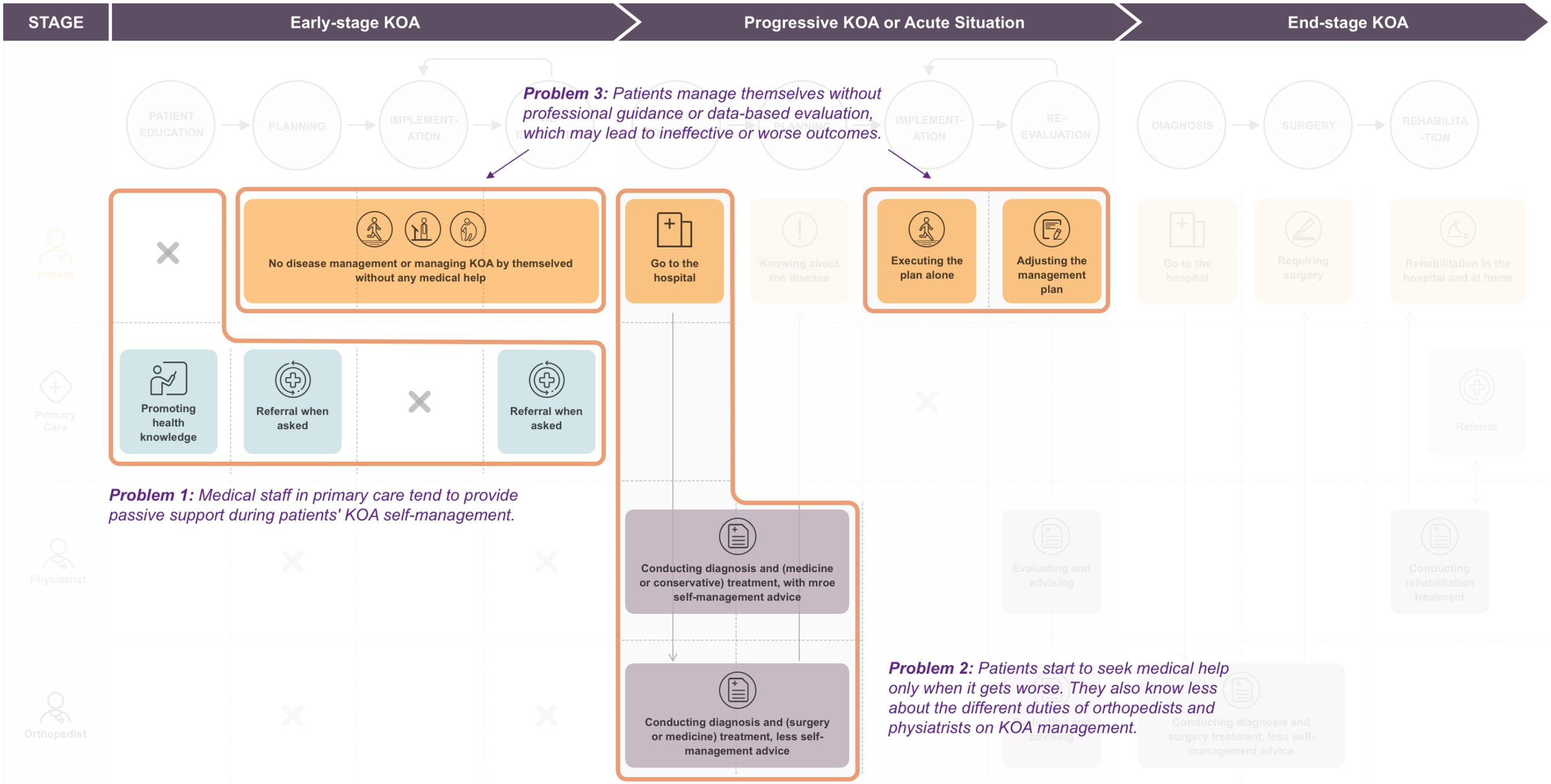


Figure 4.38 Problmes of Current process of the self-management of KOA



Problem 1: *Medical staff in primary care tend to provide passive support during patients' KOA self-management.*

Problem 2: *Patients start to seek medical help only when it gets worse. They also know less about the different duties of orthopedists and physiatrists on KOA management.*

4.3.3 At the Product Level: Personas, scenarios, and preferences of patients

Personas and target group selection

After sorting out the patient interview data and questionnaire survey data, there are big differences among patients. It is necessary to classify the patients and discuss them separately.

When using Consumer health technologies to develop a health application system for elderly chronic patients, Lerouge et al. (2007) believed that there are three main user-related factors that influence the design of healthcare products: (1) Basic demographic characteristics; (2) Specific health care characteristics, such as overall attitudes toward health, self-management behaviors, attitudes toward chronic disease management, and perceived challenges, as individuals' cognitive and behavioral patterns can influence the success of disease management or health behavior change interventions; (3) Technical characteristics, including the acceptation and usage of smart products.

The analysis of the results highlights differences among patients with different stages of KOA. Therefore, it takes age and stage of disease as the main criteria and builds the typical personas of patients with early-stage and progressive KOA. (Because of the limited time and resources, patients with end-stage KOA were not involved in the investigation.)

- Persona 1 called Zhang Ming, 52, is a KOA patient with early symptoms but has not yet been diagnosed in the hospital.
- Persona 2 called Wang Hong, 65, is an early KOA patient with more severe symptoms and has been diagnosed in the hospital, but is rarely reviewed.
- Persona 3 Li Xinzhi, 70, is an early-stage to progressive KOA patient who experienced acute symptoms and went to the hospital for diagnosis and treatment before.

KOA self-management has a greater meaning in disease prevention for patients in the early stage of KOA, and patients with more serious symptoms may need more related to pain management, drug treatment, and even postoperative rehabilitation. Therefore, in the period of product focusing, the thesis takes the patients with early-stage KOA (persona 1 & 2) as the main target groups and continues to explore the main scenarios and user needs of KOA self-management around target users.

"I hope I can do what I always like, without thinking about the disease."

SELF-MANAGEMENT BEHAVIORS

· Mainly use mobile phones to search for disease-related information
· Feel knee pain since several years ago and think herself get KOA, but has never been diagnosed by a doctor
· Pay attention to knee care gradually, trying foot bathing and massage at home
· Avoid doing some movements that are bad for joints, such as going up and down stairs, climbing, dancing, etc.
· Sometimes overuse joints when exercising or going out

LIMITATIONS

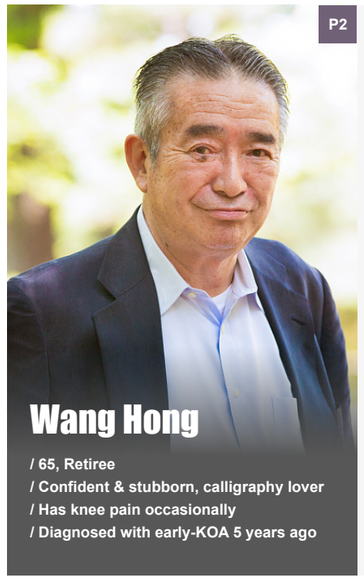
· Limited personal time
· Scheduling is always interrupted by family events
· Poor self-control, with escape and fluke mentality
· Lack of comprehensive knowledge of CDM

NEEDS

· Easy access to comprehensive and understandable knowledge of knee care management
· Get personal advice that fits her life rhythm and lifestyle
· Be reminded when exercising vigorously for a long time

USE OF RELATED PRODUCTS

Smartphone - WeChat, TikTok, ect.
Sports bracelet - Motion monitoring
Professional sports knee sleeves - Protect joints



"This is a dynamic process, take care of yourself and to maintain such a life."

SELF-MANAGEMENT BEHAVIORS

· Obtain disease management information mainly by reading relevant books and friends' personal experiences
· Rarely go to the hospital for review, only go to the community healthcare center for pharmacological treatment
· A very regular life, walking for a fixed time every day and sometimes using fitness equipment to stretch
· Pay attention to the health condition, constantly adjusting the plan to suit himself

LIMITATIONS

· Need to manage multiple diseases (like diabetes)
· Insufficient attention to joint disorders
· Do not trust doctors, believe personal experience
· Harmful movements without professional guidance

NEEDS

· Convenient way to help with exercise a moderate amount
· Co-agreed exercise program with professionals
· Joint protection during activities
· Keep knee warm

USE OF RELATED PRODUCTS

Smartphone - WeChat, Answer the call, ect. *(a bit difficult to learn)*
Smart Speaker - Music, weather forecast
Blood Glucose Meter - Non-connected medical equipment, used daily
Self-heating knee pads - Relieve joint pain

"I hope that when I get older, I can still walk outside and talk with others."

SELF-MANAGEMENT BEHAVIORS

· Go to the hospital regularly, and adhere to the doctor's advice
· A very regular life, insist on going out for walking every day, and do knee bending exercises at home
· Pay great attention to keeping warm and protecting joints, wearing knee pads and thick pants
· Often sedentary at home due to bodily functions

LIMITATIONS

· More sensitive skin
· Decreased eyesight, do not like to read text
· Can't remember things very well
· Be cautious about new attempts

NEEDS

· Knee joint protection
· Warming and pain relief
· Event and activity reminders
· Improve unsuitable lifestyle habits (like sedentary)

USE OF RELATED PRODUCTS

Smartphone - WeChat, Answer the call, ect. *(acceptance is not high)*
Joint Physiotherapy Massager - Hot compress, massage
Warm Knee Pads - Keep warming

Three major scenarios in the KOA self-management process

Through previous desk research and expert consultation, three management scenarios for KOA self-management were defined:

1) Information & Consultation: Know about disease knowledge and seek medical treatment in time to enhance basic disease management awareness and ability.

2) Daily Activity: Carry out a suitable physical activity to maintain joint flexibility;

3) Physical Therapy: Carry out targeted exercise training to prevent thigh muscle atrophy and maintain joint stability.

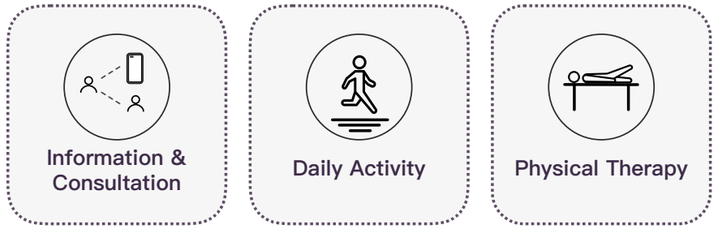


Figure 4.39 Three scenarios for KOA self-management

In each scenario, there are different self-management goals expected to be achieved by patients, but there are also different obstacles that prevent patients from achieving goals. These goals and obstacles are listed in table 4.1.

1) Information & Consultation. Patients with pre/early KOA do not pay attention to how to take care of knee health, because the symptom does not affect their daily life. Even after the diagnosis, some patients do not take active ways to treat and manage their knee health, considering it as an unavoidable thing that cannot be changed with age.

   Going to see a doctor can be a tiring and costly issue for many patients, thus using other more convenient ways, such as mobile phones, will be more likely to help patients obtain disease management knowledge.

   In terms of information acquisition from mobile phones and the Internet, middle-aged and elderly patients often obtain information through articles reposted by friends and family members, from WeChat public accounts, and search engines such as Baidu, which makes information ambiguous, If patients misunderstand the information and do harmful behavior, they will hurt knee joints.

2) Daily activity. The pain and inconvenience caused by KOA make patients take the initiative or are forced to change their previous lifestyles. Most of them reduce movement and use of joints, and form regular, gentle movements and activities gradually; This may lead to the occurrence of new undesirable behaviors, such as long-term sedentary for more than 1 hour and the phenomenon of "being afraid of movement".

   It shows that patients had the need to know about the situation of their daily physical activity, and they would use different methods to obtain relevant information. Some younger patients use mobile phones or sports braces to record and check their daily exercise volume, while older patients mainly rely on a fixed walking route and exercise duration to evaluate.

3) Exercise therapy. If exercise therapy is used in the pre/early stage of KOA, it can enhance the strength of the quadriceps muscle, which is very effective in reducing pain and delaying the deterioration of the disease. However, due to the lack of awareness, most patients with pre/early KOA are unfamiliar with the relevant concepts and do not realize the benefits of it. Some patients mix exercise therapy with general daily activity. On the contrary, some patients hold a conservative view of doing exercise therapy, the reasons include less understanding of “exercise therapy”; thinking that the usual activity has the same effects as exercise therapy; not daring to do such "professional" activities randomly.

How do patients do exercise therapy and what are the obstacles? The first is that patients are difficult to obtain professional, useful, and understandable information about the motion of exercise therapy, the similar obstacles existed in scene 1. Usually, patients can obtain limited and incomplete exercise treatment information from orthopedists when they go to the hospital. The doctor can only give a simple oral description of the movement and frequency of movement, and more information (such as standard movement demonstration, exercise effect, etc.) cannot be obtained. It would be much more useful if a video can provide, just like what the rehabilitation department did.

In addition, it is also difficult for patients to know whether their movements are standard and effective in the actual exercise process. It might need a reminder to help patients maintain the habit of doing exercise therapy.

Table 4.1 Scenarios, goals, and obstacles in the KOA Self-management

Scenarios	Health Goals	Obstacles
Information & Consultation	• Learn about disease management • Regular health assessment • Seek medical advice timely	• Less motivation to know about disease management: Don't affect normal life • Be difficult to identify real information • Don't know how to self-assess • Go to the doctor is often time-consuming • Go to the doctor is expensive • Don't know when to check
Daily Activity	• Avoid dangerous actions • Avoid long-time activity • Wear a suitable assistive product when needed	• Can’t recognize unhealthy behaviors (long-time activity or bending too much) • Can’t be aware of unhealthy behaviors • Know less about helpful types of activity • Don't want to be seen as a patient
Physical Therapy	• Complete the exercise in a safe and standard manner • Adhere to treatment plans	• Seldom heard about Physical Therapy • Don't know how to make an exercise therapy plan • Don't know the standard actions • Be afraid of getting injured • Easy to forget

Preferences of patients

When asked about the knee care product, the majority of respondents want the product to have the function of protecting the knee, fixing the knee, and providing load reduction. For older people, products with the function of heating or keeping warm will be more comfortable to use.

I bought this (sports) knee sleeve in Decathlon, and I know many students of the Physical Education Institute use it when they do sports to protect themselves from injury. It's pretty good for me too, just to stabilize my knees. I think it's useful. (R6)

They also recognized the benefits of mHealth and smart healthcare products to help them manage their disease. They were hoping smart products remind them of things. However, they were also worried about not knowing how to use them and wanted thoughtful guidance when first used.

> *I watch the number of walking steps every day, mainly on my phone... I wore the smart bracelet at first, but I think it was useless. (R2)*
>
> *A smart product doesn't need too many functions that we won't use at all, but it should remind the user not to exercise too much. (R3)*

Professional requirements on assist products

Rehabilitation doctors also gave professional opinions on the use of assistive devices in the KOA self-management Process.

1) Functional effectiveness of assist product (knee pad/sleeve): The assist product can effectively help patients with pre-early KOA, mainly because it has functions of stabilization and warm keeping. The function of "stabilization" can prevent joint wear and tear caused by the excessive bend. The function of "warm keeping" avoids the knee joint from being affected by the ambient temperature, and increases the temperature to improve local blood circulation.

2) Selection of assist product: There are many types of assist products, such as ordinary knitted knee pads, elastic bandage knee pads, and functional knee pads of metal brackets. But for patients with pre/early KOA, the ordinary elastic knee sleeves can provide what they need. In the process of self-management, patients with minor symptoms need to pay attention to keeping the knee warm and stable.

3) Time for wearing an assist product: For patients with pre/early KOA, it is recommended to wear a knee protector when doing some vigorous or dangerous activities, such as running, or going up and down the stairs. Patients can also wear the knee sleeve when the temperature is low.

4) Attention when wearing an assist product: It should be noted that the wearing time should not be too long, and the wearing should not be too tight to prevent blood circulation from being blocked.

4.3.4 Conclusions

According to the synthesis of study results, issues are discussed at the system, process, and product/service levels. Some issues at one level are special and independent, but there are also other issues discussed at different levels, which are actually different sides of the same problems.

At the system level, the main elements (7 actors and 2 physical elements) and their relations of KOA Self-management system are displays on the current system map.

In terms of the Actor, there are two points that should be highlighted. The first is a more detailed identification of the different types of healthcare service providers participating in the system and a more detailed description of their respective characteristics. The community healthcare centers which were investigated in this study seem to face fewer problems of patient trust, and their daily work is also full and busy, but they also do less work about KOA. Orthopedists and physiatrists in higher-level hospitals are the main types of doctors participating in the system. As there is a big difference between them, they need to be discussed separately.

Another point related to the definition of actors outside the health system. The investigation broadens the original perspective, from focusing only on healthcare providers within the health system to discovering other people or things that can affect patients during self-management, such as experienced patients, assistive devices, and mobile devices. All of them have the potential to improve and optimize the system.

In terms of the relations among elements, although there are connections between some of the actors, few of these connections actually take place in reality. On the one hand, community healthcare centers still have less support from higher-level hospitals. On the other hand, patients with early-stage KOA also have less connection with each kind of medical staff.

In terms of the process, it discusses the issues of the order and time that different actors intervene in patients' KOA self-management process. The problems at the process level also explain the problems and reasons for the weak relations between patients with early-stage KOA and medical staff. At the same time, it considers that these invalid relationships in the early stage may eventually lead to the inability of patients to carry out effective self-management and eventually lead to aggravation of the disease. The figure shows the relations of these problems.

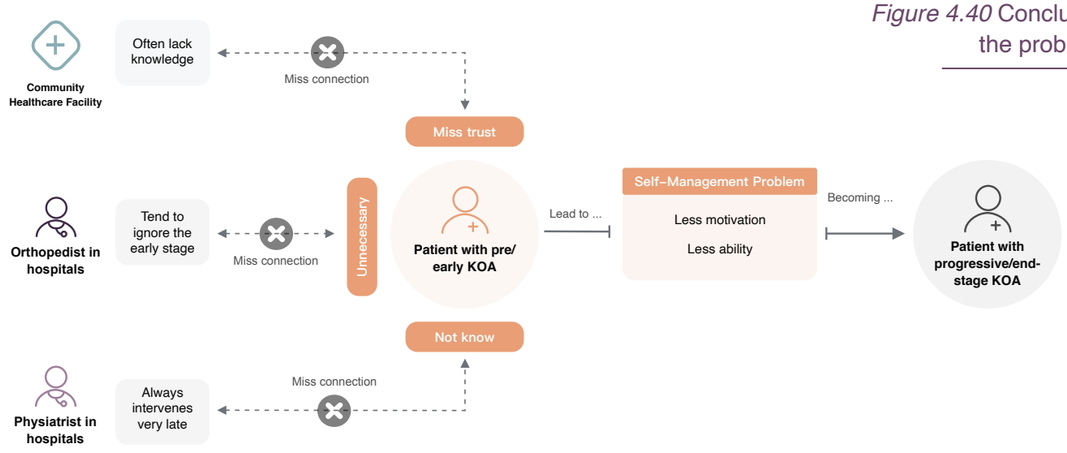


Figure 4.40 Concluding the problems

How do patients with early-stage KOA do self-management and conduct it effectively to avoid being patients with serious symptoms? At the product level, a patient-center design approach is used to find detailed information for product/service design solutions that will help patients with the self-management of KOA, while fitting and influencing the current system. Patients with early-stage KOA were identified as the target group and described as representative personas to highlight the population characteristics.

The corresponding KOA self-management scenarios are obtained through expert consultation, but patients' obstacles in these scenarios are also collected and sorted. It summarizes the functional requirements and expectations from patients for knee care products, as well as the professional constraints that need to be paid attention to for knee care products for patients with early-stage KOA.

Overall, these three levels should be considered when designing for a better CDM of Knee OA in Shanghai, China. China implements basic health insurance, and the public health institutions, such as public hospitals and community healthcare centers are important actors in the chronic disease management system. Regarding the process of KOA self-management, more efforts should be done to make the expected process in the early stage realized in reality. The specific product requirements and user needs should be focused on. No matter the patient characteristics or management content, there are many special concerns about the self-management of KOA. Therefore, how to realize them?

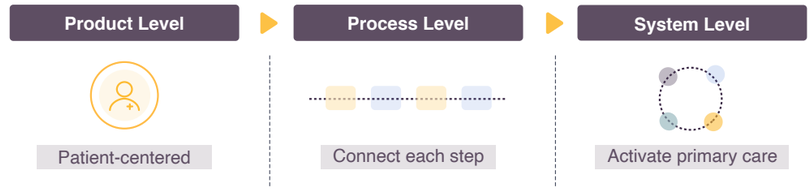


Figure 4.41 Design directions for different levels

05

Systemic Design for Knee Osteoarthritis Self-Management

Chapter 5 conducts the third and the last steps of the systemic design framework for CDM. It begins with proposing a problem-solving breakthrough and a systemic strategy according to what was found in the previous chapter. Following the systemic strategy, the design practice work is conducted to realize parts of the design strategy.

5.1 Proposing the Systemic Strategy

5.1.1 The Breakthrough

Introducing the wearable product system as a new "Actor" in the new system

Systemic design methodology focuses on the features and relations of all components of a system. It also believes that the problems of one part can be solved by others that are able to turn them into new opportunities, creating an optimized system (Bistagnino, 2011).

Digital health technology can collect and transmit information remotely, as well as improve the efficiency of data use and analysis. It can provide new abilities to a social system such as a system for chronic disease management.

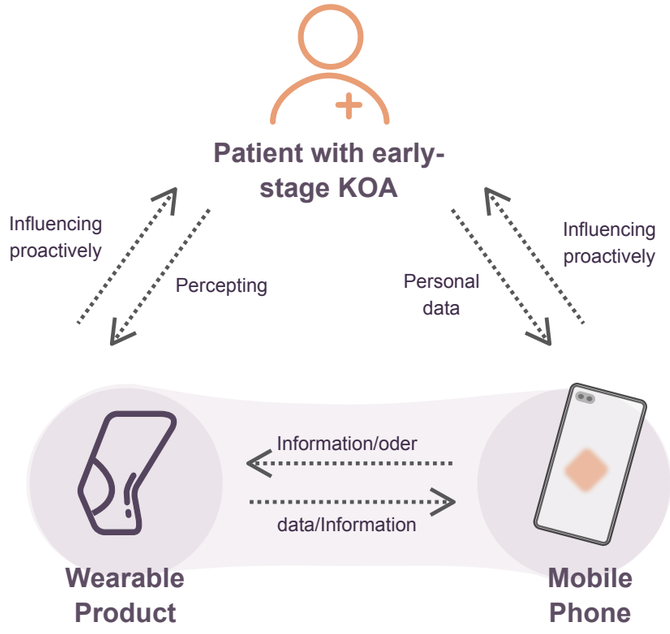
Therefore, in the stage of designing a systemic solution, a new point of view is proposed in the thesis as an important breakthrough: Introducing the smart wearable product system as a new "Actor" into the original current system, to solve the obstacles and problems existing in the system together with other actors and components.

As mentioned in the previous chapter, the characteristics of actors include “active” and “purposeful” (Tronvoll, 2017). Meanwhile, according to the system types developed by Ackoff and Gharajedaghi (1996), the most difference between the animate system and deterministic system (like an EMR system) is whether the whole system has intentionality without intervention, which seems to hold a similar point of view on dividing the "actor" with other elements.

Although there is some debate about the definition of actors in ecosystems (Granstrand & Holgersson, 2020), the thesis only uses these two characteristics to distinguish actors from other elements of the chronic disease management ecosystem, considering the system's goal.

The reason why the wearable product system can be considered an "actor" lies in the characteristics of the wearable product system. Firstly, it carries a variety of resources simultaneously, especially information data resources, and has the functions of information collection and distribution. At the same time, smart wearable devices have the ability to interact with users actively (such as collecting data and reminding users) and the purpose of initiating interaction. Although the purpose shown by computers or computer-embedded products is usually considered to be the will of designers or providers, these characteristics enable the wearable product system to be considered an independent actor in the service ecosystem.

A new actor can be added to the system as a completely new component/element, or it can replace the original entity in the system to play an effect (Granstrand & Holgersson, 2020). According to the current status of the KOA Self-management system, the systemic solution tries to adopt the second way, which is, designing a wearable product system with the form of assistive knee sleeves while matching the application of mobile phones.



5.1.2 Building a Systemic Solution

Identifying actors

The first step is to identify the actors which can help build the systemic solution. Combined with the analysis of results, the actors to be determined will be different from the actors in the current KOA chronic disease management ecosystem.

In terms of patients with KOA, it narrows the scope according to the target groups, from patients with KOA to patients with pre/early KOA. The reasons have been shown in the last chapter, as KOA self-management has more benefits for patients with pre/early KOA.

- The actor GP are replaced by Family Doctor (team). It believes that the policy and the relationship between contracted patients and family doctors can bring more possibilities to the new system.
- Two actors Physiatrist and Orthopedist remain the same. However, it should be noted that physiatrists can work in hospital departments or some community health care centers, and can also work as members of the family doctor teams to provide services for contracted patients, with greater flexibility. Meanwhile, physiatrists usually work as leaders in rehabilitation medical teams.
- The roles of Family Members and experienced patients remain the same, with a focus on potential value in the KOA self-management process for patients with pre/early KOA.

In order to have a clearer understanding of the problems faced by different actors and the existing and potential value to the system, the "Ability-Necessity-Anticipate-Threats (ANAs-Ts)" analysis matrix (Accolla, 2021) was used to sort and list the information of the 7 actors.

"Ability" reflects the existing contribution and potential value of different participants to the system in the process of KOA Self-management. "Need" indicates the basic needs and interests that actors hope to obtain from the system. "Anticipation" reflects one's expectations and is often associated with a better experience, while "Threats" represent problems or obstacles that actors may encounter when trying to participate in the new system (Accolla, 2021). Table 5.1 is a bit of different from the original ANAs-Ts matrix. It decides the four categories into 2 parts: "Ability" and "Necessity-Anticipate-Threats". The first part refers to what an actor needs to get from others, and the second part is to explain what they can output and support the system.

The information on patients with pre/early KOA, GPs, physiatrists, and orthopedists mainly came from interviews and desk research, and the content about family members and experienced patients came from the summary and extraction of related information in user interviews. The "ANAs-Threats" information of the wearable product system, which is a new "actor" of the system, can be sorted out from previous market and product research.

Table 5.1 ANAs-Ts of actors in new system

Actors	Abilities	Necessities & Anticipates	Threats/Obstacles
Patients with early-stage KOA	• Pay for products and services • Provide individual information and data	• Effective protection • Professional medical advice • Incentive and supervision • Feeling healthy • Improve the quality of life	• (See in Table 4.1)
Family Doctor (team)	• Basic diagnosis and treatment • Connect with patients conveniently • Connect with other medical resources	• Basics KOA knowledge • Get medical support from specialists • More contracted patients • Better healthcare services • Obtain patients' trust and recognition	• Insufficient professional knowledge about KOA • Managing patients leads to a heavy workload
Physiatrist (team)	• Provide professional diagnosis and treatment (such as Medication or Physiotherapy) • Professional and trusted	• Convenient communication channels (with patients and CHCs) • Efficient way to planning for patients • Reasonable fee • Increase patient adherence	• No time • patients' self-management way is wrong
Orthopedist	• Provide professional diagnosis and treatment (such as medication and surgical) • Professional and trusted	• Efficient and accurate diagnosis and treatment • Matched patients • Reasonable fee • Help more patients (kind, respect)	• No time
Family Members	• Live with patients (contact easily) • Trusted by patients	• Help patients stabilize their condition and mood • Happy family life without burden	• Spend much time and effort • Don't know what need to do
Experienced Patients	• CDM experience • Trusted by patients	• Professional medical help • Connections and friendships	• Useless or wrong information to others
Government	• Purchase several healthcare services (by the basic health insurance fund) • Formulate draft policies, etc. for health insurance, etc. • Organize and implement the management and supervision of health security fund	• Lower healthcare expenditure • Healthy people	• Higher health expenditure
Wearable system	• Knee protection • Obtain patient information • Record motion data • Motion recognition • Reminder • Connect remotely • Data/information sharing	• Professional medical resources • Tech support • Patient data	• ////

Linking resources and issues

It is necessary to comprehensively consider all actors' information, and solve the existing or possible obstacles effectively. According to the method of ANAS-Threats (Accolla, 2021), by enhancing the existing connections of different elements or building new relations between elements, try to use one's resources and ability to solve problems and obstacles of other actors.

Figure 5.1 shows the links and elements in the current system. In figure 5.2, different resources and issues are put together to form a new element (or a solution point) in the system. It can be seen that the wearable system, which takes part in the KOA Self-management Ecosystem as a new "actor", has a great impact on the construction of the entire systemic solution. Most of the new elements are generated based on the abilities of the wearable system, and they can also be considered as the functions or features that the wearable product system needs to have.

From the patient's point of view, some of the new elements promote the development of the four main influencing factors (disease cognition, self-efficacy, emotion, and social support) of chronic disease self-management in a favorable direction, thereby improving the patient's self-management ability. Not all issues can be linked or matched. Some problems may also need to be solved by actors outside the system (such as designers or tech teams), and some issues need to be solved by considering many different parts.

Figure 5.1 Links and elements in the current system

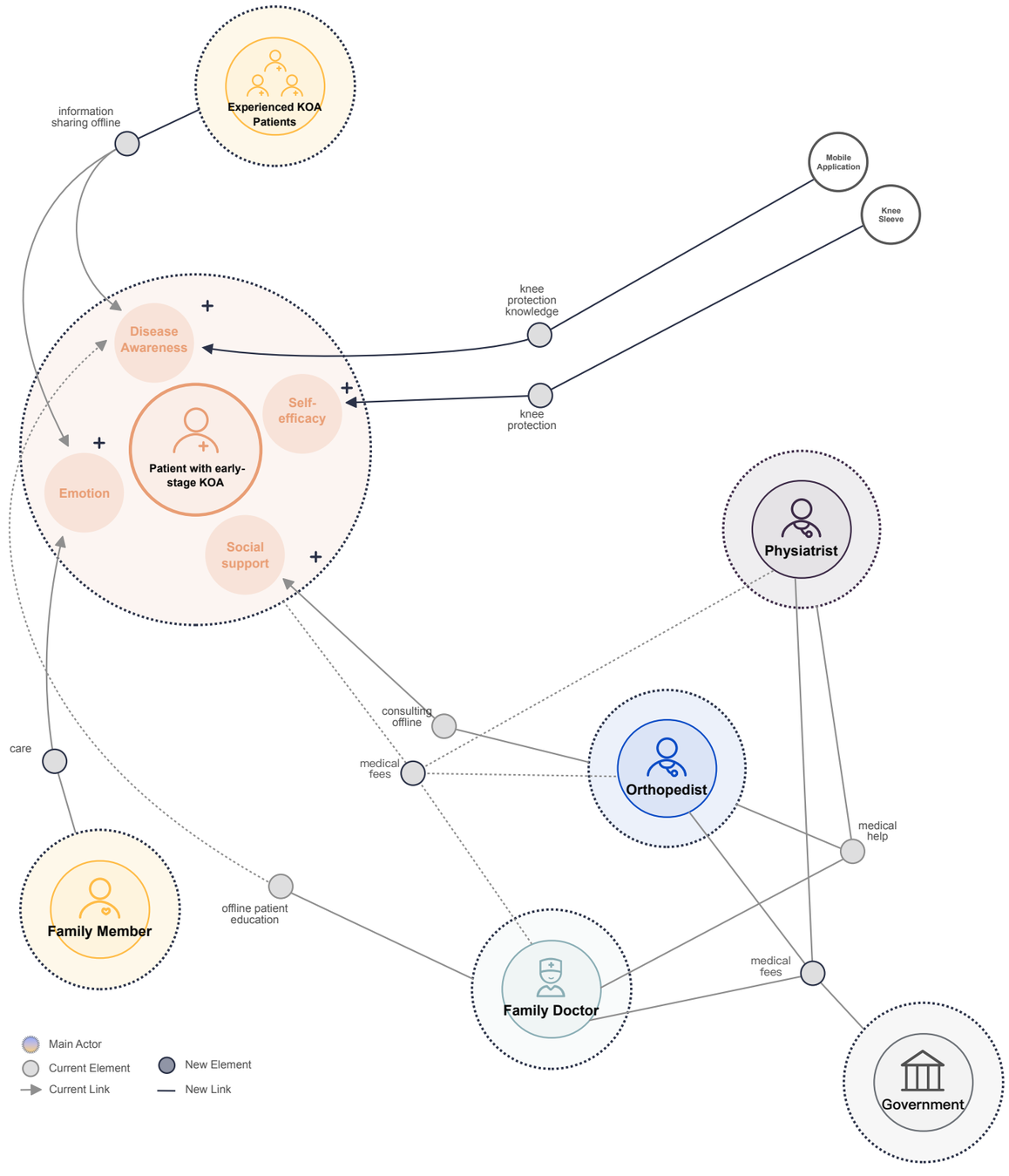


Figure 5.2 linking “resources” and “issues”

Necessities & Anticipates –Threats/Obstacles

Patient with Early-stage KOA

- · Effective protection
- · Professional medical advice
- · Incentive and supervision during the whole self-management process
- · Feeling healthy
- · Improve the quality of life
- · Less motivation to know about disease management: Don't affect the normal life
- · Be difficult to find and identify real information
- · Don't know how to self-assess
- · Go to the doctor is often time-consuming
- · Go to the doctor is expensive
- · Don't know when to check
- · Can’t recognize unhealthy behaviors (long-time activity or bending too much)
- · Can’t be aware of unhealthy behaviors
- · Know less about helpful types of activity
- · Don't want to be seen as a patient
- · Seldom heard about Physical Therapy
- · Don't know how to make an exercise therapy plan
- · Don't know the standard actions
- · Be afraid of getting injured
- · Easy to forget doing physical therapy

Family Doctor (team)

- · Basics knowledge about KOA
- · Get medical support from specialists
- · More contracted patients
- · Obtain patients' trust and recognition
- · Insufficient professional knowledge about KOA
- · Managing patients leads to a heavy workload

Physiatrist

- · Convenient communication channels (with patients and CHCs)
- · Efficient way to planning for and teaching patients
- · Reasonable fee
- · Increase patient adherence
- · No time
- · Patients' self-management way is wrong

Orthopedist

- · Efficient and accurate diagnosis and treatment
- · Matched patients
- · Reasonable fee
- · Help more patients (recognition, respect)
- · No time

Family Member

- · Help patients stabilize their condition and mood
- · Happy family life without burden
- · Don't know what they need to do
- · Spend too much time and effort

Experienced Patients

- · Professional medical help
- · Connections and friendships
- · Useless or wrong information to others

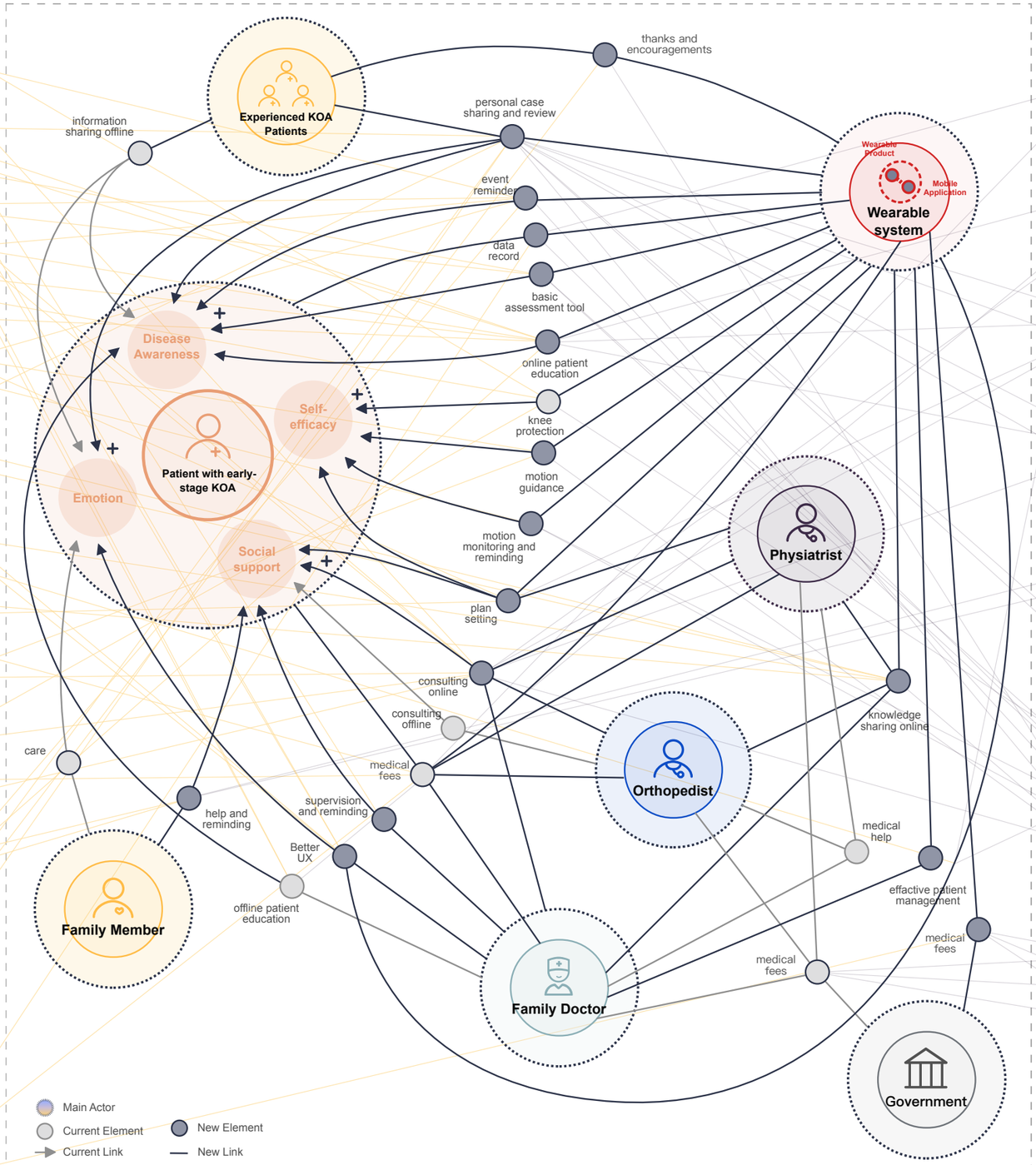
Government

- · Lower healthcare expenditure
- · Healthy people
- · Higher health expenditure

Wearable system

- · Professional medical resources
- · Tech Support
- · Financial support
- · Patient data

Elements & Links



Abilities

Patients with early-stage KOA

- · Pay for products and services
- · Provide individual information and data

Family Doctor (team)

- · Basic diagnosis and treatment
- · Connect with patients conveniently
- · Connect with other medical resources

Physiatrist

- · Provide professional diagnosis and treatment (such as Medication or Physiotherapy)
- · Professional and trusted

Orthopedist

- · Provide professional diagnosis and treatment (such as medication and surgical)
- · Professional and trusted

Family Member

- · Live with patients (contact easily)
- · Trusted by patients

Experienced Patients

- · Disease management experience
- · Trusted by patients

Wearable system

- · Knee protection
- · Obtain patient information
- · Record physiological data
- · Motion recognition
- · Reminder
- · Connect remotely
- · Data/information sharing

Government

- · Purchase several healthcare services (by the basic health insurance fund)
- · Formulate draft laws and regulations, etc. for health insurance, etc.
- · Organize and implement the management and supervision of health security fund

5.2 A New Vision for KOA Self-Management

5.2.1 New System Map for KOA Self-management

Finally, an optimization scheme is produced on the original system and will be introduced in the form of a new system map in figure 5.3 in the next page.

The new ecosystem map shows the different actors and their relations in detail. Compared with the original current KOA Self-management ecosystem, the optimized solutions made several improvements/changes in order to solve the original obstacles and avoid possible problems.

Changes in actors and elements

Firstly, as mentioned in section 5.1.1, the wearable product system is added to the new system and continues to perform the functions of "smart devices" and "assistive products" in the original system. Smart mobile devices (such as mobile phones) equipped with applications have become part of the wearable product system. On the other hand, assistive products, which only provided physiological support and protection for the knee before, have also become a part of the wearable product system and begun to undertake the function of motion monitoring.

The software and hardware of the wearable product system communicate with each other and be able to interact with other actors through different methods. The patient-side consist of “reminders", "data collection", "joint protection support", "Emotional influence", etc. The family doctor side includes "patient management" and for experienced patients, it has "personal experience sharing", etc. These new elements become solutions to the problems and obstacles of the original system.

Secondly, taking into account the tendency and advantages of Shanghai's policy, the family doctor who contracts with the patient replaces the original actor General Practitioner. Family doctors and patients will form a more stable and trustful medical relationship, which is more conducive to chronic disease management and is more likely to provide recommendations for diagnosis and treatment and referral based on patients' personal conditions. In Shanghai, many family doctors in the community maintain good relationships with older patients. A family doctor also works in a family doctor team that may include physical therapists and physiatrists. In this way, patients are more likely to get good self-management as mentioned in the systemic solution.

Another consideration for replacing GPs with FDs is about the delivery way. According to the previous case study of related products, manufacturers cooperate with companies or medical institutions to provide products to patients in need indirectly, and the companies or medical institutions bear part or all of the costs.

Therefore, in the new system, family doctors in community healthcare institutions are expected to be indirect providers. The wearable product system will be provided as an additional treatment method/service to patients in need. It can improve patients' trust in products and ensure the professionalism of medical services.

Changes in flows and relations

The first change is that new information flows are generated among different actors. This is because the smart wearable product system exerts the characteristics of the Internet of Things, which greatly promotes the collection, analysis, sharing, and exchange of different types of information in the new system.

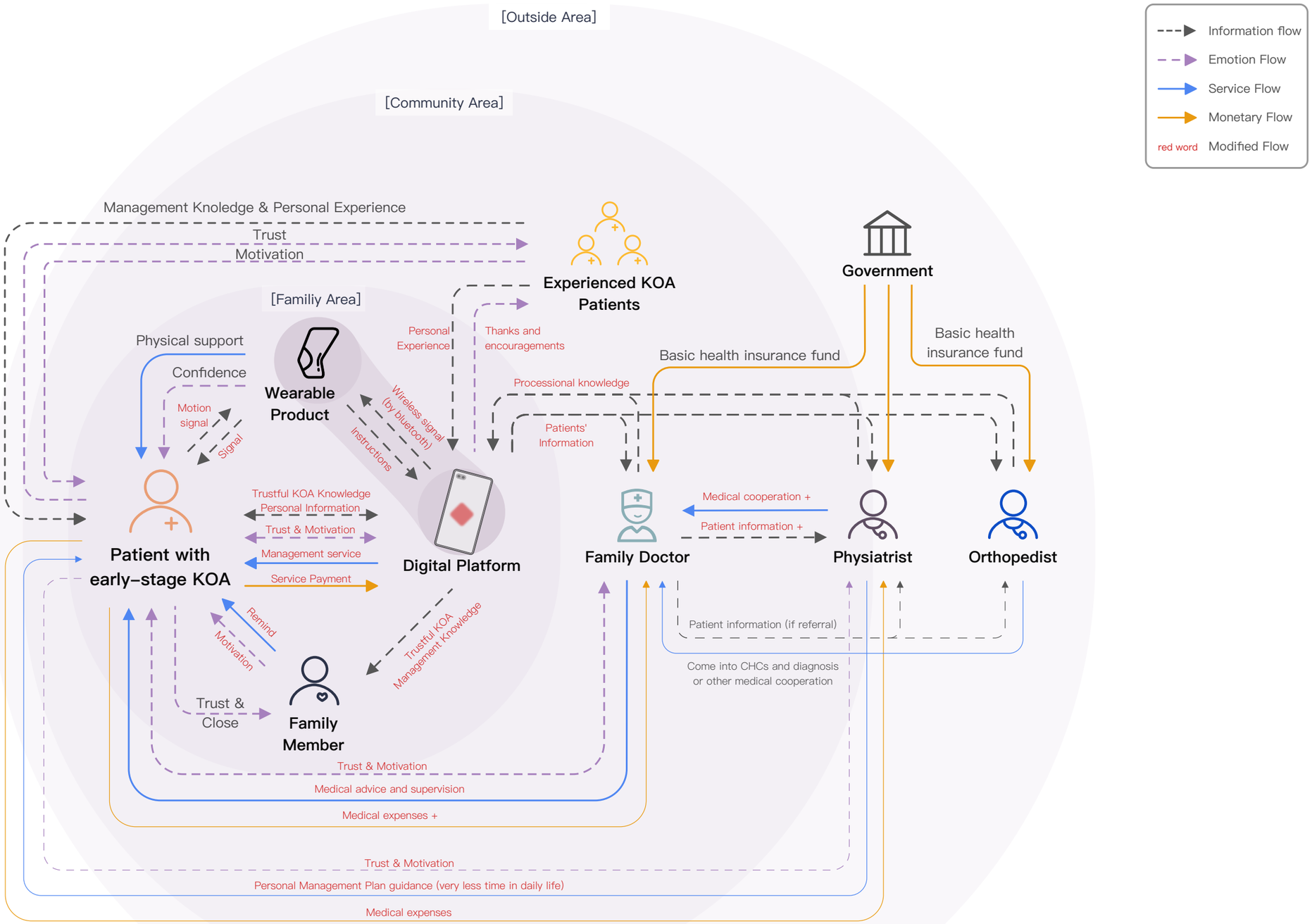
When a wearable product equipped with a sensor device is used by a patient, the patient's data can be collected and shared with different actors in the system if the user approves, making it easier for doctors who need patient data to diagnose or family doctors who need patient information to manage. At the same time, the software platform provides a convenient way for communication and information exchange remotely.

The second change is in the relations among physiatrists, orthopedists, and patients with pre/early KOA. From the analysis in the previous chapter, it concluded that patients with pre/early KOA actually need more professional guidance from physiatrists than from orthopedists. Thus, the systemic optimized solutions want to build a new connection between most patients with pre/early KOA and physiatrists. For example, on the recommendation of family doctors, physiatrists can provide patients with disease management consulting services, and patients may need to pay for medical services. Such kinds of services indirectly reduce patients' unawareness of physiatrists, helping build reasonable supply-demand matches.

In addition, some relationships that existed in the original system are reinforced in the new system. First, patients' original connection with family doctors or community healthcare institutions is enhanced. If CHCs can provide health products/services like this, it will increase communication opportunities. Meanwhile, the online connection can also help enhance the relations between patients and CHCs.

The relationship between patients and family members has also changed. The rich resources and information shown on the application not only help patients obtain related knowledge conveniently, but also make family members know about the disease better. Family members can understand the importance of KOA management and the patient's management plan through the application, making them encourage patients to self-manage.

Figure 5.3 New ecosystem map for KOA self-management



By enhancing the connection between the patient and the actors around him/her, the patient can get more support from the side, which is conducive to the patient's self-management motivation and positive self-management behavior.

5.2.2 Design requirements for the wearable product system

Summarizing the elements about the wearable product system

Figure 5.2 shows that there are many new elements generated based on the abilities of the wearable system and they can also be considered as functions or characteristics that the wearable product system needs to have.

It means that to make the new system come true, the wearable product system should be designed to realize these elements. Each element related to the wearable product system might be a cluster of multiple actors' abilities, resources, needs, and issues. Table 5.2 lists and introduces these elements for the next step of design practice.

Concluding the design requirements

Table 5.2 shows that the physical part and the digital part are responsible for realizing different elements by showing off different functions and characteristics.

The physical product mainly undertakes the needs of joint protection, motion monitoring, reminding, and achieves a better user experience. The digital platform undertakes the needs of motion guidance, reminding, online patient education, self-assessment, Plan development and management, online consultation, better user experience, and so on.

The detailed requirements about how to design need to refer to the information from the qualitative study. Therefore, combined with the previous data, the design requirements of the physical product and digital products are summarized and classified.

The design requirements of the physical product are summarized from four aspects: structure, material, appearance, and smart interaction.

In terms of the structure of the main part of the physical product, the design solution should first consider the biomechanics of the human knee joint and human factors, and use the structural shape of the assistive product to achieve the functional goals of protection that is beneficial to the knee joint. For patients with pre/early KOA, the basic elastic knee sleeve is the suitable type of assist product to ensure flexible and suitable support. The rigid materials should be avoided because it restricts patients' motion and is only required for patients with serious symptoms. Other design requirements for the structure part include:

- Larger wrap area to enhance warm keeping
- Adopt open and adjustable main structure to fit different human size
- Get adjustable pressure and prevent the product from slipping down
- Simple and labor-saving way of assembling, wearing, and disassembling

Table 5.2 Elements about the wearable product system

N.	Elements	Description	Product Type	Types of users
1	Knee Protection	• Provide patients with necessary knee joint protection and support	Physical	Patients with early-stage KOA
2	Motion Guidance	• Show correct movements to users so that they can follow	Digital	Patients with early-stage KOA
3	Motion Monitoring and Reminding	• Real-time identification of the patient's knee motion and type of activity • Remind the user to take the right action in an effective way when necessary	Physical/Digital	Patients with early-stage KOA
4	Online Patient Education	• Provide patients with professional, easy-to-understand and useful KOA-related knowledge	Digital	Patients with early-stage KOA
5	Assessment Tool (basic)	• Guide patients to self-assess their joint health	Physical/Digital	Patients with early-stage KOA
6	Plan development and management	• Patients can work with medical staff to develop a self-management plan, or obtain a basic plan after the system integrates personal circumstances	Digital	Patients with early-stage KOA
7	Event Reminder	• Remind users when they forget to follow the self-management plan	Digital	Patients with early-stage KOA
8	Online consulting	• Patients can consult professional healthcare providers online through the platform	Digital	Patients with early-stage KOA; All Healthcare Providers
9	Online Medical Knowledge Sharing	• Family doctors and specialist physician can share medical knowledge and information through the platform	Digital	All Healthcare Providers
10	Patient Management	• Healthcare providers can view and manage their patients information	Digital	Family doctors (teams)
11	Personal Case Sharing and Review	• KOA patients share personal disease management experiences through online platforms and professional health providers can provide their advice bellow	Digital	Experienced KOA Patients; All Healthcare Providers
12	Better UX	• Bring trust and peace of mind to patients • Motivate patients and improve patient confidence • Help reduce user frustration as a patient	Physical/Digital	Patients with early-stage KOA

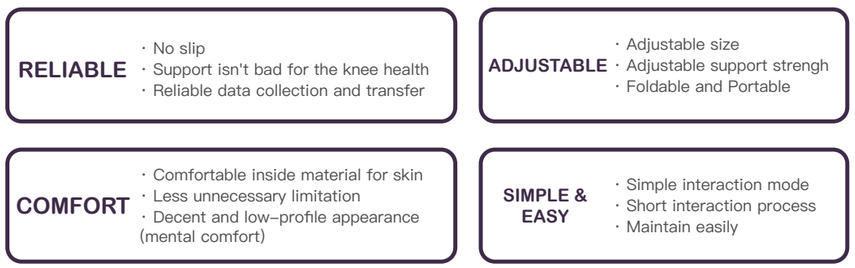
In the aspect of the material, considering the patients' habit of wearing knee sleeves in daily life (many patients wear knee sleeves under their pants), the product should choose a skin-friendly material for the part in contact with the skin, so that the product is suitable for close-fitting wear. Choose thin, durable, and easy-to-clean materials to reduce the volume and heaviness of the product; at the same time, pay attention to the thermal insulation and thermal conductivity.

The style of the physical product should be decent and unobtrusive, with less sense of medicine. Finally, in terms of smart interaction, the design requirements include:

- Confirming the suitable sensor module and measurement parameters
- Using real-time data transmission modules for information transmission
- Using devices such as vibrators to assist patients in understanding their movements from tactile sensations
- Simple interaction way

Summarize the design requirements and obtain the product characteristics of wearable physical products: reliable, comfortable, flexible and adjustable, and easy to use.

"Reliable" is mainly reflected in the structural design of the product. When users wear the product, it won't slip off or cause additional damage (such as causing poor blood circulation), and the data collection and transmission will be accurate and timely. "Comfortable" includes the use of comfortable fabrics, no inconvenient unnecessary movement restrictions, etc. "Flexible and adjustable" means that the product is adapted to a variety of situations and sizes, and "Simple & Easy" means that the interaction between the user and the product is simple and easy to maintain.



The design requirements of the digital product are summarized from five aspects: smart interaction, information content, platform connection, personal plan development and management, and user experience.

The part Information Content means the digital platform should set a column of popular science knowledge for professional medical staff to provide patients with easy-to-understand knowledge of diseases and self-management.

In terms of Platform Connection, it encourages convenient online connections between different actors. The product functions and design requirements include:

- Build a convenient online consultation channel for both doctors and patients
- Build a patient information management dashboard on the family doctor side, and optimize the management process through pre-analysis of platform data, to help the family doctor make decisions and achieve on-demand management
- Set up a harmonious online communication community to encourage experienced patients to share their disease management experiences in the community

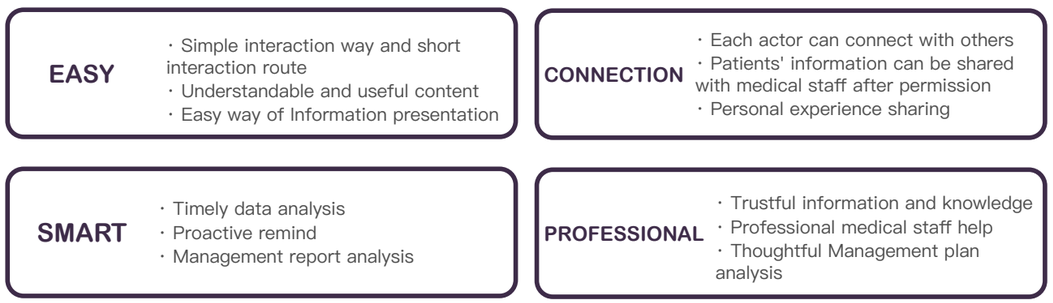
There are three requirements related to the part of Smart Interaction. Firstly, the designer can use sound and other methods to remind users in a timely and effective manner. The second requirement is to guide the patient's movements in simple and eye-catching ways such as animation and pictures. The third one is that the user's motion can be identified and reflected on the interface so that the patient can see their own situation intuitively. ·

Personal plan management is also an important function in the patient-side application. By analyzing and visualizing the collected data in the application, patients can clearly understand their daily management situation, understand their own health, and improve patient compliance and motivation. Several design requirements include:

- Use visual graphics to show management effects on patients
- Feedback on short-term results and changes in days/weeks/months
- When the patient keeps a good record for a certain period of time, give reminders to enhance the perception of results

In addition, software design can achieve the purpose of optimizing the user experience by using friendly copywriting, familiar and simple interaction methods, and simplifying the interaction process.

In the end, summarize the design requirements and obtain the characteristics of the software product: easy-to-use, connected, smart, and professional.



5.3 Design Practice

5.3.1 Project Introduction

The thesis takes knee osteoarthritis (KOA) as an example, to discuss the application value and design methods of the health wearable product system for patients with chronic diseases in chronic disease management in the community. The thesis sets the target users as patients with early/mild KOA, hoping to help them carry out effective KOA self-management through an optimized solution and product design, to avoid rapid disease deterioration and surgery.

According to the systemic design solution, the wearable product system composed of physical and digital parts joins the new patient-centered ecosystem as a "new actor", becoming an important role to realize the optimized solution.

The design practice section implements the design requirements for the wearable product system into the prototypes for verification and evaluation. The design practice mainly focuses on the design of the physical products, while also carrying out the simple user interface design of the key interface of the patient-side application.

5.3.2 Components of the Wearable Product System

According to the classification of product research, the position of the wearable product system to help KOA self-management for patients with pre/early KOA is "proactive-prophylactic". The goal of the wearable product system is to avoid the rapid deterioration of patients' conditions by helping patients self-manage with its capabilities such as active perception and reminder, and knee protection. The knee care wearable product system includes two parts: the wearable physical product and the digital platform (Figure 5.4).

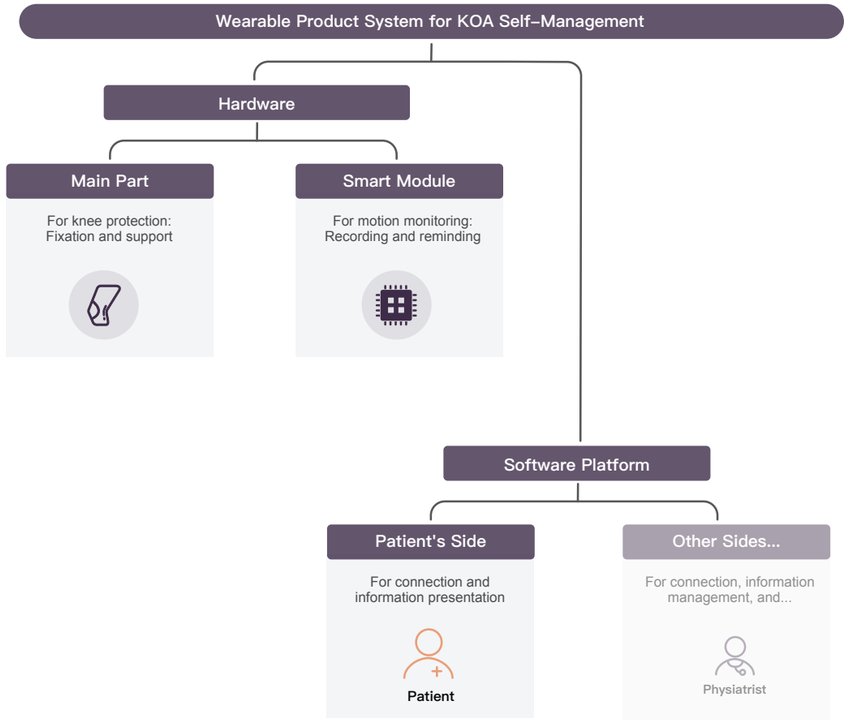
The physical product of the product system provides joint protection for patients with pre/early KOA, and monitors knee joint motion in real-time, providing certain data support for chronic disease management. It consists of two parts: (1) the intelligent module kit, which undertakes functions such as data recording, information communication, and feedback; (2) the main body of the physical product. Through the form of the knee sleeve that is suitable for patients with pre/early KOA, it can provide the necessary protection for the knee joint, relieving the user's movement concerns and bringing a sense of security.

The digital platform of the product system provides different functions and operation interfaces for different user roles. It includes a patient-side application that can help patients improve their disease self-management cognition and ability, as well as connect other actors in the ecosystem to provide patients with more support.

The digital platform on the community medical staff side provides functions such as patient information management and online consultation. It can improve the professional ability, management ability, and trust of family doctors and CHCs in chronic disease management to a certain extent. The digital platform can also provide online consultation and more information for other types of medical staff.

The design practice section only focuses on the design practice of the patient-side part of the application software.

Figure 5.4 Composition of Wearable Product System



5.3.3 Selecting Components for Smart Module

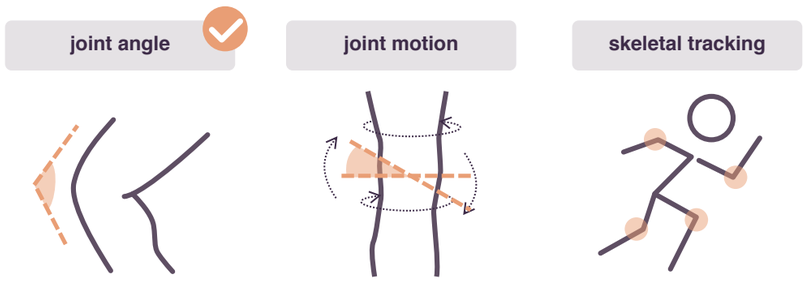
Determining the monitored parameter

As a smart product for knee care with monitoring and evaluation function, it needs to collect and deal with specific data about knee joint motion, and analyze the data at the same time so that the product can know whether the user is doing a dangerous behavior and whether it should remind its user to pay attention to their motion. Thus, the first step of designing the smart module of the physical product is to determine what monitored parameter it should measure so that it can get meaningful data to realize the function.

There are three key and common parameters for joint monitoring: joint angle, joint motion, and skeletal tracking (Faisal et al., 2019). Joint angle for the knee often refers to the flexion and extension of the joint, and each movable body joint has an optimal range of joint angles for a particular activity or movement. Joint motion includes all activities after the joint leaves the center position, such as joint flexion and extension, adduction and abduction, and rotation. It is a more detailed and accurate set of measurement parameters for a certain joint, which can reflect the joint movement on various planes. Skeletal tracking is often used for motion capture of the whole body to obtain the overall movement of the subject.

According to the design requirements of the smart module, the purpose of monitoring and evaluation includes: preventing cartilage wear caused by unreasonable knee flexion angle; identifying the type of user activity, such as sedentary, long-time standing, and long-time moving; Knowing in real-time whether the user is doing standard motions during the physical therapy (resistance knee bends, and straight leg raises). After considering all the requirements, the parameter Joint Angle is selected as a suitable choice for the product.

Figure 5.4 Selecting the parameter for joint monitoring



Determining the sensor and application methods

There are different types of sensor used to collect and obtain the parameter joint angle (Faisal et al., 2019), and figure 5.5 presents three types of sensors which are most commonly used.

Considering the accuracy, cost, and long-term reliability, it is believed that the Inertial Measurement Unit (IMU) Sensor is more suitable for health activity monitoring in daily life. Therefore, it decided to use the IMU system to realize the function of data collection. IMU units can be worn in a variety of ways. When only the joint bending angle needs to be measured, one or two inertial measurement units can be used.

When the device uses two IMU units, the joint motion angle is mainly obtained by calculating the values of the two units. In this way, more accurate values can be obtained, and different actions can be measured at the same time.

When the device only uses one inertial measurement unit When an element is used, the device can also obtain the motion of a node above the element. Kontadakis et al. (2017) used a single IMU unit to design a prototype of a wearable device for monitoring joint motion therapy, adding fun to the patient's rehabilitation process by connecting to a computer game and improving patient adherence to rehabilitation therapy.

The design solution decided to use one IMU module in the smart module, mainly considering that to make the product much easy to be used and the low data accuracy requirements of the product system.

Figure 5.5 Sensor types and introduction and selection

Source: With reference to the related discussion of Faisal et al. (2019)

Sensor Types	Method of Analysis	Pros	Cons
Inertial Measurement Unit (IMU) Sensors	Three-dimentional angular velocities and linear accelerations are used to detect the position and orientation. Relative data from tweo calibrated IMUs are compared for tracking the joint angle and gait analysis	- Compact and light-weight - Small size - Low-cost - High resolution - Built-in wireless module	- Drift error from gyroscope (can be solved by sensor fusion algorithm) - In systems where multiple IMUs are jointly monitored, higher requirements are required for the location of IMUs
Textile-Based Sensors	Change of resistance are directly proportional to joint angles	- Comfortable and suitable for long-term monitoring - Simple mechanism - One-time calibration - Low-cost	- Expensive - Low resolution - Durability not suitable for day-to-day monitoring (number of folds tolerated)
Optical Sensors	Using the relation between the attenuation and the bendign angle of the fiber	- High resolution - Flexibility - Light-weight - Long-term reliability	- limited measurement range (Angle) - Nonlinearity - Sensitive to temperature and humidity

Selecting other components for Smart Module

According to the design requirements, the smart module also needs to realize other functions such as Bluetooth communication, vibration reminder, and so on. These modules are general and standard. In the end, all the main components of the smart module are determined and their functions are shown in table 5.3.

Table 5.3 Electronic components and functional description

Components	Function Description	Number
IMU Sensors	• Real-time monitoring to obtain knee joint angle parameters	x 1
Vibration Alarm Module	• Vibration alarm after receiving microprocessor instructions	x 1
LED	• Interact with the user through the light after receiving the instruction from the microprocessor	x 2
Bluetooth & Microprocessor Module	• Receive IMU monitoring data and process joint parameter data • Send the processed data to the Bluetooth unit • Other devices in the control module • Send microprocessor data to application software • Receive application data for transmission to the microprocessor	x 1
Battery Management Module	• A rechargeable battery provides power to other units of the smart module • Charging port for battery charging	x 1

5.3.4 Designing Physical Main Part

Knee joint biomechanics and principles for joint protection

Human knee joint structure consists of the lower end of the femur, the upper end of the tibia, the patella, the ligaments, and the meniscus. This complex structure leads to the complexity of the joint movement.

During the movement of the knee joint, the tibia is pulled by the ligaments pulled by the muscle on the thigh, which promotes joint rotation. When the knee joint rotates, the lower end of the femur and the upper end of the tibia will produce relative motion in multiple planes, which may lead to uneven stress.

At the same time, the trajectory of the instantaneous motion of the knee joint is not a perfect semicircle, but a "J" shape of no more than 20mm (Niu et al., 2018), which means that the calf is far away from the knee joint when one bends the knee.

Since the knee joint has translational and rotational motions on three planes, most knee joint accessories on the market affect joint activities from three aspects: fixating and protecting, limiting extension angle, supporting and load reducing. Because the distance between the calf and the knee joint is different when the knee is flexed and extended, the relative displacement and friction between the product and the leg may be considered when designing the assistive device.

Research on product structure and materials

According to the summary of the design requirements in the last chapter, the function of joint protection and warm keeping are important points when designing the physical product, and they refer to aspects of product structure and material application.

Considering the feedback of the physiatrist, the Catalogue of Chinese Rehabilitation Assistive Products (2014), and other products analysis on sport knee sleeves (Hu & Yang, 2020), assistive products for patients with KOA can be classified into three categories in terms of structure.

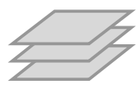
In terms of structure, common product structures can be divided into frame type, sleeve type, and open type. Frame-type products are a kind of orthosis that can provide patients with strong support and restraint functions usually composed of thigh/calf cuffs and uprights made of rigid material, while frame-type products also have adjustable restraint systems composed of straps and buckles. Sleeve-type products need users to wear from the foot up to the joints, relying on the elasticity of the fabric itself to provide pressure and protection for the patient. The open-type knee pads also have a large wrapping surface, with traps, Velcro, and other components to fix the product.

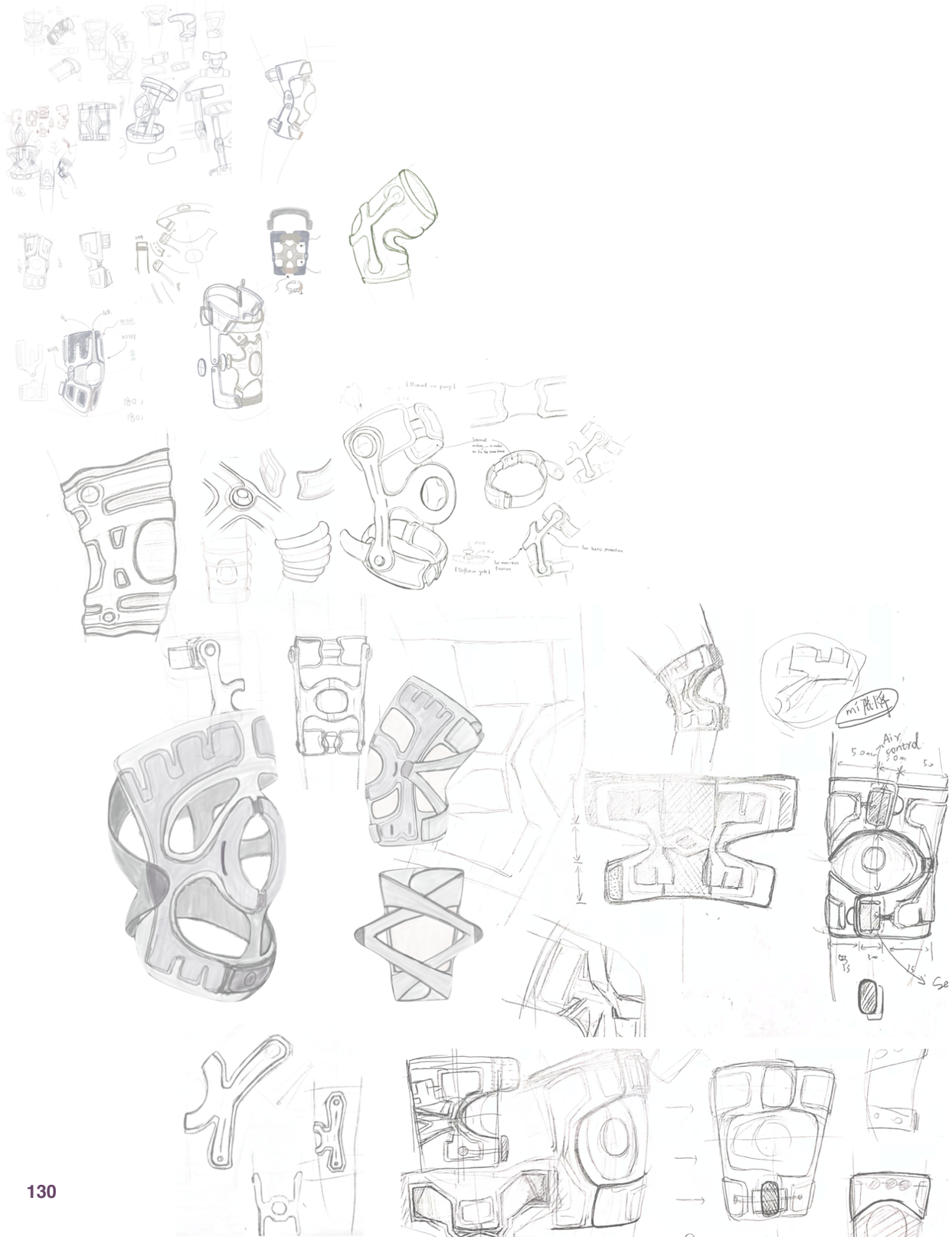
In terms of material application, the common materials often used in assistive products are elastic knitted fabrics, rubber composites, and rigid materials.

Elastic knitted fabric generally includes cotton yarn or blended yarn (polyester, spandex, nylon...). Cotton fabrics have the best air permeability and water absorption and moisture absorption, and are highly comfortable to wear on the body. But cotton fiber is easy to wrinkle, shrink, deform, stick to hair, and have poor durability. By adding other types of fibers, the fabric can overcome these shortcomings and obtain much better natures. Rubber composite knee pads are usually cut from Neoprene composite knitted fabric. Neoprene is a good material for assistive products. The fabric has good elasticity and good wrapping and can provide support and pressure to joints and muscle tissue. Rigid materials include aluminum, carbon fiber, and others. In addition, materials such as silicone and leather are often used in assistive products as additional components to help achieve or enhance functions such as fixing, changing force, and buffering.

At the same time, there is a close relationship between the product structure and its materials. Figure 5.6 shows the four most typical combinations of the structure and materials, as well as their characteristics and applicable scenarios. As for patient with pre/early KOA, the frame-type orthosis with rigid materials is not a suitable choice for assistive products.

Figure 5.6 Introduction to the four combinations and selection

Image	Structure	Material	Characteristics	Applicaitons
	 **sleeve-type**	 **elastic knitted fabrics** cotton, polyester, spandex, nylon, etc.	- Simple form of full wrapping - Provide some compression force through elastic fabric - Light and thin, with a certain thermal insulation effect - No additional support - Good breathability and elasticity	Knee joint protection for healthy people, patients with knee problem in the early stage
	 **open-type**	 **yarns and elastics** polyester and cotton fibers; elastic	- Easy winding, good air permeability, and free pressure adjustment - It can be cut to different lengths	As a protective product for different body parts and also as a first aid bandage; Use with other types of knee braces as a compression-stabilizing component
	 **open-type**	 **Neoprene** CR/SCR/SBR, etc.	- Good elasticity and wrapping, providing support and pressure to joints and muscle tissue - Poor breathability (can be perforated), with a good thermal insulation effect	Suitable for high-intensity sports, outdoor sports protection, which needs more support
	 **frame-type**	 **metal, plastic** aluminum, carbon fiber, etc.	- Contains hard structure (metal, plastic) - motion hinges adjusted to limit the joint angle - High complexity of wearing and professional adjustment	Patients with advanced disease; Patients recovering from surgery

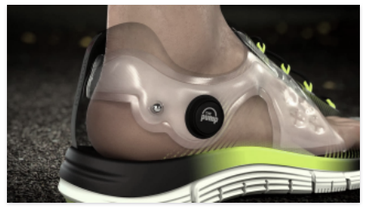


Concept design and prototyping

Following the design requirements and the concluded characteristics for the physical product (reliable, adjustable, comfortable, simple & easy), some concept design solutions were generated with the same smart module selection. A total of three conceptual solutions were produced, and each of them was tested by rapid prototyping.

In the end, the last solution was selected and refined to obtain the final design solution for the physical product.

Source: https://www.thedropdate.com/clothing/reebok-x-garbstore-commuter-pack



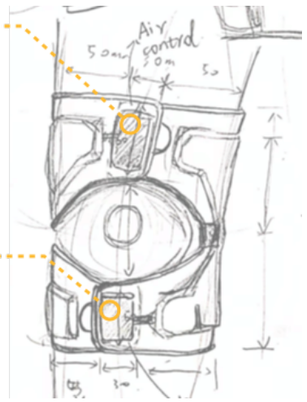
Source: https://sneakers-magazine.com/reebok-instapump-fury-boost-marc-overkill/

Air Pump &
Pressure Sensor

1. Inflating/deflating air electronically
2. Monitoring the pressure
3. Reminding the patients when the pressure is too high or wearing long

Intelligence
Mornitoring Module

Mornitoring and recording the row of motion of the knee.

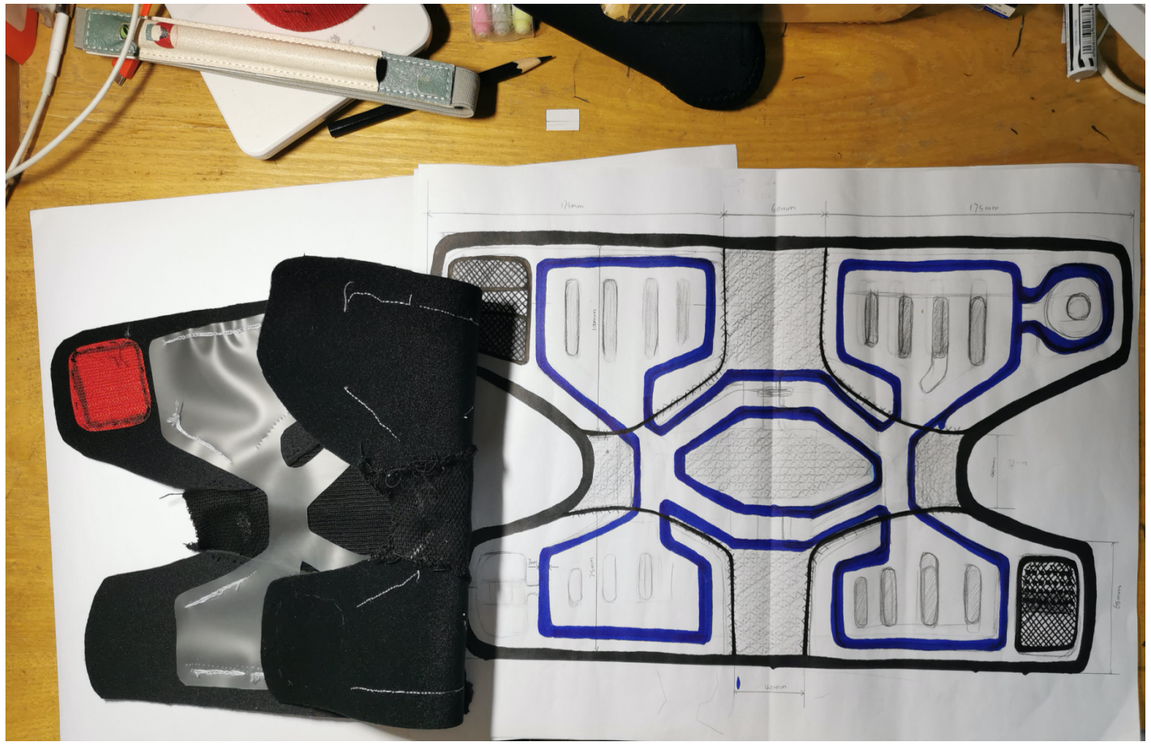


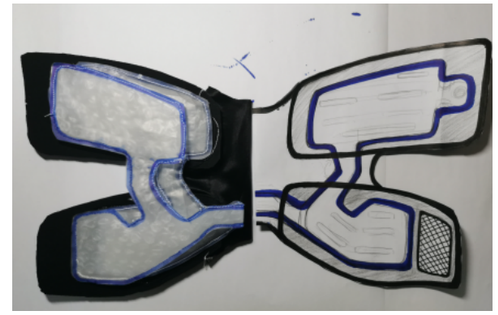
Prototyping Airbags

Source: Author's own photograph

Prototyping different components

Source: Author's own photograph





Prototyping

Source: Author's own photograph

5.4 Final Solution Display

5.4.1 Physical Parts

The final conceptual solution for the physical part of the wearable product system is shown in the figure.

The concept consists of two main items, an open-type knee brace with an airbag and a detachable smart module. Considering the requirements of patients with pre/early KOA, the knee brace provides protection and pressure for the knee joint. The smart module is responsible for data recording, information transmission, vibrate reminding, and other functions. It can be attached to or removed from the knee brace separately so that the user can maintain the product easier.

The solution hopes to realize the four characteristics by integrating different methods:

1) Reliable form of the knee brace to meet "Reliable": Expanding the area of the contact surface between the product and the user's skin can help keep the friction enough with less pressure.

2) Inside adjustable airbag to meet "Adjustable": By using the airbag, the pressure and the force of support can be controlled by the user.

3) Multi-fabric selection to meet "Comfortable": Combining different cloth according to the different performance, to create a comfortable and simple structure of the product.

4) Removable components to meet "Simple & Easy": An integrated detachable smart module can help the process of wearing, charging, and cleaning simple and easy.

Reliable form

Expanding the area of contacting skin can help keep the friction enough with less pressure.

Adjustable Support

By using the airbag, the pressure and the force of support can be controlled by user with some partd easily.

Multi-fabric

Combining different cloth according to the different performance, to create a comfortable and simple structure of the product.

Removable Module

A Integrated detachable smart module can help the process of wearing, charging and cleaning more simple and easily.

The composition and material of the knee braces

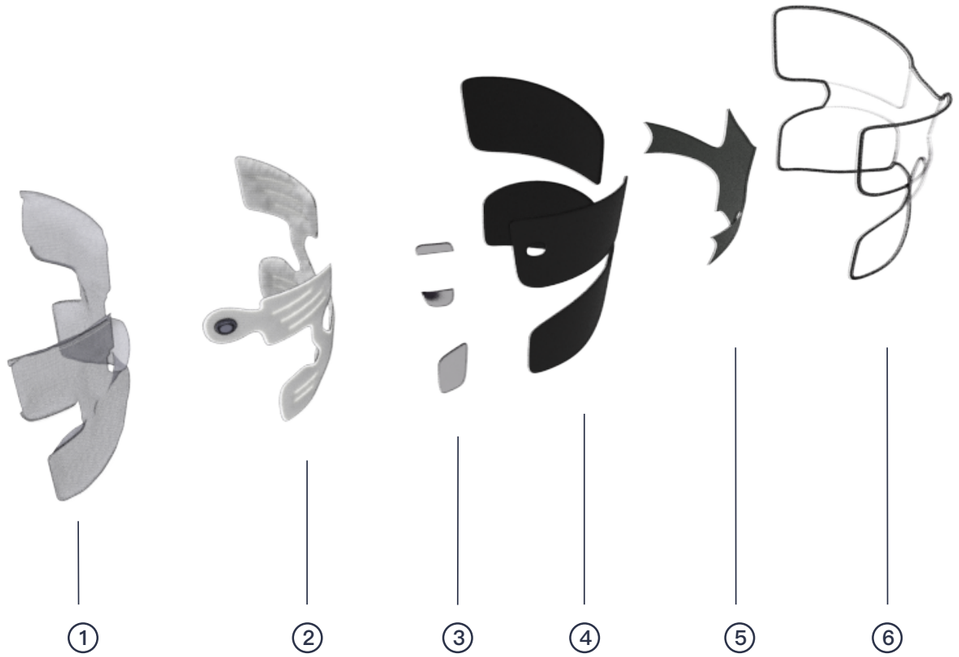
Four materials are determined reasonably according to the different functions of the main components of the product.

1) Inside lining -- Blended knitted fabric made of Polyamide (nylon) & Spandex. As the part that may come into direct contact with human skin, the inner lining material needs to have good hygroscopicity, so that the wearer's skin can maintain proper moderation. According to the characteristics of commonly used materials, nylon with good hygroscopicity and touch softly is selected as the main material of the inner lining (about 75%), and spandex is added to increase the elasticity of the fabric (about 25%).

2) Airbag -- TPU (0.3mm). TPU is an eco-friendly material widely used in medical device airbags, with excellent air tightness and high bearing capacity for inflation and deflation.

3) Leg wraps fabric -- Neoprene + OK fabric. The material is made of neoprene fabric with OK fabric fitted on the outer side, allowing the Velcro to stick and fix. It has the characteristics of softness and comfort, good elasticity, and provides protection for both joints and muscles.

4) Back side wraps fabric -- Blended single-sided Knitted fabric made of Polyester & spandex. As the back side fabric requires greater elasticity and good breathability, this kind of knitted fabric is used, which has good elasticity, high durability, and better breathability.

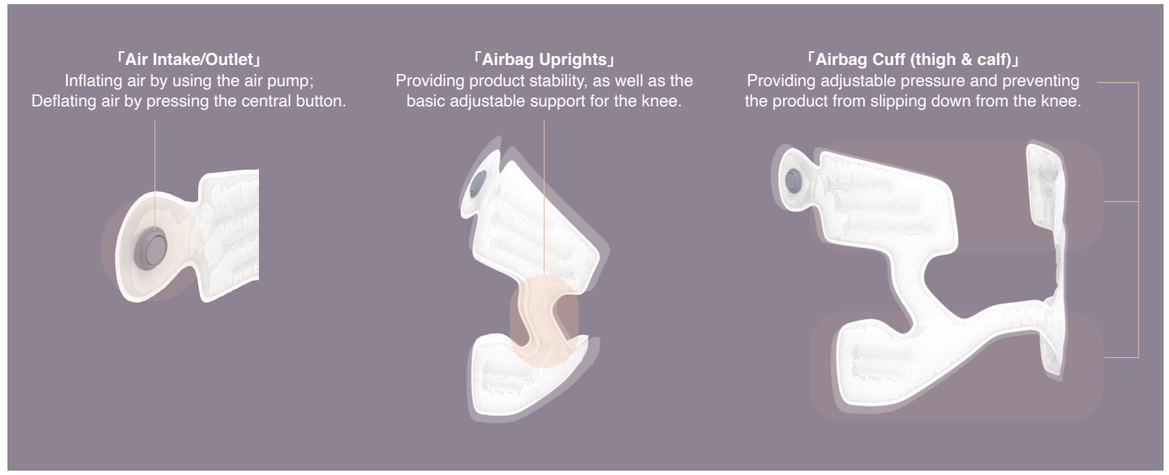


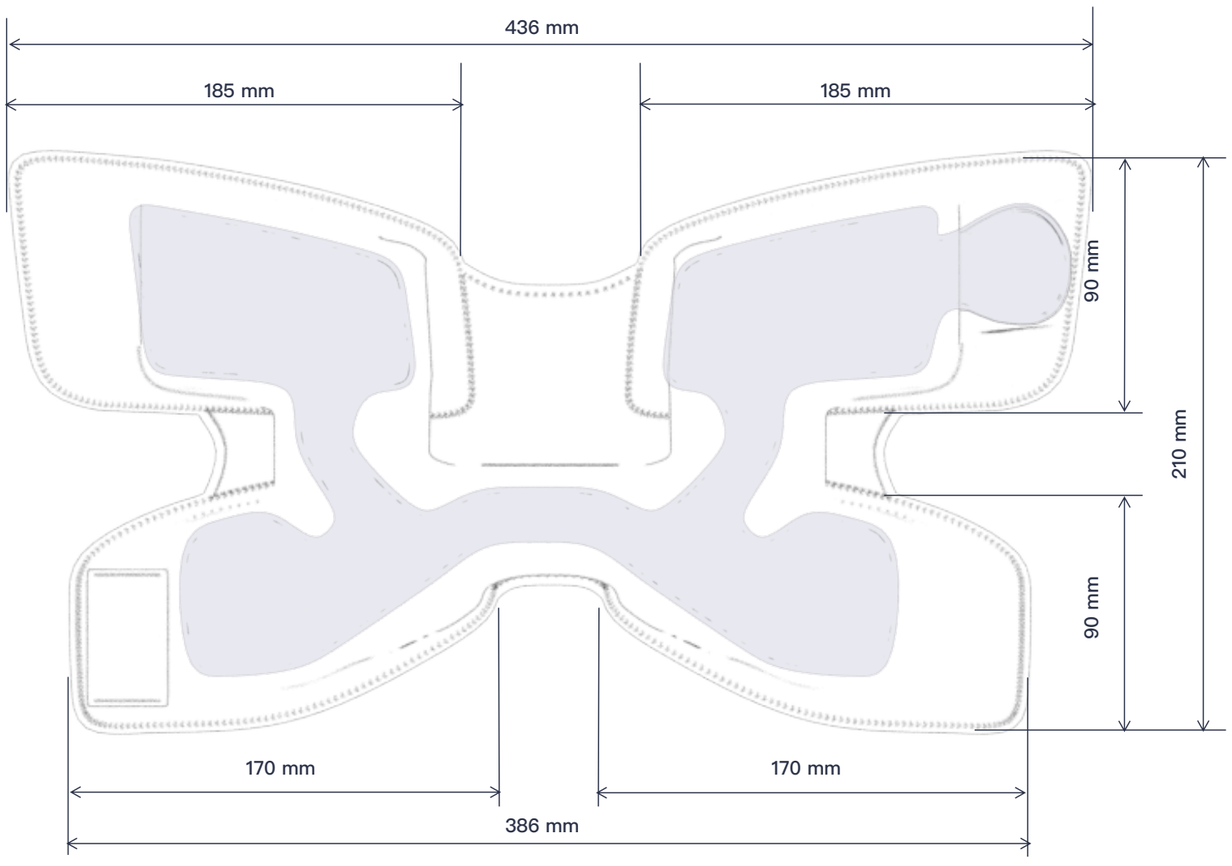
The airbag component for adjustable pressure

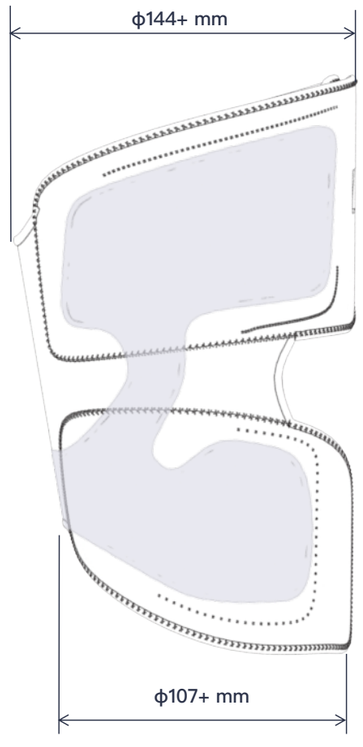
The airbag inside the knee brace is mainly used to realize the function of adjustable pressure and support. By filling a small amount of air to inflate the airbag, the pressure and friction force of the product on the legs is increased so that it can prevent the product slip off from the user's knee.

It can also provide slight support and even keep warm. Different from the common rigid uprights for fixing and preventing knee dislocation, the airbag can provide patients with pre/early KOA with slight support without influencing their normal motion.

The user can use the air pump to manually inflate at any time, and reduce the pressure by pressing the spring air inlet and outlet to release air. By controlling the airbag in this way, each user can get the right size and pressure according to their own situation.



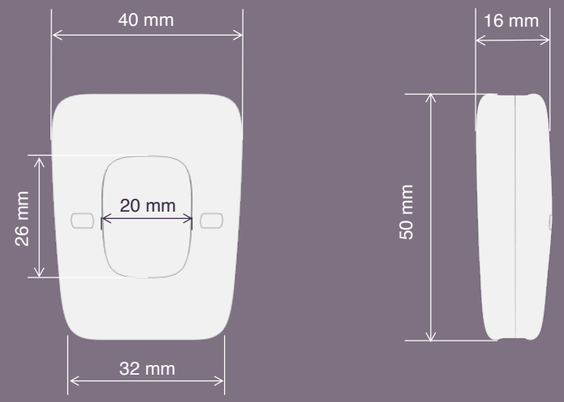




Dimensions and composition of Smart modules

When designing the smart module, it should consider that it is difficult to clean and maintain this electronic module by using the same way as the knee brace, and the smart module also needs daily charging to operate normally. Therefore, the smart module is designed to be a detachable module that can be attached to or removed from the knee brace.

Smart modules are expected to be as light and small as possible because patients don't want to be obvious, but the size is limited by the characteristics of the electronic components in them.



Li Battery

- Size: 36mm X 28mm X 4.8mm.

IMU

- Include: an accelerometer, a gyroscope, and a magnetomete
- Size: 15.24mm X 15.24mm X 2mm

Bluetooth Microprocessor

- Size: 18mm X 19.2mm X 5.2mm.

Vibrator

- Vibration mode: when IN input is high, the motor vibrates
- Size: D=8mm, H= 2mm

Micro USB

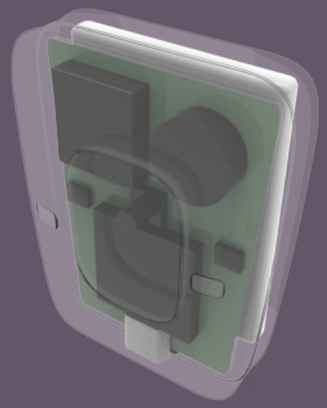
- Size: 8mm X 5.62mm X 2.2mm.

LED

- Number: 2
- Size: 2.8mm X 3.5mm X 0.7mm

Switch

- Size: 4.5mm X 4.5mm X 5mm



5.4.2 Designing Key Interfaces

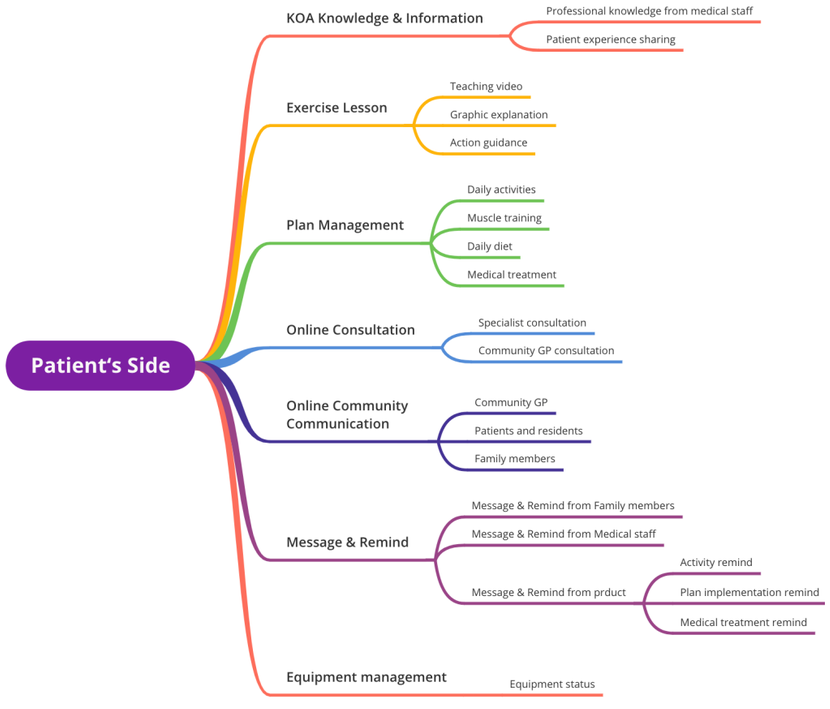
The patient-side app cooperates with the physical part of the wearable product system and plays a role in media and education. It is also a good connector to make patients able to get more outside help.

Firstly, the app provides professional and credible information to help patients understand and pay attention to knee care. Some information forms such as images and videos can be used to make patients understand easily and correctly. Secondly, the app can use a graphical interface and a simple interactive process to help patients obtain personal management reports and improve their self-assessment capabilities.

The app can use online platforms to connect patients with other actors participating in the system to get more professional and emotional support. The software can also provide interesting interactions for self-management, enriching the patient's self-management experience and motivating patients to adhere to chronic disease management.

Based on the previous analysis of the design requirements, the main functions of the patient-side application software are summarized as follows.

Figure 5.7 Software function



APPLICATION SERVICE

Planning, Guidance and Evaluation

/ Health Plan

It includes different KOA management part that the patient need to do today, such as weight record, Knee bend exercise.

/ Exercise

Using video and words to help patients understand the movement. Animation mornitoring, feedback and reminders.

/ Health Report

Getting personal health report to track and assess the self-management.

Information and Connection

/ Knowledge

Provide patients with the professional, easy-to-understand and useful KOA-related knowledge.

/ Patient Case

KOA patients share personal experiences through online platforms and professional health providers can provide their advice.

/ Help & Message

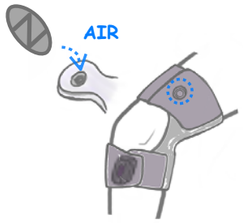
Family doctors can share knowledge and information with patients through the platform.

Use process 1: Daily self-care process

① TAKEING OUT

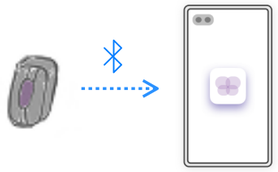
② UNFOLDING

③ WEARING



④ INFLATING

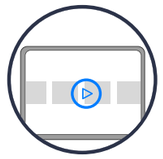
⑤ TURNING ON



⑥ CONNECTING

S1: Doing daily activity (low intensity)

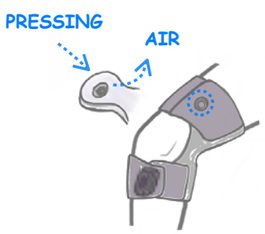
– The knee wrap protect the knee
– The smart module monitor the motion
– The smart module and mobile phone reminds when detecting the dangerous activity



S2: Doing exercise therapy

– The smart module monitors the motion and show on the interface timely
– The smart module vibrates to remind the user do the right motion

⑦ OPERATING



⑧ DEFLATING

⑨ WEARING OFF

⑩ STORING

Use process 2: Charging

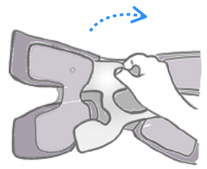
① LOW POWER WARNING

② TAKING OUT THE SMART MODULE

③ CHARGING

④ INSTALLING AND REUSING

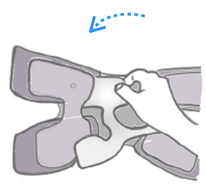
Use process 2: Cleaning



① TAKING OUT THE AIRBAG

② PUTTING THE MAIN PART INTO WATER

③ DRYING



④ INSTALLING THE AIRBAG

⑤ STORAGING THE CLEAN PRODUCT

5.4.3 New Process for KOA Self-management

The new process is shown in a similar form of a service blueprint, the main healthcare providers, patients, and digital health product system work together to conduct the process of the self-management of KOA. The software platform can facilitate most of the stage, while the physical part only interacts with patients during implementation. However, the physical part can provide protection and motion monitoring, meeting the patients' needs.

As the Shanghai government encouraged residents to contract family doctors through the online platform, the product system is expected to be connected with the family doctor platform as one of the family doctor services.

Figure 5.8 New process of the self-management of KOA

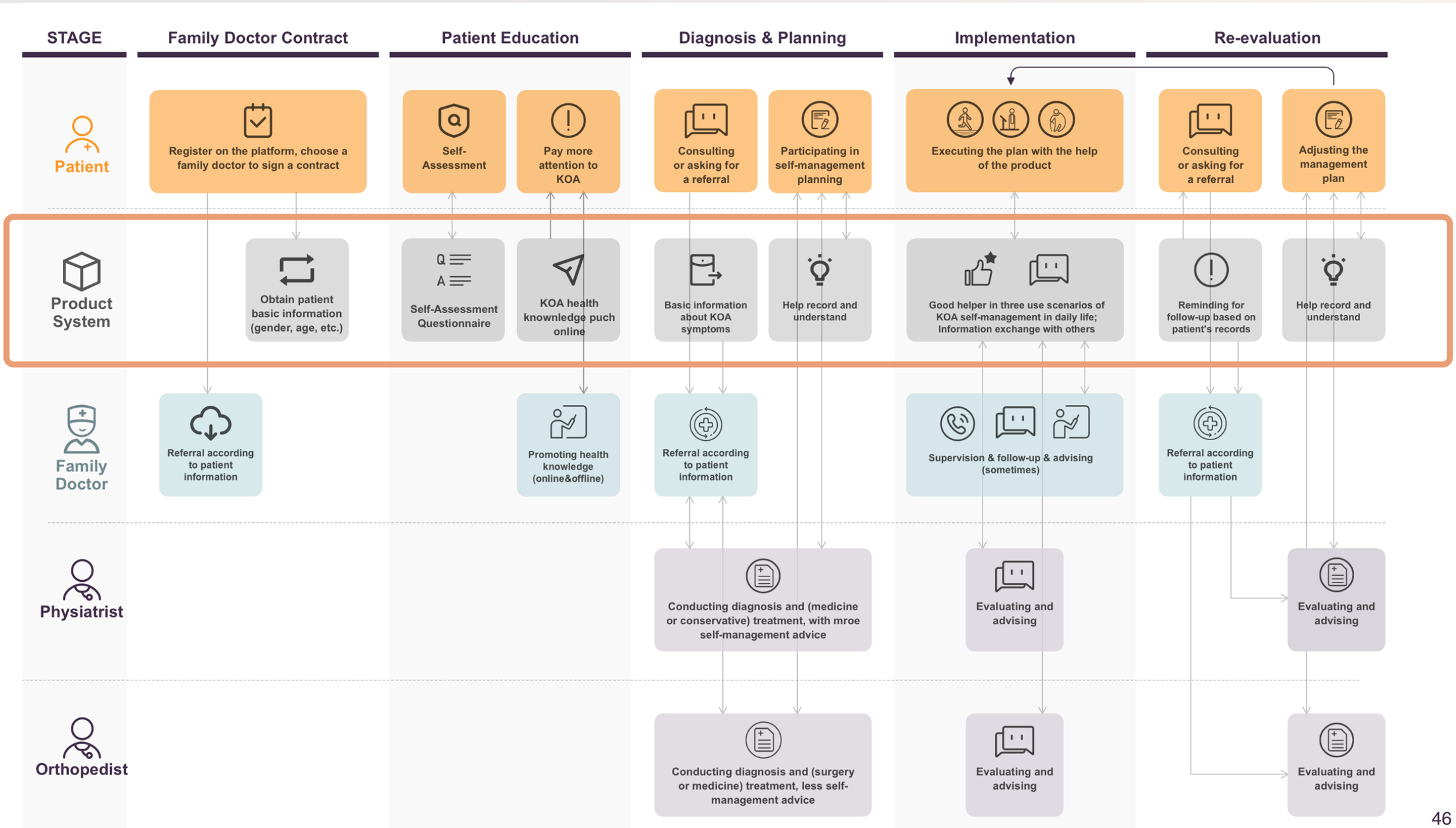
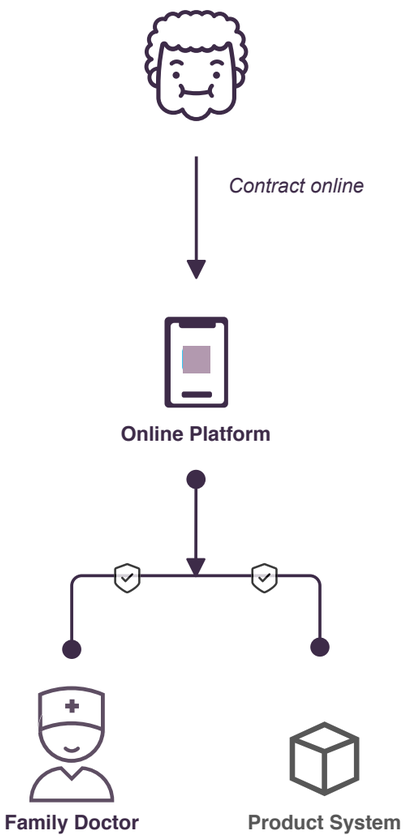


Figure 5.9 Storyboard for the new process of the self-management of KOA

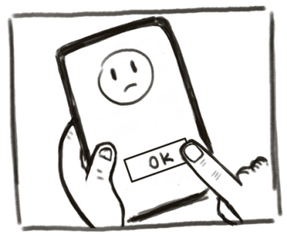
Family Doctor Contract



Patient Education

Remind potential people to pay attention to knee joint health timely.

Encourage users to complete the self-evaluation questionnaire.



Recommend users to seek medical help when needed.

Diagnosis & Planning

If the patient feel confused about the doctor's advice...

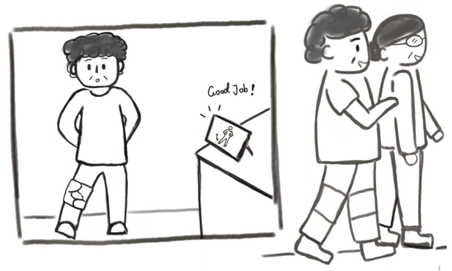
Help understand all information by video and detailed explanation easily.

Create a health plan according to the doctor's advice.

Implementation

If the patient forgets to finish daily plan ...

Remind the patient to do exercise or other activities.



Instruct patients on physical activity in an understandable, encouraging manner; Protect the knees if necessary.

Re-evaluation

Provides visual health reports that are easy to understand and motivate users.

Remind again!
Reminder to review and reassess disease.

5.5 Design Evaluation and Iteration

5.5.1 Design Evaluation

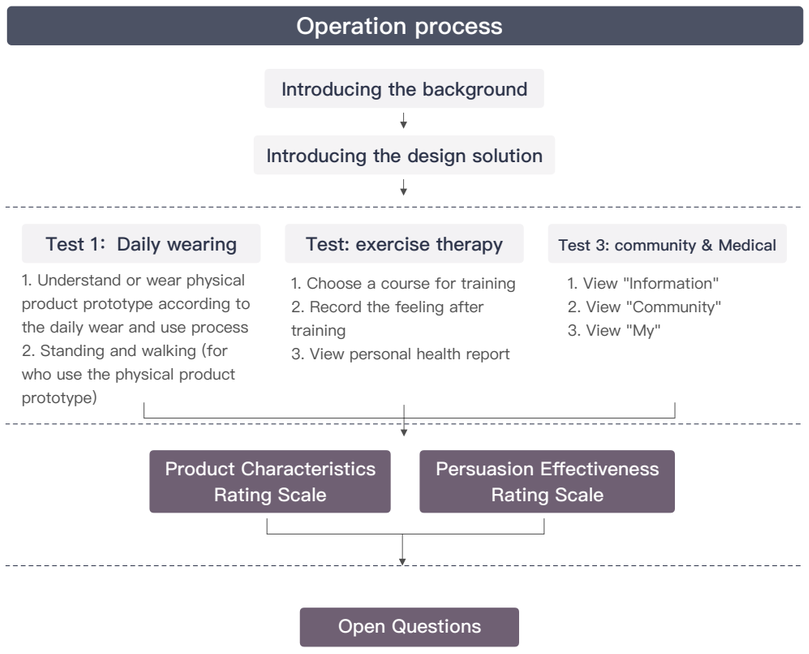
Operation process

The reasons for conducting the design evaluation according to the operation process are as follows. Firstly, it should enable users to understand the project theme and background, and the current status of the KOA self-management system, then introduce the design solution to users who participated in user test.

After that, the test lets users interact with physical product prototypes and app demos and complete the task scenarios extracted from the three major target activities, in order to:

- To obtain intuitive and real feelings about the product
- To know whether the design meets the design requirements
- To know whether the design solution has played the expected role in "motivation/capability/trigger"

Figure 5.10
Operation process of design evaluation



Participant information

- Number: 5
- Gender: female x3, male x2
- Age: 50~60
- Knee Problem: 2 participants has mild knee osteoarthritis, other 3 participants have no symptoms of knee pain but they are care about their knee health.

Implementation

The author describes conceptual solutions to users, invites users to use product prototypes, and then obtains evaluation data in the form of scales and open questions.

Two users tried on the physical product prototype, while the other three users learned about the product information through slides. All of them tried the mobile application demo.

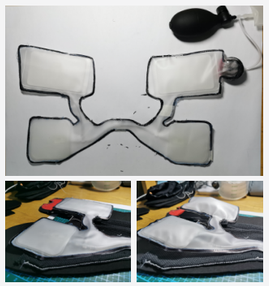
After the evaluation, add the score of each question to the scales and concluded the results..

Figure 5.11 Evaluation Materials

Note: The app demo for design evaluation is the old version

[Physical Prototype]

Optimisation of previous prototypes to allow inflating and deflating the airbag.



[APP Demo]

The interactive demo of the main interfaces.

[Slides & Questionnaire]

① A presentation containing project background introduction and graphics

② Two online rating scales (Product Characteristics Rating Scale & Persuasion Effectiveness Rating Scale)

Figure 5.12 Users is testing the prototypes

Source: Author's own photograph

From the results of the Product Characteristics Rating Scale, it can be seen that on the whole, physical wearable products can make users feel reliable, comfortable, flexible, and easy to use; and the associated software applications are easy to learn, connected, professional, and intelligent, which are also confirmed.

The main problems are about the physical product. It can be seen from the score that there is still room for improvement in the reliability and appearance of the product. Most users expect the product to be more beautiful while affirming the functionality of the product. One user said that this kind of knee sleeve cannot achieve the protective effect of the full-wrap sports knee sleeve, and she may not use it when doing vigorous exercise.

What impresses patients about the product is the wearable device's function of collecting, analyzing, and sharing activity information with doctors, and the function of detecting joint angles and prompting timely reminders, which makes them very interested; at the same time, some users expressed that they are looking forward to the participation of community doctors and rehabilitation doctors, making the early disease management more effective.

Appearance and Protection should have more improvement. It shows that physical products need to consider the appearance of the product in addition to the function and reduce the negative emotions that may occur when patients wear protective gear products due to fear of external evaluation. At the same time, the product still needs more detailed research and design to enhance the user's trust in the product and the perception that the product is beneficial to disease management.

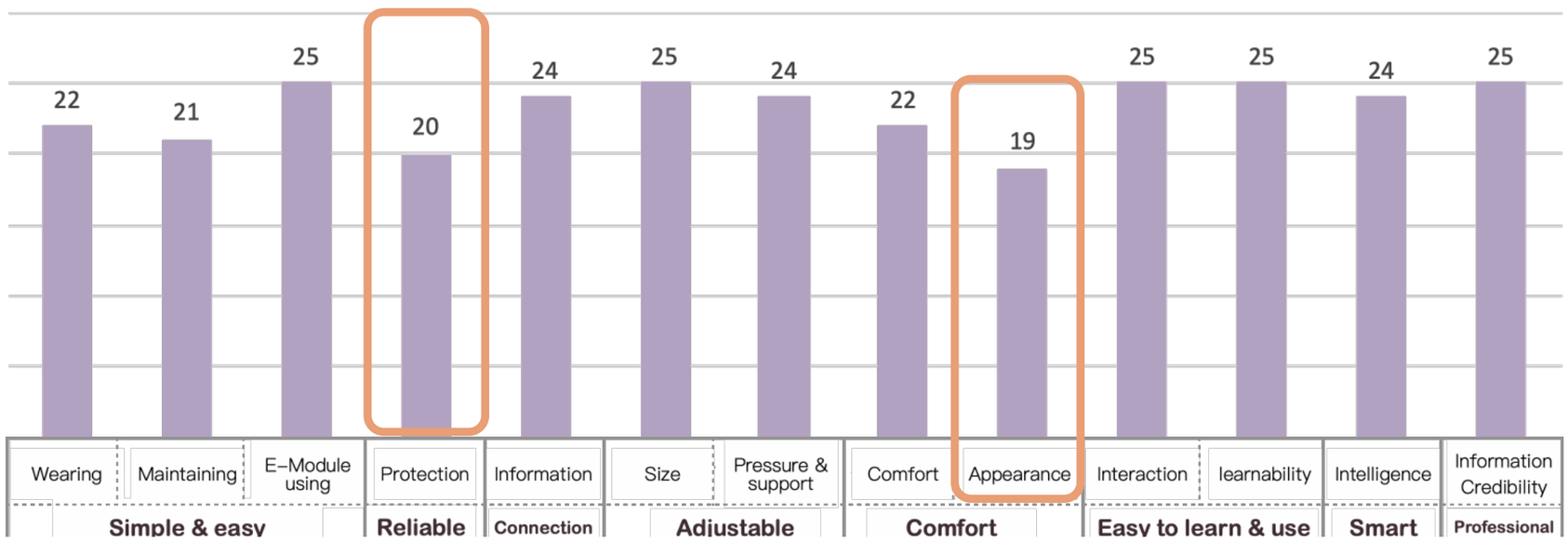


Figure 5.13 The Results - Product Characteristics

5.5.2 Concept Iteration

According to the test results and feedback, the concept of the product should be iterated to meet users' needs. The main work is to adjust the product structure to enhance reliability and appearance.

- Connecting the upper and lower neoprene parts to increase stability and reliability;
- Continuously covering the edge to increase the overall effect of the product;
- Increasing the lining area.

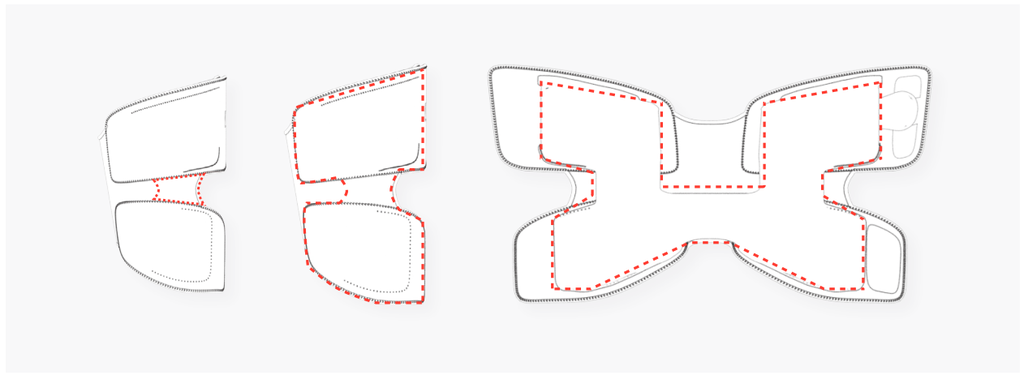


Figure 5.14 Diagram of Structural Adjustment

Figure 5.15 Final Physical Model

Source: Author's own photograph

06

Conclusion and Discussion

Chapter 6 is a Conclusion and Discussion. It discusses the research value points and the problems requiring further studies.

6.1 Conclusions

The world is always at risk of diseases, whether communicable or non-communicable (chronic). How to deal with these diseases and avoid worse situations are big challenges that every health system around the world is facing.

The 2030 Agenda for Sustainable Development highlights that information and communications technologies will be able to accelerate human progress, bridge the digital divide, and develop knowledge societies. Meanwhile, the Global Strategy on Digital Health (2020-2025) proposes that digital health should be integrated into health priorities to benefit people in a way that is ethical, safe, secure, reliable, equitable, and sustainable.

However, it is confusing and difficult when designing to integrate a new thing, such as digital health, into a complex health system, consisting of multiple stakeholders, relations, and other elements.

Systemic design is considered an available way to deal with such complex problems, which originated from systems thinking, cybernetics, and the complexity of systems. For systemic design, problems are systems in bigger systems which are needed to be analyzed starting from the interactions among their components.

The system of chronic disease management is one of the systems in health system. The model of Chronic Disease Management (CDM) is the result of the local policy context and organizational characteristics, with regional and local individual characteristics.

Thus, this thesis discusses how the systemic design approach can support the improvement of chronic disease management. In particular, when digital health product systems begin to take part in disease management, how to design such a product system for the system of disease management. It means that this kind of support can bring improvements to different stakeholders that participate in CDM, thus keep individual and social health.

In the previous chapters of the thesis, a systemic design framework for chronic disease management is formed, considering the systemic design approach, system types, and the characteristics of CDM. In order to roughly verified the feasibility and reproducibility of the framework, as well as to improve it, the thesis focuses on the self-management of one kind of chronic disorder, osteoarthritis, analyzing the related digital health product cases in three different geographical backgrounds -- the United States, England, and Germany.

After that, following the design framework, the thesis takes a case study of Shanghai in China, conducting detailed design research and design practice on the self-management of Knee Osteoarthritis (KOA) under the specific and unique context of Shanghai, from the related context, system, process, to product level.

Different types of design tools are used during the analysis and systemic solution proposing, such as the ecosystem/system map, the service blueprint, and personas, which show and determine that systemic design is an integrated way of design to solve complex problems.

In the part of proposing a systemic strategy for the self-management of KOA, the wearable product system, as one kind of digital health product, is considered as an "actor" to participate in the self-management system rather than as a determined system. It might indicate that whether we can rethink about the role that digital health technologies can undertake to work for a better and sustainable healthcare.

Overall, the thesis comes out with a design framework for chronic disease management based on systemic design approach and improved by case analysis, and use it to guide a systemic design programme for the self-management of knee osteoarthritis in Shanghai. It hopes that the thesis work and the role of digital health could be helpful to others.

6.2 Limits

There are still many shortcomings in this thesis that need to be pointed out and improved in the follow-up work, which is briefly discussed here:

1) Adopting fewer co-design methods. The systemic design approach is a way that considers the main stakeholders. Enabling dialogue, cooperation, and co-design among stakeholders is one of the expectations of systemic design. However, due to the lack of resources, the thesis program didn't gather the representative stakeholders together to hold a workshop or discussion, which may be easy to miss information and ignore the potential opportunities, as well as being misunderstood the wrong information.

2) On the other hand, more attention was given to patients, considering the feature of self-management, while the research on physicians in primary care and hospitals is insufficient. Despite the support from desk research data and questionnaires, it is still difficult to guarantee the most detailed presentation of the current status of knee osteoarthritis self-management, which needs to be improved in subsequent studies.

3) The type of stakeholders chosen for analysis is likely to be incomplete, and the analysis wasn't detailed enough. In the case study of Shanghai, the family doctor (team) and physiatrist (team) were identified as the main actors. However, there was no discussion about the team members inside the healthcare teams, such as the physical therapists and nurses, who might play important roles in patients' disease self-management. Thus, more work should be done here if going further.

4) Not researching patients with more serious symptoms of KOA. The thesis failed to fully understand the needs and requirements of patients with progressive and end-stage KOA, while it also failed to address the relationship between these kinds of patients and other participants in the system. However, chronic disease management should be the management of the entire disease course, and attention should be paid to patients at all stages. If a comprehensive disease management optimization plan needs to be constructed for patients with KOA, future research work should focus on the needs of patients at various stages of the disease.

5) More possible visions can be explored. Here, the systemic strategy for the self-management of KOA was proposed under the policy context of the Family Doctor System in Shanghai, which is also under the background of basic health insurance in China. However, Shanghai, as well as China, are also encouraging commercial insurers, private healthcare providers, and other non-profit medical institutions (non-government) to conduct chronic disease management. Thus, there are more possible models and solutions that could be found when these new stakeholders are involved in.

6) Less considering about the sustainability and eco-friendly when designing the objects. The materials and production process may not be sustainable and need more thoughtful research and considerations.

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