

From “Made in China” to “Created in China”

Development of ICT-enabled medical device and system for rural China

Proefschrift

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Summary

Background, problem and motivation

Alongside China's rapid economic development over the past twenty years, considerable attention is paid to public health in rural areas. Issues related to the establishment of community-based medical systems and public medical insurance systems are being addressed, but despite this, health problems continue to be a major concern in the country's rural regions. According to 2009 statistics, disease related deaths in rural China were almost double those in urban areas. For instance, the death rate related to hypertension in rural China was 208.8/100,000 population, while in urban China the figure was only 102.8/100,000 population. To put these numbers into perspective, the figure for rural United States was considerably lower, about 50/100,000 population.

One of the causes is shortages of medical resources, such as medical equipment and skilled medical staff. To solve this problem, Information and Communication Technology (ICT) is usually seen as a useful tool, by which medical resources in urban areas can be accessed for rural areas. Design and development of ICT-enabled Medical device and system for Rural China (DIMRC) is therefore considered to be a key approach of the Chinese central government in the development of rural healthcare, as part of the "11-5 plan" (China's 11th Five Year Plan).

In practice, however, the gap between ideal ICT-enabled medical devices and systems and what is currently available in rural markets is still huge. Both the quantity and quality of existing ICT-enabled medical applications fall short of meeting the requirements of patients and doctors.

To bridge this gap, the Chinese government has been encouraging local Chinese Research and Development (R&D) teams (from local companies and universities) to design and develop ICT-enabled medical devices and systems with appropriate innovations, suitable specifically for China. This is a part of China's recent product development strategy, dubbed "Created in China". This strategy encourages the local development of products in China by national brands, and increasingly replaces the "Made in China" strategy. "Made in China" strategy refers to products produced in the country, but developed abroad. For example, products designed by Western multinational companies that are produced in Chinese factories fall under the category of "Made in China".

With a background in biomedical engineering, the author of this thesis was focusing on DIMRC while studying in China. Before beginning this PhD project, the author had conducted research on DIMRC in 2007. Based on this research the author has proposed an initial framework for DIMRC from the viewpoint of a biomedical engineer. This initial framework proposes the collaboration of three Chinese stakeholders, namely government, industrial enterprises and academic institutions engaged. To verify this framework, four DIMRC projects were set up and executed in 2007. The results of four projects revealed that the initial framework was lacking knowledge from outside biomedical engineering sciences. For instance, other knowledge related to DIMRC, such as knowledge on how to identify user needs, and knowledge on how to make ICT-enabled medical devices and systems affordable, were not specifically addressed in biomedical engineering sciences. Following up on this conclusion, the author entered the Faculty of Industrial Design Engineering (IDE) at Delft University of Technology (TU Delft) as a researcher, with the intention of gaining the necessary design knowledge to contribute to improving the initial framework of DIMRC. This was the goal at that time.

Nature of this investigation

This investigation is in the knowledge domain of designing for the underserved part of the world (the so called Base (or Bottom)-of-the-Pyramid, BoP) in general, and product design for rural China in particular. This is a relatively new field. Scientific publications related to the subject are hard to find, and therefore this investigation (and the thesis) is qualitative and exploratory in character. Like other exploratory researches, this investigation relies on secondary research, such as reviews of available literature and/or data; qualitative approaches, such as informal discussions with diverse stakeholders; and more formal approaches, such as in-depth interviews, case studies and pilot studies.

Scope, focus and research questions

There are several steps to be taken to reduce the gap between the ideal ICT-enabled medical devices and systems and those currently available in the rural markets. The initial analysis (in year 2007) had revealed that collaborative R&D efforts are required by Chinese universities, the government and the companies to realise the ambitious “Created in China” goal, and to do this, awareness of the role of design should be enhanced among all the partners.

The main research question for this thesis is therefore: ***What design competences are needed for Chinese R&D teams to design and develop ICT-enabled Medical devices and systems for Rural China?***

This thesis focuses on one partner in particular, namely Chinese academia, which needs to take the lead role in strengthening design education because:

- (1) Strengthening competences requires a long-term and sustained effort, and it would therefore be beneficial to begin educating the Chinese graduates, who will form R&D teams in the future. This approach will lead to the enrichment of Chinese society and will have long-lasting benefits.
- (2) Literature has revealed a weak employee internal training culture in Chinese medical equipment developers and suppliers. If a Chinese medical equipment provider identifies a shortfall in its knowledge base, it dispatches its employees to Chinese universities for part-time study, to attend courses in design education at Chinese universities. This is the normal way to train these employees. Therefore the improvements and adjustments in academic education will also have an impact on training program of employees in companies.

More specifically, this thesis is intended to offer Chinese biomedical engineering an educational solution with a focus on DIMRC. Knowledge from advanced design institutes and scholars will be applied in the educational solution. Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft), The Netherlands is chosen as an example of advanced design institutes.

Hence there is another parallel research question in this thesis: ***How can knowledge and insights from advanced design institutes¹, e.g., (predominantly²) IDE, TU Delft, be made useful for Chinese biomedical engineering students regarding DIMRC?***

¹Advanced design institutes refer to institutes that train students with extensive skills to solve wicked design problems, e.g., DIMRC, through integrative approaches. IDE/TU Delft is an example of advanced design institutes..

²Knowledge of IDE/TU Delft is chosen as the entrance to achieve results of this thesis. Knowledge from other institutes and scholars may also be beneficial for Chinese biomedical engineering students. This knowledge, however, has not been explored in this thesis and will be added in future.

Research methods

To answer these research questions, three methods are used:

1. Literature Analysis: The collection, study and analysis of literature relevant to DIMRC were done by Google Scholar, consultation of diverse databases and the literature available through university library. Due to the multidisciplinary character of this research, knowledge domains from various domains were studied. This includes literature relevant to the current Chinese educational system, identifying the needs to augment design competences (Chapter 3) related to the following aspects: factors of China's culture influencing DIMRC (Chapter 4), design factors for DIMRC (Chapter 5) and Design methodologies for DIMRC (Chapter 6).

2. Practice-based research: This method was used to learn from practice, and comprised an in-depth study of two of the author's own cases: *"Exploring design opportunities in rural Shanghai"* (Chapter 6) and *"Development of blood pressure monitoring system incorporating ICT"* (Chapter 5). A prototype system was developed in this project, and an approach for identifying design factors was conducted during the case study (Chapter 5). Furthermore, an in-depth study of 24 student design projects within IDE/TU Delft was also used (Chapter 6).

3. Interviews: Three Chinese industrial design professors, and four Master students and two PhD students in IDE, TU Delft, were interviewed to identify and verify factors of design culture regarding DIMRC. All of the professors and students had practical experience in DIMRC (Chapter 4).

Thesis Structure and Results

The thesis is structured along 3 parts. See Figure 1.

PART 1 [Chapters 1& 2]

Chapter 1 describes the current status of healthcare in rural China and the requirements for ICT-enabled medical devices and systems. This is followed by an identification of the challenges faced in DIMRC in Chapter 2, leading to the proposition that when Chinese R&D teams are strengthened with design competences, they are more likely to work effectively as independent innovators, resulting in better DIMRC applications. The research question for this thesis is therefore defined as: *what design competences are needed for Chinese R&D teams to design*

and develop ICT-enabled medical devices and systems? Chapter 2 also contains a description of the methodology followed to address this question.

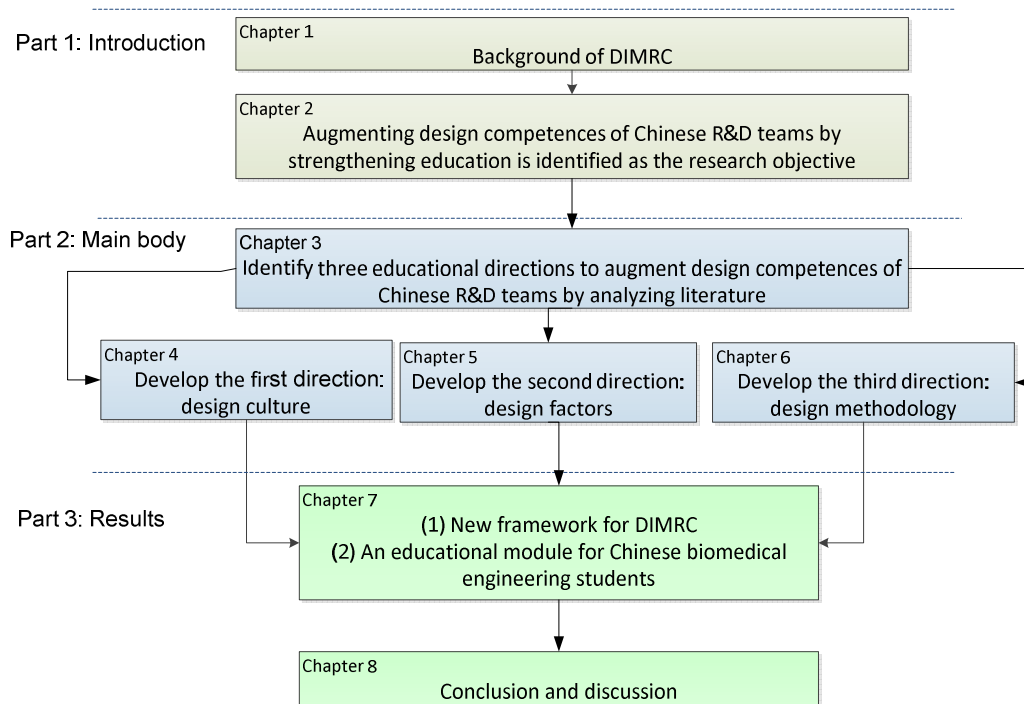


Figure 1: The research in this thesis is conducted in three parts: introduction, main body of investigation and results.

PART 2 [Chapters 3, 4, 5 & 6]

Chapter 3 analyses available literature relevant to DIMRC and confirms the existence of three relevant literature domains, namely “Design for BoP”, “User Centred Design” and “Design and development of ICT-enabled Medical device and system”. This chapter also identifies and verifies three knowledge areas that would be helpful to augment design competences of Chinese R&D teams: “understanding local design culture”, “getting the knowledge to identify design factors” and “exploring suitable existing design methodologies”.

“Design Culture” is explored in Chapter 4, leading to the result that there are 14 important factors in China’s design culture that influence DIMRC. One example is “Usability design for DIMRC should be tailored to different regional cultures”.

Important design factors for DIMRC are identified in Chapter 5, leading to a proposal to compile a reference list of design factors for DIMRC.

Chapter 6 investigates whether existing design methodologies can also be applied for DIMRC. The Delft Design Methodology (DDM) was chosen as the model methodology, and the results confirmed its suitability for application for DIMRC.

PART 3 [Chapters 7& 8]

Based on the results from Chapter 1-6, the original framework of DIMRC is revised (Chapter 7). Chapter 7 also proposes an educational module to support Chinese biomedical engineering students with design knowledge and insights from IDE, TU Delft. A suggestion is provided on how the educational module may be integrated into the current Chinese biomedical engineering education system. Discussions, conclusions and recommendations for future research are provided in Chapter 8.

Final Result 1: Revised Framework

The new version of the framework for DIMRC is composed of three blocks: initiators and organisers, concrete DIMRC projects and the knowledge base.

- (1) **Initiators and organisers:** This block includes three essential Chinese initiators and organisers, and optional collaboration with foreign partners. The Chinese initiators and organisers for DIMRC projects should be the government, companies and the academia, who should all be involved in the project preparation phase of a DIMRC project.
- (2) **Concrete DIMRC projects:** This block includes some practical issues learnt from this thesis, such as the composition of Chinese R&D teams, the design approach to identify user needs, etc.
- (3) **The knowledge base:** This block lists the requisite knowledge base of Chinese R&D teams if they are to achieve more and better DIMRC applications. Two main sources were used: previous literature, and two actual DIMRC cases: the case of “Development of a blood pressure monitoring system incorporating ICT”, and the case of “Exploring design opportunities in rural Shanghai”.

Final Result 2: The educational module

The prime target groups of the educational module are Chinese biomedical engineering professors, Chinese advanced biomedical engineering bachelor students, and Chinese biomedical engineering Master and PhD students. Secondary targets include fresher biomedical engineering bachelor students and other researchers from China without biomedical engineering backgrounds, e.g., physicians and social workers, and foreign researchers with an interest in DIMRC.

The proposed education module places strong emphasis on an integrative approach in the combination of different design issues, i.e., design culture, design factors and design methodology. The module has been designed for flexibility so that different components can be used for different types of design projects, and has been designed in such a way that it is possible to integrate into an existing biomedical engineering course. For this purpose the Chinese educational modules as being used at Shanghai University have served as an example.

Conclusions

The results of this thesis have revealed three issues that demand attention if the design competences of Chinese R&D teams are to be augmented: *(1) R&D teams should have a deep understanding of China's culture with reference to DIMRC; (2) the teams should have more knowledge about identification of design factors for DIMRC; and (3) the teams should have more knowledge to apply existing design methodologies to DIMRC.*

There are a number of approaches to augment the design competences of Chinese R&D teams. However the focus of this thesis is rather on the education of biomedical engineers.

The results of this thesis were utilised to develop a new framework for DIMRC. In addition, an education module for integration into Chinese biomedical engineering education has been created. Finally both results were evaluated by one Chinese biomedical engineering professor and one senior biomedical engineer from a Chinese medical device company. Both of the evaluators are of the opinion that the educational module is useful for Chinese biomedical engineering education, and the framework is

helpful for DIMRC researchers. Future research needs were also presented in the evaluation study.

To this end, advanced design knowledge and insights of advanced design institutes, (e.g., IDE, TU Delft was chosen as a model in this thesis.) was found to be a good source to augment design competences of Chinese R&D teams. Such knowledge can be implemented in the biomedical engineering education in Shanghai University, in the first instance, followed by scaling up to entire China. These interventions will support and accelerate the transformation from “Made in China” to “Created in China”.

Samenvatting

Achtergrond, probleem en motivatie

De ontwikkeling van de gezondheidszorg voor de plattelandsbevolking van China heeft de groeiende aandacht van de Chinese overheid en wordt mede bevorderd door de snelle economische ontwikkeling van het land in de afgelopen twintig jaar. Hoewel daarbij aandacht wordt besteedt aan de totstandkoming van lokale medische systemen, inclusief sociale zorgverzekeringen, blijven gezondheidsproblemen op het platteland van China een grote zorg. Volgens medische statistieken uit 2009, stierven in plattelandsgebieden bijna twee maal zoveel mensen aan ziektes als in stedelijke gebieden. Zo stierven gerelateerd aan een te hoge bloeddruk in dat jaar gemiddeld 208,8 mensen per 100.000 plattelandsbewoners, terwijl dit sterftecijfer in stedelijk China slechts 102,8 per 100.000 personen bedroeg. Ter vergelijking: het sterftecijfer op het platteland van de Verenigde Staten ligt aanzienlijk lager, circa 50 per 100.000 personen.

Eén van de oorzaken van het hogere sterftecijfer op het platteland, is het tekort aan medische hulpmiddelen, zoals medische apparatuur en vakkundig medisch personeel. Een strategie om dit probleem op te lossen is het toepassen van Informatie en Communicatie Technologie (ICT). Met behulp van ICT kan bijvoorbeeld de kennis en expertise van specialisten in stedelijke gebieden beschikbaar gesteld worden voor laag-opgeleid medisch personeel en patiënten in plattelandsgebieden. Deze studie richt zich op de ontwikkeling van medische producten en systemen met geïntegreerde ICT voor ruraal China (DIMRC). DIMRC is de afkorting voor het Engelse “Design and development of ICT-enabled Medical device and system for Rural China”. Binnen het “11-5 plan” van de Chinese Centrale Overheid (China’s 11^{de} vijfjarenplan), kan DIMRC een sleutelrol vervullen in de ontwikkeling van de gezondheidszorg op het platteland.

Echter, bestaande DIMRC toepassingen voldoen zowel in kwantiteit als kwaliteit niet aan de eisen van de patiënten en dokters. Om deze kloof te dichten stimuleert de Chinese overheid lokale Chinese onderzoeks- en ontwikkelingsteams (R&D-teams) -afkomstig van lokale bedrijven en universiteiten- om medische ICT-ondersteunde apparaten en systemen en merken te ontwerpen en te ontwikkelen, met innovaties die specifiek geschikt zijn voor de Chinese doelgroep. Dit beleid is onderdeel van China’s recente productontwikkelingsstrategie, “Created in China”. “Created in China” zou op termijn “Made in China” moeten vervangen.

“Made in China” is de internationaal bekende aanpak, waarbij producten geproduceerd zijn in China, maar ontwikkeld worden in het buitenland.

De auteur van dit proefschrift heeft een achtergrond in biomedische technologie en heeft tijdens zijn studie in China gewerkt aan DIMRC. Op basis van zijn onderzoek, heeft hij in 2007 een eerste raamwerk voor DIMRC ontwikkeld. In dat raamwerk wordt de noodzakelijke samenwerking van drie belanghebbenden aangegeven: de Chinese overheid, industriële ondernemingen en academische instituten. Ter verificatie van het raamwerk werden vier DIMRC-projecten opgezet en uitgevoerd. Deze projecten toonden gebreken in het initiële raamwerk, die werden toegeschreven aan een gebrek aan kennis binnen het domein van de biomedische technologie. Naast technische kennis bleek kennis over integrale productontwikkeling een vereiste voor succesvolle DIMRC, zoals kennis over gebruikersbehoeften en economische haalbaarheid. Deze conclusie heeft de aanleiding gevormd voor dit promotieonderzoek bij de faculteit Industrieel Ontwerpen (IO) aan de Technische Universiteit Delft (TU Delft). Bij de start was het primaire doel ontwerp-kennis te verwerven, die benodigd is om een verdere bijdrage te kunnen leveren aan het verbeteren van het DIMRC raamwerk, om daarmee een belangrijke stap te zetten richting effectievere DIMRC-toepassingen.

Aard van het onderzoek

Dit onderzoek vindt plaats binnen het kennisveld ‘Base (or Bottom) -of-the-Pyramid’ (BoP) oftewel het ontwerpen voor het armere deel van de wereldpopulatie, en in het bijzonder productontwikkeling voor mensen van het Chinese platteland. Omdat onderzoek naar de ontwikkeling van medische apparatuur en systemen voor plattelandsgebieden een relatief nieuw gebied is, heeft dit onderzoek (en het proefschrift) een kwalitatief en exploratief karakter. Zoals gebruikelijk in exploratief onderzoek, baseert dit onderzoek zich op secundair onderzoek, zoals literatuuronderzoek en analyse van eerder uitgevoerde ontwerp casussen; op informeel kwalitatief onderzoek, zoals informele discussies met diverse belanghebbenden en op kwalitatief onderzoek, zoals eigen ontwerp casussen en diepte-interviews.

Strekking, focus en onderzoeksvragen

Om de kloof te overbruggen tussen de nu op het platteland beschikbare medische ICT-apparatuur/systemen, en de ideale situatie, moeten diverse stappen worden gezet. Uit het vooronderzoek is gebleken dat

gezamenlijke R&D-inspanningen van de Chinese universiteiten, de overheid en de private sector nodig zijn om het ambitieuze “Created in China” doel te realiseren.

De hoofd onderzoeksvraag voor dit proefschrift is daarom ***Welke ontwerpcompetenties hebben Chinese R&D-teams nodig voor de ontwikkeling van medische producten en systemen met geïntegreerde ICT voor ruraal China?***

Dit proefschrift richt zich vervolgens specifiek op één partner, namelijk de Chinese academische wereld, welke een leidende rol kan nemen in het versterken van die competenties via het ontwerp en ontwikkelonderwijs, om twee redenen:

- (1) Het versterken van competenties vereisen continue inzet op lange termijn. Het opleiden van Chinese studenten, die de toekomstige R&D-teams zullen vormen, zal leiden tot verrijking van de Chinese maatschappij en zal langdurige voordelen hebben.
- (2) Uit het literatuuronderzoek blijkt dat er een zwakke interne trainingscultuur heerst bij Chinese ontwikkelaars en leveranciers van medische apparatuur. Wanneer een bedrijf een gebrek in zijn kennisniveau vaststelt, is het gebruikelijk dat het zijn medewerkers een deeltijd cursus in ontwerp- en ontwikkelonderwijs laat volgen aan een Chinese universiteit. Derhalve heeft het verbeteren van het onderwijs ook direct impact op professionele ontwikkelaars.

Aangezien biomedisch technologen in China een centrale en prominente rol hebben in de ontwikkeling van medische apparatuur werd tenslotte de focus toegespitst op het onderwijs aan deze groep. In het bijzonder, de eerder aangegeven kennis over integrale productontwikkeling, zoals onderwezen en onderzocht bij IO, TU Delft was de focus van onderzoek, aangezien de verwachting bestond dat deze kennis een vereiste is voor succesvolle DIMRC.

De sub onderzoeksvraag is ***Hoe kunnen de kennis en inzichten van de faculteit van het Industrieel Ontwerpen van de Technische Universiteit Delft bruikbaar gemaakt worden voor Chinese studenten biomedische technologie?***

Onderzoeksmethoden

Om deze onderzoeksvragen te beantwoorden zijn drie methoden toegepast:

1. Literatuurstudie: Een literatuurstudie was gedaan via internet, waarbij Google Scholar alsmede verschillende databases werden geraadpleegd. De focus was op verschillende kennisdomeinen, vanwege het multidisciplinaire karakter van DIMRC. De literatuur leverde de volgende inzichten op: de noodzaak van het vergroten van ontwerpcompetenties (Hoofdstuk 3) betreffende drie gebieden namelijk: factoren van de Chinese cultuur die DIMRC beïnvloeden (Hoofdstuk 4), ontwerpfactoren voor DIMRC (Hoofdstuk 5) en ontwerpmethodologie voor DIMRC (Hoofdstuk 6).

2. Praktijkonderzoek: Deze methode is toegepast om te leren van de praktijk, en omvat een diepte studie van twee eigen casussen van de auteur: “ICT bloeddruk monitoring systeem” (Hoofdstuk 5) In deze casus is een prototype van een medisch systeem ontwikkeld en een aanpak toegepast om ontwerpfactoren te identificeren. In hoofdstuk 6 wordt een andere casus bestudeerd: “*Verkennen van ontwerpmogelijkheden voor het platteland van Shanghai*”. Tevens wordt een diepte-studie van 24 afstudeerontwerp projecten uitgevoerd, allen afkomstig van IO, TUDelft.

3. Interviews: Met als doel om culturele ontwerp factoren te identificeren en te verifiëren, werden drie Chinese ontwerp-professoren geïnterviewd, vier Chinese Master studenten (van IO, TU Delft) en twee Chinese promovendi (eveneens van IO, TU Delft). Alle geïnterviewden hadden praktische ervaring op het gebied van DIMRC (Hoofdstuk 4).

Structuur van het proefschrift en resultaten

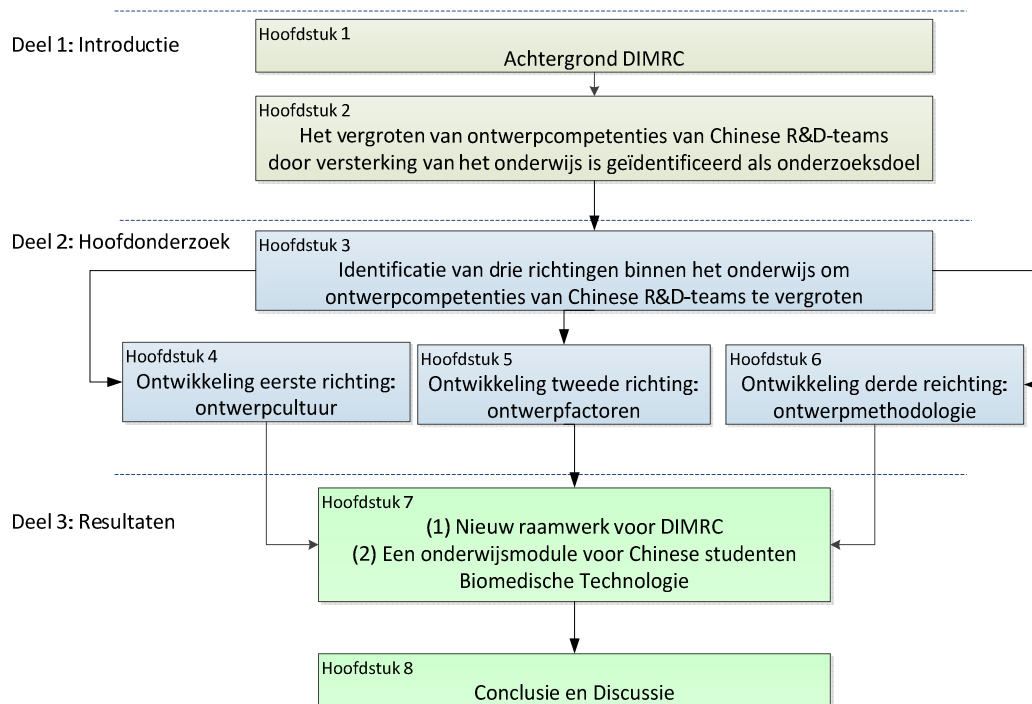
Het proefschrift is ingedeeld in drie delen, zoals weergegeven in figuur 1.

DEEL 1 [Hoofdstuk 1 & 2]

Hoofdstuk 1 beschrijft de huidige gezondheidszorg op het Chinese platteland en de eisen die gesteld moeten worden aan de medische technologieën.

In hoofdstuk 2 volgt een identificatie van de uitdagingen voor DIMRC. Dit heeft geleid tot de stelling dat als Chinese R&D-teams versterkt worden

met ontwerpcompetenties, zij naar alle waarschijnlijkheid effectiever werken als onafhankelijke innovatoren. De hoofd-onderzoeksvraag werd geformuleerd. Tevens bevat hoofdstuk 2 de gevolgde methodologie om deze vraag te beantwoorden.



Figuur 1: Het onderzoek in dit proefschrift is uitgevoerd in drie delen: introductie, hoofdonderzoek en resultaten.

DEEL 2 [Hoofdstuk 3, 4, 5 & 6]

Bepaling stand van de techniek van (DIMRC) middels literatuur studie. In hoofdstuk 3 zijn drie relevante literatuuordomeinen geïdentificeerd. Tevens is hun relevantie geverifieerd, namelijk “Ontwerpen voor BoP”, “Gebruikers gericht ontwerpen” en “Ontwikkeling van medische producten en systemen met geïntegreerde ICT”. Uit deze studie werd geconcludeerd dat het nodig is ontwerpcompetenties van Chinese R&D teams te vergroten in drie gebieden. Dit zijn: het begrijpen van ontwerprelevante (locale) culturele aspecten in China (Hoofdstuk 4), een breder palet aan ontwerpfactoren relevant voor DIMRC (Hoofdstuk 5) en ontwerpmethodologie voor DIMRC (Hoofdstuk 6).

Hoofdstuk 4 verkent het domein “Ontwerpcultuur”, en resulteert in 14 belangrijke factoren in de Chinese ontwerpcultuur die DIMRC

beïnvloeden. Een van de aanbevelingen is dat 'Usability Design' (ontwerpen voor bruikbaarheid) voor DIMRC toegesneden moet worden op verschillende regionale culturen.

In hoofdstuk 5 worden belangrijke ontwerpfactoren voor DIMRC geïdentificeerd, wat leidt tot een voorstel om een referentielijst met ontwerpfactoren voor DIMRC samen te stellen.

Hoofdstuk 6 onderzoekt of bestaande ontwerpmethodologie toegepast of aangepast kan worden voor DIMRC, uitgaande van de Delftse Ontwerp Methode (in het Engels: Delft Design Method - DDM) als voorbeeld. Het onderzoek laat zien dat DDM geschikt is voor toepassing binnen DIMRC.

DEEL 3 [Hoofdstuk 7 & 8]

Op basis van de resultaten uit deel 1 en 2 van het onderzoek is het initiële raamwerk voor DIMRC herzien (Hoofdstuk 7). In hoofdstuk 7 wordt tevens een onderwijsmodule gepresenteerd om Chinese studenten Biomedische Wetenschappen te ondersteunen met ontwerp-kennis en inzichten vanuit IO, TU Delft. Dit omvat een voorstel voor de integratie van deze onderwijsmodule in het huidige Chinese onderwijsstelsel van Biomedische Wetenschappen. De discussie, conclusies en aanbevelingen voor verder onderzoek worden gepresenteerd in hoofdstuk 8.

Uiteindelijk resultaat 1: Herzien raamwerk

De nieuwe versie van het raamwerk voor DIMRC bestaat uit drie componenten: initiatiefnemers & organisatoren, concrete DIMRC projecten en de kennisbasis.

- (4) **initiatiefnemers en organisatoren:** Deze component omvat drie essentiële Chinese initiatiefnemers en organisatoren, namelijk de Chinese overheid, Chinese bedrijven en Chinese academici, alsmede mogelijke samenwerking met buitenlandse partners. Het initiatief voor en de ontwikkeling van DIMRC projecten zou in handen moeten komen te liggen van de drie Chinese spelers, eventueel aangevuld met buitenlandse partners, die allen betrokken zouden moeten worden in de voorbereidende fase van een DIMRC-project.
- (5) **Concrete DIMRC projecten:** Deze component omvat praktische kwesties voortkomend uit dit proefschrift, zoals de samenstelling van de Chinese R&D-teams en de grotere aandacht voor het identificeren van de behoeften van de gebruiker.

- (6) **De kennisbasis:** Deze component geeft een overzicht van de kennisbasis die Chinese R&D-teams nodig hebben om meer en betere DIMRC-toepassingen te realiseren.

Uiteindelijk resultaat 2: De onderwijsmodule

De primaire doelgroepen van de ontwikkelde onderwijsmodule zijn Chinese professoren biomedische technologie en gevorderde Chinese studenten of promovendi biomedische technologie. Secundaire doelgroepen van de onderwijsmodule zijn: eerstejaars studenten biomedische technologie, andere professionals uit China, zoals artsen, sociaal werkers, of andere ingenieurs.

De voorgestelde onderwijsmodule legt een sterke nadruk op een integrale aanpak waarbij verschillende ontwerpkwesities worden gecombineerd, zoals ontwerpcultuur, ontwerpfactoren en ontwerpmethodologie. De module is ontwikkeld om flexibel te zijn, zodat verschillende onderdelen gebruikt kunnen worden binnen verschillende soorten ontwerp projecten. Daarnaast is, met Shanghai Universiteit als voorbeeld, rekening gehouden met Chinese educatiemodellen.

Conclusies

Teneinde R&D teams beter te equiperen voor hun taken in DIMRC moeten hun ontwerpcompetenties op een drietal vlakken versterkt worden: *(1) R&D-teams moeten een rijk begrip hebben van de Chinese cultuur met betrekking tot DIMRC; (2) de teams moeten meer kennis hebben voor het identificeren van ontwerpfactoren voor DIMRC; en (3) het team moet meer kennis hebben om bestaande ontwerpmethodologie uit het ontwerpdomein toe te passen voor DIMRC.*

Er zijn verschillende benaderingen om de ontwerpcompetenties van Chinese R&D-teams te vergroten. De focus van dit proefschrift ligt op het onderwijzen aan biomedisch technologen. De resultaten van de twee DIMRC casus en andere onderzoeken in dit proefschrift zijn gebruikt om een nieuw raamwerk te ontwikkelen voor DIMRC. In aanvulling daarop is een onderwijsmodule gecreëerd die volgens verwachting geïntegreerd kan worden binnen het Chinese biomedische technologie onderwijs. Tenslotte is zowel het raamwerk als de onderwijsmodule geëvalueerd door twee Chinese biomedisch technologie professionals, te weten, een professor en een expert uit het bedrijfsleven. De experts oordeelden dat het raamwerk nuttig is voor DIMRC onderzoek en dat de educatiemodule

passend en bruikbaar is voor Chinees biomedisch technologie onderwijs. Hiermee is een voorzichtige indicatie betreffende generaliseerbaarheid buiten de Shanghai setting gemaakt.

De verschillende deelresultaten inclusief deze beperkte evaluatie geven aanwijzingen dat inderdaad kennis en inzichten van de faculteit Industrieel Ontwerpen van de Technische Universiteit Delft een verrijkende bron zijn voor het versterken van ontwerpcompetenties voor DIMRC bij Chinese R&D teams, en derhalve een rol kunnen spelen in de transitie van “Made in China” naar “Created in China”.

概要

背景

中国拥有世界上最多的农村人口数（8 亿 5000 万）。医疗问题是农村人口面临的一个主要社会问题。与城市人口相比，农村人口的平均疾病死亡率要高出许多。以高血压相关的死亡为例，2009 年中国农村人口因高血压造成的死亡率为 208.8/10 万，而同期中国城市人口的死亡率为 102.8/10 万。在美国这个数字为 50/10 万。造成上述现象的主要原因之一是因为中国农村缺少医疗资源，例如缺少合适的医疗仪器；缺少有经验的医护人员等。因此看病难，看病贵成为中国农村医疗所面临的最大问题。

在国际上，提供通信与信息技术（Information and Communication Technology: ICT）基于的医疗产品是解决以上问题的一个重要手段，例如远程医疗系统，计算机辅助诊断系统等。ICT 技术不但可以解决中国农村医疗资源紧缺的问题，而且价格低廉。

早在 2004 年，中国政府、高校以及公司就意识到中国农村医疗的重要性。比较早介入为中国农村市场开发基于 ICT 的医疗产品公司包括通用电子，飞利浦，迈瑞等。这些公司开发了一系列适合于中国农村市场使用的医疗系统，例如便携式超声系统，简易 x 光机等。但是，这些产品并不能完全满足中国农村市场的需求。如前中国卫生部副部长，现中国农村医疗委员会理事长朱庆生在 2011 年所述，目前仍有超过 4 万家农村卫生院，卫生点需要购入新的基于 ICT 的医疗系统或者更新现有的系统。2012 年这个市场大概为 83 亿人民币。

为了满足巨大的市场缺口，中国政府鼓励中国公司自己的研发团队设计与开发专门面向中国农村市场的医疗产品。这属于中国产品开发大战略的一部分：“中国创造”。“中国创造”是中国中央政府于 2008 年提出的产品开发战略，旨在鼓励中国研究机构以及企业开发拥有自主知识产权的技术与产品，而不在仅仅满足于中国企业只是作为世界的加工工厂。“中国创造”战略是针对于“中国制造”的一种改进。

研究范围

然而，对于中国（中央，地方）政府，高校以及企业来说，实现针对农村医疗仪器的“中国创造”任重而道远。这需要各参与方的共同努力，例如，中国（地方）政府应该为企业提供更好的创新环境，例如提供相应的经济补贴，专利保护机制等；中国高校应该加强对创新型

人才的培养；中国企业则应加大对研发的重视和资金投入等。本论文只关注其中的一点：如何提高中国研发团队的设计竞争力。

作为一个特殊例子，本文将特别关注如何将先进的设计知识（例如，荷兰代尔伏特理工大学设计学院的设计知识）融入以及运用到中国生物医学工程教育中去。在本文中，生物医学工程师被看作是中国研发团队中的重要一员。

本文研究特征

本文的研究关于为经济底层人群（Base 或者 Bottom of the Pyramid）设计产品以及为中国农村设计医疗产品。由于目前关于这 2 个课题的文献都很少，因此本文是一个定性的探索型研究。在探索过程中本文将不断提出新的研究问题，而不仅仅是回答某个具体的研究问题。与其他探索性研究一样，本文将采取文献分析，案例分析，实地案例等方法。

研究问题

主研究问题：中国研究团队需要哪些设计竞争力来设计与开发面向中国农村市场的 ICT 基于的医疗产品与系统（Design and development of ICT-enabled Medical device/system for Rural China: DIMRC）？

特殊研究问题：针对 DIMRC，如何将将来先进的设计知识（例如代尔伏特的设计知识）融入到中国生物医学工程教育中去？

研究方法

为了回答以上的问题，本文主要采用了三种研究方法：

- 1. 文献分析：**采集，分析与 DIMRC 相关的文献并理解其中的创新。这些文献包括：当前中国教育系统，确定提高设计竞争力的需求（第 3 章），中国设计文化的相关因素（第 4 章），DIMRC 的设计因素（第 5 章），以及与 DIMRC 相关的设计方法等（第 6 章）。
- 2. 实践基于的研究：**从实践中学习并归纳知识。本文主要运用了 2 个实践案例：“Exploring design opportunities in rural Shanghai” 以及 “Development of Blood pressure monitoring system incorporating ICT”. 这 2 个案例将在第 5 和第 6 章被详细介绍。此外，24 个代尔伏特设计学院的学生案例也在第 5 和第 6 章中被分析和运用。

3. 采访: 三个中国设计学的教授以及六个在代尔伏特设计学院学习的中国学生被采访。(第 4 章) 采访的目的是为了确认文献中关于 DIMRC 设计文化的内容。这些被采访者都有 DIMRC 的相关设计经验。

研究步骤

本文主要分成 3 个部分，见图 1。

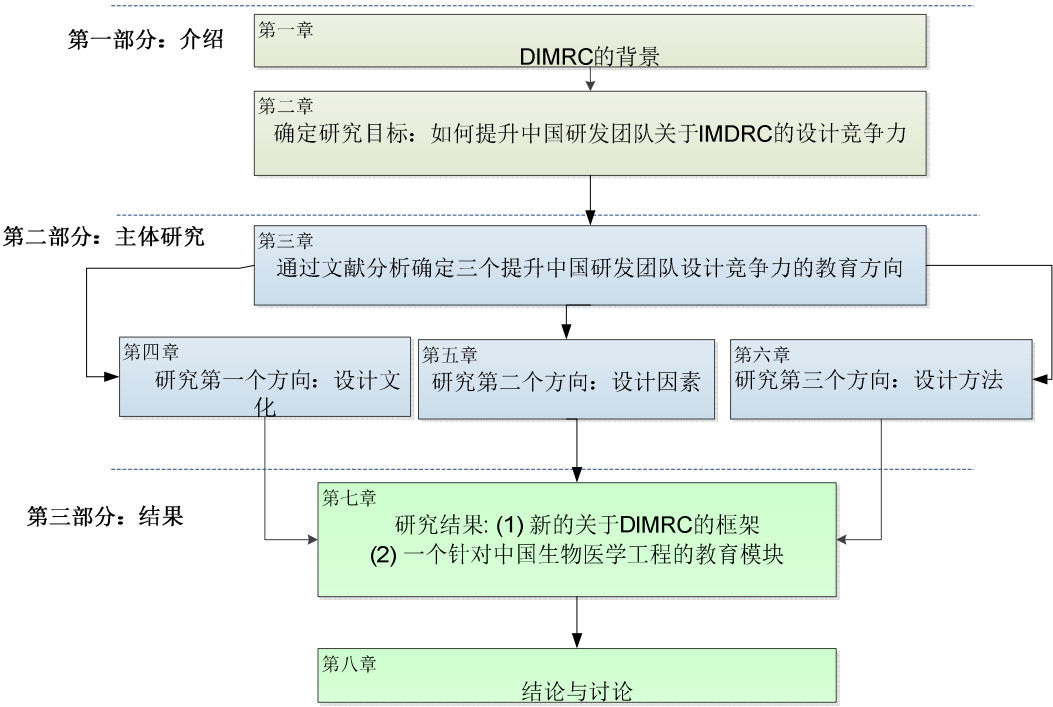


图 1: 本文的研究流程共分 3 个部分：介绍，主体研究以及结果。

第一部分包括第 1 和 2 章。

本文的第 1 章为文献综述，主要介绍了 DIMRC 的背景知识，包括介绍了中国农村医疗结构，中国政府在过去所做的努力，DIMRC 的参与方，以及 DIMRC 的复杂性等。本章同样介绍了作者在过去总结的关于 DIMRC 的的框架，以及三个最主要的 DIMRC 参与方，分别为中国政府，高校以及企业。

第 2 章介绍了 DIMRC 面临的机遇与挑战。本章的研究方法也为文献综述。相关的科学文献以及政策文件表明，成功的 DIMRC 运用需要各方的共同努力。首先中国政府需要为中国社会构建一个更好的创新环境，例如制定针对 DIMRC 的设计政策，加强知识产权保护等；其次中国高校应该加强创新性人才的培养，培育面向 21 世纪的复合型

人才；再次中国企业应该加大研发投资，创造良好的创新环境。第 2 章同样介绍了生物医学工程师在 DIMRC 中承担的重要的角色，因此本文选择研究如何提升中国生物医学工程师的设计竞争力。在本章的最后，本文的主研究问题以及特殊研究问题被罗列出来。

第二部分为第 3-6 章。

第 3 章归纳了 3 个与 DIMRC 相关的文献域：面向 BoP 的设计（Design for Base/Bottom of the Pyramid: DfBoP），ICT 基于的医疗产品设计与开发(Design and development of ICT-enabled Medical device and system : DIM)以及用户中心设计(User Centred Design: UCD)。通过学习和运用 3 个文献域中的文献，作者做了 3 个子研究：（1）作者归纳了 14 个中国研发团队在设计 DIMRC 过程中需要提高的改进需求点；（2）作者罗列了 4 个文献中现有的设计模型，并探索是否这些模型完全适用于 DIMRC；（3）作者通过比较 14 个改进需求点来提出一些针对生物医学工程的教育目标。本章的结果表明：（1）现有的设计模型不能完全适用于 DIMRC，但是部分适用；（2）3 个教育目标可以被用来提升中国生物医学工程师的设计竞争力：理解中国设计文化对于 DIMRC 的影响，确定 DIMRC 的设计因素，以及合理运用现有的设计方法。以上 3 个目标在第 4-6 章中被详细地研究。

第 4 章研究了中国设计文化对于 DIMRC 的影响。5 个与中国设计文化相关的参与方在本章中被研究，这 5 个参与方为中国政府，中国高校，中国公司，农村用户（农村医院，医生，病人等），以及其他中国社会成员。本章的研究方法为文献综述以及采访。3 位中国设计学教授以及 6 位在代尔伏特设计学院学习的中国留学生（博士以及硕士）被采访。作为结果，作者归纳了 14 条与 DIMRC 有关的中国设计文化因素。

第 5 章确定了 DIMRC 的设计因素。本章的研究方法为案例分析。24 个代尔伏特设计学院学生所做的关于 DfBoP 的设计项目，以及 1 个作者所参与的关于 DIMRC 的设计项目（“Development of a blood pressure monitoring system incorporating ICT”）被用做研究数据。作为结果，作者归纳了 24 个关于 DIMRC 的设计因素。

第 6 章探索了现有的设计方法是否可以适用于 DIMRC。本章的研究方法也为案例分析。在第 5 章中罗列的 24 个学生设计项目，以及 1 个作者所参与的关于 DIMRC 的设计项目（“Exploring design opportunities in rural Shanghai”）被用做研究数据。本章的结果表明，一些现有的设计方法（比如在代尔伏特设计学院被用作教育的代尔伏

特设计方法（Delft Design Methodology: DDM））可以被改编并用于 DIMRC。

第三部分为第 7-8 章。

在 1-6 章的研究结果基础上，第 7 章归纳了本文的 2 个主要的研究结果：（1）一个关于 DIMRC 的新的框架。新的框架延续了第 1 章中旧框架的结构，但是将框架中每个部分都具体化。例如三个主要的参与方（中国政府，高校以及企业）在 DIMRC 立项过程中的职责被具体描述；研发团队成员的组成，角色和职责被具体描述等。（2）一个针对中国生物医学工程的教育模块。作者希望通过在中国大学教育中使用这个模块来提升中国生物医学工程师设计竞争力。这个模块的内容主要来自于本文的文献分析以及案例分析。

第 8 章介绍了本文的结论，讨论以及未来研究需求。

结果

本文 2 个主要的研究结果将在此章中被介绍。

结果 1：新的关于 DIMRC 的框架

这个框架的架构与原先的旧的关于 DIMRC 的框架（图 1.4）相同，由 3 个部分组成：

- （1）提出者以及组织者。这个部分包括 3 个必须的中国利益相关者：中国政府，高校以及公司。一些国际利益相关者可以通过与这 3 个中国利益相关者合作参与 DIMRC 项目。
- （2）具体的 DIMRC 项目。这个部分介绍了一些关于 DIMRC 的实践知识，例如研发团队组成等。
- （3）关于 DIMRC 的知识库。这个部分介绍了关于 DIMRC 的理论知识。这些知识来源于 2 个部分：文献以及案例。

结果 2：面向中国生物医学工程学生的教育模块

这个模块的首要用户为生物医学工程教师，生物医学工程研究生以及高年级生物医学工程本科生，次要用户包括低年级生物医学工程本科生以及其他对 DIMRC 感兴趣的研究者以及实践者。

这个模块使用了嵌入式的方法（Integrative approaches），将不同的设计课题（Design issues）融入其中，包括设计文化，设计因素以及设计方法。来自代尔福特设计学院的相关知识都被运用在这个教育模块中。

结论

通过大量的文献综述以及案例分析，本文提出了 3 个方面来提升中国研发团队关于 DIMRC 的设计竞争力：（1）深入了解中国设计文化关于 DIMRC 的影响；（2）获取更多关于 DIMRC 设计因素的知识；（3）学会运用现有的设计方法在 DIMRC 中。关于这 3 个方面的知识在本文中被详细地研究。

文献提供了许多可行的方法来提升中国研发团队的设计竞争力，例如为中国政府以及公司提供设计模板，为中国大学改进设计教育等。本文选择了将学习代尔伏特的设计知识以及内涵并将之融入到中国生物医学工程教育中去。在这个过程中，2 个实际的 DIMRC 案例被设立并且研究。

作为本文的结果，作者提出了一个新的关于 DIMRC 的框架以及一个旨在提高中国生物医学工程设计教育的教育模块。这 2 个结果被一位生物医学工程专业的教授以及一位来自中国医疗器械公司的高级生物医学工程师所评估，评估结果表明教育模块对中国生物医学工程的教育有用，而框架对于 DIMRC 的研究者有帮助。在评估中一些本文今后的研究方向同样被给出。

PART 1

PART 1: INTRODUCTION

China has a large rural population (0.85 billion), for which healthcare problems are a major concern. In 2009, the disease-related death rate in rural China was almost double that of urban China. For instance, the death rate from hypertension in rural China was 208.8/100,000 population in 2009, compared to 102.8/100,000 in urban areas. To put these numbers into some sort of perspective, the same figure for rural United States was around 50/100,000 population. One of the main causes of the above problem is the lack of medical resources in China's rural areas, such as shortages of advanced medical equipment and skilled medical staff. Increasing accessibility to Information and Communication Technology (ICT)-enabled medical devices and systems (defined in Section 1.5) is considered to be an important factor in alleviating this problem (Martínez et al., 2005; Cecchini & Raina, 2004); and in 2004 a number of multinational companies, local Chinese companies and Chinese universities started to take steps to address this issue.

Despite this, the gap between the ideal and the available ICT-enabled medical devices and systems in rural markets is still huge. As claimed by the director of the China Rural Health Association, Zhu Qingsheng (CRHA, 2012), in 2012 more than 40,000 healthcare organisations in rural regions still need suitable medical devices and systems to the value of 8.37 billion Yuan (about 1 billion Euro). Healthcare organisations in rural regions

include county hospitals, Community Healthcare Centres (CHC) in towns and Community Healthcare Points (CHP) in villages.

To bridge this gap, the Chinese government is encouraging Chinese Research and Development (R&D) teams (from Chinese local companies and universities) to design and develop ICT-enabled medical devices and systems through innovations that are appropriate for China (CMoST, 2012). This is one part of China's product development strategy, dubbed "Created in China" (Wen, 2004).

"Created in China" refers to products actually designed and developed in China under national brands.

This strategy is intended to replace "Made in China".

"Made in China" refers to those products produced in the country, but developed outside China, such as products designed by Western multinational companies that are produced in Chinese factories.

THIS THESIS

This doctoral thesis is about Design and development of ICT-enabled Medical devices and systems for Rural China (DIMRC). Information and Communication Technologies (ICT) facilitate communication and the processing and transmission of information by electronic means; but its importance in this thesis is based on the hypothesis that more and better information and communication furthers the development of society (be it in the improvement of income, education, health, security, or any other aspect of human development), and can make healthcare more accessible. The range of available ICT tools includes radios, televisions, telephones (fixed and mobile), computers, internet, etc., and DIMRC calls for the design and development of medical products/systems that are supported by ICT for the treatment of medical issues in rural China. Some examples of ICT-enabled medical devices and systems are ultrasound systems

(medical imaging systems), Holter monitors (portable devices for the continuous monitoring of electrical activity in the heart – electrocardiography – that can be utilised as part of a patient homecare system) and tele-diagnosis systems (for instance, telemedicine). However, more and improved DIMRC applications are still needed.

Designing and developing ICT-enabled medical devices and systems for rural China is a typical “wicked problem” (Weber et al., 2008) (“Wicked problem” is defined on page 19), referring to a complex problem that is unstructured. Practically no consensus exists in how they should be defined, their cause and effect are often unclear, and attempts to resolve them often results in them morphing into different problems. They are often associated with situations in which multiple and diverse stakeholders are involved, with high levels of interdependence and social and political complexity, and with an on-going requirement for information and knowledge. This thesis addresses this knowledge requirement from the perspective of several disciplines, including science, economics, statistics, technology, medicine, politics, etc., all of which are necessary to bring about effective change in DIMRC, however such interdisciplinary collaboration necessitates also patience and perseverance. Figure 1.1 shows an overview of the different stakeholders that need to be involved in DIMRC.

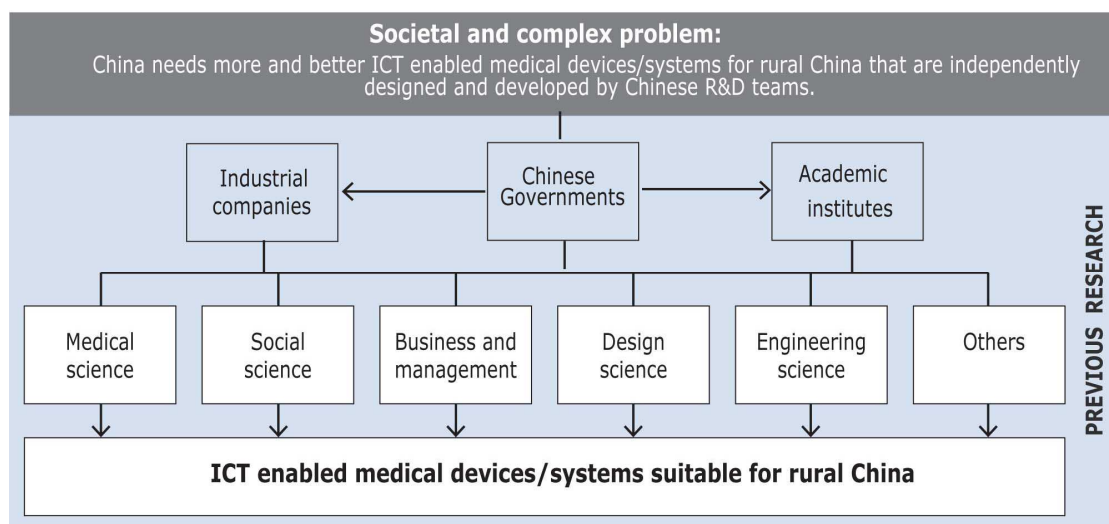


Figure 1.1: Industrial companies, Chinese (central and local) governments and academic institutions are currently the key stakeholders in DIMRC, bringing expert knowledge from different domains, such as medical science, social science, etc. The responsibilities of the three stakeholders are described in Section 1.7.

Healthcare itself is an issue involving the complex interaction of biomedical, social, economic and political determinants. ICT-enabled

medical devices and systems play an important role in the diagnosis and treatment of healthcare problems, and developing suitable CT-enabled medical applications, especially for use in rural China, is a complex issue that involves the efforts of different stakeholders. One particular requirement is the augmentation of the design competences (defined in Section 2.1.3) of Chinese R&D teams. In Western countries product designers often play a central role in mitigating the negative consequences of wicked problems. For instance, in the Netherlands, the Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft) teaches students to use integrative approaches (defined in Section 2.2.3) to resolve complex design problems, in which the field of ICT-enabled medical device/system design for developing countries can be counted. Wale (McKinsey Quarterly, 2012) claims that the design competences of Chinese R&D teams may be augmented by strengthening Chinese industrial and engineering design education with the knowledge of integrative approaches from Western countries.

This thesis explores what design competences are needed for Chinese R&D teams. The term design competence is defined as follows:

Design competences cover the design knowledge and skills that provide designers with a competitive advantage in the creation and delivery of the values of their design.

Having identified these competences, the question arises of how they may be augmented. One approach is to disseminate them in the early stages of professional education, and the existing Chinese educational infrastructure can be considered as a good platform for the training of students in design competences at a university level. In this way, a Chinese graduate that has left university and joined an R&D team will have already been trained and equipped with the appropriate competences for participating effectively in a team, developing, for instance, ICT-enabled medical devices and systems for rural China.

A design team consists of members with backgrounds in different disciplines, and in this thesis, one discipline in particular, being Chinese biomedical engineering, has been selected for analysis. Biomedical engineering is a specialty field that gives students the knowledge and skills necessary for the design and development of ICT-enabled medical devices and systems. In this thesis, knowledge and insights from IDE/TU

Delft served as a primary resource to augment the existing design competences of Chinese R&D teams.

Figure 1.2 provides an overview of the various challenges faced by China in improving healthcare for its rural citizens, while also showing areas with potential for improvement, one of which is the design, manufacture and distribution of ICT-enabled medical devices. How this opportunity may be utilised, and what steps are to be taken constitute the broad domain of this thesis, and within this breadth, the role of Chinese biomedical engineering education is granted particular focus. Figure 1.2 is described and explained in detail in the following sections.

This thesis is composed of three parts. Part I (Chapters 1 and 2) introduces the thesis, explaining the background, problem statement, personal motivation, research questions and methods; Part II (Chapters 3–6) is the main body of the investigation; and Part III (Chapters 7–8) contains results, evaluations, conclusions, discussions and recommendations for future research.

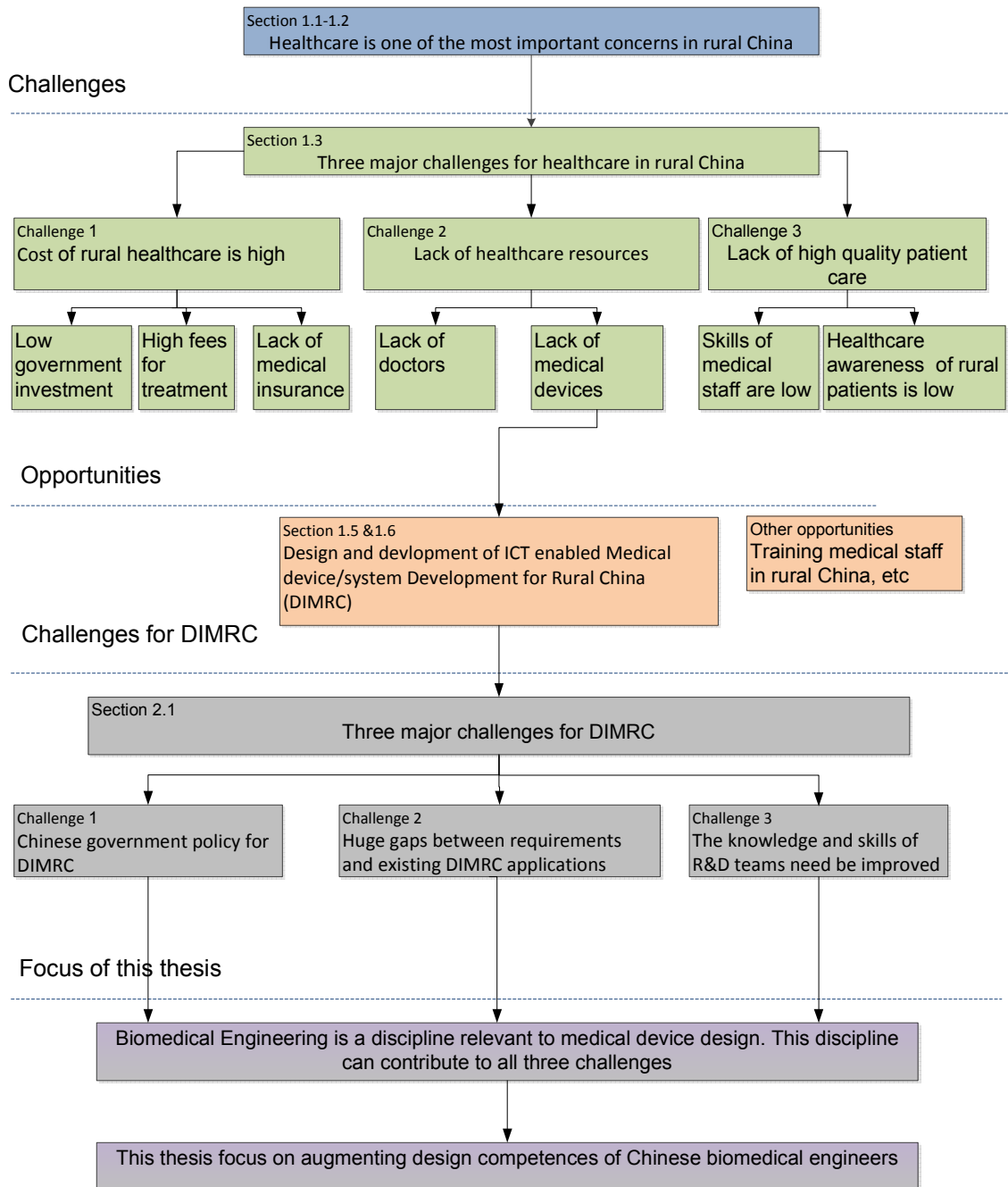


Figure 1.2: A track to converge the focus on healthcare in rural China to the augmentation of design competences of Chinese biomedical engineers.

Chapter 1 Background³

1.1 Health system and the current situation in rural China

China, one of the world's most ancient civilizations, has a recorded history that dates back 4,000 years. Today, the People's Republic of China has a population of 1.4 billion, of which more than 0.85 billion live in rural areas (China Health Statistical Yearbook, 2009).

China's administrative system has six levels (see Figure 1.3): (1) The State Council of the People's Republic of China, as the central government, the top executive organisation of the country; (2) The governments of the 33 provinces, municipalities, autonomous regions and special administrative regions, being direct subordinates of the State Council; (3) The Prefectural regions, below the provincial level, which numbered 333 in 2009; (4) The County level, below the prefectural level. There were 2,862 county-level regions in 2009; (5) Township level, below the county level. There were 41,636 township-level regions in 2009; and finally (6) Village level, below the township level. There were more than 10 million villages (rural regions) and communities (urban regions) in 2009. (China Health Statistical Yearbook, 2009)

The health system in rural China is organised in three tiers (see Figure 1.3). The first tier is made up of village doctors working out of Community Healthcare Points (CHP), who provide preventive and primary care services with an average of two doctors per 1,000 people.

The next level is made up of Community Healthcare Centres (CHC), located in towns, which function primarily as out-patient clinics for about 10,000 to 30,000 people each. These centres have between ten and thirty beds each, and the highest qualified staff members are assistant doctors. More than 90 percent of health problems in rural regions were diagnosed and treated in CHCs and CHPs in 2009, and only the most seriously ill patients were referred to the third tier, the county hospitals, which serve

³ 本章中文标题: 介绍。 This chapter is based on and extended from following publications:

J. Jiang and J. Flexman (2007), Shanghai University club uses technology to fight poverty. *Engineering in Medicine and Biology Magazine*, IEEE, 26(12):10-11.

J. Jiang, ZZ Yan, and J Shi (2006), Design of the medical digital assistant for the Bottom of the Pyramid. *Chinese Journal of Medical Instrumentation*, 30(1):173-175 (in Chinese).

J. Jiang, ZZ Yan, and J Shi (2006), Medical product designing model for the Bottom of the Pyramid in China. *Chinese Journal of Medical Instrumentation*, 30(1):22-24 (in Chinese).

200,000 to 600,000 people each and are staffed by senior doctors who hold degrees from 5-year medical schools.

Figure 1.3 illustrates the structure of healthcare in China. The Ministry of Public Health of the central government is in charge of medical universities, hospitals, drug control institutions, etc. at the state level, while the provincial, prefectural and county-level governments are in charge of the Departments of Public Health, which manage hospitals, anti-epidemic stations, drug control institutions etc., at a local level. CHCs are managed directly by local township-level governments and CHPs are headed directly by local village-level governments with no Departments of Public Health.

As can also be seen in Figure 1.3, advanced medical equipment (e.g., magnetic resonance imaging [MRI], positron emission tomography [PET] and single-photon emission computed tomography [SPECT]) and medical specialists (e.g., professors from medical universities) can be found only in the hospitals of urban regions at and above the county level (China Health Statistical Yearbook, 2009). More information about the three-tier medical system in rural China can be found in such publications as Liu (2004), Bloom & Gu (1997) and Sidel (1972). Appendix A provides the scenes of CHCs, CHPs and village doctors in rural regions.

As described in Figure 1.3, hospitals at a county level, CHCs and CHPs make up the three-tier medical system in rural China, which is the target group in this doctoral thesis. The geographical distances between rural hospitals, CHCs and CHPs in one particular rural region may be quite low (5–10 km); however, the distances between the elements of the three-tier medical system in one particular rural region and hospitals above the county level may be quite large (50–100 km). Due to the amount of time needed for travel, and the restrictive cost of public transport (the poor earn less than 2 Euro per day), it is difficult for rural patients to access medical resources from urban regions quickly in an emergency. Appendix A provides an example of this.

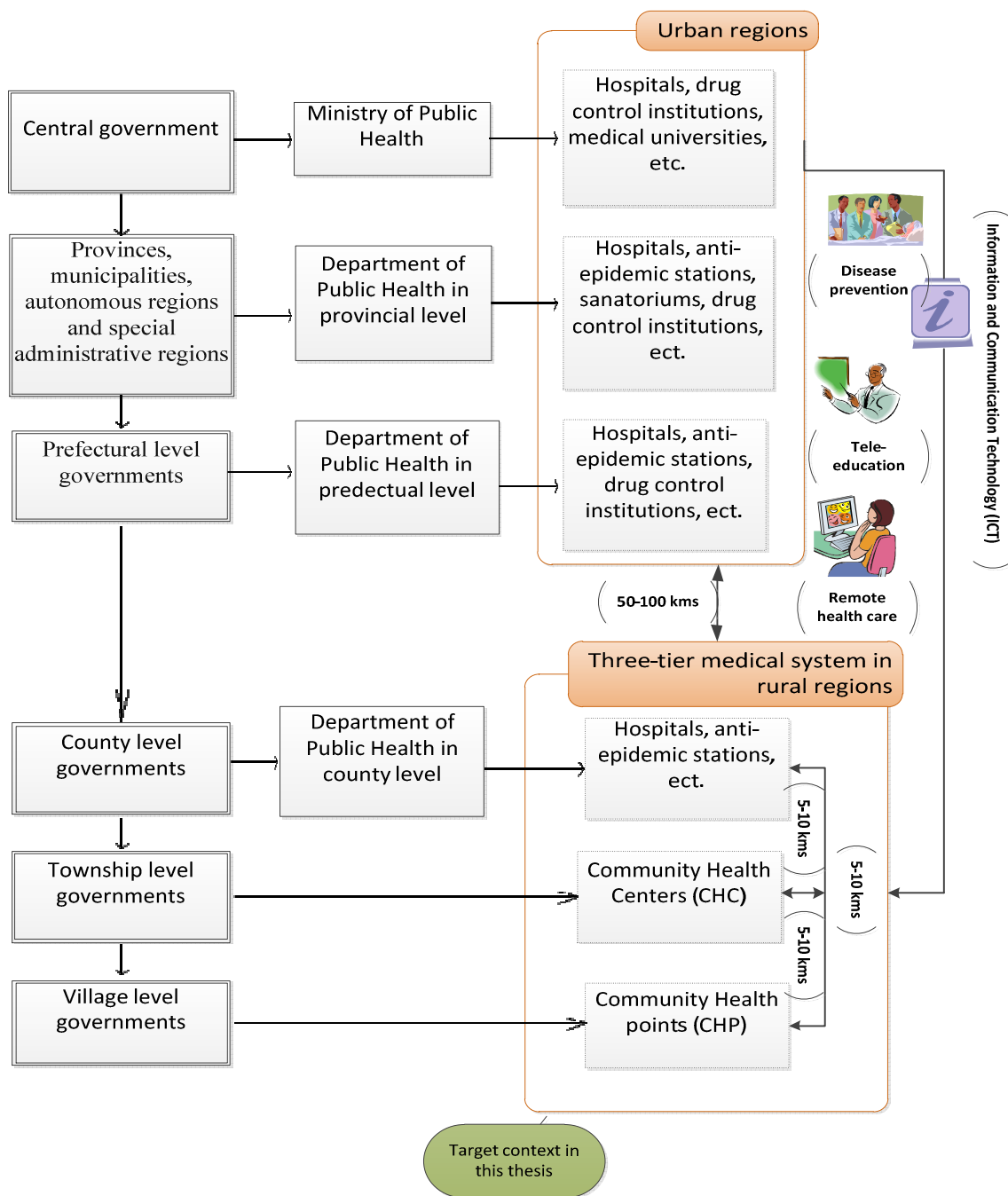


Figure 1.3 China's healthcare structure (2012). In this structure, ICT is used as an enabler to address the shortage of advanced medical equipment and qualified medical staff.

Similar to other developing countries, China is facing great challenges in the area of human health, including reducing the mortality rate of children under five years old by two-thirds (The Millennium Development Goals: MDG 4, see Figure 1.4), the maternal mortality ratio by three-quarters (MDG 5), halting and reversing the spread of HIV/AIDS, managing malaria and other major diseases (MDG 6), etc. According to medical statistics (CMoH, 2010), the average disease related death rate (<70 years old) in 2009 in rural areas was almost 1.5 times as high as in urban areas (1.38:1) and the infant mortality rate was significantly higher (1.72:1). For certain diseases, such as snail fever, the death rate in rural China was even five times higher.

Advances in the ICT field are helping to reduce information and communication scarcity as part of an overarching process of empowerment in healthcare domain (Martínez et al., 2005; Cecchini & Raina, 2004). ICT-enabled healthcare may be a solution to the problems faced by rural patients. For example, the skills of rural doctors can be improved through tele-education; serious diseases (e.g., heart disease and cancers) may be prevented by raising the awareness of rural patients through ICT solutions; some chronic diseases may be mitigated through remote healthcare, etc.



Figure 1.4 The United Nations Millennium Development Goals for 2015 (Source: <http://www.un.org/millenniumgoals/>, accessed on 16-OCT-2012)

1.2 Evolution of the rural healthcare system in China

The history of rural healthcare in China begins in 1949 following the communist victory in 1949, when Mao Zedong created an extensive healthcare system in the countryside based on the agricultural communes (known as the “*Rural Co-operative Medical Care System*”) and the government took control of all healthcare provision in the country, from local clinics to specialised facilities. “Barefoot doctors” ventured deep into

the countryside to help the poorest citizens (Barefoot doctors were farmers with basic medical and paramedical training that worked in rural villages in China, named after the southern farmers who would often work barefoot in the rice paddies). Their purpose was to bring healthcare services to rural areas where urban-trained doctors would not settle, and to promote basic hygiene, preventive healthcare and family planning, and to treat common ailments). Ninety percent of the population enjoyed life-long, government-subsidised healthcare under this system, and although the quality was limited, China's national health improved significantly: infant mortality fell, life expectancy rose and infectious diseases were brought under control (Sidel, 1972).

This rural healthcare system started to unravel in 1979 when Deng Xiaoping introduced sweeping economic reforms, resulting in the disappearance of the commune-based healthcare system which were replaced by private enterprises. Local hospitals were sold to the private sector, and the medical infrastructure all but collapsed, leaving the majority of rural residents without access to care. By 1985, the proportion of rural residents covered by the government's medical cooperative system had dropped from 90 to 9.8 percent (Liu, 2004).

The current three-tier medical system in rural China was launched in 2003 under the title of *“New Rural Co-operative Medical Care System”* (Liu, 2004), financed by both central and local governments through healthcare subsidies. Unlike in the period of agricultural communes, most local hospitals, CHCs and CHPs had bear partial responsibility for financial profits and losses – a situation that exists even today.

1.3 Major challenges in current rural healthcare in China

Although the Chinese government has built up a very good physical infrastructure for the rural healthcare system (e.g., on average every village has one CHP), several problems still exist. Zita (2009) notes that the large humanitarian problems in rural healthcare are mainly due to a lack of medical resources, such as shortages of advanced medical equipment and devices and skilled medical staff. Liu (2004) add: *“Particularly disquieting is the lack of an adequately functioning public health system in China's vast rural areas. Even though each county has a three tier medical system, public health work at the township and village level has been weak due to under-funding and a lack of supervision and coordination among rural health-care providers”*. By reviewing relevant academic publications and government reports, three major challenges in the current rural healthcare system in China can be observed. They are:

1. **The cost of rural healthcare is high:** Simply put, a significant portion of China's rural population is without access to affordable healthcare. According to a Chinese government website, 39 percent of the rural population were unable to afford professional medical treatment in 2009. Furthermore, 30 percent of respondents in rural areas indicated that they had not been hospitalised, despite being told that they needed to be (Liu, 2004). This grim situation is largely attributed to the three problems:

- **Low levels of government investment:** While overall spending on medical services has risen considerably, government budget allocations for healthcare fell to 10 percent in 2000 from 40 percent in 1997 (CMoH, 2005). In a United Nations 2000 World Health Report (WHO, 2000) in which 191 national public-health systems were evaluated in terms of their equitable funding of medical services, China ranked 188th, behind poverty-stricken Ethiopia and Honduras.
- **High fees of rural hospitals:** The lack of government funding has caused rural hospitals to raise fees, further limiting the ability of rural residents to afford care. China's official media report that 70 percent of rural hospitals are losing money or are on the verge of financial collapse, and as such are desperate for revenue. As a result, CHCs and hospitals tend to over-prescribe drugs, as they can raise their revenues by as much as 40 percent through pharmaceutical sales (Huang, 2002). The high fees also discourage many doctors from prioritising preventive care, further compounding the poor conditions.
- **Lack of health insurance:** With rapidly rising prices for medical treatment and stagnant wage levels, most rural residents are unable to pay for even the most routine medical care. Fewer than 10 percent of rural residents had health insurance in 2005, compared to about 1.5 percent in urban areas. The Ministry of Health reported that 87 percent of rural patients pay for all of their hospital care out-of-pocket, while 60 percent leave before completing treatment because they are unable to afford the bills. More than two-thirds of rural Chinese said they would not seek medical care if they fell ill, because the price is too high. Average hospital bills, at 2,236 Yuan (about 260 Euro), are nearly equal to the average annual rural salary of 2,622 Yuan. These high medical bills often contribute directly to poverty by driving 5 percent of low-income families into bankruptcy each year (CMoH, 2005).

2. **Lack of healthcare resources:** The second major challenge in rural healthcare is the lack of supply of healthcare services:

- **Few doctors:** China has a national average of about two doctors per 1,000 people, while the ratio in Beijing, for example, is more than three per 1,000 residents - more than three times the ratio in the rural Anhui province in 2005 (CMoH, 2005). As a result, rural patients often need to travel long distances, up to 800 km, to receive treatment in larger cities, such as Shanghai.
 - **Lack of medical “hardware” in rural regions:** In the past ten years, the central Chinese government has focused the majority of its healthcare spending on urban centres, leaving only one-fifth for rural areas. Consequently, government spending per capita is about seven times as high in cities as it is in the countryside. Total healthcare spending also varies widely by location. Spending per person in Beijing was more than ten times that in the remote Guizhou province in 2005, resulting in a lack of medical “hardware” in the rural regions. To give an example, in 2005 the number of hospital beds in rural regions was reported at 1.5 beds per 1,000 population, compared to 3.67 in urban settings (CMoH, 2005).
3. **Lack of high quality patient care:** The third major challenge is that the quality of patient care is low in rural regions. There are two key reasons for this:
- **The skill level of rural medical staff is low:** A 2001 study of 46 counties and 781 village doctors in nine western provinces revealed that 70 percent of village doctors had only a high school education, and had received an average of only twenty months of medical training (Wang et al., 2003). Not only is there less personnel in rural areas, it is also very difficult to attract and retain skilled personnel to work in the less developed regions of China.
 - **Healthcare awareness in rural patients is low:** A study of 16,364 rural residents in the Shangdong province showed that the prevalence of hypertension is high, but levels of awareness, treatment and control are unacceptably low. In that study 43.8 percent of the population had hypertension, among which only 26.2 percent were aware of their ailment, 22.2 percent were currently undergoing treatment, and 3.9 percent managed to control their blood pressure (<140/90 mmHg) (Li et al., 2010).

1.4 Efforts of the Chinese government

Rural healthcare is of major concern for the central Chinese government, naming it as "*the most important of all works for the (Communist) Party*" during the 2004 Central Economic Work Conference (Wen, 2004).

In the past decade the Chinese government did much to resolve the problems of rural healthcare, and some progress in the three challenges detailed above has already been made. For instance, a new rural cooperative health insurance system was established by the central government in 1998 in which every farmer pays 10 Yuan (about 1 Euro) annually, while the local city and the provincial people's government both grant no less than 10 Yuan each per capita. Each farmer can obtain up to 10,000 Yuan annually for medical expenses from this insurance fund, and at the end of 2010 this new insurance system covered more than 98 percent of all rural residents (CMoH, 2010).

In the provision of rural doctors, according to the statistics contained within a government report (The evaluation report for the 11-5 Plan [The 11th Five-Year Plan]) (CMoST, 2011) the Chinese government sent more than 10,000 doctors to work in rural regions from 2006–2010, most of which were new graduates from medical universities.

To resolve the problems related to low levels of investment, the Chinese government adopted a government-market cooperation approach. As noted by Gao Qiang, the former director of Chinese Ministry of Health, "*The gap between the need for healthcare services and the capabilities of the current Chinese rural health insurance and delivery system is still immense ... Development of the rural healthcare sector should depend on the government as well as the market ...*". The Chinese government encourages commercial companies to invest in hospitals and medical research institutes in rural China (Gao, 2007).

The Chinese government's efforts to address all the challenges are continuing. According to "Rural healthcare development in the 12-5 plan" (CMoST, 2012) three improvement goals for rural healthcare have been established for the 2011–2015 period, including: (1) strengthening the new rural health insurance system, (2) increasing the education levels of rural doctors, and (3) increasing the domestic market demands for medical devices in rural regions. This final goal entails the Chinese government providing subsidies to national medical device suppliers and manufacturers to encourage them to sell affordable, indigenously designed and developed medical devices in rural markets.

1.5 Design and development of ICT-enabled Medical device and system as an opportunity

Design and development of ICT-enabled Medical device and system (DIM) may contribute to solving the problems mentioned in Section 1.3. Examples of ICT-enabled medical devices and systems include ultrasound systems (a medical imaging system), Holter monitors (a patient homecare system), and tele-diagnosis systems (a telemedicine).

Providing DIM is a sustainable approach to overcoming healthcare challenges in terms of affordability, accessibility and quality of patient care, and is being widely applied in different rural regions of developing countries (Constantinides & Barrett, 2006; Dossani et al., 2005; Conradie et al., 2003). One example project can be found in rural Africa, known as the “Tele-radiology in Mali: Quick diagnoses and better treatments in rural areas” programme, run by a non-governmental organisation (NGO) called “The International Institute for Communication and Development (IICD)” (IICD, 2006). The requirement for this project is based on the fact that almost all radiologists in Mali are located in the capital of Bamako, which means that expert X-ray diagnosticians can be up to 1,000 km from regional hospitals. Under the project, a simple X-Ray device was designed that could be operated by medical staff in the far-lying regions, who would then send the X-ray images using ICT to a diagnostician in the capital for expert diagnosis and advice. Another example can be found in India, known as the “Heart surgeon tele-consultation” project of the Indian Ministry of Health (Solberg, 2008). In this case a heart surgeon in Bangalore gave a tele-consultation to a patient in a private hospital in Calcutta (more than 1,800 km away) via video link.

1.6 Design and development of ICT-enabled Medical device and system for Rural China (DIMRC)

The term Design and development of ICT-enabled Medical device and system for Rural China (DIMRC) first appeared in a 2001 Chinese government report (CMoH, 2001), in which Chinese central government stated that *“Rural healthcare requires ICT-enabled medical devices and systems ... They should be very cheap, durable and easy to use ... they should be different from existing products in the high-end market ... new product development is needed ...”*. Prior to 2001, hardly any companies were engaged in the design and development of ICT-enabled medical devices and systems for rural healthcare (At that time, *most small rural*

hospitals and CHCs in rural regions used second-hand technologies that were considered outdated in city hospitals [Commented by Jiehui Jiang]).

After 2001, several companies started to recognise the opportunities in rural healthcare, and launched R&D activities in DIMRC. One such company was General Electric (GE) Healthcare, which in 2005 began to see DIMRC as an important R&D strategy in China, setting up a special DIMRC team at Wuxi in 2005 that contained about sixty engineers, increasing to 100 by 2009 (Immelt et al., 2009). Another example is Philips Healthcare, which set up a R&D group called the “Emerging Market Group” in Shanghai in 2005.

At that time many multinational companies were using the “Local Growth Team (LGT)” model for DIMRC, for which model companies would hire and train local staff, including biomedical, electrical, mechanical, and physical engineers etc. All R&D activities in DIMRC were carried out by LGTs with support from Western R&D groups, and by 2005 a number of ICT-enabled medical devices and systems specifically suited to rural healthcare had been designed and developed by LGTs. GE Healthcare, for example, developed a colour Doppler ultrasound system called the “Logiq C5 Ultrasound System” in 2006 (Immelt et al., 2009).

In May 2009, General Electric announced that over the next six years it would be spending US\$3 billion to develop at least 100 health-care innovations to lower costs, increase access and improve quality. At that time, two products for development were highlighted — a US\$1,000 handheld electrocardiogram device, and a portable PC-based ultrasound machine costing US\$15,000. These are innovations were interesting, in that they were developed originally for markets in emerging economies (the ECG device for rural India and the ultrasound machine for rural China), but are now being sold in the United States, where GE is pioneering new uses for such machines. [Ref. <http://hbr.org/2009/10/how-ge-is-disrupting-itself/ar/1> accessed on 16-OCT-2012] In 2010, GE Healthcare also introduced a pocket-sized ultrasound machine to the market, stimulating physicians to make a move from stethoscopes to portable imaging devices, and bringing advanced visualisation potentials to the examination room. [Ref. http://medgadget.com/2010/02/ges_vscan_worlds_smallest_portable_ultrasound_now_available_worldwide.html accessed on 16-OCT-2012]

Away from the private sector, several Chinese universities have also launched R&D activities in DIMRC. For instance, Chong Qing University has developed a pulse data acquisition system to help rural people collect and analyse physiological parameters towards the prevention of serious

heart disease (Zhou & Qing, 2006). Additionally, Shanghai University has developed a remote monitoring system for rural China that may be used to manage patients' health information based on web server technologies (Jiang et al., 2007).

Learning from DIMRC practices, some theoretical investigations into DIMRC have been carried out by Chinese universities, one example being the Biomedical Engineering Institute at Shanghai University. As one of earliest research pioneers in DIMRC, this institute adopted ICT-enabled medical device design methods (in biomedical engineering) into Base (or Bottom) of the (economic) Pyramid (BoP). BoP refers to the 4 billion people in the world who live on less than US\$3 per day, and the 1 billion who live on less than even US\$1 per day (BoP theory is further detailed in detail in Chapter 3). Several research papers have been published on this issue, including an initial framework for DIMRC entitled "Medical Product Designing Model for the 'Bottom of the (economic) Pyramid' in China", which was published in the "Chinese Journal of Medical Instruction" in January 2006 (Jiang et al., 2006). The paper was recognised as one of "100 Chinese scientific findings with potential" by the "China Scientists' Forum" in 2006, and by 2012 had been referenced in more than twenty scientific papers in China. The author of this thesis was the principal proposer of the initial framework.

Figure 1.5 illustrates this initial framework, showing three conditional elements for DIMRC: (1) support from the Chinese government in the form of grants to universities and financial subsidies to companies; (2) knowledge integration by universities, which should provide scientific knowledge about how to provide successful DIMRC; and (3) market exploration by the private sector, which should contribute to commercialising products. The presence of these three conditional elements should allow concrete DIMRC projects to be built up by companies and universities, either individually or in collaboration; however teamwork is vital for DIMRC.

Furthermore, Jiang et al. (2006) claim that there is a need to develop a knowledge and skill base for R&D teams in DIMRC, which should include knowledge from different scientific disciplines, such as medical, design, business and management etc., however to date no progress has been made in this regard. The unanswered questions include "Who should be the members of the R&D team in DIMRC?", "What might the roles and responsibilities be of each team member in DIMRC?" etc.

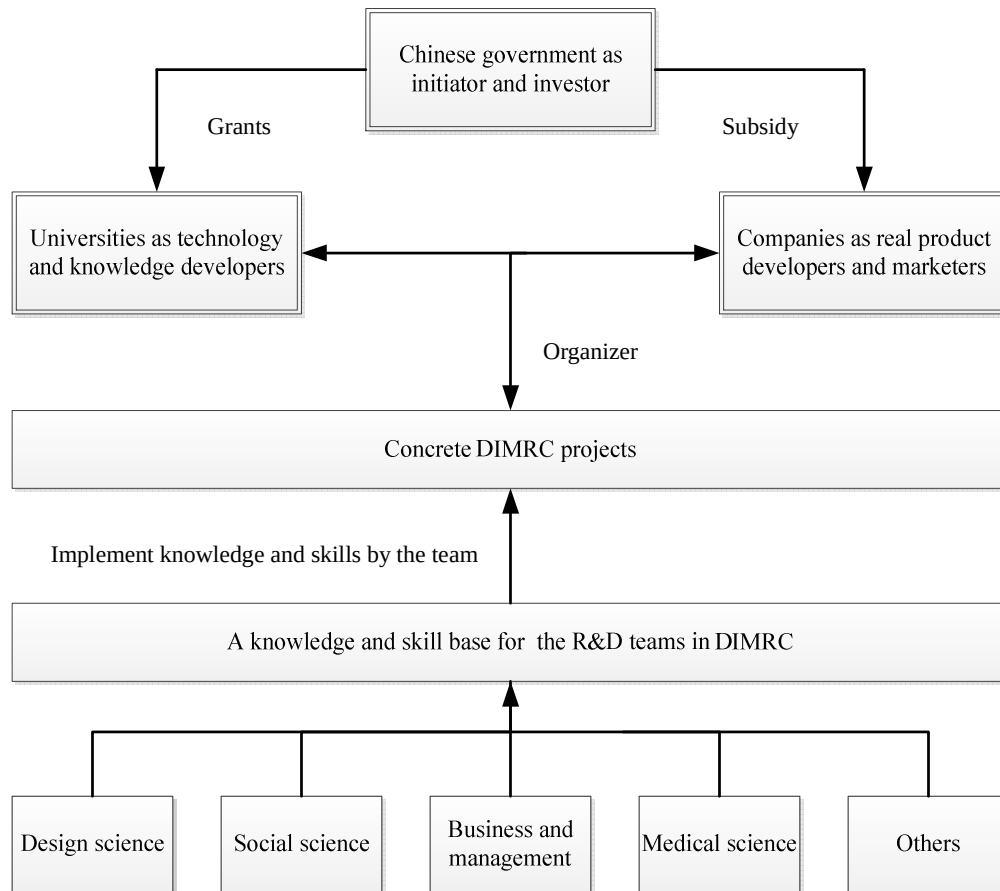


Figure 1.5: The initial framework for DIMRC proposed in 2006 (Jiang et al., 2006).

1.7 Stakeholders of DIMRC

As one part of the above initial framework, three major stakeholders for DIMRC were proposed, being the Chinese government, the academia and commercial enterprises. The proposed roles and responsibilities were (Jiang et al., 2006):

- The Chinese government (In this thesis, Chinese government refers to local governments below the state level) should be the initiator, advisor and investor in DIMRC projects. The responsibilities of the Chinese government should include the provision of financial, organisational and policy support.
- Commercial companies (In this thesis, Chinese companies refer to locally-owned companies with no foreign multinational shareholders) e.g., medical device companies, healthcare service companies, and medical insurance companies, should be the developers and marketers of DIMRC projects. Their responsibilities should include providing technical and financial support for the R&D of medical devices and systems, and setting up business cases.

- Chinese Universities (academic institutes) should be the knowledge and technology generators in DIMRC projects. Their responsibilities should include collecting, extending, analysing, combining, and translating the knowledge of existing technologies, and increasing the knowledge base by generating new knowledge models for DIMRC and developing new ICT technologies.

1.8 Complexity in DIMRC

Design and development of ICT-enabled Medical device and system for Rural China (DIMRC) is a very complex issue that requires the collaboration of different stakeholders, such as the Chinese government, universities and companies, in addition to efficient team work in practice, and qualified and talented people with extensive knowledge and skills (Jiang et al., 2006). DIMRC can thus be considered as a “wicked problem”.

According to Rittel & Webber (1973), a “wicked problem” has the following properties:

A “wicked problem” is a problem that is difficult or impossible to resolve because of incomplete, contradictory and changing requirements that are often difficult to recognize.

- The problem is an evolving set of interlocking issues and constraints. There is no definitive statement of the problem. One does not understand the problem until he/she has developed a solution.
- There are many stakeholders who care about or have something at stake in how the problem is resolved. This makes the problem-solving process fundamentally social.
- The constraints on the solution, such as limited resources and political ramifications, change over time, ultimately because human beings live in a rapidly changing world. Operationally, they change because many are generated by the stakeholders themselves, who come and go, change their minds, fail to communicate, or otherwise change the rules by which the problem must be resolved.
- Since there is no definitive problem, there is not one best solution. The problem-solving process ends when all stakeholders accept whatever solution emerges (*The process may also end under other conditions, such*

as when project budgets are exhausted, key stakeholders quit etc. [Commented by Jiehui Jiang]].

To clarify why DIMRC is a “wicked problem”, the example of hypertension monitoring in rural China can be used.

- *The problem is difficult to understand until a solution is developed.* In the design of a wearable blood pressure measurement device, some features interact with other features (Jiang et al., 2010b). If a new function is added, for example, a touch board with an advanced software interface making the device easier to use for the patients, it may also make the device less durable and heavier. Adding the touch board may also impact marketing in issues such as pricing and demand, “Are the proposed Graphic User Interfaces (GUI) usable?” At some level in the organisation, someone will ask, “Should we produce this blood pressure monitoring system at all?” All these problems interact. Once a list of potential features is attained, the conflicts among them can be explored.
- *There are a number of people who have something at stake in how the problem is resolved.* In designing any product, there are two clearly defined and opposing corporate camps: the people who know what is needed (usually in Marketing or Sales) and the people who know what can be done (usually in Engineering or Manufacturing). Virtually all product features and design problems have points that are of interest to both camps. One side may argue that there is no point building the product if it doesn't have Feature X; while the other may argue that Feature X is so expensive, complex, time consuming, untested or otherwise impossible that it should not be tackled in the project.
- *Constraints change over time.* Almost all solutions are subject to time (the problem must be resolved before some critical date, condition or event) and financial (the solution must be cost effective) constraints. Quality is usually another key constraint. In the case of a blood pressure monitoring system, design decisions, such as the addition of a touch board, might be influenced by unpredictable constraints, such as the need to impress a village doctor.
- *The problem-solving process ends when all stakeholders are satisfied.* Whatever solution is finally decided upon, it will be hard to claim that it was the ideal answer. No studies of laboratory experiments or market surveys will identify the ideal solution. At some point, all stakeholders will have to make a decision. Inevitably, once the blood pressure monitoring system is produced, critics will point out new problems, e.g., the touch board is too heavy and not durable.

Chapter 2 Current situation, problem definition, scope, research question and approach⁴

2.1 Current situation in DIMRC

This section will introduce problem statements about DIMRC.

2.1.1 The shift from “Made in China” to “Created in China” in DIMRC

To encourage China’s own innovations in DIMRC, a shift from “Made in China” to “Created in China” is being stimulated by the Chinese central government. “Made in China” refers to all products produced in the country, and includes, for example, products made in factories established by multinational companies in China. In such cases, China does not necessarily own the intellectual property rights for these products. “Created in China”, on the other hand, refers to products originating in China, for example, products developed indigenously by national brands.

The manufacture of medical equipment has become widespread in China over the past twenty years. Statistics from the Chinese Association of Medical Devices Industry (CAMDI, 2009) reveal that China had more than 10,000 manufacturers of medical devices (hardware) in 2008, and over 23,000 companies that were relevant to the medical device sector (e.g., medical software development companies). By the end of 2008, China had become the world’s largest exporter of medical devices with low technical content, such as syringes and catheters, while also becoming a major importer of ICT-enabled medical devices and systems. According to the statistics of Consulting L.E.K., some 90 percent of advanced ICT-enabled medical devices and systems (such as PET and SPECT) at use in China’s large city hospitals were imported from Western countries, having been purchased from such foreign multinational companies as Philips, GE, J&J Medical, etc. (Consulting L.E.K., 2010).

To remedy this situation, in the “12-5 Plan for the Medical Device Technology Industry” the central government set out a “Created in China” policy as a development strategy for the Chinese medical device industry for 2011–2015, including DIMRC (CMoST, 2012), indicating that the

⁴ 本章中文名称：现状，问题定义，范围，研究问题以及方法。

Chinese government was starting to become aware of the importance of product design (the term “design” is defined on page 57).

In fact, many developing countries have begun to realise the importance of design as a strategic tool for economic growth, and today consider the field of design to be on an equal footing with science, technology and economics. Examples of those countries who have taken action can mainly be found in emerging markets like Malaysia (Malaysia Design Council), Indonesia (Indonesian Design Centre, with assistance from the Japan International Cooperation Agency and the Japan Design Foundation), the Philippines (Product Development and Design Centre of the Philippines), Thailand (Office of Product Development & Design for Export), India (National Institute of Design, since 1969, educating designers and serving industry), Colombia (Artesanías de Colombia), Cuba (Oficina Nacional de Diseño Industrial - National Office of Industrial Design), Mexico (Mexico Design Promotion Centre), Brazil (Brazilian Design Centre) and South Africa (SABS Design Institute) (Amir, 2004).

Although these initiatives are laudable, such strategic design approaches appear to be directed to addressing the competitiveness of the international market, rather than looking after the needs of domestic markets in terms of alleviating poverty and fulfilling the basic needs of society. Accordingly, a national design policy that is directed to meet the social and economic challenges of developing countries and the betterment of their own societies would therefore appear to be more appropriate, although no concrete design policies for DIMRC have yet been formulated in China.

2.1.2 Huge gaps between DIMRC requirements and existing DIMRC applications

Although several companies and research institutes have developed ICT-enabled medical devices and systems for rural China, the gap between what is required and what is currently available is still huge. As claimed by the director of the China Rural Health Association, Zhu Qingsheng (CRHA, 2012): *“More than 60 percent of hospitals, CHCs and CHPs in rural regions (numbering around 40,000) require DIMRC applications ... one-third of these ... have no DIMRC applications (and a further) one-third require their DIMRC applications to be updated”*. Zhu also pointed out that the budget requirement for DIMRC in 2012 is about 8.37 billion Yuan (about 1 billion Euro).

In short, more and better DIMRC applications are required. The “12-5 Plan for Medical Device Technology Industry” (CMoST, 2012) set down three improvement goals for 2015 related to DIMRC: (1) The quality of DIMRC applications should be higher and the cost should be lower; (2) Chinese companies and research institutes should develop independent innovation capabilities in new product development; and (3) Chinese companies and research institutes should achieve breakthroughs in some key technologies and core components of ICT-enabled medical devices and systems, such as in biochips.

Overall, the Chinese government encourages local Chinese companies and research institutes to design and develop ICT-enabled medical devices and systems for rural China by themselves, thus emphasising the concept of “Created in China” in DIMRC.

2.1.3 R&D teams in DIMRC

New product development requires the close collaboration of virtually all departments of a company, as an effective cross-functional team is critical to the successful development of any new medical product (Donnellon, 1993). Also required is an improvement in the integration of the diverse skills that exist in R&D, production, marketing and other functional groups to accelerate the processes of new medical product development (Carr & Muthusamy, 2008). The “12-5 Plan for Medical Device Technology Industry” (CMoST, 2012) called on Chinese companies and research institutes to focus particularly on R&D activities; and Yang (McKinsey Quarterly, 2012) stated that increasing R&D capabilities was the most important approach to meeting the unmet medical needs of patients in China. Research and Development (R&D) can be defined as follows:

R&D is the creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications (OECD, 2008).

R&D processes are inherently iterative, including several steps such as exploration, hypothesising, clarification, design, development, testing, implementation, improvement, scaling up etc. Figure 2.1 shows the cycle of R&D, taken from the “Research and Evaluation on Education in Science and Engineering (REESE), Program Solicitation NSF (National Science Foundation) 09-601” (NSF, 2009).

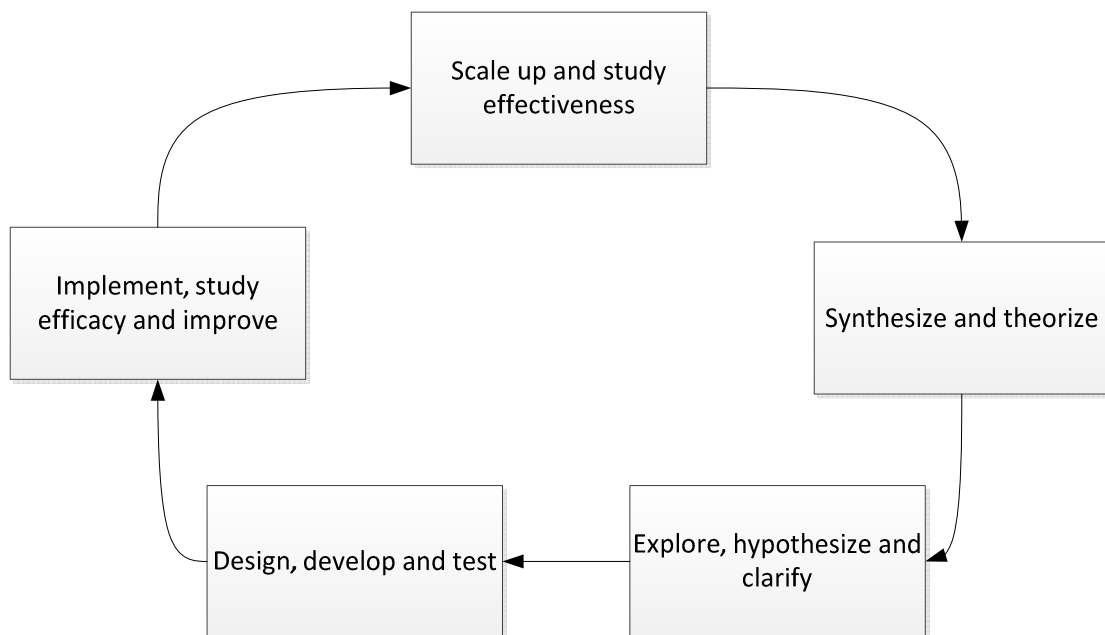


Figure 2.1 The cycle of R&D defined by NSF. The cycle has five major components, and work in each part of the cycle forms a vital and compelling foundation for transition to the next part of the cycle. This cycle has been applied in different industries, including ICT and medical device industries (NSF, 2009).

There is a rich source of information in existing literature related to the construction of an R&D team for Design and development of ICT-enabled Medical device and system (DIM). For example, King & Fries (2009) proposed a typical R&D team for DIM, comprising several individuals representing the following functions:

- Marketing
- Engineering
- Electrical
- Mechanical
- Biomedical
- Chemical
- Software
- Reliability engineering
- Human factors

- Safety engineering
- Manufacturing
- Service
- Regulatory
- Quality assurance
- Finance

According to King & Fries (2009), cooperation among individuals should be tailored to different steps in the R&D process. After observing DIM projects in a number of companies and universities he compiled a list of the most common positions in R&D teams, including project managers, business managers, biomedical engineers, electrical engineers, mechanical engineers, etc., as well as the involvement of each team member in different steps of the R&D process, as presented in table 2.1. In most cases he observed that project managers (in charge of the overall management of the project), business managers (in charge of marketing) and biomedical engineers (in charge of engineering) should be involved in the whole R&D cycle as key disciplines in DIM-related R&D.

A different school of thought claims that all team members should work together in the every step of the R&D cycle. For instance, Kucklick (2005) states that all members of medical device R&D groups (e.g., project managers, engineers, industrial designers, medical clinicians, etc.) should cooperate in the early stages of the R&D phase when identifying design requirements, generating design concepts, developing processes etc. Shah & Robinson (2007) studied the benefits of involving users in DIM R&D, stating that *“the main benefits of user involvement are an increased access to user needs, experiences and ideas; improvements in medical device designs and user interfaces; and an increase in the functionality, usability and quality of the devices”*. As a conclusion, he suggested that the end users (doctors and patients) should also be considered as part of the R&D team in DIM.

In this thesis, the team approach of Kucklick has been chosen as the most appropriate for DIMRC, involving the collaboration of all R&D team members (including the end users) in the early stages of the R&D phase, based on the author’s personal experiences (See Section 2.4). In 2007, the author decided to join the Faculty of Industrial Design Engineering in Delft University of Technology, the Netherlands as a PhD student, where the collaborative design (including the end users) is applied, adapted and adopted in design education courses and student projects.

Table 2.1 Different members in the R&D team for DIM and their involvement in different steps of the cycle of R&D. X indicates the involvement of the team member. The data within the table was derived from previous literature (King & Fries, 2009).

R&D steps Team member	Explore, hypothesise and clarify	Design, develop and test	Implement, study efficacy and improve	Scale up and study effectiveness	Synthesise and theorise
Project manager	X	X	X	X	X
Business manager	X	X	X	X	X
Biomedical engineer	X	X	X	X	X
Electrical engineer		X	X		
Mechanical engineer		X			
Chemist	X				X
Physicist	X				X
Computer scientist		X	X		
Human factor specialist	X	X			X
Industrial designer		X			
Clinical researcher (e.g., bioinformatic statistician)	X	X		X	X
Medical staff (e.g., physicians)	X		X	X	X
Public relations manager (for coordination with local governments)	X			X	
Accounting manager				X	X

2.1.4 The role of biomedical engineers in DIM and DIMRC

As mentioned by King & Fries (2009), biomedical engineers usually work effectively as key team members in DIM projects, being used to working with marketing managers, ICT developers (e.g., computer scientists), mechanical engineers, and healthcare workers, and often becoming knowledge integrators in DIM (Malkin, 2007). For instance, in the research project “ICT-Based Telemedicine System for Primary Community Health Care in Indonesia” (United Nations, ref: <http://www.share4dev.info/telecentreskb/documents/3430.pdf> accessed on 16-OCT-2012), it was the biomedical engineers that were responsible for integrating the knowledge of the ICT developers and healthcare workers. The task included applying the most recent Internet technologies in 2002 (from ICT developers) and adapting the technology to meet the existing ICT skills of local healthcare workers.

In biomedical engineering, it is common for engineering principles and design concepts to be applied to medicine and biology, combining the design and skills of engineering with medical and biological sciences to improve healthcare diagnosis, monitoring and therapy. Biomedical engineers have design and problem solving skills in such fields as electrical engineering, software, electrical hardware, human factors, quality assurance, etc. (Bronzino, 2000). The subject “ICT-enabled medical device design” is widely taught to biomedical engineers around the world, according to Harris & Brophy (2005).

Chinese biomedical engineers indeed play an important role in DIMRC R&D teams. For example, in the “emerging market group” at Philips, biomedical engineers work as principal team members (*This observation is based on the author’s personal experience from his work as an intern in the “emerging market group”. See “About the author” in the Appendix. This is the current status of the author.*)

2.1.5 Biomedical engineering and biomedical engineering education in China

The history of Chinese biomedical engineering can be traced back to the report “Biomedical engineering development outline 1978–1985”, which was published in 1979 by the Chinese central government. Biomedical engineering has grown fast in the past decade in China, driven in particular by the significant increase in research funding over the past several years, according to which Chinese academia and industry have experienced a boom period in biomedical engineering R&D. The topics covered in biomedical engineering in China today cover a broad spectrum

of research, including molecular imaging, cancer detection and treatment, health information technology, neural engineering, electrophysiology, biomedical imaging, etc.

Biomedical engineering education in China started in the 1980s, and according to the statistics of the Chinese Association of Biomedical Engineering (CABE, 2009), in 2009 more than 100 Chinese universities and colleges were giving specialised courses in biomedical engineering at both undergraduate and graduate level, and over 10,000 biomedical engineering students graduated that year. As a result, ICT-enabled Medical Device Development (DIM) is today an important education path in biomedical engineering schools and departments in China.

2.2 Broad problem definition for DIMRC

2.2.1 Challenges to effectuate “Created in China”

In general terms, China has not yet completed the strategic transition from “Made in China” to “Created in China”. As mentioned by Wen Jiabao, the premier of China, “*China is still on the way to realizing independent innovation*” (Chinanews, 2011). In the past five years, many scholars have studied the challenges faced in such a transition, including Professor Zhou Shaopeng, director and doctoral advisor of the Department of Economics at the China National School of ADMINISTRATION, who points out two major obstacles (peopledaily, 2007):

- **Lack of institutional mechanisms:** China needs to establish an enterprise- and market-oriented technological innovation system that combines manufacturing, education and research as a whole. Collaborations between national companies and research institutes should be strengthened, along with international collaboration in both academia and industry.
- **Lack of personnel and educational support:** Chinese companies should stimulate the creative capabilities of R&D teams, while educational facilities should improve the capabilities of students.

Professor Zhang Huangguo, an expert on information security for R&D in China, pointed claims that the biggest challenge to “Created in China” is the lack of protection of intellectual property, giving the example of the software sector in China: “*With the development of new technologies comes the need for stringent intellectual property rights and software copyrights. China is a developing country where some problems surrounding intellectual property rights and software copyrights still exist. The issue of protecting software copyrights is so important ... it could*

threaten the growth and development of China's software industry if Chinese society does not realize it" (Zhang, 2007).

The transition to "Created in China" in the field of Design and development of ICT-enabled Medical device and system for Rural China (DIMRC) requires three major challenges to be addressed. These are:

- ***The design competences of Chinese R&D teams for DIMRC are weak:*** In the "12-5 Plan for Medical Device Technology Industry" (CMoST, 2012), the central Chinese government identified the R&D phase as the key time to realise "Created in China" for DIMRC, and encouraged Chinese companies to establish their own R&D teams with design competences for DIMRC, for which two phases of the R&D cycle should be addressed (See Figure 2.1): (1) exploration, hypothesising and clarification; and (2) design, development and testing. R&D activities relevant to design competences include identifying design requirements, generating design concepts, applying, adopting and adapting suitable technologies etc., however; the design competences of Chinese R&D teams for DIMRC are currently still weak. For example, after observing more than twenty Chinese R&D teams in Chinese medical device companies, Yang (Mckinseyquarterly, 2012) claimed that *"China's R&D in medical device industry is not at an advanced stage in the design and development phase ... It is in short supply of talented people with enough competences ..."*
- ***Lack of guarantee mechanism legislation from the Chinese government:*** Although the central and local governments in China have begun to strengthen the protection of intellectual property rights, a comprehensive guarantee mechanism for intellectual property is yet to be established. The legal base for punishing innovation theft is still very weak in China, which makes it very tempting for Chinese R&D teams to the copy ideas of others, and in doing so, they neglect to build local experience and motivation to develop their own product development skills.
- ***Lack of innovation culture in Chinese companies:*** Chinese companies have traditionally a bias towards innovation through commercialisation – they are more comfortable than many Western companies in getting a new product or service onto the market quickly. However, the culture of new product development in Chinese companies is weak, and four reasons for this have been identified (Orr, 2012): (1) a lack of a deeper understanding of Chinese consumers; (2) a lack of clear R&D strategies; (3) a lack of ability in retaining stable R&D teams; and

(4) a lack of internal cooperation with the academia and other companies.

2.2.2 The challenge to augment design competences of Chinese R&D teams

In general, Chinese R&D teams are adept at technology-based approaches, which can be defined as follows:

Technology-based approaches are R&D approaches that are based on technology exploitation, such as developing, applying, adapting and adopting new technologies.

Chinese R&D teams have sufficient creative and analytical capabilities when they receive technology-based R&D assignments and are able to learn new technologies and come up with applications very fast. One example of this can be seen in Integrated Circuit (IC) design, as a science-based critical design. The results of a report from Gartner Dataquest on the development of China's IC-design sector during the 2006–2010 period (EE times, 2011) showed that innovations in IC design had increased enormously in China. For instance, 78 percent of IC designs in China in 2005 were for the 0.18 micron node, while only 8 percent of IC designs were at 0.13 micron and above in 2010. Chinese companies have improved in node chip design technologies very quickly, and a number of chip design houses have even managed to win a place in the ranks of chip suppliers for tier-one brands, and are no longer seen merely as competing on price and forcing prices down across the sector. Chinese companies are now represented across all areas of the mobile communications sector, and this comprehensive presence is expected to become a major driver of growth for the China IC-design sector in the future.

A similar boom is occurring in DIMRC, where Chinese R&D teams are excelling at technology-based approaches. One example is Mindray, China's largest medical equipment manufacturer, which develops, manufactures and markets such DIMRC applications as Patient Monitoring & Life Support systems, In-Vitro Diagnostic Products and Medical Imaging Systems. Mindray develops its own technologies, and has many patents, and many of its medical devices and systems, including its ultrasound devices, have the same quality and functions as the devices

and systems developed by Western multinational companies (such as GE, Philips), but at much lower prices. In 1998 Mindray started marketing its medical equipment in both Europe and the United States, and in 2009, over half of Mindray's global revenue of US\$634.2 million was earned in overseas markets.

That said, Chinese R&D teams are weak at integrative approaches, which can be defined as follows:

Integrative approaches combine several disciplinary insights and methods, such as technology, user experience, business and management knowledge, etc. during the design and development of products.

Chinese research teams are not educated or trained to be independent thinkers (Liang, 2008), and thus face many problems when they have to identify and resolve problems by themselves outside technology-based R&D assignments, such as when they need to identify user requirements or develop their own R&D strategies for DIMRC. These problems occur not only with Chinese R&D teams in local companies, such as in Mindray, but also in Local Growth Teams (LGT: hired local teams who work for Western multinational companies in R&D). GE Chairman Jeffrey Immelt pointed out several problems faced by LGTs when designing and developing ultrasound devices for rural China: *"The ultrasound LGT knew that the doctors in rural China were less familiar with ultrasound devices than the doctors in cities, however they did know how much experience rural doctors had with the technology ... LGTs cannot thrive without strong support from the top ... LGTs need the power to develop their own strategies ... LGTs need to rewrite organizational 'software' – its hiring practice, norms for working relationships, power balance between functions etc. ..."* (Immelt et al., 2009).

Immelt further suggested that the shortage of knowledge about integrative approaches resulted in additional problems for Chinese R&D teams, *"These problems may be resolved by educating and training LGTs in new integrative approaches ..."* (Immelt et al., 2009). Similar opinions can be found in other publications. For example, Xu (2009) reports that many Chinese industrial and engineering design institutes do not combine technology-based approaches and integrative approaches in their education system, and so students do not learn integrative approaches

and thus cannot apply them to resolve complex problems. Zhang & Wang (2009) suggested that Chinese students should be educated in skills associated with integrative approaches, such as problem solving skills, cooperation skills, etc.

2.2.3 Knowledge and skills in integrative approaches

Both technology-based and integrative approaches are important if Chinese R&D teams are to attain the goal of “Created in China” for DIMRC, in that DIMRC is highly complex, covering both technology-based R&D assignments (e.g., the precision and size of the medical device) and integrative-based R&D assignments (e.g., the affordability, accessibility and usability of the medical device). In this respect, improving knowledge and skills of integrative approaches could be an important approach to augmenting the design competences of Chinese R&D teams for DIMRC (McKinsey Quarterly, 2012; Immelt et al., 2009).

The integrative approach was introduced in the Ulm School of Design (Hochschule für Gestaltung), a college of design based in Ulm, Germany, in the 1950s. Tomas Maldonado, as the rector of Ulm School of Design, saw the design process as a system embodying both scientific-based and intuitive-based thinking. He was of the view that the professional designer should be an “integrator” with responsibility for integrating a large number of specialties in addition to aesthetics, including diverse requirements of materials, manufacturing and context of product use, considerations of usability, identity and marketing. Under his leadership, the school dropped the “artist” focus of his predecessor Max Bill and proposed a new philosophy of education as an “operational science”, a systems-thinking approach which embodied both art and science [Reference: <http://www.hfg-archiv.ulm.de/english/> accessed on 16-OCT-2012].

Although Ulm closed in 1968 due to a number of factors, the concept of the “integrative approach” was recognised, further developed, and applied in design education by other design researchers and institutes. For instance, Buchanan (1992), following his review of design history, claimed that the designer’s thinking should be based on an “integrative approach”, *“Without integrative disciplines of understanding, communication, and action, there is little hope of sensibly extending knowledge beyond the library or laboratory in order to serve the purpose of enriching human life ...”* Roozenburg et al. focused on developing design theories and methods for industrial designers by integrating from across the engineering disciplines, and developed an integrative process for education in product development in their book *“Product*

development: Structure and Methods” (Roozenburg & Eekels, 1995). The approach is still used as an education material in design schools, e.g., in the Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft).

In the 2000s, many scholars started to realise the importance of the integrative approach to the field of DIM and design for developing countries. Heeks (2006) pointed out that the next generation concept for ICT4D (ICT for International Development) should develop an “integrative approach”. He proposed that *“Current efforts about ICT4D often resulted in failure, restriction, and anecdotes ... We can conclude, then, that each one of these three intellectual domains — computer science, information system, and development studies — offers something to the ICT4D field. Conceptually, this means we need spaces that bring these three domains together. This has yet to be achieved and remains the key intellectual challenge during the next generation ICT4D”*; while Prahalad & Hart (2002) suggested that the integrative approach was the new approach to making sustainable improvements at the “Bottom of the Pyramid” (defined in section 3.1). In editing a book about “DIM projects in developing countries”, Wootton et al. (2009) concluded that an appropriate integrative approach was the key to developing DIM applications.

2.2.4 Three challenges in the design of DIM for rural regions

As members of R&D teams for DIM, biomedical engineers often face problems because they are not educated or trained with the knowledge or skills for integrative approaches. For example, when a biomedical engineering student is required to design and develop a blood pressure measurement device for the elderly (as a graduation project), he/she is likely to get into difficulties when clarifying the design requirements. This is due to the large number of issues that need to be addressed in the definition of requirements phase of the device development, which includes aspects of technology, psychology, management and economy. The problem here is that he/she will not be educated or trained in the use of integrative approaches to identify and integrate so many different issues.

Nevertheless, biomedical engineers have begun to develop and adopt “integrative approaches” in education. One example is the adoption of Human Factors Engineering (HFE), which is a discipline concerned with the design of tools, machines and systems that take into account human capabilities, limitations and characteristics, and in which the primary goal is to design for safe, comfortable and effective human use. HFE is based on the design-related aspects of several disciplines, including

anthropometrics, biomechanics, sensation and perception anatomy and physiology, which cover the models and theories of human performance, memory and attention (Gosbee, 2002).

HFE is widely used in large hospital environments by biomedical engineers as a typical “integrative approach”. An HFE process focuses on user needs, user characteristics and the end user testing of the human-machine interface, etc., however biomedical engineers are still in the process of adapting and adopting “integrative approaches” for other environments, such as DIM for homecare or rural healthcare. Particularly for rural regions, several challenges still exist to achieving the adaptation and adoption of “integrative approaches”. Robert Malkin, a notable biomedical engineering researcher, has a particular interest in identifying challenges to biomedical engineering design in developing countries. He set up a summer institute for biomedical engineering students in 2007, and sent 97 of them to 33 hospitals in the rural regions of ten developing countries, and enrolled them in different DIM projects. In observing all of these projects, Malkin was able to see that the students faced problems when attempting to transfer the technological advances of the developed world to the population of the developing world. He went on to propose three challenges for biomedical engineers in DIM in rural regions of developing countries (Malkin, 2007):

- Design culture (defined on page 96): Design culture refers to the set of shared attitudes, values, goals and practices that characterise an institution, organisation or group. Design culture should influence the new product development to match the stakeholders’ expectations and wishes. Biomedical engineers often meet barriers when attempting to understand cultural influences.
- Design factors (defined on page 120): Design factors refer to the aspects of a design that should be considered to satisfy the various stakeholders, such as user needs and aspirations; the needs of manufacturers and businesses; environmental and social concerns; and the designers’ own beliefs, values and need for expression, etc. Biomedical engineers often meet barriers when identifying design factors.
- Design methodology (defined on page 174): The design methodology is the systemic process comprising design methods that are, can be, or have been applied to product design. Biomedical engineers often meet barriers when using different methods and tools in practice, in that they have difficulty in applying and adapting (if needed) existing design methodologies, methods and tools in practice.

According to Malkin, these three challenges occur in parallel, and there are overlaps among the three challenges; for example, cultural factors are a kinds of design factors, and design methodologies are influenced by design culture.

2.3 Solution space for DIMRC – The role of stakeholders

This section will introduce some suggestions in previous literature related to the provision of suitable ICT-enabled medical devices and systems for all three stakeholder groups.

2.3.1 Promotion by Chinese government

To address the three challenges for DIMRC detailed in Section 2.2.1, namely, (1) that the design competences of Chinese R&D teams are weak; (2) that the guarantee mechanism of Chinese government is insufficient; and (3) that innovation culture in Chinese companies is lacking, a number of scholars (Mckinseyquarterly, 2012; Lustick & Zaman, 2011; Peopledaily, 2007; Silberglitt, 2009) have made recommendations, with all suggesting that the government, academia and companies should join efforts to contribute to “Created in China” in DIMRC.

The initial effort should come from the government, which should provide guarantees to the system and mechanism to encourage the realisation of “Created in China” in DIMRC. According to Zhou (Peopledaily, 2007) the essential aspects of the guarantee should include:

- The Chinese government should accelerate the establishment of an enterprise- and market-oriented technological innovation system that combines manufacturing, education and research as a whole.
- The Chinese government should improve the market environment for technical innovation, accelerate the development of entrepreneurial risk investment, and improve technical advice, technology transfer and other intermediary services.
- The Chinese government should implement policies and offer incentives in support of independent innovation.
- It is necessary to make good use of global scientific and technological resources, continue to introduce advanced technology from foreign countries, and participate in international scientific and technological exchanges.
- Efforts should be made to strengthen the protection of intellectual property. China's intellectual property protection system is not yet perfect, and this is having a negative effect on technological

innovation. The nation, society and enterprises need to work together on this.

2.3.2 Strengthening education at universities

Secondary effort should come from Chinese universities. Lustick, a biomedical engineering expert, suggests that biomedical engineering institutes in the world (including China) need to improve their education to augment the design competences of biomedical engineers for DIM (Lustick & Zaman, 2011). Therefore, as a first effort, Chinese universities need to augment the design competences of their students by strengthening education. This follows also recommendations from Wale (McKinseyquarterly, 2012), who proposes, based on observations of the Chinese automotive sector, that the quality of Chinese R&D teams (industrial and engineering) could be increased by providing supplementary courses and training from other disciplines, both nationally and internationally.

This route is further explored in this thesis in Chapters 3–8.

2.3.3 Efforts from Chinese companies

Finally, Chinese companies, according to Silberglitt (2009), need to address three issues to improve their R&D environment:

- They should improve institutional capacity, e.g., setting up workshops of R&D teams.
- They should offer more financial incentives to R&D teams, e.g., rewarding R&D teams if any patent is published.
- They should create a culture of innovation, e.g. giving R&D teams opportunities to take risks and demonstrate new products and processes to encourage their adoption.

2.4 Personal motivation

With a background in biomedical engineering, the author of this thesis was focusing on DIMRC when studying in China. Before undertaking the PhD project, some research on DIMRC had been done by the author, and based on this research, the author gradually put together the initial hypothesis for DIMRC (See Figure 1.5).

To create the initial framework for DIMRC, the author also participated in four DIMRC projects in China (See “About the author in the Appendix”), including the “Remote monitoring system for rural China” project (MSc

graduation project in the year 2006), in which he worked with other teammates (electrical engineering, healthcare workers), integrated knowledge from medical design development and BoP design theories, and developed a prototype system for remote monitoring. (Jiang et al., 2006) This prototype system received positive feedback from other engineering scientists, and was published in the “IEEE Potentials” journal (Jiang & Flexman, 2007). When invited to evaluate the project, experts from other domains (e.g., governmental representatives, managers from Philips, etc.) gave many negative comments. For instance, one comment from a Philips manager was that *“simple integration between engineering principles (e.g., ISO standards) and marketing principles (e.g., BoP approach) is not enough to support ICT-enabled Healthcare Design for Rural China (DIMRC). You lack considerations about cultural differences (e.g., do you think rural patient will trust your system?) and non-technical factors (e.g., economic factors). Furthermore, there is not enough user research in your project”*. As a result it was not possible to raise funding for the prototype system for further implementation in rural China.

After this experience, the author began a search for knowledge outside the biomedical engineering sciences, and discovered that the Faculty of Industrial Design Engineering (IDE) at Delft University of Technology (TU Delft) could be a valuable source, because:

- Being an intern student at Philips, the author had worked with MSc students from IDE/TU Delft (who had been sent from Delft to China for internships) in several industrial ICT-enabled healthcare projects for high-end markets in China. These projects received more positive comments from the company than others the author participated in.
- As one of the largest design schools in the world, IDE/TU Delft has been giving education and investigating multidisciplinary design topics, ranging from user needs identification to technology transformation and business development. Design and development ICT-enabled Healthcare (DIM) is an important topic within this faculty (e.g., Medisign: <http://www.io.tudelft.nl/medisign> accessed on 16-OCT-2012).
- IDE/TU Delft has extensive research experience in combining its own knowledge with that garnered from engineering in DIM projects.
- IDE/TU Delft carries out academic research into design for rural regions in developing countries. By 2011, more than 150 student projects and three PhD projects about “Design for BoP (Product design and development for poor people who lived at the bottom of economic Pyramid)” had been or are being carried out. Several researchers in IDE/TU Delft have a wealth of practical experience in this topic.

- Industrial design engineering is currently evolving from a set of mono-disciplinary sciences into a trans-disciplinary field of knowledge, where research is conducted between disciplines, across different disciplines and beyond individual disciplines. IDE/TU Delft is taking a lead role in this transformation (Ref: IDE Research Portfolio 2008-2012).
- IDE/TU Delft has an overall research objective: *Fostering sustainable well-being by exploring, generating and transferring knowledge and technologies for industrial design* (Ref: IDE Research Portfolio 2008-2012). IDE/TU Delft has knowledge of how to apply and adapt integrative approaches into design practice. Research at IDE/TU Delft targets the solving of concrete problems encountered by people and society through the knowledge and technological development of both the designer and/or the design process. Taking into consideration the nature of design research, three methodological approaches are recognised at IDE/TU Delft: (1) research in design context; (2) design-inclusive research; and (3) practice-based design research. In a general sense, these approaches are considered instrumental in bridging the knowledge gap between fundamental science and industrial product development. See Figure 2.2.

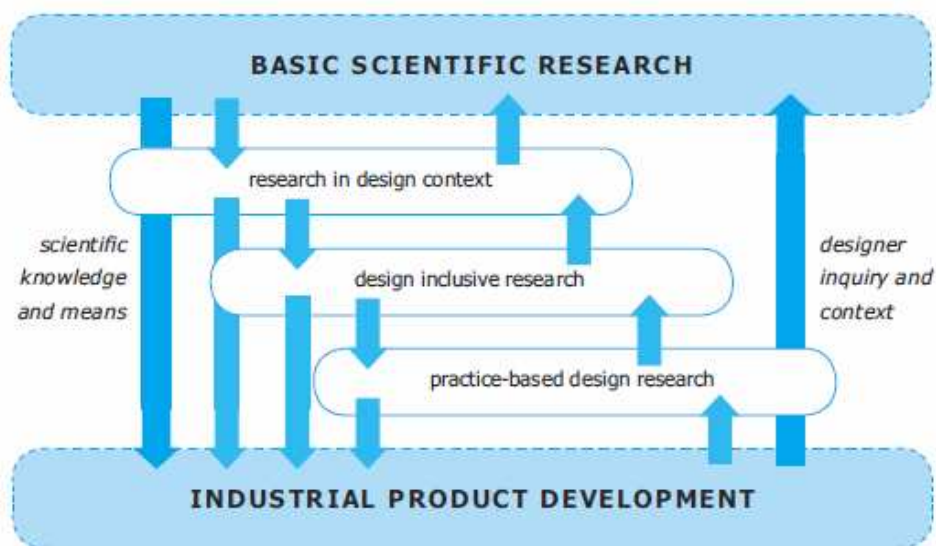


Figure 2.2 Research approaches at IDE/TU Delft (Source: IDE Research Portfolio 2008-2012). The three research approaches are applied in IDE/TU Delft to generate both foundational (disciplinary) knowledge and operative (practical) design knowledge. The approaches support a scientifically rigorous but design-oriented way of conducting research.

Figure 2.2 shows these three research approaches:

- *Research in design context* is conducted as analytical disciplinary research aiming at the creation of insights and rules. It is based on the knowledge and research methods of design-related disciplines (i.e. engineering, psychology, ecology). The contextualisation of the explored knowledge is based on a concern for (1) people (individuals, teams and communities) who are involved in, and are influenced by, design, (2) artefacts (concepts, designs and products) that form the input and output of design processes, and (3) the environment (natural, social, economic, ecological, technological and cultural surroundings).
- *Design inclusive research* is also known as Research through Design, and is a specific design research method that involves various manifestations of “design” as a means of research. The goal is to create new opportunities for generating knowledge that cannot be obtained otherwise. “Design” as a means of research may be an evolving artefact, or a process, phenomenon or piece of knowledge.
- *Practice-based design research* is mainly concerned with operative research towards general principles and patterns. It reflects the endeavours of designers to extend the knowledge base of design as part of their professional responsibility, and explores and generalises knowledge based on design activities and products.

These observations motivated the author to enter IDE/TU Delft as a PhD student with the primary aim of gaining knowledge from IDE/TU Delft that could contribute to improving Chinese biomedical engineering education in DIMRC.

2.5 Scope of this thesis

As one of the critical steps along the path to the realisation of “Created in China” for DIMRC, focus in this investigation is on the augmenting design competences of Chinese R&D teams. In general, a lack of competence in design is a common issue in developing countries (Diehl, 2011; Lieshout, 2010; WWR, 2010). Researchers have provided some practical approaches to the augmentation of the design competences of local R&D teams in developing countries. It is expected that these approaches could be applied or adapted (if needed) for DIMRC, and Figure 2.3 presents several possible approaches to achieving this. These approaches target the three essential Chinese stakeholders of DIMRC projects: government, companies and academia.

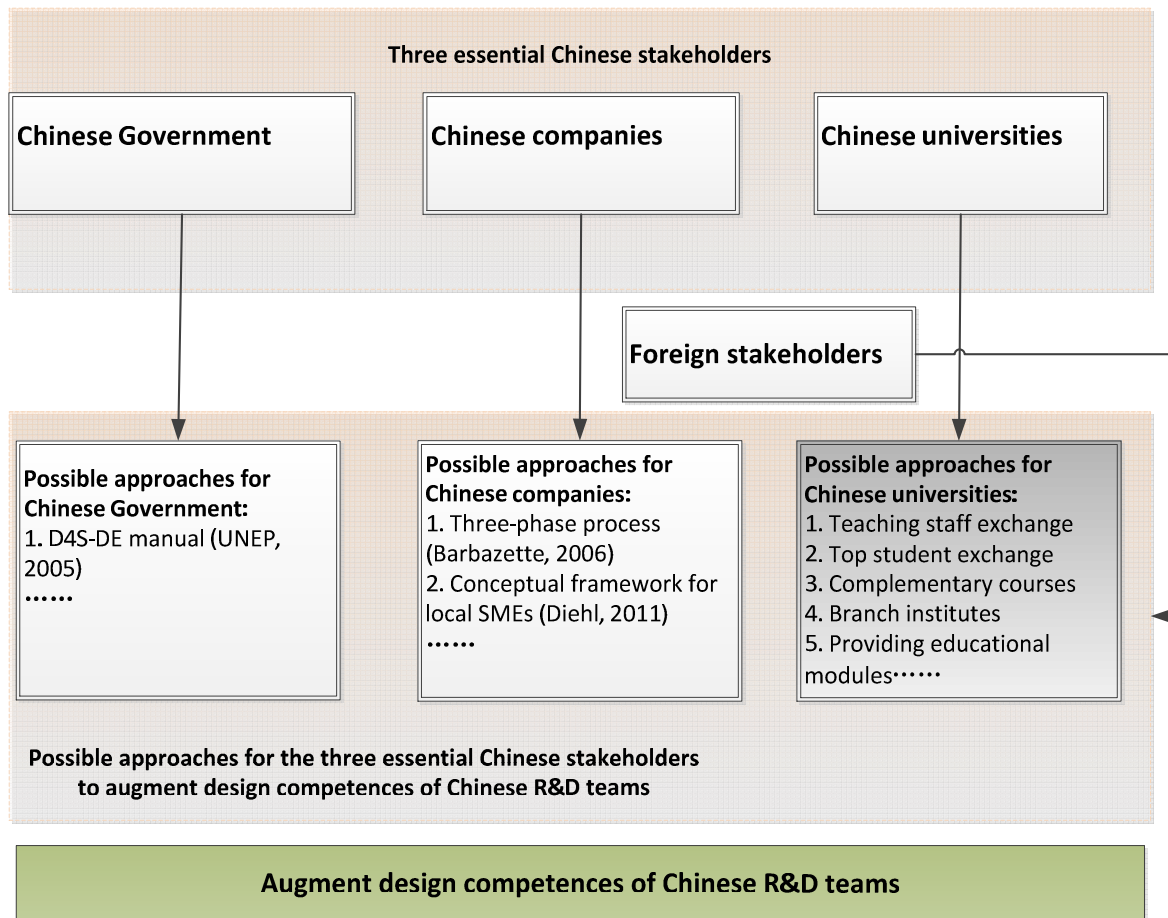


Figure 2.3: The picture about augmentation of the design competences of Chinese R&D teams, which includes three blocks: (1) Who should be involved; (2) How can the aim be achieved; and (3) What should the aim be.

Figure 2.3 is composed of three blocks. The first block includes the three essential stakeholders, being the Chinese government, companies and universities. These are the target groups who need to take a level of responsibility in the augmentation of design in Chinese R&D teams.

The second block shows some practical approaches that are available to the three stakeholders. At this time, foreign stakeholders (foreign universities, multinational companies, foreign governments etc.) are knowledge providers for these approaches. Some examples of possible approaches for the Chinese government and companies include: (1) a three-phase process from Barbazette (2006), in which it was proposed Multinational Companies (MNC) train their local R&D teams in developing

countries. The knowledge within this process was to come from the experiences of industrial companies; (2) a conceptual framework from Diehl (2011), in which it was proposed to help local SMEs (Small and medium enterprises) in developing countries to augment the design competences of their R&D teams. The conceptual framework was developed by Dutch MNCs and SMEs; and (3) a manual of Design for Sustainability for Developing Economies (D4S-DE manual) from United the Nations Environment Programme (UNEP, 2005). This manual targets governments in developing countries, with the knowledge contained within the manual coming from Western governments, such as the United States and the United Kingdom. This manual has been successfully tested in developing countries.

There are also many routes for Chinese universities to follow. For example, academic staff exchanges with advanced design schools would be one possible approach. Some academic staff from IDE/TU Delft have already been sent to the design school of Hong Kong Polytechnic University to augment the quality of design education in 2009 (<https://intranet.tudelft.nl/live/pagina.jsp?id=6e820e32-61f3-433e-90e4-7156e842b00c&lang=nl> [accessed on 16-OCT-2012]), and similar programmes could send teachers to other universities on mainland China. Another possible approach would be a student exchange programme. In recent years, summer schools involving the Netherlands and Shanghai were set up, during which many top Dutch students were sent to Shanghai to join on-going Chinese projects (<http://www.summerinasia.nl/> [accessed on 16-OCT-2012]), and DIMRC assignments could be included in similar projects in the future. A third possibility could be complementary courses, providing educational modules to strengthen or extend the existing Chinese education system; while a fourth idea would be to establish international academic institutes in China. TU Delft has already established a branch campus in Beijing, China, focusing on LED (light-emitting diode) lighting technologies (<http://www.rnw.nl/english/bulletin/tu-delft-opens-beijing-campus> [accessed on 16-OCT-2012]), and a similar approach could be used to establish a joint research centre focusing on healthcare in cooperation with Chinese universities.

All of the approaches from the second block should be carried out to augment the design competences of Chinese R&D teams in the near future. As a first step, this thesis focuses on providing design knowledge to Chinese universities, for two reasons:

- (1) The strengthening of competences requires long-term and sustainable effort, and it would therefore be useful to begin the

process during the education phase of the upcoming Chinese graduates.

- (2) Previous literature has shown that Chinese medical device companies have only a limited employee training culture in the field of design education (McKinsey Quarterly, 2012). In practice, if a Chinese medical device company recognises a need, they send their employees to Chinese universities for part-time study. Providing design education in Chinese universities will bring efficiency to the training of employees.

It is the intention with this thesis to strengthen Chinese biomedical engineering education by, for example, providing Chinese biomedical engineering students with supplementary educational solutions from Western countries. More specifically, the intention is to apply and adapt knowledge of integrative approaches from advanced design schools, e.g., the Faculty of Industrial Design Engineering, Delft University of Technology, the Netherlands, and introduce these insights into Chinese biomedical engineering education. Knowledge from other institutes and scholars may also be beneficial for Chinese biomedical engineering students, and they will be investigated in future.

The third block of Figure 2.3 shows the objective of this thesis: augmenting the design competences of Chinese R&D teams. The objective may be achieved by applying all of the different approaches in the second block.

Figure 2.4 shows how this doctoral thesis locates within a larger vision to improve the context of healthcare in rural China, illustrating the entire approach to the development of suitable DIMRC solutions. The starting point in this illustration is the societal and complex challenge: “China needs more and better ICT-enabled medical devices and systems for rural regions that are designed and developed by Chinese R&D teams”.

Figure 2.4 comprises two parts: “The initial hypothesis” and “Focus in this thesis”. “The initial hypothesis” refers to the level of knowledge that had already been attained in the early stage of the PhD project (before finally deciding to conduct a PhD project). For instance, in the “Medical Product Designing Model for the ‘BOP’ in China” the author already noted that successful DIMRC applications needed to be supported by different stakeholders, such as academic organisations, Chinese governments and industrial companies (Jiang et al., 2006). The knowledge integration from different sciences is necessary because the societal problem is related to several knowledge domains. For example, business should be a particular domain, as affordability is a key challenge; education should be a domain, because medical staff in rural China have not been educated to a

sufficient level; technology development should be a domain, as the physical medical infrastructure and logistics in rural China still need to be upgraded, etc.

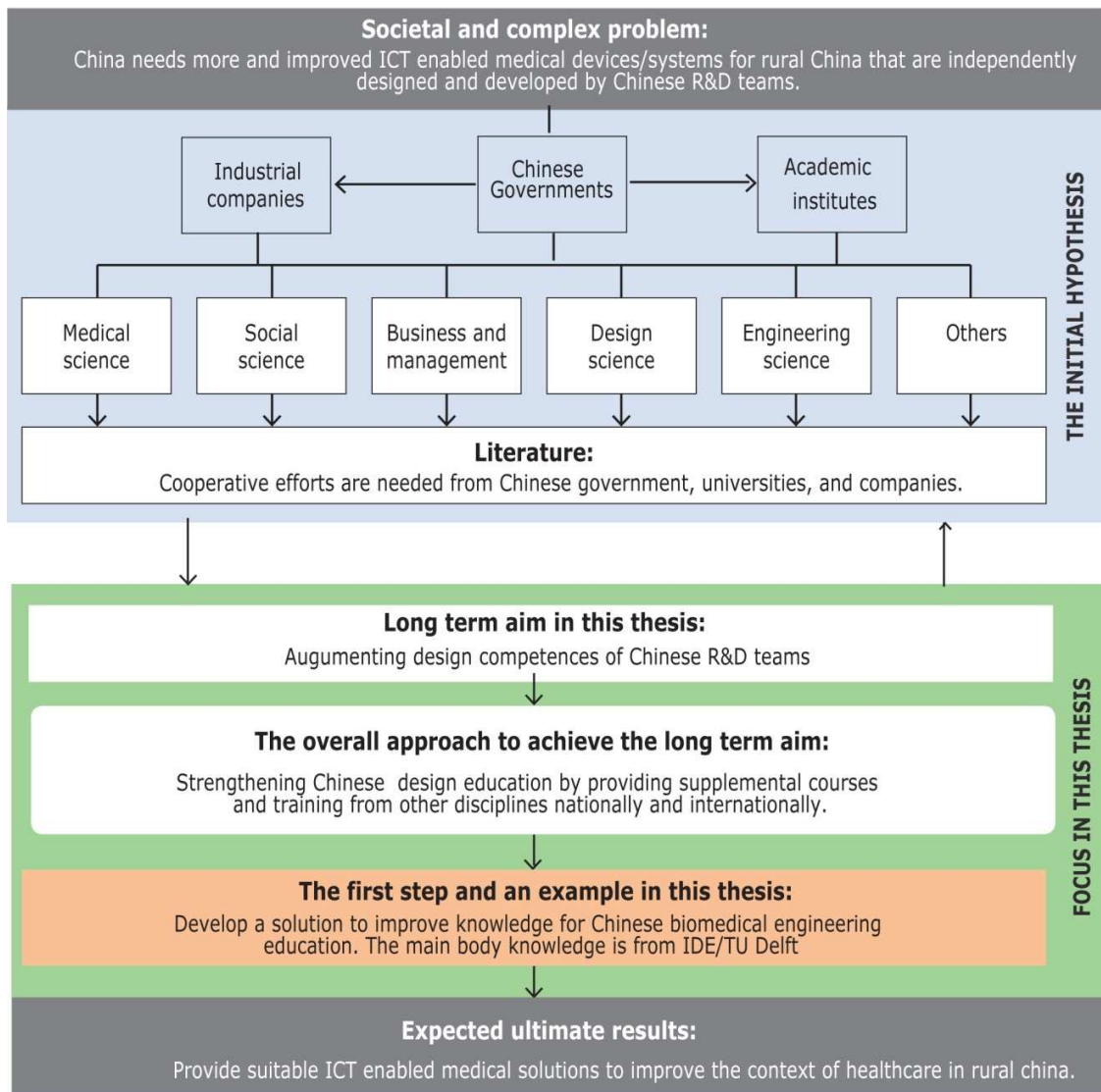


Figure 2.4: The place and role of this doctoral thesis within a larger vision to improve the context of healthcare in rural china.

The second section of Figure 2.4 is “Focus in this thesis”, referring to the investigation focus in this thesis. The starting point in this domain is the long term aim, which is to augment the design competences of Chinese R&D teams; and the overall approach to achieve the long term aim involves the strengthening of Chinese (industrial and engineering) design education through the provision of supplementary courses and training from other disciplines, both nationally and internationally. As the first

step, and as an example, a proposed solution to improving the knowledge of integrative approaches in Chinese biomedical engineering education is developed in this thesis. IDE/TU Delft is chosen as the main knowledge contributor in the solution.

The two parts of Figure 2.4 are iterative. On the one hand “The initial hypothesis” presents the big picture of DIMRC (e.g., three stakeholders are important in DIMRC; integrative approaches are important in DIMRC, etc.), and points out the research directions for the “Focus in this thesis”. “The initial hypothesis” will be updated and improved after learning from “Focus in this thesis”. For instance, when DIMRC projects are set up to explore how to augment design competences, some outputs from the projects may also contribute to “The initial hypothesis”, e.g., recommendations for Chinese universities, government and companies (*As one part of the results from this thesis, a new framework for DIMRC is proposed in Chapter 7 as an improvement on the “The initial hypothesis” [Commented by Jiehui Jiang]*).

Finally the results of both parts are expected to help realise the ultimate objective, which is that “Chinese R&D teams should be able to design and develop appropriate DIMRC products”.

2.6 Research objective and question

As noted in Figure 2.4, the objectives of this investigation are divided into short- and long-term objectives:

1. In the long term, the results from this thesis are intended to contribute to the knowledge and insights in the augmentation of the design competences of Chinese R&D teams.
2. In the short term, this thesis is intended to offer Chinese biomedical engineering an educational solution with focus on DIMRC. Knowledge and insights from IDE/TU Delft will be applied in the educational solution, while knowledge from other institutes and scholars will be applied into the educational solution in future. This is expected to be a first step towards realising the long-term objective.

The main research question for this thesis, therefore, is ***What design competences are needed for Chinese R&D teams to design and develop ICT-enabled medical devices and systems for rural China?***

Specifically, ***How can knowledge and insights from advanced design institutes, e.g., (predominantly) the Faculty of Industrial Design***

2.7 Research process and methodology

Figure 2.5 shows the outline of this thesis, which is in three parts:

- Introduction: In which the background, problem statement, personal motivation, research questions and methods are described. See paragraphs 1.1–2.6.
- Investigation: The three key investigation areas to answer the main research question are identified and explored in detail.
- Results: The main research question is answered, and a solution to address the problem in practice is proposed.

In the main body of the investigation, three methods are used, literature analysis, interviews and practice-based research (Murdoch, 2009). The practice-based research will be introduced in this section.

As an investigation of the knowledge domain of designing for the underserved part of the world (the so called Base/Bottom-of-the-Pyramid, BoP) in general and product design for rural China in particular, the topic of this thesis is new, and as such has to date not been studied to any great extent. Scientific publications related to the subject are few and far between, and so this thesis is qualitative and exploratory in nature; and research efforts lead to the definition of precise questions rather than the delivery of concrete answers. As is the case with other exploratory researches, this investigation has often relied on secondary research, such as reviews of available literature and/or data; qualitative approaches, such as informal discussions with diverse stakeholders; and more formal approaches through in-depth interviews, case studies and pilot studies.

This investigation is also iterative. Three issues of product design, i.e., design culture, design methodology (and methods), and design factors, are the focus in this thesis. Some other issues relevant to DIMRC, either of or beyond product design (e.g., production risk management, scalability of DIMRC projects), will be partly discussed in this thesis and investigated in next iterations.

2.7.1 Practice-based research

Practice-based research is a key part of this thesis, meaning investigation through learning from practice, which is a frequently used method in the medical domain. For instance physicians often learn about certain drugs through their own clinical practice (Murdoch, 2009). The method has also

been adapted into other research domains, such as community-based research in the area of ICT4D (ICT development for developing countries) and in industrial design research.

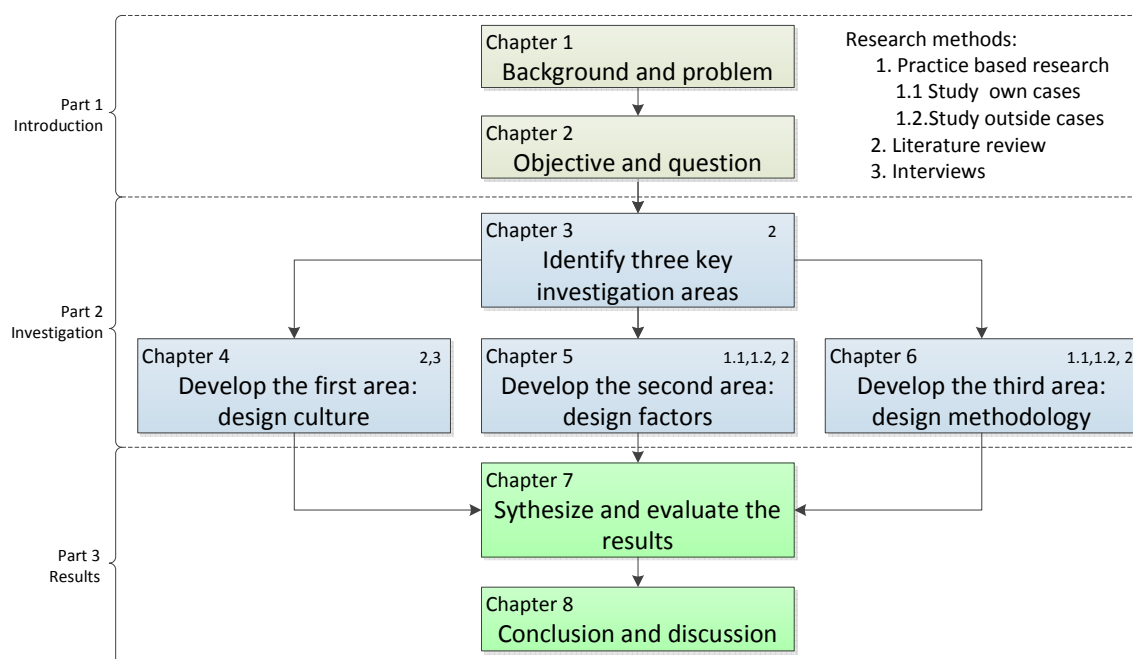


Figure 2.5. The research in this thesis is composed of three parts: introduction, main body of investigations, and results.

Practice-based research has been widely adopted by design researchers, and is one of three research approaches practiced within IDE/TU Delft (see Figure 2.2). Murdoch (2009) proposed four steps in practice-based research:

- Prepare: Plan research activities, prepare materials and organise stakeholders;
- Conduct: Conduct and record research activities;
- Measure: Conduct assessments for the project;
- Correct: Reflect on the project.

In this thesis, practice-based design research is divided into two sub-methods, which are used in Chapters 5 and 6:

1. A study of the author's own cases (cases in which the author participated): This sub-method consists of five steps: project preparation, project development, project implementation, project evaluation, and reflection (learning from the project). Two DIMRC cases developed in this thesis were used as data sources, which were analysed to explore design factors and a design methodology for DIMRC.
 - Case 1: "Exploring design opportunities in rural Shanghai" (4:2006-10:2006). This case was funded by Philips Medical and Apptech, Shanghai, and the aim of the project was to find design opportunities for DIMRC (pilot in rural Shanghai). The research team included students from three academic stakeholders: IDE/TU Delft, the public health department at Erasmus University (Netherlands) and BME/Shanghai University (China).
 - Case 2: "Development of a blood pressure monitoring system incorporating ICT" (5: 2008 – 4: 2010). This project was funded by the Shanghai government and Philips, with the aim being to address hypertension problems in underserved regions of China. To come up with an appropriate solution, a research/design group was created with students from BME/Shanghai University (China) in March 2009, supported by IDE/TU Delft. A prototype system was developed, and an approach to identifying design factors was conducted.
2. An in-depth study of other cases (in which the author did not participate): This part consists of four steps: cases chosen, data collecting, data analysing, and results generating. The data used in this section came from 24 student design projects from within IDE/TU Delft, which were analysed to identify design factors and design methodologies for Design for BoP. All materials came from the MSc graduation projects of students from IDE/TU Delft.

Learning from above cases, as well as the literature analysis and the interview, the outcomes of this thesis are concluded, and pilot evaluations of the results have been achieved through interviews with biomedical engineering experts.

2.8 Structure of this thesis

This thesis is composed of three parts.

Part 1 (introduction): Chapters 1 and 2.

1. The background of Design and development of ICT-enabled Medical device and system for Rural China (DIMRC) is described in Chapter 1, detailing healthcare in rural China, Design and development of ICT-enabled Medical device and system, and complexity of DIMRC.
2. The current status and challenges in DIMRC are identified from literature in Chapter 2, leading to the long-term research objective that when Chinese R&D teams are strengthened with design competences, they are likely to work more effectively as innovators, and accordingly, better DIMRC applications are expected to be designed and developed in the future. This in turn supports the “Created in China” strategy of the Chinese government. The research question for this thesis therefore is: ***what design competences are needed for Chinese R&D teams to design and develop ICT-enabled medical devices and systems?*** The chapter also describes the methodology to be followed to address this question.

Part 2 (main body of investigations): Chapters 3, 4, 5 and 6.

3. A literature analysis of publications related to DIMRC is presented in Chapter 3, in which definitions of frequently used terms related to DIMRC in both this thesis and in other literature are introduced. After reviewing relevant literature, three aspects of the educational solution are proposed to strengthen Chinese biomedical engineering education for DIMRC: design culture, design factors and design methodology.
4. Important factors in China’s culture influencing DIMRC are defined in Chapter 4. The research methods used in this chapter are literature analysis and interviewing. Three Chinese industrial design professors and six MSc/PhD students in IDE/TU Delft were interviewed to verify the findings of the literature analysis. All of the professors and students interviewed have practical experience in DIMRC.
5. A list of design factors for DIMRC is proposed in Chapter 5. The research methods in this chapter include a literature analysis and practice-based research. The data used in this section came from 24 student design projects from IDE/TU Delft, as well as the author’s own DIMRC case “Development of a blood pressure monitoring system incorporating ICT”.

6. Design methodologies for DIMRC are explored in Chapter 6 by applying and adapting existing design methodologies. The research methods in this chapter include a literature analysis and practice-based research. Insights from the Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft) served as a model for this purpose. The Delft Design Guide (DDG) was chosen as the most appropriate methodology for application to the DIMRC case “Exploring design opportunities in rural Shanghai”, and was adapted to the DIMRC case “Development of a blood pressure monitoring system incorporating ICT”.

Part 3 (results): Chapters 7 and 8.

7. To support Chinese biomedical engineering students with knowledge of integrative approaches, a prototype for an educational module (comprising supplemental courses and training) has been designed, and is described in Chapter 7. As a first step in the testing of this prototype, a biomedical engineering professor and a senior biomedical engineer from a Chinese medical device company made an assessment of the course. Besides the educational module, an additional result of this thesis is a new framework for DIMRC. The new framework was developed based on the initial framework (Figure 1.4), however several lessons learnt in Chapters 1–6 were taken into account in the new framework.
8. Discussions, conclusions, and recommendations for future research are given in Chapter 8.

PART 2

PART 2: MAIN BODY OF INVESTIGATION

This is the 2nd part of the thesis, in which all data from literature, interviews and case studies are collected to answer the main research question: ***What design competences are needed for Chinese R&D teams to design and develop ICT-enabled medical devices and systems?***

Figure 3.1 shows the structure of this thesis and the location of this part.

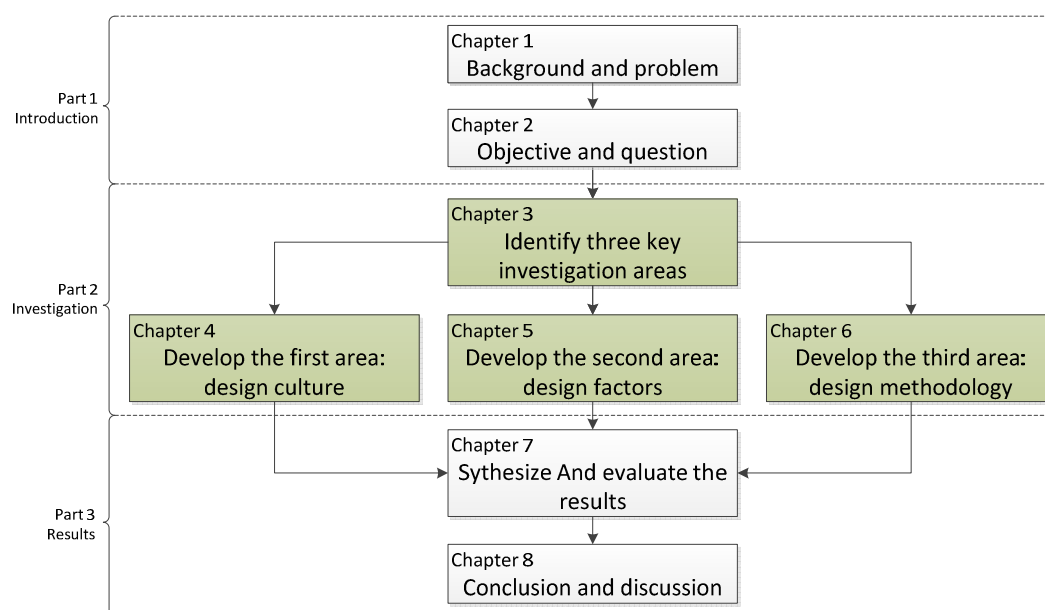


Figure 3.1: The Structure of this thesis. Part 2 consists of four chapters.

Chapter 3 Literature analysis on Design and development of ICT-enabled Medical device and system for Rural China⁵

A literature analysis is presented in this chapter. As DIMRC is a wicked problem, an integrative approach is used in this chapter to decrease the scope of literature relevant to DIMRC from a broad field of publications to identify the educational areas for the development of an educational solution in this thesis, with the ultimate objective of augmenting the design competences of Chinese R&D teams (Section 2.6).

Accordingly, the research question raised in this chapter is:

RQ: What opportunities exist to augment the design competences of Chinese R&D teams by means of educational intervention?

There are five sub-research questions under the main question for this chapter:

SRQ1: What literature domains are relevant to DIMRC based on key elements in the R&D phase of product development?

SRQ2: What are the likely problems (defined in literature) that Chinese R&D teams face in DIMRC?

SRQ3: What existing design models might be relevant to DIMRC?

SRQ4: Can existing design models be used directly to build an educational solution with the aim of augmenting the design competences of Chinese R&D teams?

SRQ5: Can the three challenges in BME, proposed by Malkin, be used as three educational areas to augment the design competences of Chinese R&D teams?

The three challenges from Malkin (2007) were already introduced on page 33, Section 2.2.4. They were: (1) understanding cultural influences, (2) identifying design factors, and (3) applying and adapting (if needed)

⁵ 本章中文名称：关于 DIMRC 的文献综述。This chapter is based on:

J. Jiang, A. Freudenthal and P.V. Kandachar (2010), Exploring the influence of design culture on ICT healthcare product and service design for rural China, Proceedings of Knowledge Collaboration & Learning for Sustainable Innovation ERSCP-EMSU conference, Delft, the Netherlands, 2010.

J. Jiang, P. V. Kandachar, A. Freudenthal (2011), Overview of literature relevant to Information and Communication Technology based healthcare design in rural China, Journal of Emerging Knowledge on Emerging Markets, Volume 3.

design methodologies. In this chapter the relevance of these challenges for education will be further verified.

To answer the above sub-research questions, five research steps were conducted in this chapter. These five steps are:

- (1) Understand the state-of-the-art in DIMRC through an analysis of literature domains that are close to/relevant to DIMRC (Section 3.2).
- (2) Identify problems that Chinese R&D teams face to augment their design competences regarding DIMRC, through an analysis of literature findings (Section 3.3).
- (3) Choose existing design models that may be suitable for the education of future Chinese R&D teams addressing DIMRC (Section 3.4).
- (4) Verify whether existing design models from literature can be used directly to improve the design competences of Chinese R&D teams regarding DIMRC (Section 3.5).
- (5) If existing design models are deemed unsuitable, a new design model is required. To explore the development of the design model, Malkin's three proposed challenges for BME are verified to check their use as focus areas for the educational solution to improve the design competences (Section 3.6).

Figure 3.2 presents the structure of the chapter, in which there are a total of seven sections. Section 3.1 is the introduction, while the core contents of the five steps are covered in sections 3.2–3.6 (dark parts). The conclusion is presented in Section 3.7.

In Figure 3.2, the results of step 1 are used to achieve steps 2 and 3; the results of step 2 are used as data for the investigations in step 5; and the results of both step 2 and 3 are used as the data to explore step 4.

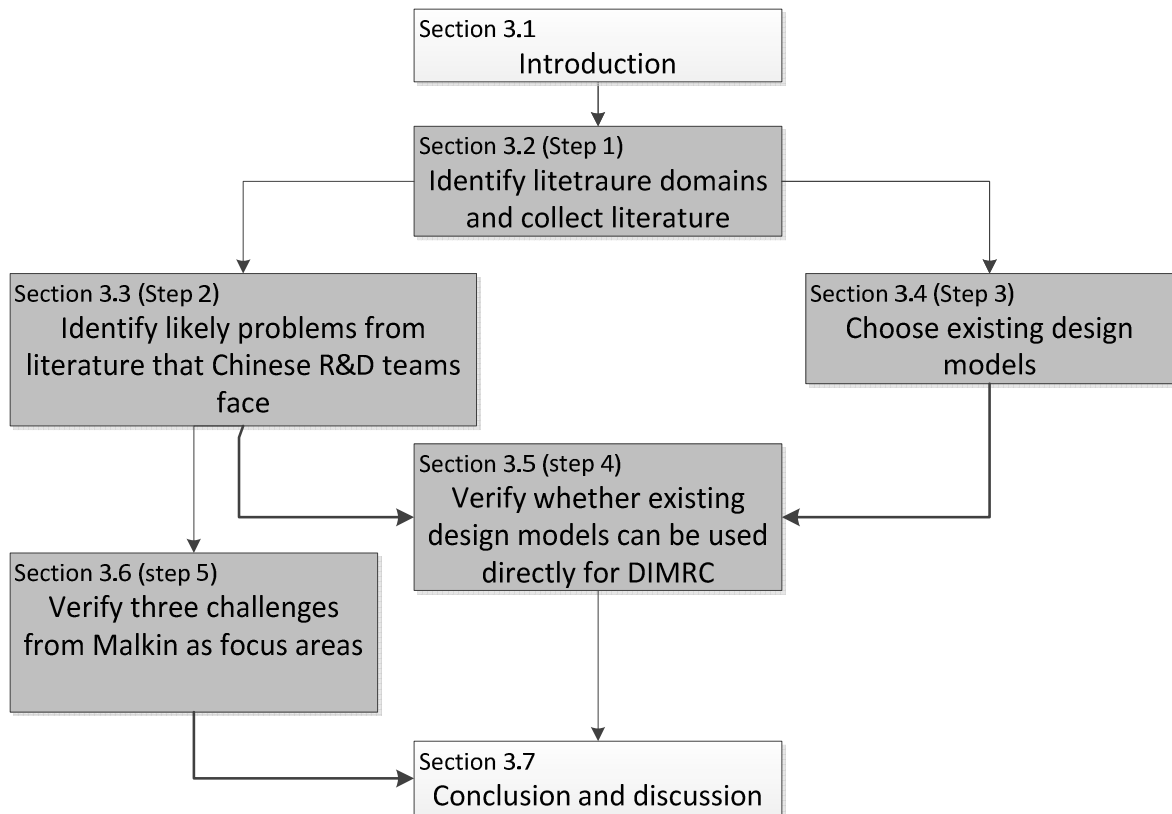


Figure 3.2: The Structure of Chapter 3. The core contents of Chapter 3 are divided into five research steps (dark parts).

3.1. Introduction

3.1.1 Background

As mentioned in Section 1.8, DIMRC is a complex issue with several components, such as Information and Communication Technology (ICT) development, medical device and system development, design for rural China, etc. Although some theoretical studies and practical R&D activities for DIMRC have been carried out in the past ten years (See Section 1.6), the requisite knowledge of DIMRC is still incomplete, fragmented and only partly integrated. No overview could be found in literature on this topic; and so a literature analysis relevant to DIMRC is presented in this chapter. During the process of collecting and studying literature it became clear that the available publications on the issue of DIMRC were mostly policy documents of the Chinese government. Scientific open-access publications specific to DIMRC are still limited, and furthermore are related to different scientific domains. For example, the initial framework for DIMRC comes from theories of Design for Base/Bottom of

the Pyramid (DfBoP) and Design and development of ICT-enabled Medical device and system (DIM) (Jiang et al., 2006). Accordingly, the scientific domains relevant to DIMRC will be explored and identified.

3.1.2 Definitions

Five frequently-used terms in this research: “ICT”, “healthcare”, “medical device and system”, “design” and “Base/Bottom of the Pyramid (BoP)”, are defined and described in this section.

A Definition of Information and Communication Technology (ICT)

ICT is the acronym of “Information and Communication Technologies”, and is often used in the context of an “ICT roadmap” to indicate the path that an organisation will take with their ICT needs. The Information Technology Association of America (ITAA) defines ICT as (Adelman, 2000):

ICT is the study, design, development, implementation, support or management of computer-based information systems, particularly software applications and computer hardware.

As it pertains to technology, ICT spans a wide variety of areas that include, but are not limited to, information processes, computer software, computer hardware, programming languages and data constructs. In short, technologies that render data, information or perceived knowledge, in any visual or multimedia format, are considered to be a part of the domain space known as ICT.

The term ICT has expanded over time to encompass many aspects of computing and technology, and has become very prominent. ICT professionals perform a variety of functions that range from installing applications to designing complex computer networks and information databases. A few of the duties that ICT professionals perform may include data management, networking, engineering computer hardware, database and software design, as well as the management and administration of entire systems. Information technology has spread beyond conventional personal computer and network technologies and today is frequently integrated into such technologies as cell phones, televisions, automobiles, healthcare products and more, thus increasing the demand for ICT professionals.

ICT is considered as a form of value creation, according to Bird (2010), who proposes that with the growing competitiveness between organisations, ICT enables value creation, which is heavily dependent upon the alignment of technology and business strategies. It requires business and technology management to work as a creative, synergistic and collaborative team instead of a purely mechanistic span of control.

B Definition of healthcare

Various definitions of healthcare can be found in literature. In this thesis we choose Bond & Bond's definition (1994):

Healthcare is the treatment and prevention of illness that is delivered by professionals in medicine, dentistry, nursing, pharmacy and allied health.

Phelps (2002) points out that the healthcare sector includes several social and political aspects, such as medical management of illness, reimbursement of healthcare costs, and the collective state and range of health in a population. Krugman (2008) proposes that the delivery of modern healthcare depends on an expanding group of trained professionals coming together as an interdisciplinary team. Similar and related definitions for healthcare can be attributed to Arrow (1963), William (1987) and USDL (2007) etc.

The modern healthcare sector provides healthcare services and products in several sectors. According to industry and market classifications, such as the Global Industry Classification Standard and the Industry Classification Benchmark (USDL, 2007), the health-care sector includes healthcare equipment and services, as well as pharmaceuticals, biotechnology and life sciences. The particular sectors associated with these groups are: biotechnology, diagnostic substances, pharmaceutical delivery, pharmaceutical manufacturers, hospitals, medical equipment and instruments, diagnostic laboratories and nursing homes. ICT-enabled medical devices and systems are one important part of the modern healthcare sector.

Healthcare systems depend largely on the health policies enacted by country governments. For instance, as mentioned in section 1.1, the

Chinese healthcare system in rural regions is a three-tier system from which primary healthcare is encouraged for rural China.

C Definition of medical devices and systems

According to the definition of the European Commission (Medical Device Directive (MDD) 93/42/EEC, 1993):

A medical device is any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*
- *investigation, replacement or modification of the anatomy or of a physiological process;*
- *control of conception;*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Article 12 of the MDD 93/42/EEC (1993) also offers a definition of medical systems:

Medical systems are medical devices that are assembled for use in combination as a unit.

In this definition medical devices are the most crucial components of a medical system.

D Definition of design

The foundations for “science of design” were laid in 1969 by Herbert Simon (Simon, 1969), an American economist, psychologist and Nobel Laureate. Simon defined the domain as *“a body of intellectually though, analytic, partly formalisable, partly empirical, teachable doctrine about the design process”*. The design domain may also be differentiated as a subject in its own right, apart from sciences or humanities, through such arguments as: *“The natural sciences are concerned with how things are design, on the other hand, is concerned with how things ought to be”* (Simon, 1969) and *“there exists a designedly way of thinking and communicating that is both different from scientific and scholarly ways of thinking and communicating, and as powerful as scientific and scholarly methods of enquiry when applied to its own kinds of problems”* (Archer, 1979).

Design is one kind of human activity that is central and pervasive to our lives. Every artefact we use, from an apple peeler to an airplane, from a stapler to software, results from a process of design. The design of a complex artefact, for example a passenger plane, a cellular telephone, or a software application, requires the skills of diverse designers — mechanical and electrical engineers (for the plane or telephone) as well as programmers and software engineers, interaction designers, anthropologists, and cognitive scientists. Similarly, designing medical devices requires the considerable involvement of bio-medical engineers. Designing for Base/Bottom-of-the-Pyramid (BoP, see below) requires additionally insights into the culture, habits and other characteristics specific to the target group. Hence, the terms design and designer mean many different things to many different people. In this thesis, the term “design” is limited to Industrial Design, and specifically to product design, which is defined as:

Product design is the creation of products with new or different characteristics that offer new or additional benefits to the customer.

It may involve the modification of an existing product or its presentation, or the formulation of an entirely new product/service that satisfies a newly defined customer requirement or market niche.

E Rural China at the Base/Bottom-of-the-Pyramid (BoP)

The last term to be furnished with background information is “rural China”, which in the context of this thesis means Chinese end-users (e.g., patients and doctors) in rural regions. Rural end-users are dissatisfied with the current situation concerning personal care, medical insurance and medical information management as a result of the shortage of medical resources in rural areas.

As a target group, “rural China” has several typical features. For instance, this group generally has low and unsteady incomes; and besides health problems, this group often suffers from a diversity of other problems, such as limited power resources.

In this thesis, a general strategy referred to as “Base/Bottom of the Pyramid” (BoP) has been explored for its applicability to “rural China”.

The initial reminiscence about BoP was made by US President Franklin D. Roosevelt in his April 7, 1932 radio address, The Forgotten Man, in which he said: *“These unhappy times call for the building of plans that build from the bottom up and not from the top down; that put their faith once more in the forgotten man at the bottom of the economic pyramid.”*

A more recent use of the term “BoP” was made in 1998 by Prahalad and Hart (Prahalad & Hart, 2002), who indicated that:

“Base/Bottom-of-the-Pyramid” (BoP) refers to the 4 billion people who live on an income less than US\$3 per day and the 1 billion who live on less than even US\$1 per day.

According to this definition, more than 60 percent of China’s rural residents can be considered as BoP (The average income of rural Chinese residents in 2009 was US\$2.5 per day [Chinese statistic yearbook, 2010]) Other definitions are also proposed in the world; for instance, London (2007) defined BoP as “an informal economic body who live outside mainstream markets”.

In November 2011, China redefined the level at which people in rural areas are considered poor by raising the official poverty line, according to which 128 million Chinese in rural areas now qualify as poor, 100 million more than under the previous standard. The new threshold of about US\$1 a day is nearly double the previous level. While the revised poverty line is still below the World Bank threshold of US\$1.25 a day, the change brings China closer to international norms (The Guardian Newspaper, 2011).

The strategy of “Base/Bottom of the Pyramid” (BoP) is introduced in the publication “The Fortune at the Bottom of the Pyramid” (Prahalad & Hart, 2002), in which they proposed a framework for the active engagement of the private sector and suggested a basis for a profitable win-win engagement. Win-win refers here to a situation in which poverty is reduced and profit is generated through entrepreneurial intervention. They argue that the re-design of products and services is an innovation approach to meet the needs of the world’s poor.

3.2 Three literature domains

This section deals with important literature domains covering theories that are most relevant to DIMRC, and provides the answer to SRQ1.

Several authors have proposed three key elements that Research and Development (R&D) teams should consider in the R&D process of new product development: (1) R&D contexts (e.g., local end-users, local regional product policies, etc.); (2) R&D methodology; and (3) the (to be applied) technology (i.e., Pahl & Beitz, 1980; Rozenburg & Eekels, 1995). These three key elements can also be recognised in the three improvement goals for DIMRC, as formulated by the Chinese central government. According to the “12-5 Plan for Medical Device Technology Industry” (CMoST, 2012), the three improvement goals for DIMRC from 2011-2015 are: (1) DIMRC applications should be affordable and reliable for local rural hospitals and patients, i.e. matching R&D contexts; (2) Chinese R&D teams should improve their innovation capabilities in new product development – this is a R&D methodology issue; and (3) Chinese companies and research institutes should achieve breakthroughs in some key technology issues (For detailed information of these three improvement goals, see Section 2.1.1.)

The intention in this chapter is to target the three literature domains of: Design for Base/Bottom of the Pyramid (DfBoP: about contexts), User-Centred Design (UCD: about methodology) and Design and development

of ICT-enabled Medical device and system (DIM: about technology). To understand what state-of-the-art is in these three domains, a review of scientific publications in the area of “ICT, Base/Bottom of the Pyramid, medical device and/or system, product design, user-centred” was carried out by Internet and TU Delft library service (In this study the terms “Base/Bottom of the Pyramid, and product design” were indexed for the DfBoP domain; the terms “product design, and user-centred” were indexed for the UCD domain; the terms “ICT, and medical device and/or system” were indexed for the DIM domain. The terms for each domain were combined for the cross areas of each domain, e.g., the terms “Base/Bottom of the Pyramid, product design, and user-centred” were indexed for the cross areas of the DfBoP domain and the UCD domain). The search systems are: TU Delft repository of graduation reports (<http://repository.tudelft.nl> [accessed on 16-OCT-2012]) and Google scholar (<http://scholar.google.com> [accessed on 16-OCT-2012]). In this search Google scholar often directed us to IEEE publication database, PubMed database, and to TU Delft website: PhD and Master thesis databases.

Figure 3.3 provides an overview of the results of literature analysis.

- In the DfBoP domain, principles and innovative methods of DfBoP are presented, e.g., twelve design principles (Prahalad & Hart, 2002), disruptive innovation (Christensen et al., 2006) and the Great Leap approach (Hart & Clayton, 2002);
- The UCD domain incorporates participatory design (Greenbaum & Kyng, 1991) and multidisciplinary cooperative design (Mark & Stephen, 1990), etc;
- In the DIM domain, both methodologies and the implementation of DIM are presented from literature, e.g., Haux et al. (2002 and 2010) and Virmarlund & Olve. (2005).

More details about these references will be introduced in Section 3.2.1-3.2.3.

By going through the results, it can be seen that there are a number of references in the DIM domain and the UCD domain, and few sources in the DfBoP domain. The literature in the overlap between two domains is limited, while there is very limited literature in the overlap of the three domains. In this thesis, the overlap of the three domains constitutes the target research area – DIMRC.

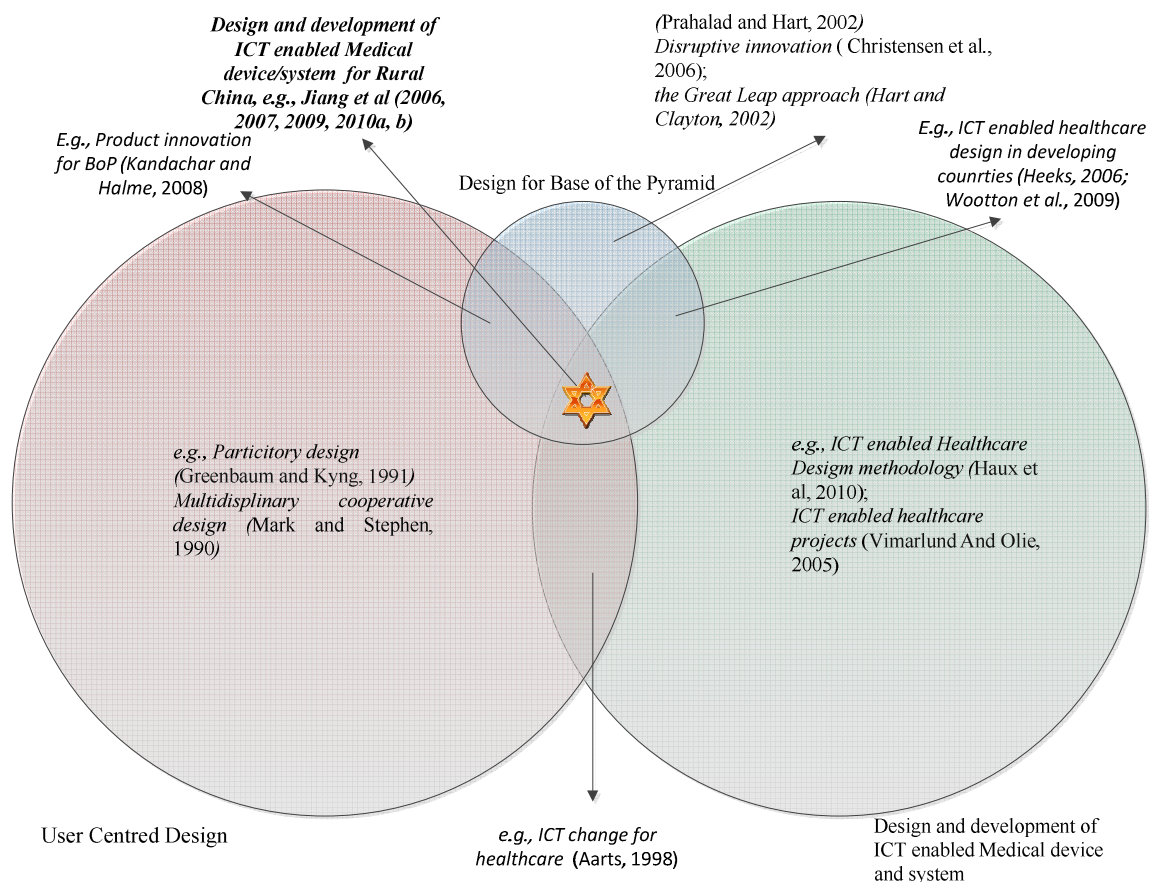


Figure 3.3: Areas of literature relevant to DIMRC. The three literature domains concern Design for Based of the Pyramid (DfBoP), User-Centred Design (UCD), and Design and development of ICT-enabled Medical device and system (DIM). The circles of UCD and DIM are bigger than the circle of DfBoP because much literature can be tracked in the UCD and DIM domains by literature while less literature can be tracked in the DfBoP domain. The target area of this research (DIMRC) is located at the intersection of all three domains (the star). Note that in the intersection of the three circles (indicated by the star), hardly any scientific literature is available. (Publications by Jiehui Jiang published before 2011 were included in the literature search as existing publications for DIMRC.)

3.2.1 Design for Base/Bottom of the Pyramid (DfBoP)

The first literature domain relevant to DIMRC is “Design for Base or Bottom of the Pyramid (DfBoP)”. DfBoP is a concept proposed by design academicians following Prahalad’s BoP market theory (Prahalad & Hammond, 2002; Prahalad & Hart, 2002). Many scholars have published articles about DfBoP in these fields of knowledge: BoP theory, social impact theory and innovation management theory. For example:

- BoP theories: Prahalad (Prahalad & Hart, 2002) pointed out twelve innovation principles in BoP communities; Christensen et al. (2006) claims that disruptive innovation (an innovation that disrupts an existing market) from BoP users could be achieved through cooperation with local communities; while Hart (Hart & Clayton, 2002) presented a protocol to achieve the innovations.
- Social impact: Arnould (Arnould & Mohr, 2005) proposed that BoP local cultures (social-cultural impact) affect design activities.
- Innovation management: Barczak et al. (2006 and 2009) offered their ideas about innovative investigations of new product developments; Bart et al. (2002 and 2007) mentioned that content exploration and management would affect product design processes, and Swan et al. (2005) made suggestions regarding innovation for robust product development.

Several other researchers (Penchansky & Thomas, 1981; Braimah & Kwame, 2010; Diehl et al., 2008; Diehl, 2011) have defined principles of DfBoP in terms of sustainability. The four main requirements for product development and implementation have been identified for DfBoP (Anderson & Markides, 2007):

- Affordability is the degree to which a company's goods or services are affordable to consumers at the low end of the market. This is fundamental to reaching the new "who" — being customers who are non-consuming or under consuming due to low income. Many consumers in developing markets survive on daily wages, meaning that cash flow is an issue, and so companies need to deliver their products at a price that enables consumption by even the poorest consumers.
- Acceptability is the extent to which consumers and others in the value chain are willing to consume, distribute or sell a product or service. In markets where consumers have limited resources, the most successful strategic innovators create products and services that are adapted to the unique needs of customers, distributors, or both. Companies respond to specific national or regional cultural or socioeconomic issues, or address the unique requirements of local business practices.
- Availability is the extent to which customers are able to acquire and use a product or service. Distribution channels in developing markets are often fragmented or non-existent, so basic distribution can be a major hurdle. Strategic innovators are resourceful about distributing or delivering products or services to the most isolated communities.
- Awareness refers to what customers know about the products or services being sold. Since many poor customers are not reachable by

conventional advertising, building awareness can be a challenge. Accordingly, companies must learn to use alternative communication modes and methods.

Several design schools around the world have pioneered DfBoP over the past nine years, one example of which is the Illinois Institute of Technology's Institute of Design. Initiated in 2003, this project explored *"Human-centred design strategies and concepts for new products, services and businesses capable of generating sustainable economic improvement in the lives of people living in the vast base of the global economic pyramid"*. This project is an initiative to develop human-centred design strategies and concepts for new products, services and businesses in BoP .

A similar effort is underway at the Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft). Several DfBoP cases have been set up starting from 2003, such as "Solar Lamp for Africa" or "Adoptable Woodstove for India" (Kandachar et al., 2009). By 2011, about 150 student design projects had been executed in the domain of DfBoP, and by studying these student cases some observations have already been made:

Kandachar & Halme (2008) found that all cases started from investigating the needs of the BoP users. They observed that several design methodological innovations were taking place to serve the unmet needs of the BoP-community, including:

- For user studies, ethnographic tools, cultural probes, business innovations such as hybrid business models, corporate responsibility;
- For technology matters like disruptive innovations, open source designs, etc.;
- Regarding business microfinance, social entrepreneurship.

3.2.2 User-Centred Design (UCD)

The second literature domain relevant to DIMRC is about "User-Centred Design (UCD)". UCD is a frequently used design approach in which the needs and wants of the user are the focus in the design project (Norman & Draper, 1986). In past decades, UCD was used to design ICT applications such as interfaces for software systems (Troyer & Leune, 1998; Vredenburg et al., 2002), and attention was paid to situation awareness (Endsley et al., 2003), virtual environment (Hix et al., 1999), and cross-language information (Petrelli et al., 2004).

UCD is also widely adopted for ICT-enabled healthcare solutions. For example, Mark & Stephen (1990) presented a run-time conflict resolution UCD model among designers, market experts and manufacturing experts; Hong et al. (2002) proposed a multi-agent UCD design model, which may resolve communication problems among different design teams; and Sleswijk Visser (2009) further developed a “context mapping process”⁶ including preparation, sensitisation, session, analysis, sharing and conceptualisation.

The education and research profiles in IDE/TU Delft strongly emphasise UCD. An education course (amongst others) for all bachelors and MScs, the “Delft Design Guide (DDG)” includes UCD approaches and models, and thus is influencing “design thinking” in IDE/TU Delft among the designers and researchers, including the author.

In practice, there are a number of approaches to UCD. In the following sections four approaches are introduced: participatory design, co-creation, multidisciplinary cooperative design, and contextual design, however there are many more UCD approaches e.g., applied ethnography (Chambers, 2000) and empathic design (Zades, 2004).

A Participatory design

Participatory design, as developed in Scandinavia in 1970s (Greenbaum & Kyng, 1991; Mogensen & Trigg, 1992), calls for the involvement of potential end-users in several stages of an innovation process. They should participate during the initial exploration and problem definition, both to help define the problem and to focus ideas for a solution. They should also help evaluate the proposed solutions.

Participatory design can be seen as a move by users into the world of design and research, allowing community opinions to be taken into account in decision-making processes (Wheeler, 2004). Miller (2001) listed many participatory design methods and tools, including co-development, card games, cooperative prototyping, cooperative evaluation, storyboard prototyping etc.

Kaulio & Karlsson (1998) proposed three kinds of customer participatory approaches in product development: design for customer, design with customer and design by customer. He identified seven customer involvement activities for different phases of the design process,

⁶ The “context mapping process” is a procedure for conducting contextual research with users, where tacit knowledge is gained and analyzed regarding the context of use of a product.

including user-oriented, user-led, concept testing, beta testing, consumer idealised design, participatory ergonomics and quality function deployment.

B Co-creation

Co-creation is a form of marketing or business strategy that emphasises the generation and on-going realisation of mutual firm-customer value. It views markets as forums in which firms and active customers can share, combine and renew each other's resources and capabilities to create value through new forms of interaction, service and learning mechanisms (Prahalad & Hart, 2002).

In co-creation cases, customers would no longer be satisfied with making “yes” or “no” decisions on what a company offers. Co-creation between the firm and the customer can increase the value of the design, in that it not only describes a trend of jointly creating products, but also describes a movement away from the mere buying of products or services by a customer as a transaction, to purchases being made as part of an experience.

C Multidisciplinary cooperative design

Multidisciplinary cooperative design means that experts from different disciplinary background work together to contribute to the product design (Hoog & Boeijen, 2008).

As a creative activity with an evolutionary nature, design is a team effort, in which close collaboration will accelerate product development, improve product quality and reduce investments. For example, the design of a lamp may require experts in properties of materials, ease of manufacturability, potential markets for the lamp, and so on. Multidisciplinary cooperation is becoming increasingly popular in design projects.

D Contextual design

Contextual design is a UCD process developed by Beyer & Holtzblatt (1998) that describes a design process, and comprises the following steps: contextual inquiry, work modelling, consolidation, work redesign, user environment design, prototyping and implementation, and several working models, such as flow models, sequence models and cultural models. Ethnographic methods for gathering data relevant to the product incorporate such methods as field studies, rationalisation of workflows and the design of human-computer interfaces, and are included in this process (Holtzblatt, 2001).

3.2.3 Design and development of ICT-enabled Medical device and system (DIM)

The third literature domain relevant to DIMRC is “Design and development of ICT-enabled Medical device and system (DIM)”, which can be considered as the backbone of DIMRC. Most DIMRC are redesigns of DIMs from developed countries. Studies in DIM have developed quickly since 2000 due to the increasing demands of ICT usage and healthcare requirements. For instance, home healthcare is becoming popular in the United States – which is the world’s largest market for medical devices. The aging population and the rise of chronic diseases in the United States necessitate longer hospital stays (Engelhardt & Greenhalgh, 2010), which means increased healthcare costs; and this, coupled with the longer waiting lists, is driving a shift towards more economical home care (De Rouck et al., 2008). Patients now express a need for greater participation and control in healthcare decision-making (Lemire et al., 2006), and this increases the need for access to information at home through different media, such as the Internet.

Unlike other consumer products, support is emphasised in DIM, including physical infrastructure support, social-technical support, political support etc. For example, a typical DIM requires administrators to maintain the whole system; it requires channels for the transmission of data; it requires standards which are regionally recognised by (local) governments, medical practitioners and public health support staff; and it requires consideration of medical insurance.

In general, articles about DIM can be divided into two categories: methodologies and other aspects.

A Methodology

References to approaches that are applicable to ICT-enabled medical device and system projects can be found in earlier researches, in which a number of specific aspects have been highlighted. For instance, Haux et al. (2010) emphasises five important aspects about the future of DIM over the coming decade:

- The main goal of expanding ICT should be to further improve the quality of care, while maintaining reasonable costs;
- Drawing upon the support of modern ICT, the boundaries between inpatient and outpatient care should fade, enabling a more efficient, patient-centred healthcare system;

- Cooperation among healthcare professionals should increase, and the means of communication with the patient should be expanded to include modern ICT;
- Society must be concerned with achieving equal opportunities in being informed about, and in using, new ICT;
- Misuse of data should continue to be considered a serious problem and an obstacle to progress.

B Other studies relevant to DIM

Other publications relevant to DIM focus on different design-related features of DIM projects. For example, Vimarlund & Olve (2005) conducted an economic analysis for DIM in which it was suggested that studies of DIM should be combined with different indicators into an overall evaluation. Sanderson (2007) provides the perspective of a cognitive engineer, arguing that simulators for DIM (e.g., run on software platforms) are also important for the field. Berler et al., (2004) point out that integration of knowledge is important in DIM in order to meet its clinical, organisational and managerial needs.

3.3 Likely problems for DIMRC defined from literature

This section addresses question SRQ2.

A Background

Before attempting to augment the design competences of Chinese Research and Development (R&D) teams, it is first necessary to understand what knowledge is needed to address the problems they face today, or what they may face in the future when designing for rural populations. This will be identified initially from literature, and although specific problems for DIMRC could not be traced in any publication, scholars have identified several problems faced by R&D teams in related fields, i.e., DfBoP, UCD and DIM.

The problems defined in literature in adjacent fields have been put forward by researchers from different sciences. For instance, economists Prahalad (Prahalad & Hart, 2002) and Hart (Hart & Clayton, 2002) emphasised that the community should be considered as the basis of healthcare innovations in rural areas, but this is often not pursued in DfBoP. Design researcher Kandachar (2008 and 2009), on the other hand, argues that the needs of the rural user (human) should be considered as the starting point, but that the approach needs to be optimised in UCD. A number of publications in the social and design sciences fields (Carayannis, 2005; Braimah & Kwame, 2010; Diehl et al., 2008) have

suggested that 4A (Accessibility, Availability, Awareness and Affordability) is important, but that these aspects are rarely considered in practice during development.

B Methodology

To identify the problems R&D teams face in DIMRC, four steps were taken: (1) Literature mentioned in Chapter 1 and 2, and Section 3.1, 3.2 and 3.4 was used in this section (In total 118 open publications); (2) the objective, discussion and recommendation sections of these publications were read; (3) if any objective, challenge, recommendation or future study in the publication was related to improving the design competences of R&D teams, it was recorded; finally (4) problems were identified by summarising the records, and were defined as a word or phrase by the author of this thesis. For instance, in one particular publication an author claimed that *“When telemedicine projects begin in the developing world, it will therefore be crucial that appropriate ICT infrastructure and environmental support is devoted to supporting them and to monitoring their effects on the health-care system ... this aspect was usually ignored in some pilot projects”* (Wootton et al., 2009). From this it was concluded that “ICT infrastructure and environmental support” was a problem faced by R&D teams in attempts to augment their design competences.

C Results and discussion

This analysis revealed that 17 of the publications contained references to improving the design competences of R&D teams, and a total of 23 issues were identified and summarised as likely problems for DIMRC. See Figure 3.4. These 17 publications are: Wootton et al. (2009), Prahalad & Hart (2002), Arnould & Mohr (2005), Simanis & Hart (2008), Hart & Clayton (2002), Heeks (2006), Christensen et al. (2006), Diehl et al. (2008 and 2011), Kandachar et al. (2008 and 2009), Wells & Wells (2007), Jiang et al. (2006, 2007, 2009, and 2012a), and IICD (2006).

By reading 17 publications it can be found that each issue is described as objective, problem or challenges in at least one open publication. Textbox 3.1 lists 23 issues and their relevant evidences from open publications. Note that 17 publications provide more than one evidence for each issue. However, only one evidence is presented in textbox 3.1.

Textbox 3.1 23 important issues from literature and their evidences.

Issue 1: ICT infrastructure and environmental support

Evidence: *"When telemedicine projects begin in the developing world, it will therefore be crucial that appropriate ICT infrastructure and environmental support is devoted to supporting them and to monitoring their effects on the health-care system ... this aspect was usually ignored in some pilot projects"* (Wootton et al., 2009)

Issue 2: Solving medical needs

Evidence: *"The uniqueness of our Faculty of Industrial Design Engineering lies in its human centered approach. Needs are the central driving force uniting technology and business...it is a challenge... by designing products and services to meet the needs of the world's poor..."* (Kandachar et al., 2009)

Issue 3: Cross-cultural study

Evidence: *"Similar to other "design for BoP" projects, students often meet challenges to address non-physical design aspects such as the pleasure by objects, the experience and emotion in design, the sense of connectedness with product, and culture... Industrial designers are not specifically educated to understand and overcome their own culture in favour of incorporating the cultural requirements of a potential user's group."* (Jiang et al, 2010a)

Issue 4: Cooperate with local communities

Evidence: *"Lesson 1: Develop a local presence, build local networks, and develop local leadership. CFA was able to become viable and successful by basing part of their operations in Uganda, by developing relationships with local stakeholders, and by ultimately having local leaders in charge of the implementation of the projects."* (Wells & Wells, 2007)

Issue 5: Social-Cultural impact

Evidence: *"Lesson 5: Evaluation, evaluation, evaluation. Even organizations which are well-intentioned and understand their stakeholders well can not be sure that projects are having the impact which they assume."* (Wells & Wells, 2007)

Issue 6: Appropriate technology

Evidence: *"An extension of cultural understanding and the avoidance of hegemonic behavior is the need to understand the local context as it relates the project itself... For example, CFA envisioned Linux as the operating system of choice since it was open-source and freely available. They soon had to adapt, however, when they received feedback informing them that the local context was not favorable to this."* (Wells & Wells, 2007)

Issue 7: Trust in product/service

Evidence: *"The focus of the homestay is not about collecting ethnographic data nor scoping out potential business opportunities. It is about building trust and rapport..."* (Simanis & Hart, 2008)

Issue 8: Sustainability and business model

Evidence: *"Doing business with the 4 billion poorest people...will require business model...It also represents the chance for social sustainability..."* (Prahalad & Hart, 2002)

Issue 9: Local content and service

Evidence: *"Even organizations which are well-intentioned and understand their*

stakeholders well cannot be sure that projects are having the impact which they assume. This is true of any organization, but is especially true of small organizations in challenging development environments.” (Wells & Wells, 2007)

Issue 10: *Ethnographic tools, cultural probes, business innovations*

Evidence: “These innovations should include: on user side ethnographic tools, cultural probes, business innovations such as hybrid business models, corporate responsibility, ... These methods are under exploration...” (Kandachar & Halme, 2008)

Issue 11: *Design factors from management, etc*

Evidence: “In the health sector, driving forces for adoption of ICT include such factors as government pressures to control costs, chronic and ever-increasing health work force shortages, greater expectations by consumers for higher quality and safer care, and changing models of health care delivery.” (Wootton et al, 2009)

Issue 12: *Medical policy will and public support*

Evidence: “Policy reform processes in countries can provide an opportunity for the health sector to participate in consultations when ICT policy is being developed or revised... Countries trying to improve policy making may also require training or guidelines for the public sector policy process that specifically mandate broad consultation with stakeholder groups”(Wootton et al., 2009)

Issue 13: *Understand healthcare awareness and education level of patients*

Evidence: “The case study showed that healthcare awareness and education level of patients is an important issue in DIMRC, however, which is rarely investigated by current R&D teams.” (Jiang et al, 2009)

Issue 14: *Culture*

Evidence: “Building competence in the local culture is likely the only way to improve this. Of course, there will be missteps and misunderstandings, which should be addressed and corrected as they arise rather than ignored.” (Wells & Wells, 2007)

Issue 15: *Understanding lifestyle of users*

Evidence: “One difficulty for development teams to design and develop medical devices and services for rural China is to understand users’ lifestyle.” (In Chinese) (Jiang et al, 2006)

Issue 16: *Disruptive innovation and green innovation*

Evidence: “Developing countries are ideal targets for disruptive technologies...disruptive innovations at the Base/Bottom of the Pyramid- has more potentials...they are only opportunities now...” (Hart & Clayton, 2002)

Issue 17: *Affordability, durability and reliability*

Evidence: “ ICT infrastructure within an economy refers to the accessibility, reliability and efficiency of computers, phones, television and radio sets, and the various networks that link them... Nevertheless, developing countries are increasingly concerned with design promotion and practice about them...” (Diehl, 2011)

Issue 18: *Macro- and local economic environment*

Evidence: “Current existing medical devices and services in rural markets of China are not satisfied by doctors and patients. The prices of devices should fit local economic environment and fit macro-economic environment at a country-level.”(In Chinese) (Jiang et al, 2006)

Issue 19: Usability

Evidence: *"The designer has a specific mindset. There are several established design factors in IHDRC including usability of product and design through anticipation of user's interactions, acceptations and satisfactions...They are lacking in DIMRC."* (Jiang et al, 2010a)

Issue 20: Physical access

Evidence: *"Lack of access combined with the low quality and high cost of telephony and Internet connectivity remain key limitations to the effective and sustainable implementation of ICT for development."*(IICD, 2006)

Issue 21: Understanding medical skills and training level of rural doctors

Evidence: *"In the previous cases, one lacking aspect for biomedical engineers in DIMRC is to understand medical skills and training level of rural doctors."*(Jiang & Flexman, 2007)

Issue 22: Lacking human-centered strategies and concepts for DfBoP

Evidence: *"The uniqueness of our Faculty of Industrial Design Engineering lies in its human centred approach...DfBoP are still challenges for industrial designers in this topic..."*(Kandachar et al., 2009)

Issue 23: Commercial medical insurance

Evidence: *"Current public medical insurance is not enough...Medical device development for rural Chinese should involve commercial medical insurance as well..."*(In Chinese) (Jiang et al, 2006)

To categorise these 23 likely problems, four terms were used: satisfying users, market exploring, product innovation and managing change. These four terms were initially proposed by Kandachar and Wootton, who were experts in Design for Base/Bottom of the Pyramid and ICT4D.

The first three terms (satisfying users, market exploring and product innovation) were proposed by Kandachar (Kandachar & Halme, 2008) who, after observing several student DfBoP projects from IDE/TU Delft, proposed that product innovation for DfBoP requires an integrative approach (See Figure 3.5) through the integration of social sciences, management sciences and technical sciences. In social sciences, the research focus should be about collecting and analysing user data to **satisfy users**; in management sciences, it should be about making suitable business plans to **explore markets**; and in the technical aspects, attention need to be given to applying and adapting enabled technologies and engineering technologies to achieve **product innovation**. This process also requires a collaborative effort involving other stakeholders, such as entrepreneurs, policymakers Government (G) and non-governmental organisations (NGOs). Even at the entrepreneurial level, innovations are taking place (Kandachar et al, 2009).

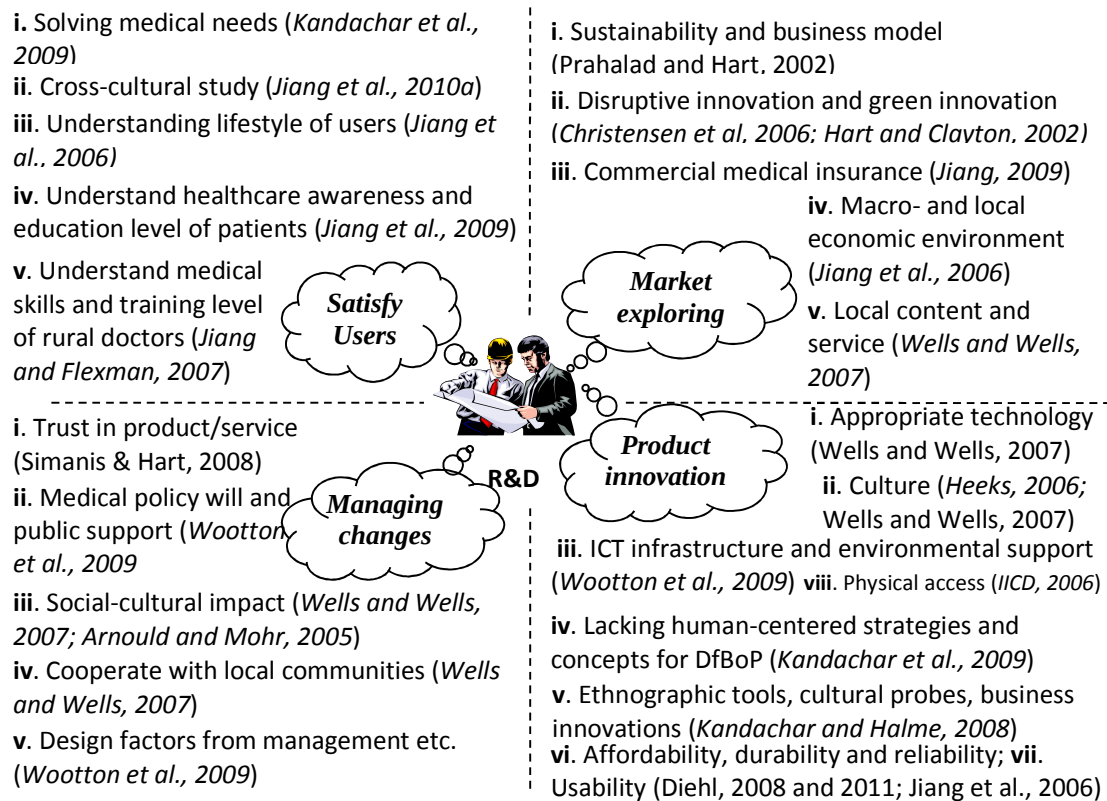


Figure 3.4: An overview of likely problems faced by R&D teams regarding DfBoP, UCD and DIM, defined from literature. These problems are categorised into four aspects of new product development. The R&D teams are located at the centre.

The fourth term (managing changes) was proposed by Richard Wootton, professor at the Scottish Centre for Tele-health. In his book “Tele-health in developing countries” he claimed that the rapid development of e-health is causing many changes, the social outcomes of which will be mixed. Winners will be best placed to **manage changes**.

These four terms were further explained and described by the author:

- Satisfying users: End users should be satisfied with the newly designed product. Understanding the end user needs requires insights mainly in the domain of social sciences, and to achieve this non-governmental organisations (NGO) should be involved, given their wealth of knowledge about the poor.
- Market exploring: The products should be marketable. This aspect requires competences in Management Sciences
- Product innovation: The developed product should not be an existing product on the market, however it may be an improved product

based on an existing product in the market. The leading contributors to this field are from mainly the Technological Sciences.

- Managing changes: Products should be kept updated. Any changes should be under control in the product development lifecycle. Entrepreneurs, policymakers (such as governments, GO) are to be involved in this process.

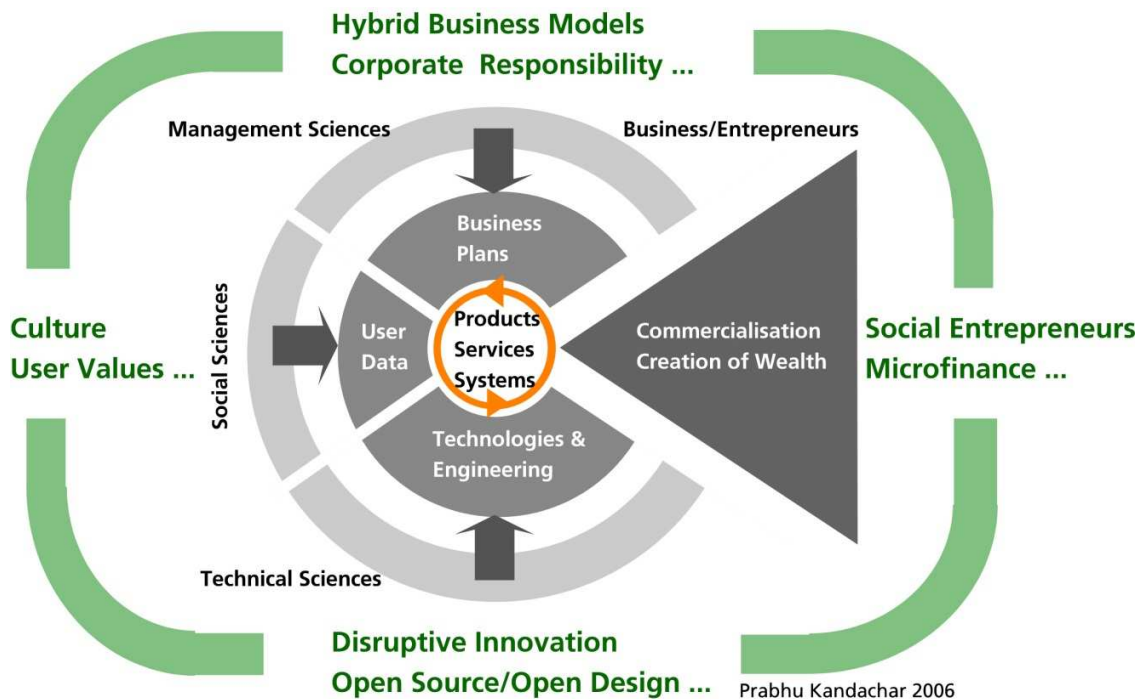


Figure 3.5: A framework for the design of products and services for the Base/Bottom-of-the-Pyramid (Source: Kandachar & Halme, 2008)

According to the above descriptions of the four terms, the 23 likely problems were categorised under the four headings.

- Satisfying users: Contents of this category include problems in solving patients' medical needs (Kandachar et al, 2009), problems of improving the healthcare awareness of patients (Jiang et al, 2009) and problems of enriching the skills of medical staff (Jiang & Flexman, 2007).
- Market exploring: Contents of this category include problems of sustainability and the business model (Prahalad & Hart, 2002), problems in building local content and services (Wells & Wells, 2007), problems in adopting to a macro- and local economic environment (Jiang et al, 2006) and problems in the provision of commercial medical insurance (Jiang et al, 2006), etc.

- Product innovation: Contents of this category include problems in designing for usability in DfBoP (Diehl et al., 2008; Diehl, 2011), problems in keeping designs affordable, durable and reliable (Diehl, 2011), problems in using appropriate technologies (Wells & Wells, 2007) and problems in adapting physical access (IICD, 2006), etc.
- Managing changes: This category includes problems in developing social-cultural impacts (Wells & Wells, 2007, Kandachar et al., 2009), problems in building user trust in products/services (Simanis & Hart, 2008) and problems to get medical policy will and public support (Wootton et al., 2009), etc.

3.4 Existing design models relevant to DIMRC

This section is a response to SRQ3.

Existing design models will be introduced in this section, as it is expected that some existing design models may be used directly in the educational solution.

3.4.1 Design models regarding DfBoP

Design models dealing with DfBoP come from three knowledge fields: BoP theory, innovation management and social impact study. For example, the “user information exchange model” (Lundvall, 1985) can be used by designers to manage innovations, in that it raises several important aspects regarding information exchange between users, designers and companies. Other examples include those from Gupta & Wilemon (1990), who proposed a model in which exploring the market is usually a start of product innovation; and Nicosia, whose model simplified customer decisions.

In this section two models are chosen for further investigation:

A The Base/Bottom of the Pyramid Model 2.0

The first model is “Base/Bottom of the Pyramid Model 2.0” (Simanis & Hart, 2008), which was originally created in 2004 and was further developed into the second version in 2008. Figure 3.6 illustrates the three interdependent activities of the model: (1) The selection of an appropriate BoP project site(s); (2) the formation and training of a multidisciplinary corporate field team; and (3) the selection of local community partners. A fourth core activity is the creation of an enabling environment (R&D White Space) within the corporation that supports experimentation outside of the current business model and business development process. The length of time needed to complete pre-field

activities will typically range from two to four months, depending on the company's experience in the Base/Bottom of the Pyramid and the extent of its social networks in the region of interest. A concrete protocol known as "Base/Bottom of the Pyramid Protocol 2.0" was developed and tested in a field study in rural India.

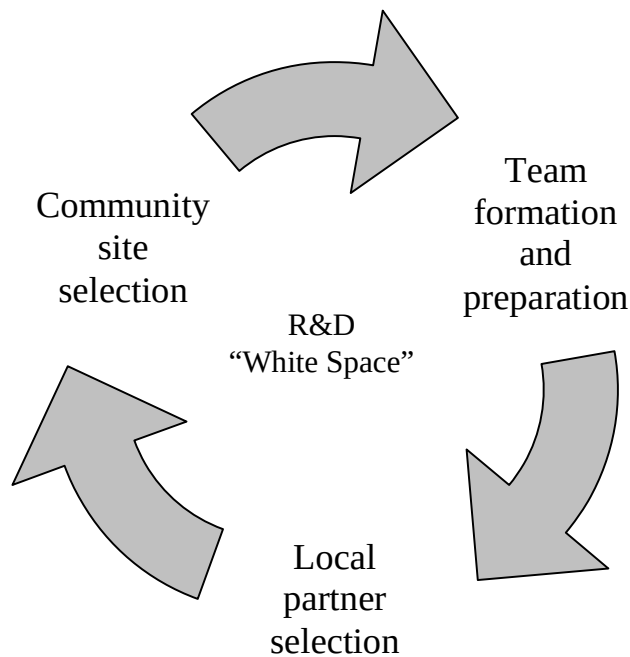


Figure 3.6: The Base/Bottom of the Pyramid Model 2.0 (Simanis & Hart, 2008)

This (as well as "Base/Bottom of the Pyramid Model 1.0") is one of the most commonly used models in DfBoP, having been applied by many BoP researchers (London, 2007; Christensen et al., 2006; Arnould & Mohr, 2005; Braimah, 2010; etc.). The model covers elements of "UCD" (e.g., team formation etc.) and "DIM" (e.g., ICT). This is the model that fits best into the domain of DfBoP, and is the closest to DIMRC. Hence it is chosen as the represented model in the DfBoP domain.

B Knowledge chain model: activities for competitiveness

The second design model is a knowledge chain model – a so-called "Competitiveness Model" (Holsapple & Singh, 2001) – which emphasises innovation management in developing countries. It is based on a descriptive Knowledge Management (KM) framework developed in a

Delphi-study⁷ involving an international panel of prominent KM practitioners and academicians (Holsapple & Joshi, 2000). The framework identifies five major knowledge manipulation activities that occur in various patterns within KM episodes, while also identifying four major managerial influences on the conduct of knowledge management. Respectively, these form the five primary and four secondary KM activities in the knowledge chain model (Holsapple & Joshi, 2000). As Figure 3.7 suggests, these activities yield organisational learning (i.e., changes in an organisation's state of knowledge) and projections (i.e., organisational resources being released into the environment); and a basic premise of the knowledge chain model is that how well an organisation learns and how well it projects determines the organisation's viability and success in a competitive environment.

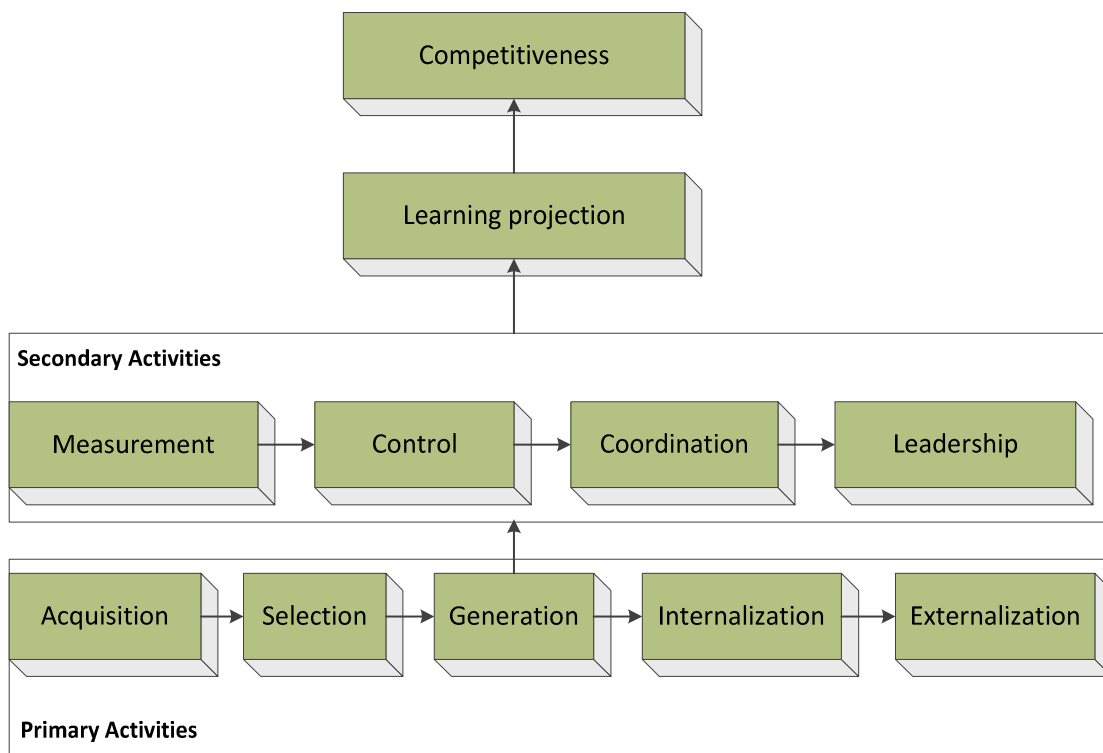


Figure 3.7: The knowledge chain model (Holsapple & Singh, 2001)

This design model strives for the same long-term objectives as this thesis, namely, the augmentation of the design competences of R&D teams, and also contains elements of “UCD” (e.g., coordination). Hence this model is chosen.

⁷ The Delphi-study essentially provides an interactive communication structure between the researcher(s) and experts in a field, in order to develop themes, needs, directions or predictions about a topic.

3.4.2 Design models regarding User-Centred Design

Many design models incorporating UCD can be tracked in literature, such as ISO 13407, which standardises “human centred design processes for interactive systems” and proposes five steps: analysis, design, evaluation, implementation and deployment. In this section, Sanders’ model will be introduced in detail.

Sanders’ model

Sanders’ model (Sanders, 2009) is based on her practical experience working with both western industrial designers and architects, during which she observed them thinking on five levels when planning and executing design projects: culture (to learn about cultural aspects that are alien to them in the usage domain), mindset (intentionally drawing their attention to important issues, e.g. user centred design, towards the user), methodologies (the framework of methods applied), methods (usually several in one project) and tools and techniques (what is actually done and materials used). The model describes different levels of design (research) thinking, in which there are five layers, see Figure 3.8:

- Layer A: Culture. This layer describes the customs, arts, social institutions and achievements of a nation, people or other special user group – a set of learned beliefs, values and behaviours shared by a group of users.
- Layer B: Mindset. This layer describes the established set of attitudes held by designers –the designers’ frame of references.
- Layer C: Methodologies. This layer describes methodologies used in a particular area of study or activity.
- Layer D: Methods. This layer describes a particular form or procedure for accomplishing or approaching something, especially a systematic or established one.
- Layer E: Tools and techniques. This layer describes a device or implement used to carry out a particular function or a way of carrying out a particular task.

There are two reasons why Sanders’ model is chosen in the UCD domain. (1) Two levels of Sanders’ model, namely “culture” and “methodologies” are the same as two investigation areas of this thesis (this thesis investigates three areas: design culture, design factors and design methodologies); (2) Sander’s model is developed for the augmentation of design competences and for improving the thinking of design researchers and practitioners. This is same to the long term objective of this thesis.

Other UCD models, such as “ISO 13407”, are intended to guide the selection of methods and tools across the entire design process.

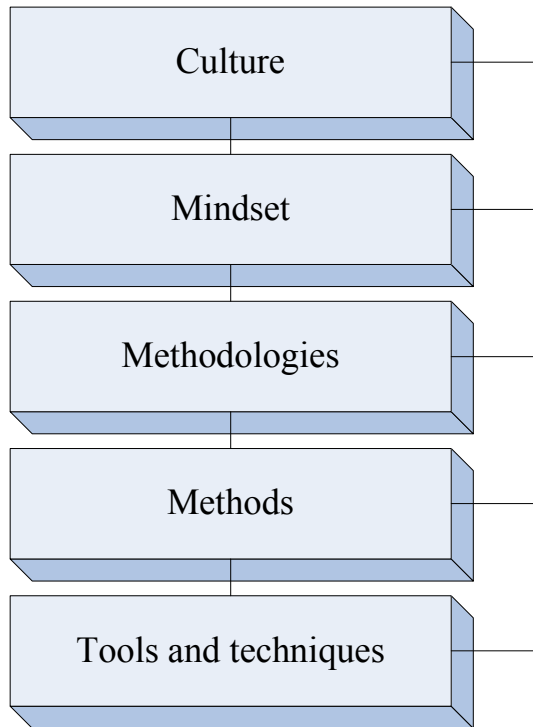


Figure 3.8: Sanders' model (Sanders, 2009)

3.4.3 Design models regarding DIM

Design models specific for DIM can also be found in literature. For example, Zimmermann & Vanderheiden (2008) proposed a four step model for the development of software applications; and Berg (1999) proposed a sociotechnical model to increase the understanding of how ICT solutions are developed, introduced and become a part of social practices. In this section the “model of ICT change for healthcare” (Aarts et al., 1998) was chosen as the represented model.

The model of ICT change for healthcare (Aarts et al., 1998)

This model consists of eight stages or domains that are considered essential when designing a system in a healthcare organisation. (See Figure 3.9)

- Stage 1: Assessing and understanding what key activities occur at each level. This stage requires the implementer or researcher to understand the nature and content of clinical work and its context,

especially how the context (legislation, rules, cultural values, etc.) may determine clinical work.

- Stage 2: Assessing and understanding the context and identifying the consequences for clinical work and imperatives for change. Important in this stage is the fact that clinical work is very much determined by external factors, such as political goals for the healthcare system, local situations, economic circumstances, cultural values and personal motivations, and that it is important to identify those factors which are imperative for change.
- Stage 3: Selecting and prioritising opportunities, problems, imperatives and requirements for change. There are many factors that may prompt change, however it is important to select and prioritise those factors that matter most in a particular system. Listening is very important, but it is informed decision making and organising support that are the most important features of this stage
- Stage 4: Knowledge of appropriate technological developments and relating them to information requirements; knowledge of opportunities and imperatives for change. An appropriate knowledge of information and communication technologies is required.
- Stage 5: Creating a financial plan for information and technology implementation. This stage is either seen as so obvious that it is often not considered in healthcare organisations, or it is seen as a mechanistic and low-level task.
- Stage 6: Involving, informing, persuading and preparing for new technologies and other changes. This stage calls for a whole array of social and organisational skills, including inter-personal skills and as well as technical credibility.
- Stage 7: Planning and introducing new technologies with other changes. This stage requires what are often seen as a different set of more formal, project and program management skills, techniques and behaviours.
- Stage 8: Evaluating, reviewing and assessing the impact and valuing it. Every implementation of change requires its impact to be evaluated, reviewed and assessed using formal qualitative and quantitative methods, however it must also be valued to allow judgments to be made of future improvements and changes.

The above eight steps are repeated iteratively.

This model incorporates both DIM and UCD, by which inter-personal skills and behaviours are emphasised, and has been selected on the basis of its consideration by the author as the most appropriate DIM model for the augmentation of design competences.

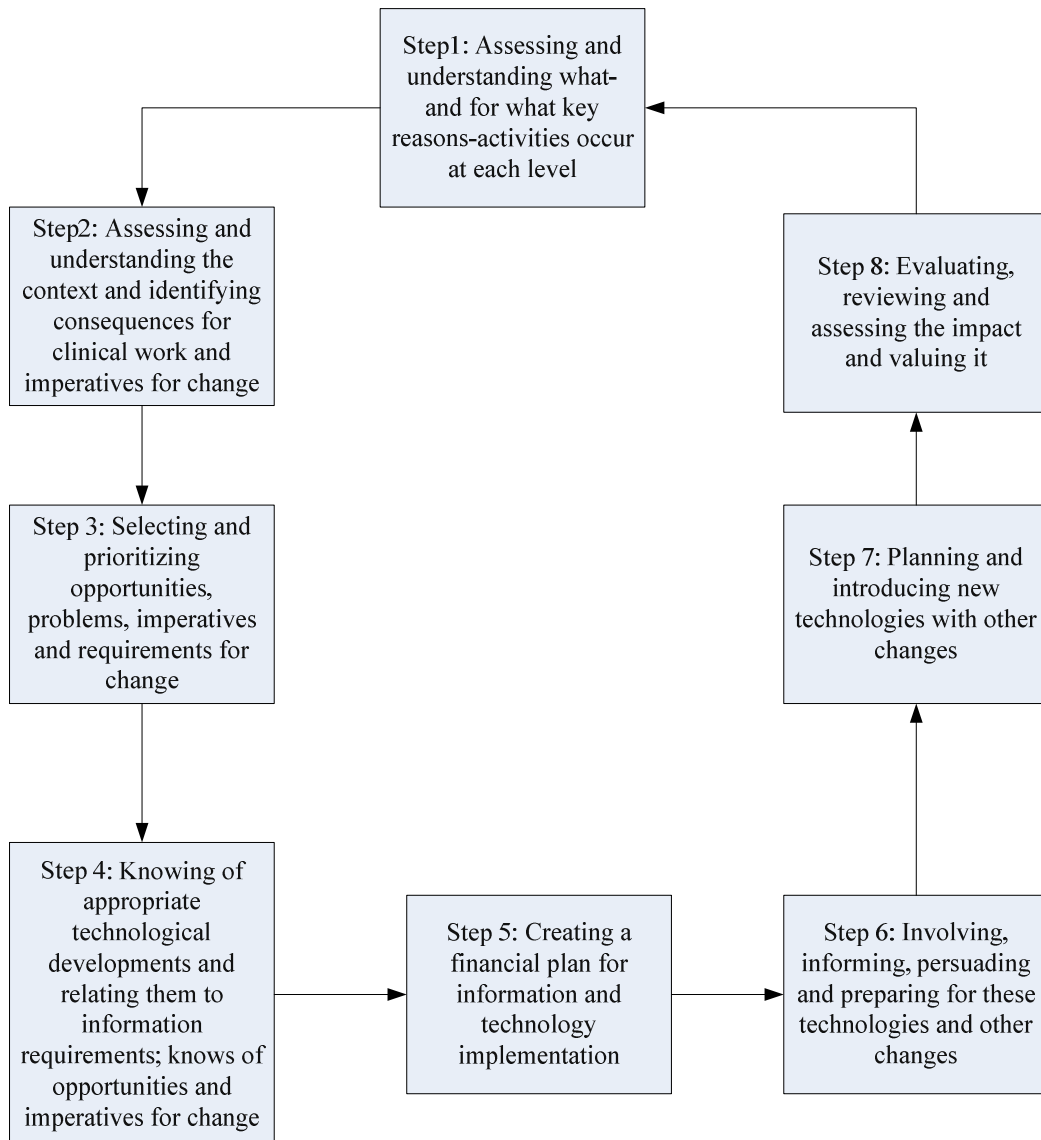


Figure 3.9: The model of ICT change for healthcare (Aarts et al., 1998)

3.5 Verifying whether the four chosen models can be used directly for DIMRC

This section is a response to SRQ4. In this section the intention is to explore whether existing design models can be used directly in the educational solution. The four chosen models introduced in Section 3.4 will be compared to the 23 likely problems defined in Figure 3.4. The research process included three steps: (1) A matrix was established in which the rows represented the 23 problems and the columns

corresponded to the four chosen models from Section 3.4; (2) Publications related to the four models were read. All steps, methods, tools and techniques of each chosen model were listed, and the aims of all the steps, methods, tools and techniques were recorded; and (3) The aims of all the steps, methods, tools and techniques were compared to the 23 likely problems defined from literature. If found to be the same or similar, the steps, methods, tools and techniques were selected and inserted into the matrix.

Table 3.1 lists the results of the comparison. The cells contain the steps, methods, tools and techniques targeted to resolve problems. As sometimes the methods, tools or techniques from an existing design model target more than one problem, the 23 problems were combined under 12 rows in Table 3.1. (Medical need, lifestyle, awareness and skills are combined under “user information”; Local content and services, ICT infrastructure, physic assessment, design factors on management, medical will, and appropriate technology, are combined under “local context research”).

The results show that no single design model covers all likely problems, however each model can be helpful in targeting some of the problems. For example, Sanders’ model (2009) provides methods and tools for the collection of user information and identifies user needs (about “satisfying users”), but it lacks methods addressing “change management”; the “Base/Bottom of the Pyramid Model 2.0” (Simanis & Hart, 2008) also provides helpful methods for “satisfying users”, e.g. suggesting the hiring of local partners to decrease the influence of cultural differences, but it lacks methods for “productivity”, e.g., usability and affordability of product; the “knowledge chain model” (Holsapple & Signh, 2001) suggests several methods for “change management,” but lacks methods for “satisfying users”; and the “model of ICT change for healthcare” (Aarts et al., 1998) provides methods for “productivity”, e.g., how to build the trust of the users and how to make the system accessible, but is short on methods for “market risk taking”.

In conclusion, these four models may not be used directly, however they may prove to be useful as building blocks for a new design methodology for DIMRC, which could then be used to augment the design competences of Chinese R&D teams in DIMRC.

Hence a new design model for the educational solution will be developed in this thesis, and the focus areas of this new model will be explored in the following section.

Table 3.1: The matrix comparing the 4 existing design models and the 23 likely problems defined from literature. X indicates that the model does not resolve those problems.

Design models Likely problems	Sanders	Knowledge chain	Base/Bottom of the Pyramid model 2.0	ICT change for healthcare
User information (including medical needs, lifestyle, awareness, skills)	Observation, personas and scenarios to explore information	Knowledge generation model	Building deep dialogue	Understand contexts in Stage 2; Plans and introduction of technologies in stage 7; Select requirement for change in stage 3
Local context research (including local contents and services, ICT infrastructure, physical assessment, design factors on management, medical will, appropriate technology)	X	Knowledge internalisation model	Building shared commitment	Access the context in stage 2
Macro and local economic environment	X	Knowledge externalisation model	Collective entrepreneurship development	X
Sustainability and business mode	Transition Planning	Knowledge coordination model	Building the Market base	Create a final plan in Stage 5
Usability	Usability test	X	X	Training in ICT technologies in stage 6

Affordability, durability and reliability	X	Knowledge control model	X	X
Trust in product/service	X	Knowledge leadership model	X	Introduction of technologies in stage 7
Social-cultural impact	X	Knowledge measurement model	New capability development	Identify impact in stage 2 and measure impact in stage 8
User Central Design strategy for DfBoP	X	Systematic design thinking	Co-creation	X
Cooperate with local communities	Experience models, Experience timelines, Participatory modelling,	X	Field study	Tell, Observe and enquire
Ethnographic tools, cultural probes, business innovations	Three-dimensional toolkits	Delphi Study	The Base/Bottom of the Pyramid Protocol 2.0	X
Contribution to three key investigation areas to develop the guideline for DIMRC	Contents of “design methodology”, including strategy, methods and tools	Contents of “design methodology”, including strategy, methods and tools	Contents of “design methodology”, including strategy, methods and tools	Contents of “design methodology”, including strategy, methods and tools

3.6 Verifying three challenges from Malkin as the educational areas

This section intends to answer SRQ5.

The last section offered an explanation why none of the four existing design models could be used directly in an educational solution to augment the design competences of Chinese R&D teams, and as such, it is necessary to develop a new educational model. In this section the three challenges defined by Malkin are suggested as potential educational areas, and their usefulness will be explored.

Malkin, a biomedical engineering researcher who investigated how to transfer ICT-enabled medical devices and systems from developed countries to developing countries, established a summer institute for biomedical engineering students in 2007, and sent 97 biomedical engineering students to 33 hospitals to rural regions in ten developing countries. The students were enrolled in different DIM projects, and after analysing the results of all these projects, Malkin proposed three major challenges that biomedical engineers face as part of local R&D teams: (1) understanding cultural influences; (2) identifying design factors; and (3) applying and adapting (if needed) design methodologies (Malkin, 2007) (For definitions of the three challenges, see Section 2.2.4).

Literature verified that the above three challenges were faced by Chinese R&D teams in DIMRC. For example, Immelt et al. (2009) mentioned that *“R&D knowledge is still under development for LGTs (Local Growth Teams) i.e., The team did not completely understand the local culture, for example they did not know how experienced rural doctors were with the technology ... LGTs need the power to organize their own R&D activities to get an overview of the important factors in product development ... Innovative R&D processes for LGTs are needed ...”* De Jong (2006) mentioned that the “Emerging Market Group” at Philips had also faced these three challenges, i.e. the design culture was rarely systemically investigated; only limited time (half a day, or even a couple of hours) was spent on identifying design factors for DIMRC; knowledge of complete R&D processes for DIMRC was lacking.

Skilled in biomedical engineering, the author of this thesis worked as a team member in the “Emerging Market Group” at Philips on three DIMRC

projects prior to 2007 (See About the author in the Appendix.), and he also confronted these three challenges in practice.⁸

To identify the relationships between Malkin's three challenges and the 23 likely problems defined from literature in Figure 3.4, a mapping study was carried out using a checklist. Three steps were followed:

- (1) A matrix was created, with the 23 problems defined from literature placed in the rows, and the three challenges heading the columns; see table 3.2.
- (2) 17 publications related to the 23 problems was read carefully (Relevant literature listed in Figure 3.4), and descriptions of the problems faced by R&D teams in augmenting their design competences were summarised and recorded. For example, in the literature related to "cross-cultural study (Jiang et al., 2010a)", it was emphasised that local R&D teams lack knowledge of cross-cultural studies, i.e. "*what are important investigation factors of a cross-cultural study*", or "*what are existing methods that can be applied in a cross-cultural study*". This was recorded as: "Local R&D teams lack knowledge about identifying important design factors of cross-cultural study" and "Local R&D teams lack knowledge about applying methods in cross-cultural study".
- (3) All records of the problems defined in literature were compared to the three challenges to test whether the 23 problems could be mapped to the three challenges. It was found that one problem could be mapped to more than one challenge.

Table 3.2 shows the results of the mapping. The results show that eight of the 23 problems were related to design culture; seven were related to design factors, and twelve were related to design methodologies.

This means that the observations of Malkins for biomedical engineers are likely also to be observed by researchers in the fields of DfBoP, DIM and UCD. In this thesis, focusing on rural China, the above three challenges are chosen as the three educational areas in need of development as an educational solution for Chinese biomedical engineering students.

⁸ This situation has not been changed until 2012. The author talked with two medical device scientists from big multinational companies, one senior biomedical engineer in a Chinese medical device company and two biomedical engineering academia in August 2012. During the conversations, the author found Chinese R&D teams still faced such challenges.

Table 3.2: The matrix of the 23 problems defined from literature and the three challenges. In the cells are selected elements from the article which relate to the challenge. An X indicates an article in which no element was found.

		Three challenges for biomedical engineers as part of local R&D teams in Design and development of ICT-enabled Medical device and system in rural regions		
Three challenges Problems faced		Design culture	Design factors	Design methodology
23 improvement areas proposed to augment design competences of Chinese R&D teams for DIMRC	<i>Solving medical needs (Kandachar et al, 2009)</i>	X	X	Designers need to learn how to apply existing methods and tools to meet healthcare needs.
	<i>Cross-cultural study (Jiang et al., 2012a)</i>	Local R&D teams lack knowledge of cross-cultural studies.	Some local R&D teams lack knowledge of how to identify important design factors in cross-cultural studies .	Local R&D teams lack knowledge of the methods of cross-cultural study.
	<i>Understanding lifestyles of users (Jiang et al., 2006)</i>	R&D teams need to learn how to identify local culture, which may influence design decisions for DfBoP.	X	Local R&D teams need to develop skills in the application of methods, tools and techniques to involve BoP users in the design process.
	<i>Understanding healthcare awareness and education level of patients (Jiang et al., 2009)</i>	X	X	Chinese R&D teams need more knowledge of how to choose suitable methods and tools to measure healthcare awareness and education levels.
	<i>Understanding medical skills and training level of rural doctors (Jiang and Flexman, 2007)</i>	X	X	Chinese R&D teams need to learn how to choose the most suitable methods and tools for measuring medical skills and training levels.
	<i>Sustainability and business model (Prahalad and Hart, 2002)</i>	X	X	Business managers need more knowledge of approaches to developing sustainability and a business model for DfBoP.
	<i>Disruptive innovation and green innovation (Christensen et al, 2006; Hart and Clayton, 2002)</i>	X	X	Local R&D teams need to develop a holistic approach to conducting disruptive innovations for BoP.

Commercial medical insurance (Jiang et al., 2009)	Commercial medical insurance is generally overlooked by R&D teams in design thinking for medical device development in China's R&D culture.	X	X
Macro and local economic environment (Wells & Wells, 2007)	X	X	Methods to make the designs suitable in DfBoP are not available to business managers.
Local content and service (Wells and Wells, 2007)	R&D teams need more knowledge of how to increase local content and service under local cultures.	X	X
Appropriate technology (Wells and Wells, 2007)		Local R&D teams do not understand the key factors in the provision of appropriate technologies to existing physical infrastructures.	
Culture (Heeks, 2006; Wells and Wells, 2007)	R&D teams need more knowledge and skills in the consideration of national and regional cultures.	X	X
ICT infrastructure and environmental support (Wootton et al., 2009)	X	X	Local R&D teams need to develop a holistic approach to ensure investment in ICT is coherent and sufficient to meet common needs across sectors.
Lack human-centred strategies and concepts for DfBoP (Kandachar et al, 2009)	X	X	Designers need human-centred strategies and concepts for DfBoP
Ethnographic tools, cultural probes, business innovations (Kandachar and Halme, 2008)	X	X	Designers need more knowledge about applying ethnographic tools, cultural probes, business innovations such as hybrid business models, and corporate responsibility for DfBoP.
Affordability, durability and reliability (Diehl, 2008 and 2011; Jiang et al, 2009)	X	Designers face problems in identifying factors that keep design affordable, durable and	R&D teams need to learn some basic approaches to being effective advocates for improving infrastructure, access and

			reliable.	affordability.
	Usability (Diehl, 2008 and 2011; Jiang et al, 2009)	X	Designers face problems in identifying factors that make a design easy to use.	X
	Physical access (IICD, 2006)	X	R&D teams are unaware of the important factors related to physical access.	X
	Trust in product/service (Simanis and Hart, 2008)	R&D teams need to develop knowledge of how to build trust in products/services in local cultures.	X	X
	Medical policy will and public support (Wootton et al., 2009)	Medical policy and public support from the government is still in short supply.	X	X
	Social-cultural impact (Wells and Wells, 2007; Arnould and Mohr, 2005; Kandachar et al., 2009)	X	R&D teams need to be able to identify design factors with social-cultural impacts.	X
	Cooperate with local communities (Wells and Wells, 2007)	Multiple stakeholder involvement and a supportive environment are needed in local culture.	X	A protocol to cooperate with local communities for local R&D teams is needed.
	Design factors from management etc. (Wootton et al., 2009)	X	R&D teams need to increase their ability to identify design factors related to management, needs of users, technical innovations and market development.	X

A closer study of related literature in Section 3.1, 3.2 and 3.3 reveals that some overlaps exist amongst the three educational areas. For instance, from the perspective of Jiang et al (2009), design culture can be considered as a part of design factors; while Hart & Clayton (2002) claim that design culture results in design methodology, etc. In this thesis some overlaps are also identified from among the three educational areas. See Figure 3.10.

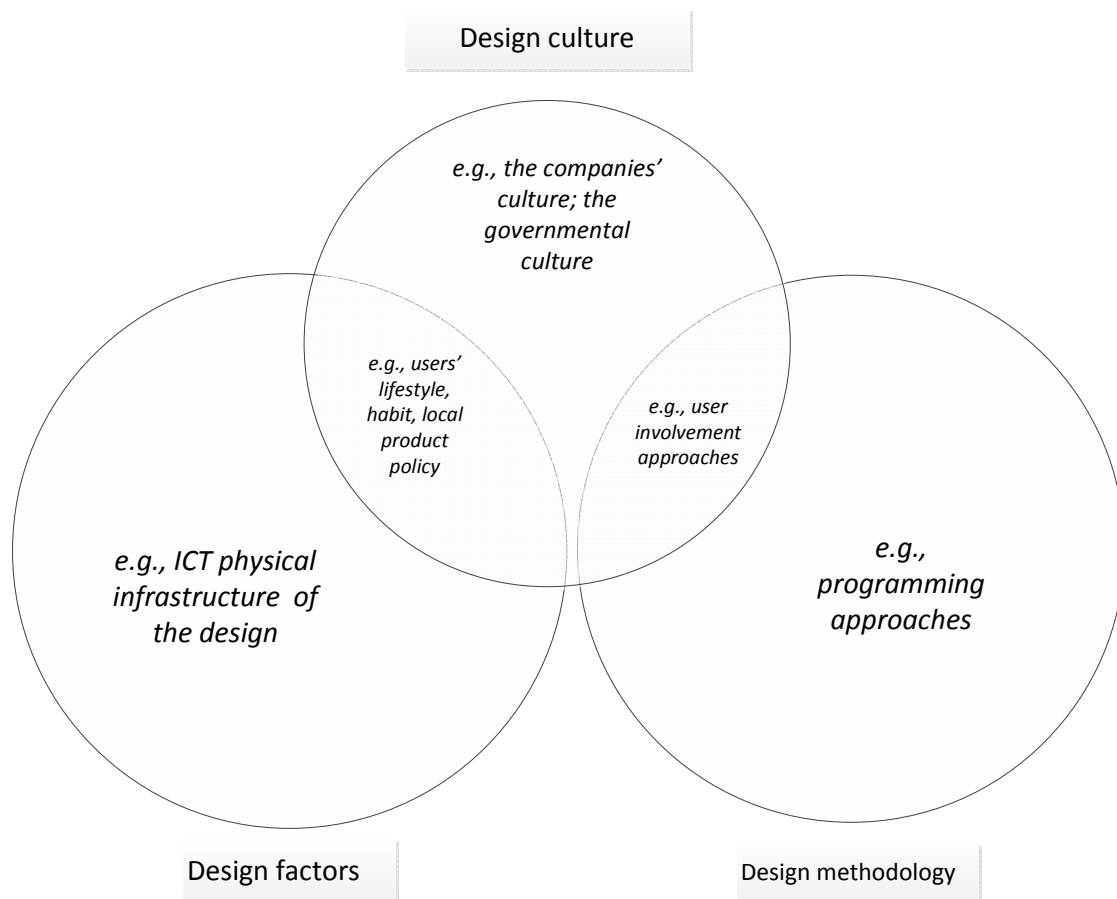


Figure 3.10: The overlaps and differences of the three educational areas in this thesis.

In Figure 3.10 the overlaps between design factors and design culture, and between design culture and design methodology are shown. There is no overlap between design factors and design methodology in this thesis. Some cultural factors can be considered as design factors, such as users' lifestyle, habits etc.; and some design methodologies also depend on local design cultures, e.g., user involvement approaches, etc. Besides the overlapping areas, some elements are specific to each educational domain. For example, ICT physical infrastructure can be listed as one design factor for DIMRC, but it bears no relevance to design culture or design methodology; software programming approaches are not relevant

to design factor or design culture; and the cultures of companies and governments are not relevant to design methodology or design factors.

More comprehensive definitions and descriptions of the three educational areas will be given in Chapters 4–6.

3.7 Conclusion and discussion

This chapter has taken the form of a literature analysis, followed by an analysis, with the objective being to identify opportunities for the augmentation of the design competences of Chinese R&D teams by means of educational intervention. A five-step process was employed to this end: (1) Identifying literature domains relevant to DIMRC; (2) identifying likely problems that R&D teams face for DIMRC; (3) searching for existing design models, and choosing existing models that may be suitable for the educational solution; (4) comparing the four chosen design models with the list of likely problems garnered from literature, and deciding whether any of the four models could be used directly as an educational solution; and (5) exploring whether Malkin's three challenges can be adopted as three educational areas in the educational solution. The three challenges are: (1) understanding cultural influences; (2) identifying design factors; and (3) applying and adapting (if needed) design methodologies. Malkin mentioned that biomedical engineers usually face these three challenges when working as part of an R&D team in the design and development of ICT-enabled medical devices and systems.

The conclusions of this chapter can be summarised as: **(1) *Three literature domains were assessed as relevant to DIMRC: Design for Base/Bottom of the Pyramid (DfBoP), User Centred Design (UCD) and Design and development of ICT-enabled Medical device and system (DIM); (2) there are 23 likely problems that R&D teams face in DIMRC. (See Figure 3.4); (3) Four existing design models from the three literature domains are deemed useful for DIMRC: Sanders' model, the "knowledge chain model", the "Base/Bottom of the Pyramid model 2.0" and the "ICT change for healthcare model"; (4) The above four models cannot directly be used as educational solutions, however parts of them might be useful. Accordingly, a new comprehensive design model will be developed; (5) To develop the new model, Malkin's three challenges were proposed as the basis of the three educational areas.***

Consequently, the research question for this chapter has been answered: ***Three educational areas – "design culture", "design factors", and "design methodology" – were proposed as areas with potential in the***

development of an educational solution to augment the design competences of Chinese R&D teams regarding DIMRC. How these three educational areas may be refined in practical terms will be addressed in Chapters 4–6.

As an advanced design institute, knowledge and insights from IDE/TU Delft may be useful in addressing the three above educational areas. By observing the research profile within IDE/TU Delft (IDE/TU Delft research profile 2008-2012), four aspects from Figure 3.4 were found to be part of the research focus within IDE/TU Delft. IDE/TU Delft has six comprehensive research programs: (1) strategic design, (2) user experience, (3) technology transform, (4) healthcare, (5) personal mobility and (6) living/working. The four aspects were mentioned in all six research programmes. For instance, in the user experience programme the research profile mentioned that *“Products are designed to contribute to our wellbeing: to make us (end-users) happy, feel connected or safe, to enable us to belong, to preserve our health, to challenge us, to develop ourselves, or in general, to reach or maintain a high quality of living.”* In the living/working programme, the research profile mentioned that, *“Similar to recent developments in automotive design, sustainable product and service design can offer new commercial opportunities for companies struggling to find the cutting edge in the market.”* In the technology transform programme, the research profile mentioned that, *“The research is especially important for the entrepreneurial/service context and regional creativity for the eventual success of sustainable product innovations.”* Finally, in the user experience programme the research profile states that, *“It aims to investigate ... how we can begin to recognise changes and adapt to the user context of interaction from individual and social perspectives...”*.

Therefore IDE/TU Delft is proposed as a specialist to contribute to these three educational blocks. In next chapters, in addition to defining a research question on each of the three educational areas mentioned before, a parallel research question about how to learn from IDE/TU Delft will also be defined.

Chapter 4 Understanding China's design culture for DIMRC⁹

In Chapter 3, three potential educational areas were identified for the strengthening of the design competences of Chinese Research and Development (R&D) teams in Design and development of ICT-enabled Medical device and system for Rural China (DIMRC). They are: (1) understanding local design culture, (2) identifying design factors, and (3) applying design methodologies. In this chapter the first area will be further explored and discussed. See Figure 4.1. The research question covered in this chapter is:

What are the important factors in China's design culture that influence Design and development of ICT-enabled Medical device and system for Rural China (DIMRC)?

It is the expectation of this thesis that knowledge and insights from IDE/TU Delft could strengthen the design education of Chinese biomedical engineering students, and so a parallel research question is also addressed in this chapter:

How can knowledge and insights from IDE/TU Delft be applied to the design education of Chinese biomedical engineering students in order to help Chinese them understand China's design culture for DIMRC?

⁹ 本章中文名称：理解中国文化对于 DIMRC 的影响。This chapter is based on the following conference paper:

J. Jiang, A. Freudenthal & P.V. Kandachar (2010), Exploring the influence of design culture on ICT healthcare product and service design for rural China, Proceedings of Knowledge Collaboration & Learning for Sustainable Innovation ERSCP-EMSU conference, Delft, 2010.

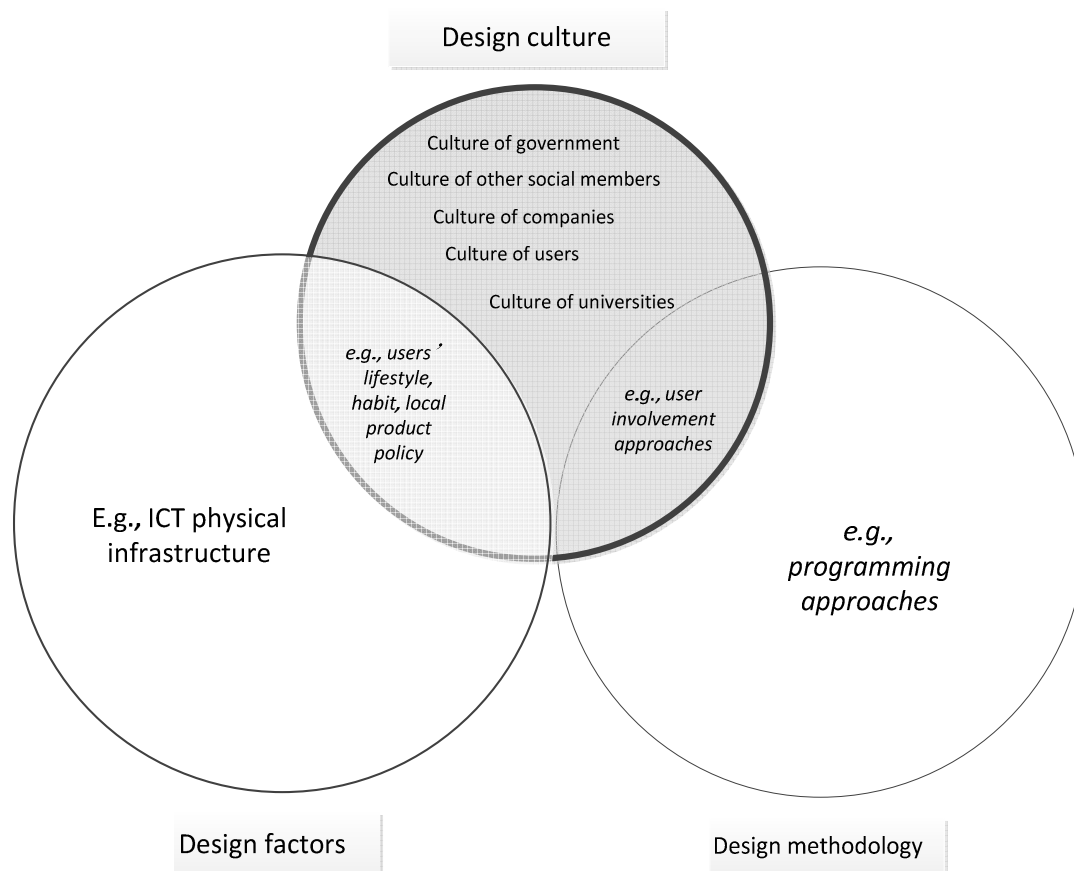


Figure 4.1: In this thesis, three educational areas are investigated. This chapter focuses specifically on exploring the issue of design culture (the shaded section)

Research methodology

The two research questions are to be answered in five steps:

- (1) Firstly, definitions of design culture and the background of Chinese design culture is introduced in section 4.1;
- (2) Secondly, two existing models for design culture are explored through a literature analysis and described in Section 4.2. The dimensions of design culture were sourced from the two existing models, and these dimensions are used to categorise factors of design culture for DIMRC later in the chapter;
- (3) Thirdly, an analysis of available literature unearthed factors of China's design culture that influence general product development in China (Section 4.3).
- (4) Fourthly, interviews with Chinese design professors and students, all of whom have experience with DIMRC, were carried out in Section 4.4 (The interview method is introduced in Section 4.4). The data from the interviews was recorded and analysed, according to which

fourteen important factors in China's design culture that influence DIMRC were identified (Section 4.5).

- (5) Finally, the findings from the interviews were further verified by comparing them with the factors of China's design culture that influence general product development in China. Furthermore, the possible contributions from IDE/TU Delft to help Chinese biomedical engineering students understand China's design culture for DIMRC were identified and discussed (Section 4.6).

Five main stakeholders for DIMRC

A number of different stakeholders play important roles in DIMRC, although ideally other groups need to get involved. Figure 4.2 shows both the current and the ideal stakeholders, and indicates how they are interrelated. Currently, China's design culture is influenced by the cultures of stakeholders from two regions: urban and rural. The stakeholders in the urban regions include Chinese universities and companies, while those in the rural regions include rural hospitals, doctors and patients. The government and other members of Chinese society (e.g., rural patients' families) fall under both classifications. Chinese R&D team members may originate from two sub-stakeholders in urban regions, being Chinese universities and companies, making the R&D team generally urban-based.

It is apparent that the current composition of Chinese R&D teams far from ideal for DIMRC. At present, Chinese R&D teams are predominantly composed of stakeholders from urban regions, but in the future it would be desirable to include also stakeholders from rural regions, and even move the Chinese R&D teams in part to rural regions (*This complies with envisioned composition of Chinese R&D teams for DIMRC [See Section 2.1.3]*).

An ideally composed R&D team would see the cultures of different stakeholders influencing the decisions of the team concerning DIMRC, with the needs of both the urban and rural regions affecting the decision-making process. For example, the cultural influence from urban regions may include the knowledge and skills gained during education at Chinese universities, the company culture in organisations that develop DIMRC, etc.; while the cultural influence from the rural regions may include knowledge of patient lifestyles and habits, etc.

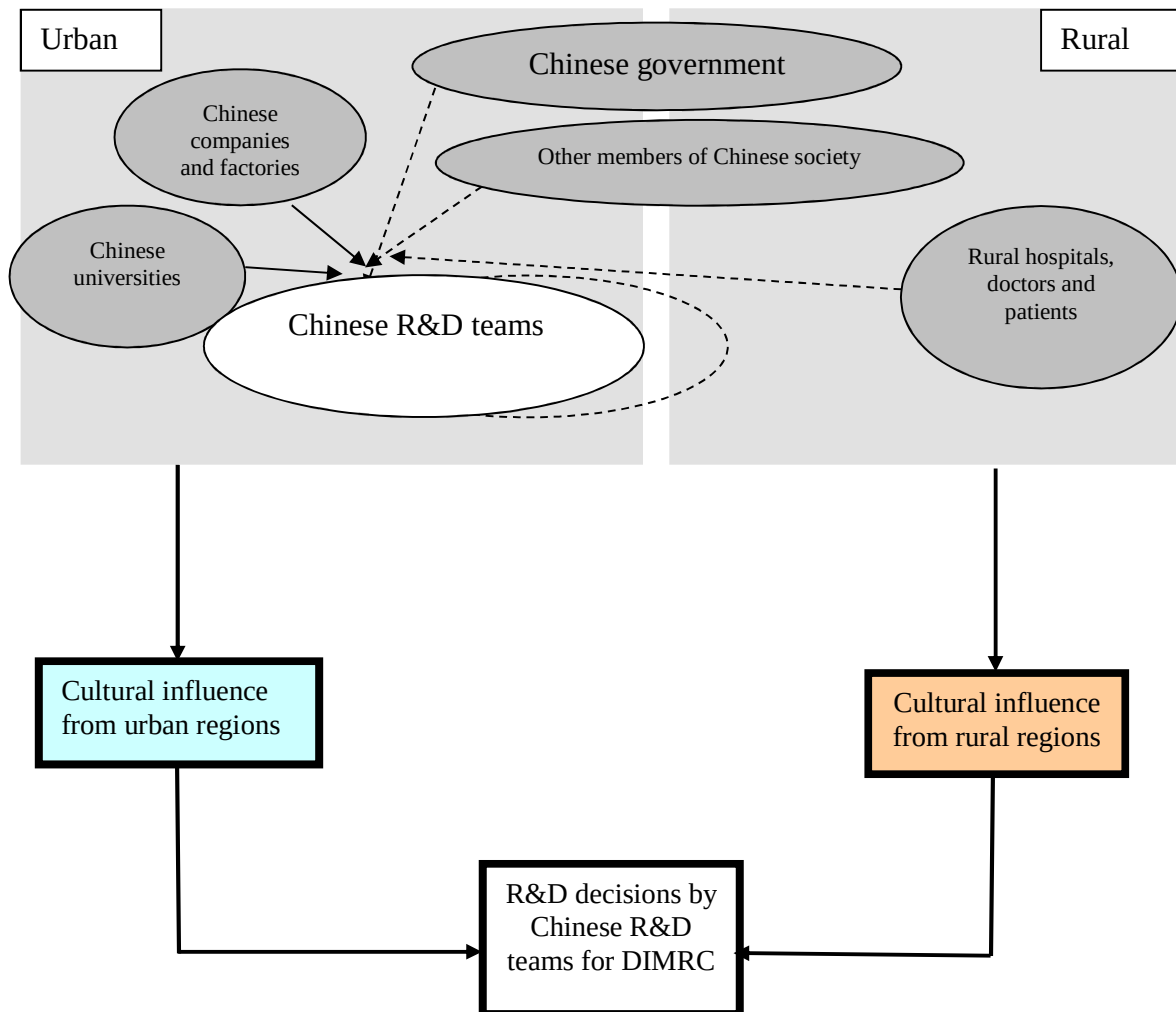


Figure 4.2: An overview of the different stakeholders in DIMRC, and the relationships between their cultures and the R&D decisions from Chinese R&D teams in DIMRC. The solid lines refer to the current stakeholders, while the broken lines refer to the proposed and desirable situation in the future.

4.1 Introduction

4.1.1 Background about culture and design culture

Research and Development (R&D) teams consider many issues when designing and developing ICT-enabled Medical devices and systems for Rural China (DIMRC), and one such issue is local culture. For example, the education level of the user is an important aspect to consider when designing a user interface. One of the usability heuristics requires that the interface system should speak the users' language, using words, phrases and concepts familiar to the user, rather than system-oriented

terms. Understanding local culture, therefore, becomes essential when designing an appropriate interface.

Then what is culture? According to dictionary (ref: <http://www.merriam-webster.com/dictionary/culture> [accessed on 16-OCT-2012]), the term “culture” refers to:

Culture is the set of shared attitudes, values, goals and practices that characterise an institution, organization or group.

Every nation, every society and every region has its own culture; and these different cultures compel companies to make different strategies, including R&D, marketing, manufacturing, etc. To investigate cultural influences specifically in product design, Julier (2007) proposed another term “design culture”, being “*the study of the interrelationships between design artefacts, in all their manifestations, the work of designers, design production (including advertising and distribution) and their consumption.*” Based on the definitions of both dictionary and Julier, in this thesis, design culture is defined as:

Design culture is the set of attitudes, values, goals and practices of different stakeholders that influence product design.

Design culture has developed out of the interrelationships of social, political, commercial and technical innovations, and has also been formed in discussions of consumption behaviour in cultural studies, anthropology and geography (Miller, 1987). For instance, Hannerz (1996) argues that different elements of culture learned and acquired in social life are highly integrated and act as packages of meaning and meaningful forms, however Hofstede (2001) believes that this integration is largely unconscious, and that no mental activities of humans can be culture free. This suggests that design activity is unconsciously influenced by the designers’ cultural values and preferences. Collins & Pinch (1982) coined the phraseology “frame of meaning” to describe the affective role of cultural patterns on designers’ actions, behaviours and preferences. Carlson (1992) referred to this process as “cultural creep”, and suggested that designers intrinsically enforce on a new product their own pre-

existing frames based on their past experience, rather than inventing new frames.

Recently, the need to integrate design culture into product development has been widely propounded by a number of design researchers (Holt, 1989, Banathy, 1992, Vanka, 1997, De Souza & Dejean, 1999, De Souza et al., 1999, Gagliardi, 2001, Powell, 2001, Rose & Zuhlke, 2001, Ellsworth et al., 2002, Kemnitzer & Grillo, 2002, Salimi, 2002, Bell et al., 2003, Hidaka, 2003). This extensive list of researchers supports the notion that cultural integration plays a noteworthy role in effective product development.

4.1.2 Cultural differences between China and Western countries

The cultural diversity in product development, reflected in the different products people use, results in various functionalities of products or in people's behaviours with similar products. The amount to which cultural diversity is reflected in differences between products and product forms, depends on the type of products, the situation and cultural habits (de Leur et al., 2006). Cultural diversity can be observed internationally and nationally. As a product designer, Liu provided some examples of cultural diversity between China and Western countries (Liu, 2010). See Table 4.1.

Table 4.1: Some differences between China and Western countries regarding cultural diversity (Liu, 2010).

	China	West (e.g., Netherlands)
Opinion	The Chinese do not provide their opinions directly, especially when their opinions differ to those of others.	Westerners like to express their opinions directly.
Anger	Anger cannot be read on Chinese faces.	Anger can be read on the faces of Westerners.
The Boss	Leadership is very strong in Chinese cultures.	Leadership is not so strong in Western cultures.
Elderly in day-to-day life	Elderly Chinese people like to stay with their grandchildren.	Elderly Western people like to stay with their dogs.
Party	The Chinese like to sit at a round table to party.	Westerners like to chat in small groups.

Table 4.1 shows some cultural differences between the Chinese and Western cultures. These cultural diversities are currently considered by

Western product designers when designing for Chinese end-users (Liu, 2010).

Furthermore, there are also significant cultural differences between urban and rural China. For instance, rural Chinese people like a “*Kinship-gathered habitat*”, meaning that they like to live with their kin, leading to most residents in a village sharing the same family name. In contrast, in urban Chinese communities living with one’s kin is uncommon; also, rural Chinese women in general like to maintain a courteous relationship between husband and wife, while many urban Chinese women like to pursue freedom. Finally, rural Chinese people believe in patience and resignation, while the urban Chinese believe in the pursuit of success through hard work. Knowledge of such cultural diversities could prove useful to Chinese R&D teams, who are generally located in urban areas.

4.1.3 Influence of design culture on R&D

Every team member in an R&D team is influenced by his/her personal cultural background and that of the end-user of the product. A prime example of this can be seen in the case of industrial designers, who were recently challenged and encouraged by the International Council of Societies of Industrial Design to foster cultural diversity in the face of world globalisation (ICSID, 2002). Industrial designers are encouraged to integrate the cultural desires, preferences and attributes of people into the products that they create in order to make them culturally suitable and pleasurable for use by all potential users. Samuels (2002) went even further, suggesting a need to redefine industrial design in order to subsume “culture” into its definition as a goal for optimising the lives of individual users.

Furthermore, the influence of design culture on R&D can also be observed in Design for Base/Bottom of the Pyramid (DfBoP) projects. For example, industrial designers from the Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft) have faced the challenge of culture in BoP regions. IDE/TU Delft launched DfBoP ventures through MSc graduation projects in 2003, and by 2011, some 150 student projects had been carried out within the faculty. In these projects students often face challenges to address non-physical design aspects, such as the pleasure imparted by an object, the experience and emotion of a design, the sense of connectedness with a product, and culture.

The influence of design culture can also be relevant for biomedical engineers in DIMRC cases, with examples provided by the author’s MSc

graduation project (“A remote monitoring system for rural China” in 2006) and an MSc graduation project from IDE/TU Delft (“Support tool for [Chinese] village doctors”, item 7, Table 5.2, Section 5.2.3. This project was executed as a collaborative effort between biomedical engineering students in Shanghai University, students in IDE/TU Delft and professional engineers from Dutch company IMPACT), in which it was found that in particular non-physical factors such as “communication with users and companies” etc. played a decisive role in DIMRC. These factors are likely to have resulted from cultural and culture-related situational factors (Jiang et al., 2010b), including:

- Cultural values of Chinese users
- The role and responsibility of Chinese R&D teams
- Cultural values in Chinese industrial companies

However, to the best of our knowledge, factors of design culture in DIMRC have never before been described in literature; and Chinese R&D teams therefore lack a point of reference from which to consider design culture in the R&D phase of DIMRC. Accordingly, the outcomes from this chapter could be a potential source of reference for them.

4.2 Models of culture

Obviously, there are hundreds or possibly thousands of values related to culture, at the level of society, organisation or the individual, and different researchers have proposed different models of culture to conclude these values. These include the Onion Model, the Pyramid Model, the Iceberg Model and the Objective and Subjective Culture Model, etc. (Hoft, 1996). In this chapter Hofstede’s onion model (Hofstede, 2001) is used as the reference model, having been widely adapted to investigate design culture, for instance, by Mohammad & Mariano (2005), who adopted Hofstede’s onion model to investigate design culture for industrial designers.

Figure 4.3 shows Hofstede’s onion model, in which he itemises the main manifestations of culture that can be seen in practice the world over, including values, rituals, heroes and symbols. He argues that every person carries within him/herself patterns of thinking, feeling and potential action that have been learned throughout their lifetime. Furthermore he empirically defines five common dimensions of values for design culture, being:

- Power Distance Index (PDI): Measuring the distribution of power and wealth between people in a nation, business or culture.

- Individualism versus Collectivism (IDV): Meaning that in an individual environment, the individual person and their rights are more important than those of the groups to which they may belong.
- Masculinity versus Femininity (MAS): Meaning the degree to which “traditional” gender roles are assigned in a culture; i.e., men are considered aggressive and competitive, while women are expected to be gentler, and concerned more with the home and family.
- Uncertainty Avoidance Index (UAI): Meaning the extent to which a culture values predictability. UA cultures have strong traditions and rituals, and tend toward formal, bureaucratic structures and rules.
- Long- versus Short-term Orientation (LTO): Meaning the cultural trait that focuses on to what extent the group invests for the future, is persevering, and is patient in waiting for results.

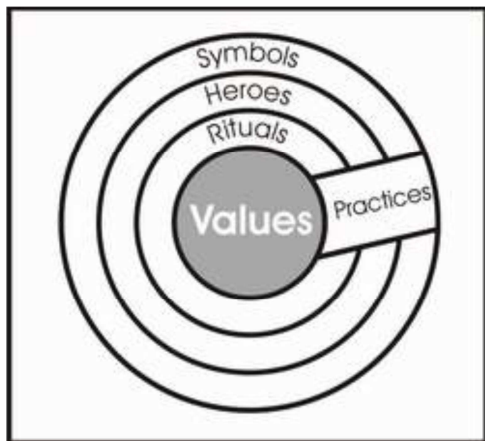


Figure 4.3: Hofstede's onion model regarding design culture (Hofstede, 2001).

4.3 Adaptation of Hofstede's model for product design

4.3.1 Mohammad and Mariano's model

As Hofstede's model is general and not specific enough for product developers to apply in practice, it has in the past been adapted by design researchers to suit their own ends. For instance, Mohammad & Mariano (2005) proposed a model relating to design culture for industrial designers, featuring five relationships between the product concept and design culture-related aspects, as the values of design culture (See Figure 4.4). These five relationships are: Concept-Function Relationship (CFR), Concept-Manufacturer Relationship (CMR), Concept-User Relationship (CUR), Concept-Designer (or R&D team) Relationship (CDR), and Concept-Context Relationship (CCR). They measured their model using the design case of an automatic teller machine (ATM) in India through a

questionnaire, and found that the scores of the five relationships are similar to the scores of the five dimensions of Hofstede's model in India. It is worthwhile that Mohammad and Mariano have used a multidisciplinary approach while adapting Hofstede's model to product design.

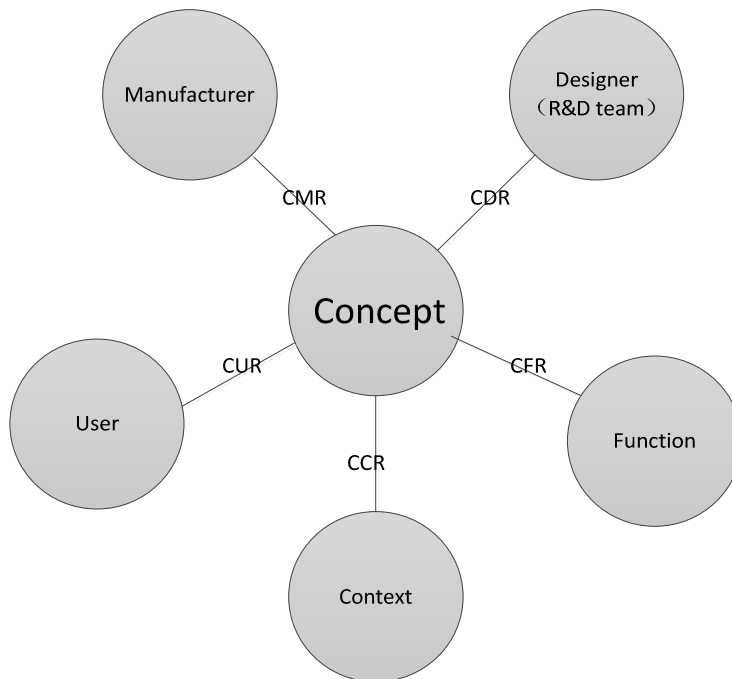


Figure 4.4: Relationships between the product concept and the five design-related aspects that are influenced by design culture, including the designer (R&D team), product, user, context and manufacturer (Abbreviations: CFR-Concept-Function Relationship, CMR-Concept-Manufacturer Relationship, CUR-Concept-User Relationship, CDR- Concept-Designer Relationship, CCR- Concept-Context Relationship), based on Mohammad & Mariano (2005)

4.3.2 Previous studies of China's design culture and its influence on product development in China

As noted earlier in the literature analysis in Chapter 3 (see Figure 3.2), to the best of our knowledge there exists no open publication specifically investigating cultural factors for DIMRC, however certain cultural influences relevant to product development in China can be observed in literature. For instance, Tan & Zhou (2010) claim that the “*bottleneck in design education in China is in the absence of internal qualities of designers and a shortage of the application of the research in social science*”; Zhang & Qiang (2009) studied the development of cell phones for older Chinese citizens, and concluded that usability among the

different cultural user backgrounds is a major challenge in mobile R&D in China; finally, Zhang & Wang (2009) investigated the requirements for product innovation under the new industrialisation model in China, recognising several challenges that result from the design culture, including *“community awareness of design in China is weak”* and *“design-oriented culture of independent thinking and innovation is lacking in Chinese companies”*.

To judge whether the above investigations are relevant to China’s design culture, a two-stage assessment was made by the author of this thesis: (1) An Internet search of literature throughout Google scholar (<http://scholar.google.com/> [accessed on 16-OCT-2012]) was carried out by using the key words “China”, “industrial design”, “education” and “culture” and from Year 2008-2010. The resulting references were read carefully, and all descriptions found relevant to the five relationships in Mohammad & Mariano’s model were summarised.

(2) After reading all summaries, only those relevant to the five Chinese stakeholders in DIMRC were chosen. The chosen summaries were proposed as the factors of China’s design culture that influence general product development in China. Table 4.2 shows the results of the assessment.

Table 4.2 presents a summary of the ten problems related to China’s design culture, collected from six publications, as mentioned in second column of Table 4.2. These ten factors are relevant to the four relationships of Mohammad and Mariano’s model: CDR (Concept-Designer Relationship), CMR (Concept-Manufacturer Relationship), CUR (Concept-User Relationship), and CCR (Concept-Context Relationship), and cover all five stakeholders of DIMRC (See Figure 4.2):

- Cultural influence from Chinese universities: Chinese universities do not provide students with enough opportunity to work with end-users in practice. Students receive no education or training in the knowledge and skills of social science.
- Cultural influence from Chinese companies: Chinese companies do not possess a design-oriented culture of independent thinking and innovation.
- Cultural influence from the Chinese government: The Chinese government does not provide sufficient incentives or encouragement for the exchange of design knowledge between Chinese companies and universities.

- Cultural influence from end-users (e.g., rural doctors and patients): Usability and emotional support for the product relies on different regional cultures.
- Cultural influence from other members of Chinese society: The Chinese community lacks design awareness, believing that industrial design is only about art, aesthetics, style, etc.

Table 4.2: Results of the assessment to explore factors of China's design culture influencing general product development in China.

Item	China's design culture influencing general product development in China	Relationship in design culture	Related stakeholder involvement
1	Chinese R&D teams lack knowledge and skills in social sciences, such as user research (<i>Tan and Zhou, 2010</i>).	<i>CDR (Concept-Designer [or R&D team] Relationship)</i>	<i>Chinese companies; Chinese universities</i>
2	Internal cooperation within Chinese R&D teams is weak in product development. Teamwork among engineers, business people and industrial designers etc., is needed (<i>Chen et al., 2010</i>).	<i>CDR (Concept-Designer [or R&D team] Relationship)</i>	<i>Chinese companies; Chinese universities</i>
3	Design-oriented culture of independent thinking and innovation is lacking in Chinese companies (<i>Liang, 2008; Zhang and Wang, 2009</i>).	<i>CMR (Concept-Manufacturer Relationship)</i>	<i>Chinese companies</i>
4	Cooperation among different Chinese companies is weak in the R&D of product development (<i>Zhang and Wang, 2009</i>).	<i>CMR (Concept-Manufacturer Relationship)</i>	<i>Chinese companies</i>
5	Usability for people from different user cultural backgrounds differs regarding mobile phone design in China (<i>Zhang and Qiang, 2009</i>).	<i>CUR (Concept-User Relationship)</i>	<i>Chinese end-users</i>
6	Emotional support for medical device R&D relies on different regional cultures (<i>Chen et al., 2010</i>).	<i>CUR (Concept-User Relationship)</i>	<i>Chinese end-users</i>
7	Chinese students in universities rarely have opportunities to work with end-users in actual product development projects now (<i>Zhang and Wang, 2009</i>).	<i>CCR (Concept-Context Relationship)</i>	<i>Chinese universities</i>
8	Awareness of industrial design in Chinese society is currently weak (<i>Liang, 2008</i>).	<i>CCR (Concept-Context Relationship)</i>	<i>Chinese end-users; Other Chinese society members;</i>

9	Chinese government does not provide an efficient protection mechanism for intellectual property (<i>Chen, 2008</i>).	CCR (Concept-Context Relationship)	<i>Chinese government</i>
10	R&D knowledge is rarely exchanged between companies and Chinese universities (<i>Zhang and Wang, 2009</i>).	CCR (Concept-Context Relationship)	<i>Chinese government; Chinese universities</i>

Accordingly, the above ten factors are used in a preliminary study in this chapter, and will be compared to important factors in China's design culture influencing DIMRC in Section 4.6.

4.4 Interviews

In previous sections, design culture has been defined, and literature relevant to design culture for general product development in China has been reviewed and analysed. As a result, ten factors of China's design culture that influence general product development in China are presented in Table 4.2. In this section, important factors of China's design culture influencing DIMRC are explored through interviews, corresponding to Step 4 of the research process of this chapter.

The interviews were conducted in two rounds. In the first round, three Chinese industrial design professors were interviewed, and in the second round six Chinese design students were interviewed at Delft in the Netherlands (two PhD students and four Master students). All of the respondents had previous design experience as former members of Chinese R&D teams focused on DIMRC.

4.4.1 Interviews with Chinese industrial design professors

In the first part, three Chinese professors, all of whom have more than ten years of experience in industrial design education, research and project development, were posed open questions. One of the respondents is the vice chair of a top academic design school in China, while the other two are department heads at common academic design schools. All three professors possess a strong knowledge and interest in design culture in rural China.

In the interviews, first, the objective of the PhD project was introduced; second, the objective of the interviews was explained (to explore important factors of China's culture influencing DIMRC for Chinese R&D teams); and third, the professors were posed the research question, ***"What factors of China's culture could influence DIMRC, according to***

your experiences?” The respondents were free to give their comments and answers.

Their replies of the respondents were taken down as notes, and were analysed in two steps:

- (1) Collecting and summarising: All topic-relevant information from the notes was collected and summarised. Some relevant quotes were also recorded in this step.
- (2) Categorisation: The summarised comments were categorised under five headings: Cultural influences from Chinese universities, companies, government, end-users and other members of China society (the stakeholders from Figure 4.2).

As all interviews were conducted in Chinese, the quotes and summaries were translated into English by the author after the interviews.

4.4.2 Interviews with students from IDE/TU Delft

In the second round of interviews, the findings from the interviews with the professors were verified by six Chinese MSc/PhD students, all of whom were studying at IDE/TU Delft at that time, had been educated previously in China, and had R&D experience in DIMRC (either through their graduation projects or via their half-year internships in Chinese companies). Each interview lasted approximately half an hour and was conducted in Delft, the Netherlands.

The interviews were conducted in four sections:

- (1) Attendee’s introduction: Participants were asked to give a three minute self-introduction, including his/her name, MSc department, bachelor institute, department and a short description of his/her bachelor graduation project.
- (2) Project introduction: This part took two minutes. In this part the attendees were asked to describe an example DIMRC project in which he/she had taken part.
- (3) Main body questions: This part took about twenty minutes. Based on their experiences and described DIMRC projects, 14 questions were asked regarding the results of the professors’ interview. This part contained such questions as: “Were you systemically educated with design theories and methodologies in your university?”, “What was your role in your DIMRC project?” etc.
- (4) Open comments: Finally, the participants were given five minutes to make their own comments related to the questions.

The protocol of these interviews can be found in Appendix B.

All interviews with the students were recorded using a digital voice recorder, and the answers were analysed in a two-stage process:

- (1) Collecting and summarising: Topic-relevant information from the interviews was collected and summarised.
- (2) Comparison: The summaries of the student interviews were compared with the findings of the interviews with the professors. If a finding was found to be the same or similar to the finding of at least one professor for at least two students, that finding was considered verified.
- (3) The findings which were not verified were given no further consideration.

4.5 Results of interviews

This section gives the complete notes as made in the professor interviews (quotes and textbox 4.1, translated from Mandarin). In the first round, the professors provided their understandings and comments on China's design culture. For example, Professor 1 (P1) was of the opinion:

"The creative capability of Chinese R&D teams in DIMRC is limited in China ... they lack knowledge and skills to get the insights of user requirements in DIMRC ... They are not trained as researchers as such ..."

Professor 2 agreed with this statement, claiming that Chinese universities do not provide advanced industrial design education. He introduced his own school as an example:

"Courses in our design schools have to be changed. Right now, most courses train students to become craftsmen rather than developing their creative capabilities ..."

Furthermore, P2 described the relationship between his school and companies: *"Knowledge of DIMRC is never exchanged between us and the companies ... Multinational companies do not think our academic design knowledge is useful for them; and in the case of local small companies, they do not think they need design knowledge ..."*

The professors also talked about the cultural influences of the end-users in DIMRC. For instance, P1 said:

“In my DIMRC projects, usability and affordability were major concerns ... the end-users (rural Chinese) were hard to satisfy ... they were concerned very much about cost ... they believe that the quality of similar medical devices from different Chinese companies is the same ...”

Textbox 4.1 shows the results of the first round interviews. In total twenty findings were concluded from the summaries of notes.

Textbox 4.1: Summary of responses based on the notes from interviews with professors.

Professor 1:

Chinese universities do not provide enough education in design methodologies. [finding1] Students are not given enough opportunity to apply and adapt design methodologies in social research. [finding2] They are trained as craftsmen rather than researchers or independent thinkers. [finding3] Students rarely have the opportunity to work with other students in practice. Teamwork is weak in Chinese design education. [finding4] Cooperation among different companies is not as strong as in Western countries. [finding5] The Chinese government does not provide strong encouragement. [finding6] The protection of intellectual property is still weak. The Chinese government and society need to address this. [finding7] Different Chinese companies do not often cooperate. [finding5] Chinese companies do not believe product design is a part of their core competences. [finding8] The public health insurance system is not strong enough to resolve the financial problems of rural patients. [finding9] The current health services in rural regions are not affordable for most patients. [finding10] Medical devices and systems in rural regions should be more user-friendly. [finding11] Chinese R&D teams think the qualities of medical devices from different Chinese companies are the same. [finding10] Chinese R&D teams consider fashion as a cultural factor in DIMRC. [finding12] Industrial design is not emphasised in Chinese companies. [finding13] Most Chinese people think industrial design is art. The same though also happened in DIMRC projects. [finding14]

Professor 2:

Universities mainly train students with skills to optimise product appearance and modelling. [finding15] Cooperation between universities and companies is rare. [finding16] The exchange of design knowledge between the academia and Chinese universities is rare. [finding16] Most Chinese people think industrial design is only about product appearance and modelling. Industrial design is art in their minds. [finding14] Rural Chinese people are poor and need more support from public health insurance systems. [finding9] Affordability is the most crucial concern in DIMRC. [finding10] Designs for DIMRC should be easy to use. [finding11] They should be acceptable under local culture. [finding17]

Professor 3:

Most students in the department have backgrounds as artists. [finding18] Many people think aesthetics is the only key element in industrial design. [finding14] Students do not really work with end-users in the design process. [finding19] They draw pictures and ask for feedback from end-users. [finding20] The Chinese government does not provide an

efficient protection mechanism for intellectual property. [finding7] In DIMRC, end-users focus mainly on low-cost healthcare service. They expect medical devices to be cheap. [finding10] Medical devices should be easy to operate for local doctors, [finding11] and within the local regional culture. [finding12] Cooperation between Chinese companies should be strengthened, especially in design. [finding5] Many companies do not emphasise the design phase in new product development. [finding13]

In the second round of interviews, this time with the students, the answers were more specific, relating more to the students' own DIMRC projects. Their answers confirmed the findings from the interviews with the Chinese professors. For instance, Student 1 (S1), a PhD student described his role in his DIMRC project: *"I was only responsible for product appearance design and modelling ... I also had this role in other DIMRC projects."* This concurred with the comment of P2 *"In our universities we mainly train students with skills to optimise product appearance and modelling"*. Student 2 (S2), an MSc student with three years of industrial experience in China, gave the following answer *"My duty in that project was medical system infrastructure design ... I did everything in my office ... I had no opportunity to talk with other stakeholders, except my manager ..."* This confirmed the statement of P1, that *"Students rarely have opportunities to work with other students in practice"*.

Table 4.3: A comparison of the opinions of professors and students. A ✓ indicates a similar or identical answer given by a student and a professor.

Finding number	Summaries from the interviews with professors	S1	S2	S3	S4	S5	S6
1	Courses in design methodology are weak in China, and also for DIMRC.	✓		✓		✓	✓
2	Students have little opportunity to apply and adapt design methodologies in social research.		✓				
3	Chinese industrial designers are trained as craftsmen.						
4	Chinese students lack practical opportunities to work with teammates from other disciplines. Team work is weak in Chinese industrial design education, including DIMRC.			✓	✓	✓	✓
5	R&D cooperation between different Chinese companies is weak.	✓	✓	✓	✓	✓	✓
6	The Chinese government does not provide an efficient mechanism to encourage the			✓		✓	

	exchange of R&D knowledge between companies and universities, including DIMRC.						
7	The Chinese government does not provide an efficient mechanism for protecting intellectual property, including DIMRC.	✓	✓	✓			
8	Chinese companies do not consider product design to be one of their core competences.						
9	Reimbursement for DIMRC services to rural patients by public medical insurance is still low.	✓	✓			✓	✓
10	Affordability (in DIMRC) is not solely dependent on cost, as it also relies on different regional cultures, and is a matter of emotional experience.		✓	✓		✓	
11	Usability of design for DIMRC should be tailored to different regional cultures.	✓	✓	✓	✓	✓	✓
12	Emotional support, e.g. fashion of the product, is important in DIMRC. Suitable emotional support should be provided for the various regional cultures.	✓	✓			✓	✓
13	Chinese companies lack design-oriented culture of independent thinking and innovation, this is also the case for DIMRC.	✓	✓	✓	✓	✓	✓
14	Most Chinese people think design is related only to art, also for DIMRC.		✓				✓
15	Chinese industrial design education emphasises product appearance and modelling, including DIMRC.	✓	✓		✓		✓
16	The exchange of design knowledge between Chinese universities and companies is rare, including DIMRC.			✓		✓	
17	The DIMRC solutions should be acceptable under local culture.						
18	Most Chinese industrial design students in Chinese universities have artistic backgrounds.		✓				
19	Chinese students lack practical experience in working with users in DIMRC		✓				✓
20	Chinese industrial design students draw pictures and ask for feedback from the end-users.						

Table 4.3 shows a comparison of the opinions of professors and students. Table 4.3 reveals that three of the comments made by the professors were verified by all six students; five were verified by four students; two were verified by three students; four were verified by two students; two were verified by one student; and four were not verified by any student. Accordingly, 14 of the findings from the first round of interviews were confirmed.

Table 4.4 presents the final results of the two rounds of interviews. In this step, only those findings, which were mentioned by one or more professors and confirmed by two or more students, are used as 'confirmed' findings. In total, 14 findings are noted and classified among the five stakeholders in Figure 4.2.

Table 4.4: The results of all interviews (P=Professor; S=Student). The discussed factors can be categorised into five aspects: cultural influences from the government, universities, companies, end-users and other members of Chinese society.

Finding number	Factors of cultural influences from Chinese universities	Interviewees
4	Chinese students have little opportunity to work with teammates from other disciplines regarding DIMRC.	P1,S3,S4,S5,S6
19	Chinese students have little practical experience in working with users in DIMRC.	P3, S2,S6
15	Chinese industrial design education currently emphasises product appearance and modelling regarding DIMRC.	P2,S1,S2,S4,S6
1	Design methodologies in Chinese biomedical engineering institutes are not very advanced regarding DIMRC.	P1, S1,S3,S5,S6
	Cultural influences from the Chinese government	
6	The Chinese government does not provide an efficient mechanism to encourage the exchange of R&D knowledge between companies and universities, including DIMRC.	P1, S3,S5
7	The Chinese government does not provide an efficient protection mechanism for intellectual property, including DIMRC.	P1,P3, S1,S2,S3
9	The Chinese government should encourage more reimbursements for DIMRC services from public medical insurance to rural patients.	P1,P2,S1,S2,S5,S6
	Cultural influences from end-users	
11	Usability design for DIMRC should be tailored to different regional cultures.	P1,P2,P3,S1,S2,S3,S5,S6
10	Affordability (in DIMRC) is not solely dependent on cost, as	P1,P2,P3,S2,S

	it also relies on different regional cultures, and is a matter of emotional experience.	3,S5
12	Emotional support, e.g. fashion of the product, is important in DIMRC. Suitable emotional support should be provided for the various regional cultures.	P1,P3, S1,S2,S5,S6
	Cultural influences from other members of Chinese society	
14	Most Chinese people consider design to be related only to art, also regarding DIMRC.	P1,P2,P3,S2,S 6
	Cultural influences from Chinese companies	
5	R&D cooperation among Chinese companies is weak.	P1,P3,S1,S2,S 3,S4,S5,S6
13	Chinese companies lack a design-oriented culture of independent thinking and innovation; this is also the case for DIMRC.	P1,P3,S1,S2,S 3,S4,S5,S6
16	The knowledge exchange between Chinese companies and universities is still poor.	P2, S3,S5

By observing table 4.4, four main results may be concluded: (1) industrial design is not advanced in the Chinese society. Most researchers, practitioners and politicians do not understand the importance of industrial design in product development, and for the transformation from “Made in China” to “Created in China”; (2) Design education in Chinese universities lack training of practical skills; (3) In the field of product development, the environments of “independent innovation” in China society are not good. Many Chinese research institutes and companies still like to copying design ideas from western countries; (4) The research cooperation between academia and commercial sectors is weak. These four challenges may result in blocks for Chinese R&D teams to understand China cultural influences in DIMRC. As one potential direction, we expect that improving design education in Chinese universities can be a solution to overcome those challenges, see Section 4.6.4.

4.6 Discussion

In last section 14 findings on “China’s cultural influence regarding DIMRC” were proposed by analysing the results of interviews. In that study although three experts (professors) were interviewed, and the results were confirmed by interviewing junior researchers (PhD and Master students), these ‘confirmed’ findings are still based on limited numbers of interviewees. They are not strictly verified. Hence in this section those findings from interviews will be verified by compared to external

literature (Section 4.6.1). Besides it, parts of findings will be further verified by other sources, such as learning from actual DIMRC cases (Section 4.6.2) or future researches (Section 4.6.3).

4.6.1 Comparing the findings to literature

Table 4.2 provides ten factors hindering China's design culture for general product development, while Table 4.4 provides important factors in China's design culture influencing DIMRC, based on information garnered from the interviews. A comparison of Tables 4.2 and 4.4 reveals that most factors from Table 4.2 also appear in DIMRC. For example, Zhang & Wang (2009) mentioned that in the general community, awareness of design in China is weak, while in Table 4.4 the professors and students mentioned that Chinese society tends to associate design with art. Scholars (Zhang & Qiang, 2009) have suggested that people from different cultural backgrounds require different usability and different levels of emotional support in the mobile phone and medical device design in China, which was echoed by both the professors and students when referring to DIMRC.

Compared to Table 4.2, two new issues were mentioned in the interviews, being affordability and Chinese industrial design education. All three professors mentioned affordability as an important factor in China's design culture. In their view, affordability refers to both the initial cost of purchase and the running costs: Firstly the prices of ICT-enabled medical devices and systems should be competitive in local regions, as if the prices are not competitive, the rural hospitals, CHCs and CHPs will not buy or use the devices. In the minds of rural Chinese doctors, all ICT-enabled medical devices and systems produced by different Chinese companies (under Chinese brand names) are the same in terms of quality, and purchasing decisions are based mainly on price. Secondly, the costs involved in using such medical devices and systems should be covered by local medical insurance systems according to local economics and regional culture.

In Chinese industrial design education, product design is considered as a specialisation area of industrial design. In some Western universities (e.g., IDE/TU Delft), problem-solving skills are taught in industrial design, and so industrial designers from IDE/TU Delft can play an important role in product design projects in such fields as user research, design concept generation, business model design etc. Western industrial designers are given opportunities to work with other team members, such as engineers and marketing experts, and in companies, even during their studies. However, in many Chinese universities, industrial design is still taught as

part of the art discipline. Chinese industrial design students rarely have opportunities to work with other engineers or marketing experts, which may be an important reason why Chinese R&D teams rarely include Chinese industrial designers as key players in DIMRC.

4.6.2 More data from other Chinese stakeholders

The interview results in Table 4.4 are also partly verified by other Chinese stakeholders later in this thesis. For instance, in an actual DIMRC case “Development of a blood pressure monitoring system incorporating ICT” (See Section 5.4), one Chinese end-user mentioned that aesthetics was an important factor of design culture in DIMRC, while another end-user mentioned that he would like a blood pressure measurement device that looked like a watch. Cultural influences from end-users can be partly verified in this case. In Section 2.2.1, Professor Zhou Shaopeng, director and doctoral advisor of the Department of Economics at the China National School of Administration (and former expert in the central Chinese government), suggested that China needed to establish an enterprise and market-oriented technological innovation system that combines manufacturing, education and research as a whole. Cultural influences from the Chinese government can also be partly verified through a reading of policy documents.

4.6.3 Future research needs

Future investigations in the topic “identifying factors of China’s cultural influence regarding DIMRC” will focus on verifying and extending findings of this Chapter. This is because there are two main limitations in current study.

- (1) The numbers of interviewed experts are limited. In this Chapter In future we plan to interview more experts in DIMRC (e.g., professors, scientists from companies, governmental officers, etc.). We expect findings from this chapter will be verified by a quantitative research at that time. We also expect some new findings will be identified.
- (2) The research methodology need be improved. In current study all research activities, e.g., interview data collecting, translation (from Chinese to English), summarizing and analysing, were carried out by the author of this thesis alone. It is possible that some important messages from the interviews were missed. In the future we propose other independent researchers, with different backgrounds, to be involved to collect and analyse the

data from different viewpoints, in order to avoid subjective influences.

4.6.4 Possible contributions from IDE/Delft to help Chinese biomedical engineers understand China's design culture

In the previous sections the research question, *What are the important factors of China's design culture that influence DIMRC?* was investigated. In this section the parallel research question, *How can knowledge and insights from IDE/TU Delft be applied to the design education of Chinese biomedical engineering students in order to help them understand China's design culture for DIMRC?* will be explored.

The research process of this section consists of three steps: (1) first, the history and current situation of industrial design education at IDE/TU Delft is introduced; (2) second, the advantages of industrial design education at IDE/TU in understanding design culture is discussed; (3) finally, recommendations for the current Chinese biomedical engineering education system are given to answer the parallel question.

Industrial design education at IDE/TU Delft

Industrial design education at IDE/TU Delft forty years ago resembles the level of industrial design education in China today. For example, in the 1980s industrial design at IDE/TU Delft was predominately considered as falling under the realm of art, and consequently, industrial designers at IDE/TU Delft had little opportunity to work with others in the R&D phase of new product development (Cross, 1999).

The 1980s was often referred to as the “design science decade” (Cross, 1999). The Design Research Society's 1980 conference on “Design: Science: Method” (Jacques & James, 1981) provided an opportunity for industrial design researchers to combine science and practical industrial design, and develop the field of “design science”. Industrial design at IDE/TU Delft became a problem-solving discipline, requiring industrial designers to have a broad range of knowledge and skills, and understanding design culture therefore became one part of the problem solving skills taught at IDE/TU Delft.

As an example, retail design is a training programme in IDE/TU Delft in which cultural influence is considered an important issue. (Ref. <http://www.io.tudelft.nl/en/education/master-studies/specialisations/retail-design/> [accessed on 16-OCT-2012])

In retail design, industrial designers are primarily concerned with consumer experience in the shopping environment – be it physical or virtual. It is the retail designer's task to shape this experience through visual, spatial and communicative expression, based on an empathic understanding of the culture of shopping. To a large extent, culture reflects society with respect to social, economic, political and environmental issues, and to understand these factors of design culture, IDE/TU Delft teaches students to build up knowledge in four issues: the retail (design) context, retail strategy, innovation in retail and retail communication. This theoretical knowledge is backed by concrete design practice, such as in internships in commercial companies or academic-industrial collaboration projects.

The advantages of industrial design education at IDE/TU Delft in understanding design culture

Since understanding design culture is one important problem-solving skill, how to understand design culture is taught as an educational task at IDE/TU Delft, following currently two approaches:

- (1) IDE/TU Delft provides theoretical courses about design methods and tools to help students understand design culture. One example is the Master elective course “context mapping skills” (ID5663) (A definition and description of the term “context mapping” can be found at <http://www.contextmapping.com> [accessed on 16-OCT-2012]). In this course, students are educated with many context-mapping skills to carry out user research, including skills to obtain data from users and contexts so as to understand the cultural influences on product design.
- (2) IDE/TU Delft also provides a great deal of practical training to students, in which they are given the opportunity to work on actual design cases in new design contexts, e.g., design for residents in developing countries. By working on these cases, students are able to augment their skills and experiences in understanding different cultural influences, and can take these influences into account in the design process.

Practical training at IDE/TU Delft includes:

- Group projects: Students solve cases affecting businesses, applying the knowledge garnered from training courses. Different phases of the design process are discussed and practiced.

- Individual final year graduation projects: Companies provide assignments featuring complex design problems. A student will work full-time on such a project for about six months.
- Internship: While not a compulsory part of the study, many students choose to gain practical experience reflecting the student culture at IDE/TU Delft. A student can work for a period of 6 weeks to 3 months in a company on an individual project or as part of a team.

Courses from other advanced design institutes may also be useful to help Chinese biomedical engineering students understand China's design culture. It is recommended to explore these options.

Unfortunately, Chinese biomedical engineering students rarely have the opportunity to join similar theoretical courses or practical training sessions. There are two reasons for this:

- (1) Compared to other educational fields (e.g., mathematics, electrical engineering), Chinese biomedical engineering education is fresh. Most Chinese biomedical engineering institutions have backgrounds in electrical engineering, computer sciences, medicine or biology (CABE, 2009), and so have no idea what contributions product designers can bring to biomedical engineering education. Hence, product design methods and tools are unfamiliar to them, and thus are not being used in biomedical engineering education.
- (2) At present the academic-industrial cooperation mechanism in China is not as advanced as in Holland. For instance, Dutch universities encourage students to do internships, which count as academic credits. Many Dutch universities have offices that help students look for internship positions, and it is also normal for Dutch companies to provide internship positions. The Chinese education system lacks such a mechanism, and so most Chinese biomedical engineering students never have the chance to work as an intern in companies or to work as part of a team in company assignments.

To resolve above problems and transfer knowledge and insights from IDE/TU Delft to Chinese biomedical engineering education, efforts are needed from Chinese government, companies and academia, and seven recommendations will be given in the next section.

4.7 Conclusion and recommendations

In Chapter 3 three investigation areas for this thesis were identified: “design culture”, “design factors” and “design methodology”, after which, the first of these – design culture – was subjected to further analysis. The research objective in this chapter is to identify important factors of China’s design culture that may influence Design and development of ICT-enabled Medical device and system for Rural China (DIMRC); and to this end, a three stage process was followed: (1) Two existing models from literature were introduced, being: Hofstede’s onion model for culture in general, and Mohammad & Mariano’s model specifically related to design culture; (2) based on existing models, a literature analysis to analyse China’s design culture and its influence in general product development in China was carried out, revealing at least 10 major factors that influence general product development in China (See Table 4.2); and (3) to identify factors of China’s design culture influencing DIMRC, three Chinese industrial design professors and six Chinese students from IDE/TU Delft with relevant DIMRC experience were interviewed. Table 4.4 listed the results of the interviews in detail, but in short, the interviews revealed **at least 14 important factors of China’s design culture that could influence DIMRC, such as “Usability design for DIMRC should be tailored to different regional cultures”**.

Furthermore, this chapter also explored the possibilities of learning from a specialist institute, namely IDE/TU Delft, in order to help Chinese biomedical engineering students understand China’s design culture. The results showed that **the adoption by Chinese universities of the industrial design education methods practiced at IDE/TU Delft, e.g. theoretical courses about “context mapping skills”, student group projects, individual final year graduation projects and internships, may prove helpful to Chinese biomedical engineering students, providing them with an understanding of China’s design culture for DIMRC.**

Learning from this chapter, seven recommendations for Chinese universities, companies and government are proposed to augment the skills and experience of Chinese biomedical engineering students to understand China’s design culture.

Recommendation 4.1 (for Chinese universities): Courses on new product development should be provided to Chinese biomedical engineering students. Chinese universities could adopt and adapt (if needed) the curriculum design from Western industrial design universities, such as IDE/TU Delft.

Recommendation 4.2 (for Chinese universities): Academic-industrial collaboration courses could be useful for Chinese universities.

Recommendation 4.3 (for Chinese companies): Chinese companies should strengthen their cooperation with Chinese universities to include R&D knowledge exchanges and the establishment of collaborative projects between the academia and industry, both at staff and student levels.

Recommendation 4.4 (for Chinese companies): Chinese companies should create a design-oriented company culture, emphasising, for instance, the importance of user research for different regional cultures (e.g., usability for users, price, emotional support for users, etc.). The employees of the company involved in design should also spend time in rural China doing observational research.

Recommendation 4.5 (for the Chinese government): The Chinese government should develop a better system and mechanism for the encouragement of academic-industrial collaboration.

Recommendation 4.6 (for the Chinese government): The Chinese government should provide more subsidies and funding to Chinese DIMRC manufactures, and encourage them to develop medical devices and systems that are affordable to local rural hospitals, CHCs and CHPs. The government should encourage the staff and students of universities, as well as company employees, to spend time in rural China understanding the needs of the rural Chinese.

Recommendation 4.7 (for The Chinese government): The Chinese government should increase awareness of the importance of industrial design in Chinese society. Furthermore, the Chinese government should devise design policies for new product development in general, but also specifically for DIMRC.

These seven recommendations will be used further in the following chapters.

Chapter 5 Identifying Design Factors¹⁰

In Chapter 3, three factors for the development of an educational solution were identified: (1) understanding China's design culture influencing DIMRC, (2) identifying design factors for DIMRC, and (3) applying and adapting (if needed) design methodologies for DIMRC. See Figure 5.1. This chapter focuses on the second investigation area, "identifying design factors for DIMRC".

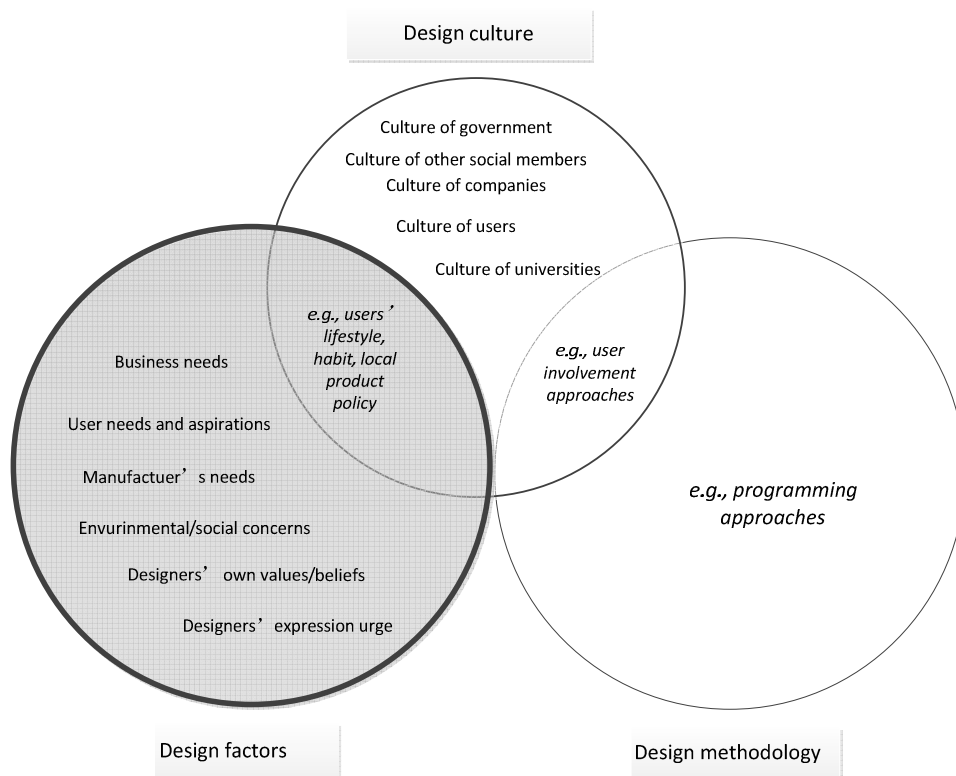


Figure 5.1: In this thesis, three educational areas are investigated. This chapter focuses specifically on exploring the issue of design factors (the shaded section)

¹⁰ 本章中文名称：确定设计因素。This chapter is based on following publications:

J. Jiang, Z. Z. Yan, J. Shi, P.V.Kandachar, A. Freudenthal (2010), A Mobile Monitoring System of Blood Pressure for Underserved in China by Information and Communication Technology Service, Information Technology in Biomedicine, IEEE Transactions on, Volume: 14 Issue:3, pp: 748–757.

J. Jiang & P.V.Kandachar (2009), What kind of decision factors will affect Design for Base of the Pyramid (DfBoP)? – An analysis research based on 24 case studies from IDE/TU, Proceedings of IAENG International Conference on Industrial Engineering, (ICINDE'09), Hong Kong, 18–20 March, 2009.

J. Jiang & P.V.Kandachar (2009), Roadmap research of process in Design for Base of the Pyramid (DfBoP) Proceedings of IAENG International Conference on Industrial Engineering, (ICINDE'09), Hong Kong, 18–20 March, 2009.

5.1 Introduction

5.1.1 Background of design factor

Design factors refer to:

Design factor is a term describing the capabilities of designs that satisfy various stakeholders, such as user needs and aspirations, the needs of manufacturers, businesses, environmental and social concerns, the designers own beliefs, values and urge for expression, etc.

There are various design factors in every design project, and scholars have identified several important¹¹ examples during observations of concrete projects in the authors' expertise domains. For instance:

- In the book “The mechanical design process”, Ullman (2009) identified the accuracy of load, strength and wear estimates and the environment as major design factors for mechanical design;
- Buchanan (1988) and Burr & Cheatham. (1995) identified cognitive ergonomics, usability, human/computer and human/machine interaction, and user experience as important design factors for software design;
- Hubka & Eder (1985) identified more than forty design factors for general product development, including durability, strength etc., and divided these design factors into four groups: core properties, internal properties, external properties and detailed prosperities;
- Kearsley & Frost (1985) proposed seven design factors for successful videodisc-based instructions: interactivity, visual design, organisation, active participation, metaphors and models, personality and a team approach;
- Lee & Lee (2003) identified nine design factors for electronic commerce websites, e.g., “customised design” (which provides differentiated functions and services representing the site's characteristics to satisfy user's specific requirements) and “ease of

¹¹ In this thesis important design factors refers to factors that contribute significantly to the success of the design.

use” (which refers to the degree to which the prospective user expects the use of the EC sites to be free of effort);

- Kim et al. (2005) discussed several design factors for successful e-commerce systems, identifying product-related information, depth and variety of the system structure, consistency of product and background presentation, and variety of presentation for product information as important design factors;
- Choi & Kim (2004) identified customer loyalty to online contents, concepts of customer loyalty, flow, personal interaction, and social interaction as design factors in developing online network games.

In practice, Research and Development (R&D) teams often generate checklists of design factors, as they can help to reduce failure rates and save costs, while also ensuring consistency and completeness when carrying out design work. A checklist of design factors usually corresponds to the design requirements in an R&D process (See Figure 5.2 and 5.3).

5.1.2 Identifying design factors as one step in the R&D process

Identifying design factors is an important step at the early stage of a design process in new product development. For instance, identifying design factors is recognised as part of the “idea generation” phase in Delft Design Methodology (DDM, defined in section 6.2, Hoog & Boeijen., 2008). DDM is a general systemic design process for industrial designers that is taught in the Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft).

Figure 5.2 shows a design process adapted from DDM, which emphasises the identification of design factors. The left part of Figure 5.2 shows the idea generation activities of the industrial designer, and the right part shows the activities towards the development of solutions. In the left part, industrial designers begin by identifying design issues, meaning all the necessary aspects relevant to the design project, including design methodologies and methods, design culture, design factors etc.; secondly, as one particular aspect of design issues, the important design factors (defined in Section 5.1.1) are identified; thirdly, the design requirements, which are usually based on the design factors, are identified, describing how interims of performance should be met in the design. For example, if affordability is an important design factor, one possible design requirement is “decrease the production cost of the product”; fourthly, design ideas or integrated concepts are proposed to satisfy the design

requirements; fifthly, the design ideas or integrated concepts are evaluated; and finally a decision of whether to continue or not is made, bringing to an end the idea generation phase.

In the right part, industrial designers develop solutions based on design ideas. In this part design requirements are analysed and documented; design specifications are identified; and prototypes are developed and evaluated. Design specifications describe the technical solution (of the following standards) to achieve the functionality of a product, such as its length. Finally, a decision of whether to continue or not is made.

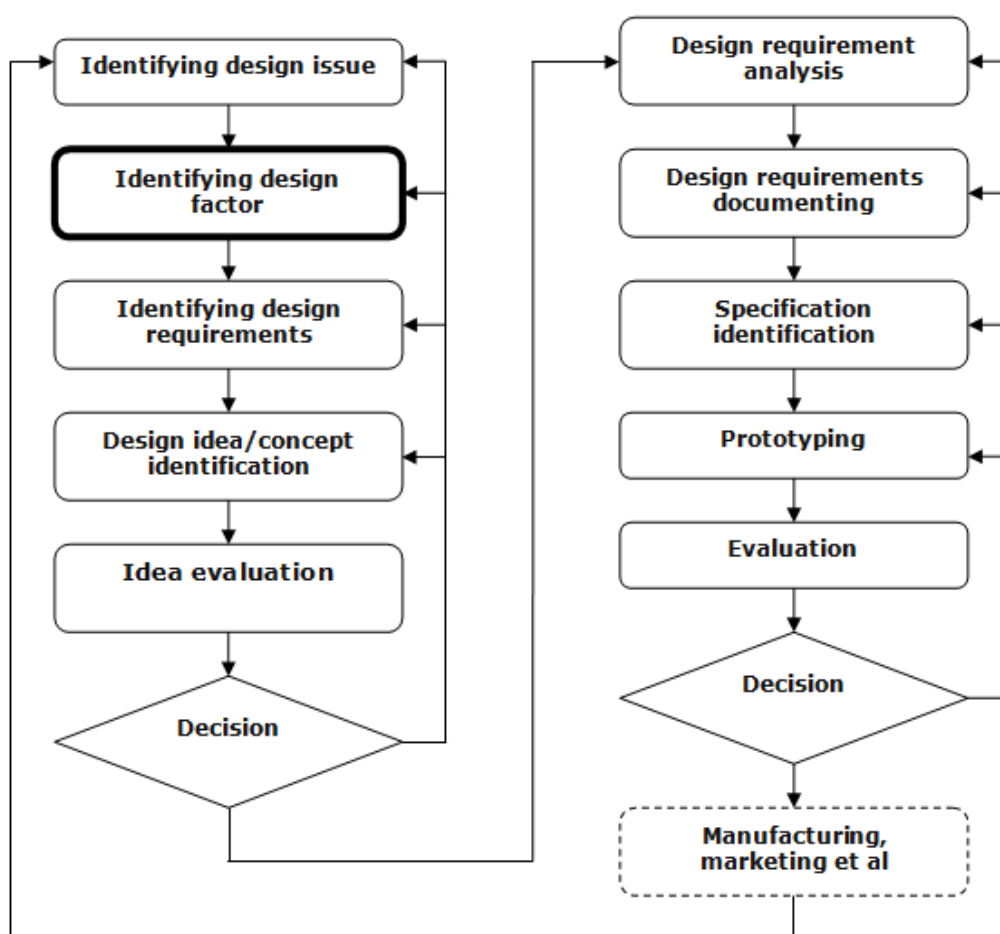


Figure 5.2: A systemic design process for industrial designers that emphasises the identification of design factors. The Figure has been adapted from DDM.

Biomedical engineers follow similar steps, as identifying design factors is also a key step in Design and development of ICT-enabled Medical device and system (DIM) for biomedical engineers. For example, in the book “Design of Biomedical Devices and Systems” (King & Fries, 2009), the

author considers the identification of design factors as one step of the outline design in biomedical engineering device design (See Figure 5.3).

Figure 5.3 shows a systemic design process of biomedical devices and systems for biomedical engineers. This process has been simplified from an existing methodology of biomedical devices and systems (King & Fries, 2009) and consists of five steps. Identifying design factors for different items is the first sub-step in the outline design step, which results in the design requirements. In Figure 5.3 the entire design process is iterative, as is the prototyping.

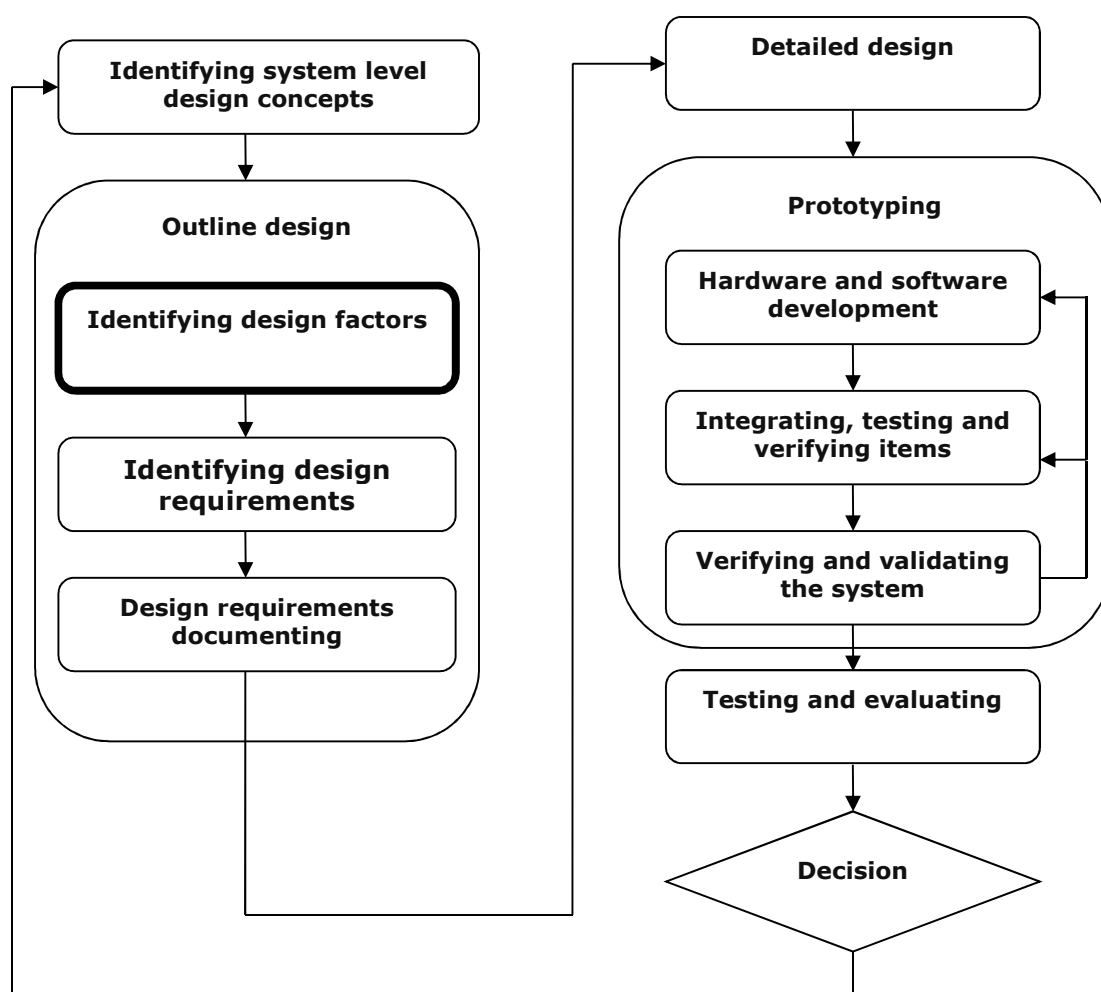


Figure 5.3: A simplified design process for biomedical engineers. The identification of design factors takes place at an early stage as part of the outline design (adapted from King & Fries, 2009).

5.1.3 Frequently used approaches to identify design factors

Industrial designers from IDE/TU Delft and biomedical engineers have their own approaches to identifying design factors. Figure 5.4 shows the two approaches from IDE/TU Delft (Hoog & Boeijen., 2008, simplified by the author of this thesis) and from biomedical engineering (King & Fries, 2009). Figure 5.4 shows that tacit knowledge plays a prominent role in the approach followed by industrial designers (left part), while the focus of biomedical engineers is on formal or explicit knowledge (right part).

In this thesis, tacit knowledge is defined as (Polanyi, 1958):

Tacit knowledge refers to work-related practical knowledge that is neither expressed nor declared openly, but rather implied or simply understood, and is often associated with intuition. This kind of knowledge is difficult to transfer to another person through written or verbal means.

For industrial designers from IDE/TU Delft (left part of Figure 5.4), design factors are initially garnered from literature, personal experience and research. Based on these three resources, industrial designers from IDE/TU Delft generate as complete a list of design factors as possible, which is continuously updated with data collected by the designer in the course of their design research activities. The whole approach therefore is iterative. In practice, an industrial designer from IDE/TU Delft usually spends a great deal of time on this process. For example, in the DIMRC project “Support tool for (Chinese) village doctors” (de Groot, 2007),¹² the R&D team studied more than 60 publications to extend practical knowledge, e.g. in the field studies to identify design factors.

Biomedical engineers (right part of Figure 5.4) usually identify design factors from existing formats and standards (e.g., ISO documents), identifying the categories of design factors in the outline design stage, and generating a list of design factors based on a literature analysis and personal project experiences. In practice, however, the identification of design factors is often ignored by biomedical engineers (Bronzino, 2000).

¹² For more information on the project, see item 7, table 5.2, Section 5.2.3. This project was carried out through the collaborative efforts of biomedical engineering students at Shanghai University, students of IDE/TU Delft and professional engineers from Dutch company IMPACT.

There is a significant difference between the two approaches. For example, industrial designers from IDE/TU Delft draw up as complete a list of design factors as possible in the early stages of the design process. They emphasise the participation of end-users and identify additional design factors from context studies that include brainstorming sessions, interviews and questionnaires. In contrast, biomedical engineers often like to create prototypes at the start. Following a frequently used approach known as “action research” (Reason & Huang, 2001), they tend to work from the technology or product, and usually identify important design factors from user tests. As noted earlier, tacit knowledge plays a prominent role in the approach followed by designers, while the focus of biomedical engineers is usually on formal or explicit knowledge.

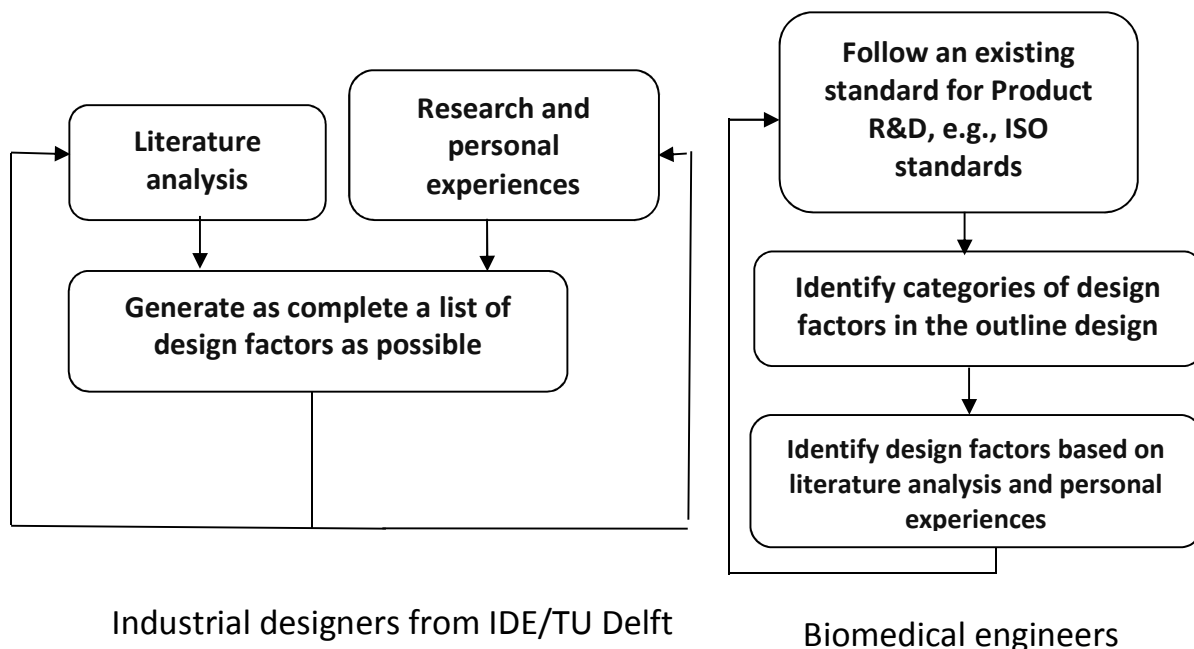


Figure 5.4: Two simplified aligned approaches to identifying important design factors: the industrial design approach, adapted from IDE/TU Delft (left); and the biomedical engineering approach, adapted from King’s approach (right).

Deciding which of the two approaches is more effective in DIMRC projects is difficult, as previous design efforts have revealed that several improvements are needed in both. For example, in an DIMRC case “Support tool for village doctor” (de Groot, 2008) the industrial design approach was used, however the industrial sponsors pulled their financial support because the required research investment using this approach was too high. In another DIMRC case, “Remote monitoring system for rural China” (Jiang & Flexman., 2007), the biomedical engineering approach was used, but the end-users (doctors and patients) were not

satisfied with the prototypes, and so the industrial sponsors refused to provide the funding for further investigations. A healthy combination of both approaches is perhaps what is needed.

5.1.4 Objectives and research questions in this chapter

Although the approach presented on the right hand side in Figure 5.4 is an existing approach to identifying design factors for biomedical engineers, problems may occur when applying it in practice. The most significant problem is that an existing standard may not always be available for all design topics (Bronzino, 2000), including DIMRC. In such a situation they have difficulties to identify categories of design factors and find out suitable literature in a sufficient way. Hence, identifying design factors can easily become a barrier for Chinese biomedical engineers. The intention in this chapter is to overcome this obstacle by devising a checklist of design factors relevant to DIMRC for Chinese R&D teams (Especially for biomedical engineers). The research question for this chapter is thus:

What are the important design factors for Design and development of ICT-enabled Medical device and system for Rural China (DIMRC)?

As mentioned previously, it is the intention in this thesis to select knowledge from IDE/TU Delft that may be integrated into Chinese biomedical engineering education, according to which a second parallel research question is also asked in this chapter:

How can knowledge and insights from IDE/TU Delft be applied to help Chinese biomedical engineering students identify design factors for DIMRC?

To achieve these two objectives, three sub-studies are carried out in this chapter. In the first sub-study (section 5.2), a literature analysis is made to identify design factors for DIM (Design and development of ICT-enabled Medical device and system). In the second sub-study (Section 5.3), design factors for DfBoP (Design for Base/Bottom of the Pyramid) are identified through a study of student design projects at IDE/TU Delft. In the third sub-study (Section 5.4), an actual DIMRC case is studied to investigate design factors for DIMRC. A deeper description of the methods in the three sub-studies will be made in section 5.1.5.

The following six sub-research questions will be answered in the three sub-studies:

SRQ1: What are important design factors for DIM (Design and development of ICT-enabled Medical device and system) that can be garnered from literature?¹³

SRQ2: What are important design factors for DfBoP (Design for Base/Bottom of the Pyramid)?

SRQ3: Can design factors for DIM and DfBoP from previous studies be used directly in an actual DIMRC case?

SRQ4: What roles of the industrial designers from advanced design institutes could be beneficial to R&D teams in future DIMRC cases?

SRQ5: Who should be the key members of the R&D team in future DIMRC cases?

SRQ6: Can DDM be applied to identify design factors for DIMRC in an actual DIMRC case? (The answer of this sub-research question will also be used in Chapter 6)

5.1.5 Research methodology

The research methodology of this chapter consists of three steps (three sub-studies):

- (1) A search of literature to identify design factors for DIM (Section 5.2): In Chapter 3, three literature domains were defined that are deemed relevant to DIMRC: DIM, DfBoP and UCD. The search came up with several design factors for DIM, which will be identified in this step, thus answering SRQ1.
- (2) Case studies to identify design factors for DfBoP (Design for Base/Bottom-of-the-Pyramid) (Section 5.3): As scholars have not provided a checklist of design factors for DfBoP (For more information on this, see Section 5.3.1.), student cases from IDE/TU Delft were studied to identify design factors for DfBoP (For details of the research methods used in this step, see Section 5.3.2). SRQ2 will be answered in this step.
- (3) An actual DIMRC case study was executed (Section 5.4), and the design factors from previous studies (from steps 1 and 2) were tested on this case, with the aim being to verify whether, and in what way, design factors from previous studies can be used in DIMRC in practice. Industrial design students from IDE/TU Delft and biomedical engineering students from Shanghai University

¹³ As design factors for DIMRC absent in literature, a stepwise approach is taken. Firstly, design factors for DIM and DfBoP were explored. (Design factors for UCD are not specifically investigated, as a study of previous literature revealed that most DIM and DfBoP cases used UCD approaches. Hence, design factors for UCD overlapped with design factors for DIM and DfBoP.) Secondly, important design factors for DIM and DfBoP were combined as likely design factors for DIMRC. These factors will be verified by an actual DIMRC case in Section 5.4.

worked together as a team on the project. The method followed in this sub-study was a “Study of the author’s own case”. SRQ3–6 will be answered in this step.

Combining the results from the above three steps, a checklist of design factors for DIMRC is presented as the main result of this chapter.

5.2 Prior studies on design factors for DIM

This sub-study answers SRQ1. The method in this section is literature analysis. A search of scientific publications in the field of “Design factors for ICT-enabled medical device- and system development” was carried out through Google scholar (<http://scholar.google.com> [accessed on 16-OCT-2012]) and from Year 1960-2010. To make the search more focus, following journals and databases are chosen: Journal of Medical Internet Research, International journal of medical informatics, Health informatics journal, PubMed publication database, and IEEE publication database.

By reading relevant publications, it can be found that studies of design factors for DIM have been carried only for the last twenty years (1990-2010). Harvard Medical Practice Study in New York (Leape et al., 1991) signalled the need for heightened concern for the many mistakes in healthcare that are likely occurring outside hospital environments. The emotions of patients (e.g., the blood pressure of some patients rises when they talk with doctors) and fear of blame are likely to be main causes of underreporting in healthcare. Moreover, idleness among patients is another significant factor, as some people terminate their medical treatment once they feel better, which may result in a recurrence of the initial problem.

After accumulating the best practice researches identifying user needs, Matinez et al. (2005) proposed several design factors relevant to DIM, such as time and costs to fill in and send medical information. Heeks (2006) noted that DIM should consider components from both designers and users. Design factors about the users’ activities, skills, culture and objectives, and factors related to the user organisation’s structure and infrastructure need to be investigated and taken into account in design thinking for DIM. Current researches into DIM in developing countries, such as Rithey et al. (2009), reveal three facets of design that need to be emphasised: human factors (e.g. willingness to participate/collaborate, adoption, satisfaction, cultural competence, supportive political environment), economic factors (e.g. sustainability, affordability, marketability, profitability) and technological factors (e.g. usability,

interoperability, scalability, transferability). Calvin et al. (2009) propose five design factor constructs: (1) persons (e.g., medical staff's and patients' characteristics); (2) task and job design (e.g., task complexity, availability of resources such as time, staff and information); (3) tools and technology used (e.g., order forms, medication lists, computing technologies and websites, blood pressure monitors); (4) the environment (e.g., space and lighting in patients' homes); and (5) organisation characteristics (e.g., the structure and culture of the home care nursing organisation, nurse practice models, care policies). Table 5.1 gives a few design factors noted by these authors.

Table 5.1: A few design factors relevant to DIM from literature.

Related literature	Specific Focus	Design factors
Harvard Medical Practice Study (1991)	Culture of patients	Emotions of patients, blame and shame, idleness
Matinez et al. (2005)	Partnership, Project Management, Medical staff conditions	Profile of health personnel (profession, age and experience); Profile of the DIM physical accesses; Features of administrative and health information systems; Training needs; Perceptions of the use of telecommunication systems at work; Working conditions (feelings of isolation, possibilities of promotion, motivation)
Heeks (2006)	Components from the designers' own context Conceived assumptions about the situation of the user	Information; Technology; Processes; Objectives and values, regional culture; Staffing and skills; Management systems and structures;
Rithey et al. (2009)	Human factors, economic factors and technological factors	Willingness to participate/collaborate, adoption, satisfaction, cultural competence, supportive political environment; Sustainability, affordability, marketability, profitability, Expandability; Usability, interoperability, scalability, transferability
Calvin et al. (2009)	Persons, tasks and job design; tools and technology; the	Characteristics of medical staff and patients; Involvement of local government;

	environment; organisation characteristics	Task complexity, availability of resources such as time, staff and information; Order forms, medication lists, computing technologies and websites; Space and lighting in patients' homes; Structure and culture of the home care nursing organisation, nurse practice models, care policies

5.3 Identifying design factors for DfBoP

This sub-study is to answer SRQ2.

5.3.1 Introduction

Unlike DIM (Design and development of ICT-enabled Medical device and system), the history of Design for Base/Bottom of the Pyramid (DfBoP) is short (started in 2003, see Section 3.2.1). Currently, many Multinational Companies (MNC) such as HP, Intel, Philips and Microsoft, as well as some design institutes, such as Delft University of Technology (TU Delft), Illinois Institute of Technology (IIT), Berkley and Stanford are aware of the design opportunities in this market, and several pioneering DfBoP projects have been launched. Relevant design cases from institutes and companies have been published by Prahalad & Hart (2002) and Jamie & Niels (2007), among others.

In the Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft), various DfBoP student design cases were launched in 2003, such as “Solar Lamp for Africa” and “Adoptable woodstove for India”. By 2011, more than 150 student DfBoP projects had been carried out at IDE/TU Delft, mostly initiated by Dutch or European business enterprises, or by NGOs with interests in BoP (Kandachar et al., 2009). Figure 5.5 presents an overview of these projects from the 2004–2009 period.

Unfortunately, theoretical research identifying design factors for DfBoP is still limited, although some scholars have passed comment on DfBoP, for example Simanis & Hart (2008), who said: *“Now it is time for enterprise ICT at the BoP. Infrastructure build-out, improving cost and revenue projections, and customer awareness and uptake – are bringing ICTs to a near-term tipping point.”* Although “cost” and “infrastructure build-out” have been emphasised as important aspects of DfBoP in his paper, these scholars have not defined them as design factors in literature.



Figure 5.5: Overview of student DfBoP projects at IDE/TU Delft (Source: Kandachar & Halme, 2008)

Accordingly, the objective of this sub-study is to generate a checklist of design factors for DfBoP, for which selected student cases from IDE/TU Delft have been used as data sources. These design factors will be compared to previous literature to ascertain whether they are to be regarded as “approved” design factors. The SRQ2 research question is addressed in this sub-study.

5.3.2 Method

The overarching method in this sub-study is an “in depth study of external cases” (in which the author did not participate – For more information about this method, see Section 2.7.1). The research process of this sub-study comprises four steps: (1) criteria for case selection; (2) data collection; (3) data analysis; and (4) generation of results.

A. Criteria for case selection

For the selection of suitable student cases from student DfBoP projects from IDE/TU Delft, three selection criteria were defined: (1) open publications of the projects should be available by searching TU Delft master thesis database (by using search system TU Delft repository (<http://repository.tudelft.nl/> [accessed on 16-OCT-2012]) The student names of these cases were mentioned in Kandachar et al (2009). They

were used as key words.); (2) descriptions of the project should be complete, including problems, methods, results, evaluations and reflections; and (3) all design activities should be published in detail.

B. Data collection

The publications of the selected cases were read, and the executed design activities were identified and summarised.

C. Data analysis

The summarised design activities were analysed using a “High Frequency Words in Context” (HFWC) technique, which is used to identify important terms by sorting and aligning words that have highest occurrence rate within an article (Manning & Schütze, 1999). In this sub-study, the words with the highest occurrence rate were defined as important design factors. The data analysis comprised three stages:

- (1) HFWC searching: The ten words (phrases) with the highest occurrence rate within the publications were sought using Visual Basic for Applications for Microsoft Office (With a maximum of ten high frequency words per project. Personal pronouns and “be” verbs were filtered). The basic protocol of this function is from a vector model (Salton et al., 1975).
- (2) HFWC cross-test: Once all of the words (phrases) with the highest occurrence rate in the publications were found, they were cross-tested in all cases. Only those words that appeared in more than three projects were identified as important design factors. All other words were disregarded.
- (3) Definitions and explanations of the words: The related chapters of the publications were studied, and the summaries of the design activities from the publication were used to define and explain the important design factors.

To demonstrate the above process, a design case “Design for mothers’ health”¹⁴ will be used as an example. The results of three sub-steps of data analysis were:

- (1) By searching in the MSc thesis of the “Design for mothers’ health” case, the ten words (or phrases) with the highest occurrence rate were identified: “partner characteristics”, “life style”, “culture”,

¹⁴ This case is included in Table 5.2. For more information on this case, please read “Design for emerging market” (Kandachar et al., 2011).

“awareness”, “business characteristics”, “product policy”, “incomes”, “mother”, “diseases”, and “birth”.

- (2) The first six of these words or phrases were found in at least two other projects, and so it was these six words or phrases were selected as the proposed design factors (See Table 5.5).
- (3) The chapters in which the words or phrases appeared were studied, and related design activities were summarised. These summaries were used to describe and explain the key design factor (See Table 5.4).

D. Result generation

All of the proposed design factors and the summaries of related design activities were recorded and categorised for clarity, and a “cross-case comparison” method was applied. A “Cross case comparison” is a detailed analysis that involves the comparison of two similar cases in different design countries (Naturally, the results of the two similar cases will be different). Probable reasons for the differences were identified by analysing the design activities of both cases.

5.3.3 Results

A. Data collection

24 MSc graduation projects were found to meet the criteria and so were selected for further study. These projects revolved around several BoP design issues, such as water, healthcare, energy, housing, etc., in developing countries like India, Indonesia, China, Brazil, Ghana, Tanzania, Honduras, the Philippines, Pakistan, Madagascar, etc., and the MSc theses of these projects were used as the data source. Table 5.2 presents an overview of the cases. In Table 5.2, columns 1–4 list the item number, the company, the title of the project and the project completion date; Columns 5–14 list the relevant topics (Six from the Millennium Development Goals [education, health, food/nutrition, energy, water and entrepreneur] and the others from the design research outline within IDE/TU Delft [IDE research profile 2008-2012]); and Column 15 is the country in which the case study took place.

B. Data analysis

Table 5.3 shows the results of the HWFC. A total of 14 design factors were identified that appeared in at least three different DfBoP projects. Table 5.4 presents the results of the data analysis of the sample case “Design for mothers’ care”. Column 1 lists seven important design factors; Column 2 lists the related design activities described in the thesis; and Column 3 gives summaries of these design activities.

Table 5.2: The chosen 24 design cases from IDE/TU Delft. (+ indicates an element of the project)

				Education	Health	Food/nutrition	Water	Energy	Housing	Material	Connectivity	Design/tools	Entrepreneur	
Item	Company/Organization	Title	Date of completion											Country
1	Helps International	Improving the climate of cooking area	2006/06		+	+		+	+					Guatemala
2	NPSP Composite	Natural Fibres in doors and windows	2005/10						+	+				India
3	Ecofys/Kamworks	Solar lighting	2005/10					+						Cambodia
4	Vestegaard Fransen	Personal water purifier	2006/04	+	+		+							Ghana
5	Bosch/Siemens	Product service system for plant oil stove	2006/07		+	+		+						Philippines
6	INBAR	Human-powered splitting tool	2006/06					+		+			+	India
7	Impact	Support tool for village doctors	2006/09	+	+						+			China
8	Philips Healthcare	Oral cancer Screening device	2005/11		+									India
9	Philips Research	Design of malaria diagnosis tool	2006/08		+									India
10	Philips Apptech	Adoptable woodstove	2006/04		+	+		+					+	India
11	Movendi/MAK-D	Tricycle for disabled	2006/07		+								+	Ghana

12	EYE, Padan	Reeling machine for silk farmers	2006/11							+			+	India
13	Philips Apptech	Safe drinking water	2006/4		+		+							India
14	Philips Design	Contextualising products	2006/2		+							+		India
15	Philips Healthcare	Creating market insight	2005/12		+						+	+		India
16	Microsoft	Online Microfinance	2006/02								+	+	+	Africa
17	Philips Appetch	Adoptability of the U-Specs	2005/10	+	+							+		India
18	TU	Water supply in slums	2006/04		+		+		+				+	Brazil
19	ECOFYS	Rural Energy system	2008/04	+				+	+				+	Africa
20	Phillips Apptech	Cooking in rural China	2007/06		+			+				+		China
21	Phillips Apptech	Safe drinking water for China	2007/06		+		+			+				China
22	Intel Healthcare	Mother health	2008/06	+	+						+		+	India
23	Intel Healthcare	Child health	2008/06		+						+		+	India
24	Intel Healthcare	Interface for diabetes monitor	2008/06	+	+						+		+	India

Table 5.3: Identified design factors. Grey indicates the word/phrase appeared in at least two projects.

Category	User aspects				Economic aspect							Product aspects		
Design factor	Culture	Awareness	Lifestyle	User habit	Local economic content	Affordability	Business model	Team building	Policy	Social impact	Medical insurance	Advanced technology	Cost	Material
Project Title														
Improving the climate of cooking area														
Natural Fibres in doors and windows														
Solar lighting														
Personal water purifier														
Product service system for plant oil stove														
Human-powered splitting tool														
Support tool for village doctors														
Oral cancer screening device														
Design of malaria diagnosis tool														
Adoptable woodstove														

Tricycle for disabled														
Reeling machine for silk farmers														
Safe drinking water														
Contextualising products														
Creating market insight														
Online microfinance														
Adoptability of the U-Specs														
Water supply in slums														
Rural Energy system														
Cooking in rural China														
Safe drinking water for China														
Design for mothers' care														
Child health														
Interface for diabetes monitor														

Table 5.4: The important design factors, name and summaries of the design activities in the “Mother health” project

Selected high frequency words	Name of activity	Activity description (from the report)
Partner characteristics	Trends & developments analysis at Aravind Eye Hospital	<i>Identify design trends and developments from a hospital</i>
Partner characteristics	Getting successive attempts	<i>Stimulate partners to continue with the results of the project towards concrete solutions</i>
Partner characteristics	Focus group about opportunity exploration	<i>Identify trends, developments from the team of Harischandra Hebbar, BoP chair Maniple and earlier student connections</i>
Lifestyle	Observational research in the delivery Room	<i>Identifying problems and needs from actual user situations</i>
Culture	Exploring the needs of community healthcare organisations	<i>Identify issues, problems and needs in children’s delivery room</i>
Awareness		
Business characteristics	Design of strategic directions	<i>Design of strategies for development of new solutions</i>
	Evaluation of strategic options	<i>Select the best strategic options and collect suggestions for improvements</i>
Product policy	Obtaining policy and support from government	<i>Identifying issues, problems and needs through interviews with Government</i>

Table 5.5: Proposed design factors for DfBoP and their definitions and explanations ([1] basic definitions from other literature; [2] descriptions from MSc reports; and [3] definition and explanation from the author of this thesis).

Item	Design factors	Definitions and explanations
1	User behaviour	Behaviour refers to the actions and mannerisms of organisms, systems or artificial entities in conjunction with their environment, in which other systems or organisms exist as well as in the physical environment (http://dictionary.reference.com/browse/behaviour [accessed on 16-OCT-2012]) [1]. The design reports show that consumer behaviour directly affected decisions of the industrial designers who are trained to focus on user centeredness. [2].
2	Awareness	Awareness refers to the perception and cognitive reaction of a human or animal to a condition or event (Fritjof, 1996) [1]. Awareness research is used in design research in certain design cases, such as in product brand name improvement. [2] It is related to education and skills. [3]
3	Lifestyle	Lifestyle is a characteristic bundle of behaviours that make sense both to others and to oneself at a given time and place, including social relations, consumption, entertainment and dress (http://www.etymonline.com/index.php?allowed_in_frame=0&search=lifestyle&searchmode=none [accessed on 16-OCT-2012]) [1]. Reports show that user needs are based on lifestyle, especially for BoP populations in developing countries.[2]
4	Habit	Habits are habitual routines of behaviour that are repeated regularly, and tend to occur subconsciously without direct consciousness about those behaviours. Everybody has certain behavioural habits (Gillian, 1995). [1] Industrial designers can gain competitive advantages by discovering the behavioural habits of the user, and incorporating them into the usability of product design. [2] The impact of user habit for BoP is indirect, but it should be considered in that it improves the competition of the design for the BoP population. [3]
5	Affordability	Affordability refers mainly to the money paid by users for the solution. [2] This aspect is also related to the priorities of consumers.
6	Local economic content	Local economic content refers to the consumption opportunity gained by an entity within a specified local context. [2]
7	Business model	Business model is a term used to describe a profit-producing system that has an important degree of independence from the other systems within an enterprise (http://sloanreview.mit.edu/the-

		magazine/2012-spring/53310/creating-value-through-business-model-innovation/ [accessed on 16-OCT-2012]] [1]. Business models are mentioned in industrial companies who have interests in BoP market to build a healthy market (Win-win situation). [2]
8	Building of the team	Building of the team means organising stakeholders that are intending to start a collaborative activity, for instance, a new product development. [2]
9	Advanced Technology	Advanced technology is a broad concept that deals with a species' usage and knowledge of technology, methods, tools and crafts, and how it affects a species' ability to control and adapt to its environment. [2]
10	Cost	Cost is the amount of money used up to create something, and hence is no longer available for use (Sheffrin, 2003). [1] Sometimes cost is related with user income and the business model in this definition. [2]
11	Materials	Materials are the physical substances used as inputs for production or manufacture, or simply to create something new. [2] Low costs are welcomed; local materials (bamboo etc.) are used in some DfBoP cases to add value.[3]
12	Product policy	Product policy is a deliberate plan of action to guide new product development and achieve rational outcome(s). Product policy is also very important in concept design and a company investment strategy. [2]
13	Social impact	Social impact refers to the processes of analysing, monitoring and managing the intended and unintended social consequences, both positive and negative, of planned interventions (policies, programmes, plans, projects) and any social change processes invoked by those interventions. [2] Social impact is often a key motivation for governmental and non-governmental organisations to set up DfBoP projects. [3]
14	Medical insurance	Medical Insurance is a form of collectivism by means of which people collectively pool their risk, in this case the risk of incurring medical expenses. [2] Cases show that medical insurance (public social insurance and company insurance) play an important role in DfBoP. In almost all successful cases, medical insurance involvement could be found through observation. [3]

C. Results generation

Table 5.5 lists the proposed design factors for DfBoP. Column 1 lists the design factors, while Column 2 gives a description and explanation based on three sources: descriptions from project publications, basic definitions from literature, and explanations provided by the author of this thesis.

Identifying three categories

By using a “cross-case comparison”, three categories of design factor were identified:

a) User aspect

The user aspect is the first crucial aspect that influences DfBoP, and the category includes factors relevant to users, such as lifestyle, habit, etc. To illustrate this, the “Adoptable stove” case will be used (item 10, Table 5.2). A woodstove was developed that sold well in rural India in 2006, and in 2007 Philips decided to introduce the stove also to rural China. However, the stove proved to be unpopular with rural Chinese women. This was due to the different user aspects of Chinese and Indian women, related in particular to their cooking habits and their preferred pan sizes (Kandachar et al., 2009): Indian women like to cook while sitting on the ground, while Chinese women like to cook while standing up; and pans in India are generally small, while Chinese pans are much bigger (See Figure 5.6).



Figure 5.6: Pictures from two different design reports. Indian women like to cook while seated using small pans, while Chinese women like to cook standing up and prefer using big pans (Picture source: Kandachar et al., 2009)

b) Technical aspect

The second category is the technical aspect, and includes factors relevant to products (which are expected to be developed in the project), such as material, physical infrastructure, etc. For instance, in the case “Screening

device for oral cancer” (item 8, Table 5.2), the product-related technology “Light-Inducing Fluorescence (LIF)” was emphasised many times by the industrial designers; while in the case “Personal water purifier” (item 4, Table 5.2) the biochemical material was regarded as the key factor responsible for the success of the project. In the case “Online Microfinance” (item 16, Table 5.2), the ICT infrastructure was regarded as the key factor related to success.

c) Economic aspect

The economic aspect is the third category of design factors, and includes factors relevant to economy, such as production costs, user expenditure capability, etc. For example, in the case “Tricycle for disabled” (item 11, Table 5.2), not only was a product designed, but also a business model for the sale of ice cream by disabled people from the newly designed bicycle.

5.3.4 Discussion

Table 5.5 provides a reference checklist of design factors for DfBoP. This checklist is based on a study of practical design cases from IDE/TU Delft. To verify whether these design factors may be effective outside IDE/TU Delft, relevant publications from the general DfBoP literature domain were selected and studied.

A. Methodology

This research process comprised three steps:

- (1) 18 relevant publications from the DfBoP literature domain (in Section 3.2.1) were selected, and the 14 important design factors for DfBoP listed in Table 5.5 were indexed as key words in these publications. These 18 open publications are: Prahalad & Hart (2002), Prahalad & Hammond (2002), London (2007), Kandachar et al. (2008 and 2009), Diehl et al. (2008 and 2011), Bart et al. (2002 and 2007), Barczak et al. (2006 and 2009), Anderson & Markides (2007), Arnould & Mohr (2005), Christensen et al. (2006), Hart & Clayton (2002), Swan et al. (2005), Penchansky & Thomas (1981), and Braimah & Kwame (2010).
- (2) Paragraphs containing the terms (the 14 important design factors) were recorded. If the meanings of the design factors in those paragraphs were similar to the explanation in Table 5.5, the design factor was considered as verified by the publications. For example, in the publication “What works: serving the poor, profitably” (Prahalad & Hammond, 2002), the authors stated, *“The lesson for multinationals approaching this market is not to be concerned about deploying **advanced technology** solutions at the bottom of the pyramid simultaneously with, or even ahead of, deployment in advanced countries.”* Here, the meaning of the design factor “advanced technology” is same as the explanation in Table 5.5, and so the

meaning of the term “advanced technology” was verified in the publication.

- (3) All related paragraphs containing references to design factors were recorded as evidence. To judge whether the authors mentioned and recognised the importance of those design factors, the conclusions and recommendations of the 18 publications were read. If the authors mentioned the importance of those factors (e.g., one author stated that, “A successful business model for the poor is the key in BoP cases” [Prahalad & Hart, 2002]), the related paragraphs were selected. Some of selected paragraphs were listed in Table 5.6.

B. Results

Table 5.6 presents the results of the verification phase. It can be seen from the table that all 14 design factors were verified in DfBoP publications outside IDE/TU Delft. Although the authors of publications did not define the 14 words or phrases specifically as design factors, they mentioned and recognised the importance of these factors in their DfBoP topics.

Table 5.6: Design factors and evidence of design factors mentioned in 18 publications. This table contains some sample quotes from 18 publications. Note that in some cases one design factor appears in more than one publication. However, only one quote is listed in table 5.6.

Design factors	Evidence of design factors in relevant DfBoP publications
User behaviour	“By entering into alliances in the bottom of the pyramid market, MNCs gain insight into developing countries’ user behaviour and local knowledge.” (Prahalad & Hart, 2002)
Awareness	“Now it is time for enterprise ICT at the BoP. Infrastructure build-out, improving cost and revenue projections, and customer awareness and uptake – are bringing ICTs to a near-term tipping point.” (Simanis & Hart, 2008)
Lifestyle	“It’s a good bet that many companies and marketing firms know more about your health, spending preferences, and lifestyle than you likely do yourself.” (Simanis & Hart, 2008)
Habit	“The potential for erosion of competitive position was limited ... Shared use of capital equipment (e.g., different families use one same toilet) was enshrined in their habits .” (Arnould & Mohr, 2005)
Affordability	“In other words, a company needs to use strategic innovation to achieve what we define as affordability and acceptability.” (Prahalad & Hart, 2002)
Local economic content	“Through their decades of on-the-ground experience in poor countries, MNCs have probably already realised that there is no fortune at the bottom of the pyramid, or that ... emergence of local private entrepreneurs who provide economic as well as non-economic content ...” (Prahalad & Hart, 2002)
Business model	“Converting the very poor into active consumers will foster innovations in technologies and business models . It will challenge managerial (and public product policy) assumptions about sustainable development.”

	(Prahalad & Hart, 2002)
Building of the team	<i>"The presence of existing facilities and staff also facilitates relationship building between the corporate team and the community partners by providing a tangible place (e.g., an office) or partners to visit that reflect the corporation's culture and nature of operations."</i> (Simanis & Hart, 2008)
Advanced Technology	<i>"The lesson for multinationals approaching this market is not to be concerned about deploying advanced technology solutions at the bottom of the pyramid simultaneously with, or even ahead of, deployment in advanced countries."</i> (Prahalad & Hammond, 2005)
Cost	<i>"Now it is time for enterprise ICT at the BoP. Infrastructure build-out, improving cost and revenue projections, and customer awareness and uptake – are bringing ICTs to a near-term tipping point."</i> (Simanis & Hart, 2008)
Materials	<i>"This involves sourcing available raw materials and services from community based vendors, as well as working closely with them to continuously improve the quality of their products and services."</i> (Simanis & Hart, 2008)
Product policy	<i>"Converting the very poor into active consumers will foster innovations in technologies and business models. It will challenge managerial (and public product policy) assumptions about sustainable development."</i> (Prahalad & Hart, 2002)
Social impact	<i>"Development sector initiatives are confronted with the challenge of having to serve too many 'customers' and increasing pressure to expand their social impact."</i> (London, 2007)
Medical insurance	<i>"It is critical that business prototyping activities are structured so that community team members can generate income and that the Project Team is organised in a manner that creates a health insurance mechanism to respond to financial contingencies."</i> (Simanis & Hart, 2008)

5.3.5 Conclusions

As previous literature contains no checklist of design factors for Design for Base/Bottom of the Pyramid (DfBoP), the objective of this sub-study has been to identify design factors for DfBoP. An "In depth study of external cases" (in which the author did not participate) was used as the prime method, and 24 student DfBoP projects from IDE/TU Delft were used as data. As a result, **14 important design factors for DfBoP were proposed, including user behaviour, awareness, lifestyles, habit, affordability, local economic content, business model, building of the team, advanced technology, cost, materials, product policy, social impact, and medical insurance**, which can be categorised into three groups: economic aspects, user aspects and technical aspects.

The definitions of the above factors and their importance in DfBoP were confirmed through a comparison with literature from outside IDE/TU Delft.

Although none of the authors in the publications defined the 14 words or phrases as design factors, they mentioned and recognised the importance of these factors in their DfBoP topics.

5.4 Identifying important design factors for DIMRC

There are two major objectives in this sub-study: (1) To identify design factors in an actual DIMRC case. Later, these factors will be compared to the design factors for DIM and DfBoP; (2) To propose a design approach that allows biomedical engineers to identify design factors. (This approach will be used as one result of the “design methodology for DIMRC” in Chapter 6.) To achieve above two major objectives, an DIMRC case “Development of a blood pressure monitoring system incorporating ICT” is examined as a case study.

In addition, SRQs 3, 4, 5 and 6 will also be answered in this sub-study. See Section 5.1.4.

5.4.1 Introduction

The DIMRC case “Development of a blood pressure monitoring system incorporating ICT” was intended to solve hypertension problems in the underserved regions of China. More than 100 million people suffer from hypertension in China, but only 36 percent are aware of their condition (16 percent in rural areas) (Thomas, 2005), which leads to more serious ailments, such as atherosclerotic cardiovascular disease. The unmet and growing needs of the population in such fields as BP diagnosis, monitoring and electrical record management are further hindered by the limited physical infrastructure and the unbalanced distribution of medical resources.

Currently, various integrated homecare systems are commercially available on the global market, developed by such players as Philips, Toshiba and Ericsson, among others. These high-end systems include home blood pressure monitoring, web services and call centre facilities, combined with pharmacist-assisted care. The problem with these systems is that the related services are often complex, too expensive and are often not reimbursed. In addition, tele-monitoring systems are mostly based on a closed technology standard instead of an “open technology platform” that allows the connectivity of various monitoring systems. For example, the CodeBlue Initiative of Harvard University (Malan and Jones, 2004), MARSIAN by CNRS (Axosa et al., 2003 and 2004), and Lifeguild by NASA (Mundt et al., 2005) focus only on technical innovation, and overlook the innovation of implementation procedures into the societal context. Projects from industrial companies such as Lifeminder by Toshiba (Ouchi et al., 2002) provide too much physiological data, which is difficult to process by the unskilled care workers at the Community Healthcare Centres (CHC), who lack the skills and knowledge of the workers employed in similar roles in urban China; and MyHeart by Philips (Josef, 2004), which targets only wealthy users. MobiHealth by Ericsson (Konstants & Herzog, 2003) only focuses on mobile technologies (rather than networks and services).

These systems have yet to be implemented with any level of success in rural China.

To come up with an appropriate solution, in 2009 a research/design group was set up, composed of two biomedical engineering professors and two biomedical engineering Master students from Shanghai University (China), and two researchers from IDE/TU Delft (the Netherlands). Additionally the author of this thesis worked as a remote academic mentor from IDE/TU Delft in the research group.

5.4.2 Method

A “Study of the author’s own case” (in which the author participated) is used as the prime method in this sub-study (For more information on this method, see Section 2.7.1). This investigation consisted of three steps: (1) project preparation, in which the research team proposed a research process for the case; (2) project development and implementation, in which the research team applied the research process to the case and recorded the results; and (3) project evaluation and reflection, in which all stakeholders evaluated the results of the case study and provided reflections.

A. Project preparation

A design approach for the project was proposed in the early stage of the project by the author of this thesis (in 2008), combining existing theories from IDE/TU Delft (Hoog & Boeijen., 2008) and well-known methods from BME (King & Fries, 2009). See Figure 5.7. In particular, the identification of design factors was emphasised in this approach.

Figure 5.7 shows the proposed approach, which includes five steps, plus an optional step:

- (0) Literature analysis and market survey. This step is optional. Industrial designers or biomedical engineers may invest time in a literature analysis to identify design factors, but this is not conditional in this approach.
- (1) Initial prototype development. Based on existing products on the market, a first-generation prototype system (version 1) should be built within a short timeframe.
- (2) Context study, user test and prototype test. Using the first generation prototype system (Version 1), research activities to identify design factors should be launched through a context study and user test.
- (3) Design factor identification. After analysing the data from step 2, a list of design factors should be generated that may include also explanations of these design factors.
- (4) Create a new specification. The outputs from step 3 should result in a new design specification.

(5) Re-prototyping. A new prototyping system (version 2) should be created according to step 4.

After this an iteration from step 2 will start if needed.

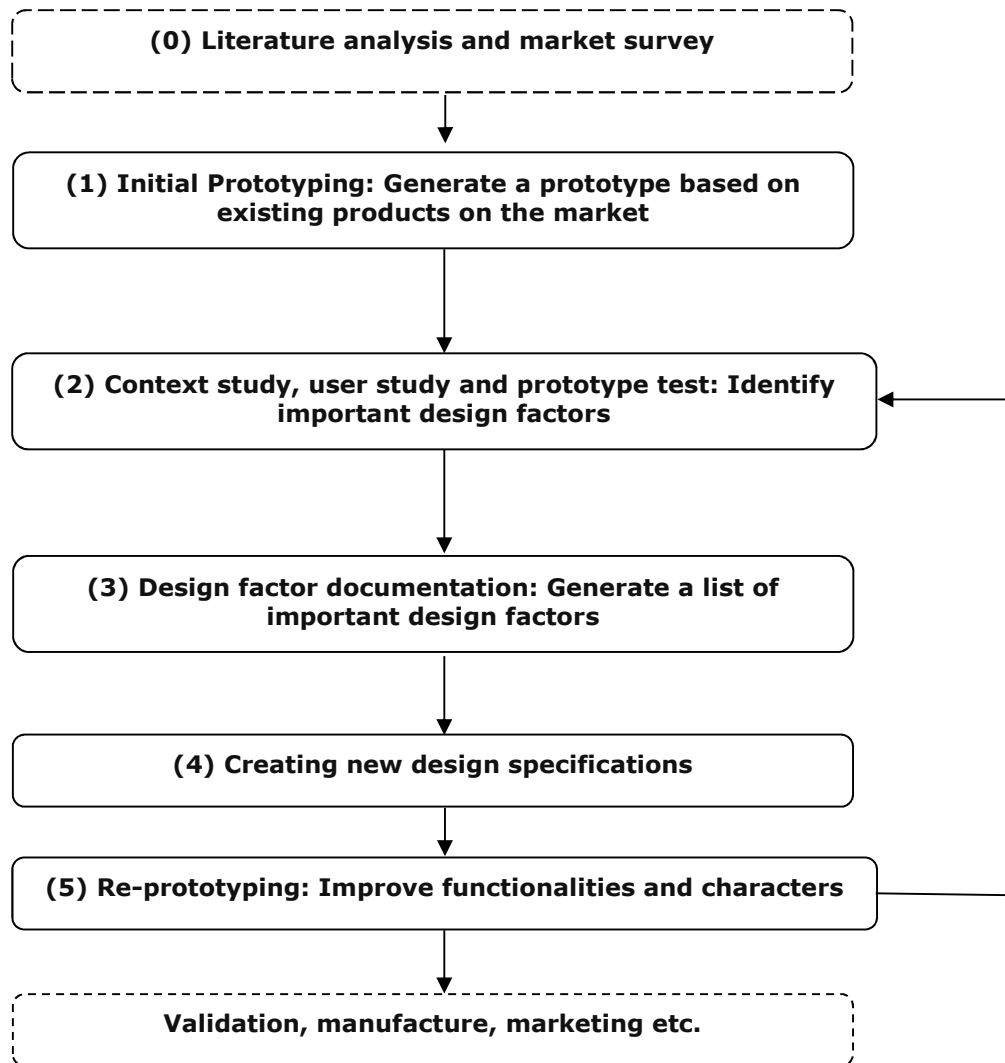


Figure 5.7: The proposed approach to identifying important design factors in DIMRC by combining approaches from industrial design (from IDE/TU Delft) and biomedical engineering. In this approach, the R&D team can increase or decrease the iterations of prototyping times according to the available time, demands and financial constraints.

B. Project development and implementation

The proposed approach was used in the case “Development of a blood pressure monitoring system incorporating ICT”, which involved several design activities.

B.1. Step 1: Initial prototype development

The initial design idea was based on existing blood pressure monitoring systems on the market (Jiang et al., 2007 and 2008), and included three domains (see Figure 5.7):

- **User domain:** The system comprises a wearable measurement device and an information receiver terminal. Patients should be able to measure their BP values independently via a wearable wrist device. Data is to be transferred automatically to a data server in hospital real time, where it would then be analysed at a server terminal, and if necessary, a Short Message System (SMS) alarm is sent to the user's mobile phone or a voice alarm to a fixed phone number or e-mail address. The data would then be stored in the server terminal for manual analysis by the general practitioner.
- **Channel domain:** The Global System for Mobile Communications (GSM) network was chosen as the wireless transmission channel and the Digital Subscriber Line (DSL) was chosen as the wired network.
- **Server domain:** The medical staff in the hospitals are in charge of BP data management and analysis. The communication modem and database were designed for them. At the same time, the server terminal can be connected via the Internet to specialist at the larger hospitals (Physicians with MD degrees and more than five years clinic experience), who are able to give advice if needed.

By using this system, BP measurements are automatically delivered to a server at certain times throughout the day, set by a responsible physician and depending on the patient's situation. The doctors in the Community Healthcare Centre are able to observe the data from the server and analyse the results (such as BP trend analysis) for every patient through dedicated software (to be developed). If a medical problem occurs, e.g., should a patient's BP rise to unacceptable levels, feedback would be sent to the user terminal (patient) and the database server.

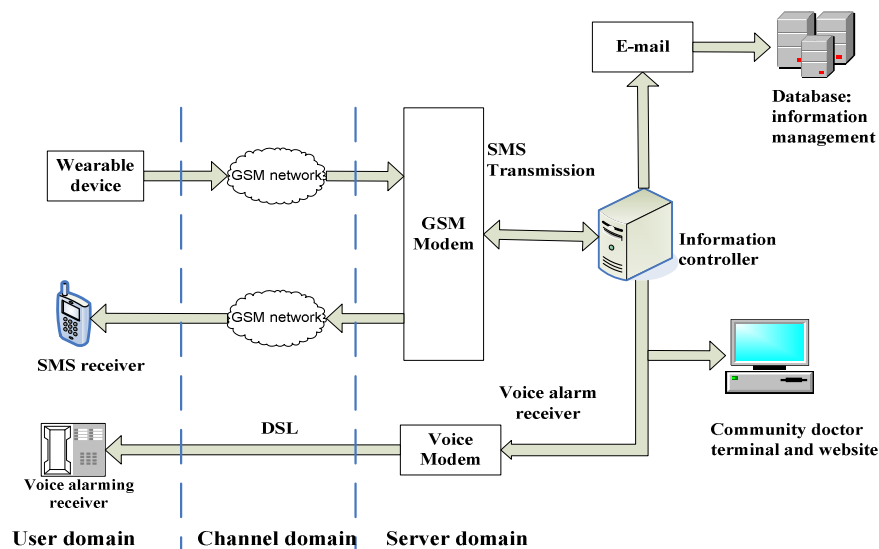


Figure 5.8: The systemic framework of the design proposal for a Blood Pressure monitoring system for underserved Chinese (Version 1) (Source: Jiang et al., 2010b).

Based on this concept, a prototype system (version 1) was built in May 2009 using several existing hardware and software interfaces, which were integrated into the prototype system. In version 1, “Omron HEM—1000” was chosen as the measurement device, a USB flash drive was used to store BP values every day in place of the GSM module, and a database from a previous project (Jiang et al., 2007 and 2008) was used as a temporary server unit.

B.2. Step 2: Context and user study

Using the prototype system (version 1), the research team set up three research activities in a context study that ran from June to August 2009, which included:

- Expert interviews: Four ICT and hypertension experts from medical organisations and companies were interviewed. Their comments were recorded.
- User needs research: Thirteen patients of the Daning community health centre (Shanghai) were invited to take part in a questionnaire about user needs. The data from questionnaire was recorded.
- User test: Three patients and one medical staff member were involved in a six-week user test, simulating actual use in a real context after a coaching session. Their comments, suggestions and questions during the test were recorded and analysed.

B.2.1. Interviewing experts

In June 2009 one hospital, one community health centre and one healthcare company in Shanghai (China) were visited, and four experts were interviewed. The purpose of interviews was to garner information about design factors that are relevant to this pilot project. These interviewees were as follows (see Table 5.7 for an overview of the questions):

- Interviewee 1 (I1) – a hypertension expert from Ruijin Hospital. In the interview he described his experience in hypertension management and offered several suggestions on socio-technical systems for our system.
- Interviewee 2 (I2) – an ICT-supported healthcare designer and engineer with 20 years of experience in Company KingStar Winning (a leading telemedicine provider in China). In the interview he provided input on the technical factors that are important in a BP project, mentioning the suitability of a MySQL database as the workstation in the system due to its free source code and its ability to connect with other databases in a hospital.
- Interviewee 3 (I3) – the director of the Community Healthcare Centre (CHC) in Daning, Shanghai. In the interview he described the current status of hypertension monitoring in CHCs and the administrative

perspective that CHC used in clinics. He also made comments and suggestions related to the BP project.

- Interviewee 4 (I4) – the director of the Hypertension Department of Ruijin Hospital. As an expert in hypertension prevention and treatment, the respondent provided detailed professional information about hypertension measurement standards and conditions, public health policy and future plans in China.

Table 5.7: Overview of the interview questions:

Item	Question	Interviewed expert
1	Is it necessary to introduce collected data into the existing electronic medical report systems in this project?	I1
2	What kind of health information is needed in this project?	I1
3	In your experience, what kind of problems may occur with the introduction of this system into the existing Hospital Information System (HIS)?	I1
4	What kind of additional function is needed?	I1, I2
5	For how long is medical data stored usually?	I1, I2, I3
6	What kind of analysis function is needed in this system?	I1
7	What are the scenarios (target customers) and business models for such projects in your company in China?	I2
8	What are the important factors in maintaining the system?	I2
9	How would system administrators be trained?	I2
10	What are the important parameters for blood pressure measurement?	I3
11	What are the environmental and accuracy demands in blood pressure measurement?	I3
12	What is the battery requirement for such a measurement device?	I3
13	How can CHCs benefit from this kind of project?	I3
14	Does your CHC have an electronic medical report system? How does it work?	I3
15	What are security requirements for the transmission of measurements and data?	I3
16	How do you share medical information with big hospitals?	I3
17	Is this system feasible for your CHC?	I3
18	Could you please provide some comments and suggestions regarding this system?	I4

B.2.2. Questionnaire for patients

A total of 13 patients were invited to the community healthcare centre in Daning to fill in a questionnaire of ten questions on 16 June, 2009.

The questionnaire was compiled based on the comments of experts (See textbox 5.2 in the result section of this sub-study). For example, I3 made the comment “You should understand how much patients are willing to pay”,

which was reflected in the question “*What would you consider an affordable price for such a system?*” (For details of the questions and answers, see textbox 5.3). The questionnaire was given to the respondents after a ten minute introduction to the prototype system.

B.2.3. Coaching session

A user test for the prototype system was carried out between June–August 2009. Before user testing the prototype system, the participants were given training in its use.

B.2.3.1. Training of patients

The patient training session was held at the community healthcare centre of Daning on 25 June, 2009. Three patients from Daning volunteered to take part in the user tests, and each was provided with a prototype of the wearable device, which contained measurement and data transmission modules (See Figure 5.8). In the training session, the participants were given a ten-minute demonstration of how to operate the device, and key instructions were illustrated. A list of these key instructions (see textbox 5.1) was printed as a guide for the participants to take home.

Each participant received personal training. At the end of this session they left their contact information (home address, home and mobile phone numbers) so that they could be monitored.

Textbox 5.1: Operating instructions for the wearable device given to the patients to take home.

Start	
Wear the device on the wrist	
Tie the bandage	
Switch on the device	
Measurement posture	
Sit	Sit, put hands on knees, keep body straight, without backrest
	Sit, put hands on knees, keep body straight, with backrest
	Sit, put hands on desk, keep body straight, without backrest
	Sit, put hands on desk, keep body straight, with backrest
Lie	Lie on your back, hands by your sides
	Lie on your side, hands on the top of the body
Stand	Stand up straight, hands by your sides
	Stand up straight, raise hands to the heart position
Limited exercise	Stand up straight, hold bags in both hands
	Writing and typing in an office while seated
Exercise	Walk (80–90 steps/minute)
	Brisk walk (2 steps/s)

Canter (2.5 meter/s)
Mop or sweep the bathroom
Shadowboxing

Maintaining the Device

Gas pump control (patients can choose for themselves when to measure their blood pressure during the day)

Change battery (#7 dry battery was used in the prototype)

Information upload (The SMS system was not working in the prototype, so the patients were required to upload their BP information via the internet)

Finish

Switch off the device

Take off the device

B.2.3.2. Training of medical staff

Training in how to operate the server domain was given to one member of medical staff in the meeting room of Ruijin Hospital on 26 June, 2009. The doctor from the Chronic Disease Department at the hospital volunteered and was shown how to operate the server system on a number of frequently-used tools, such as a laptop computer, a mobile phone or a Personal Digital Assistant (PDA) (See Figure 5.9).



Figure 5.9: Training a member of the medical staff to operate the server using two different tools (Version 1) (Source: Jiang et al., 2010).

In this training session, the doctor was invited into the room, and was requested to carry out several tasks. The task flowchart used in the training session is shown in Figure 5.10. In total, training was given for 40 activities on the flowchart.

B.2.3.3. User test

All three test subjects were asked to wear the device (version 1) during their regular life from 27 June–7 August, 2009. The measurement times were set at 8:00, 14:00 and 20:00 every day, during which only actions from textbox 5.1 were allowed, with no strenuous exercise. One researcher visited the patients every evening to collect the measurement data (by means of a USB flash

drive), and was in charge of inputting the data into the server (For this pilot system, the server was set up in Shanghai University).

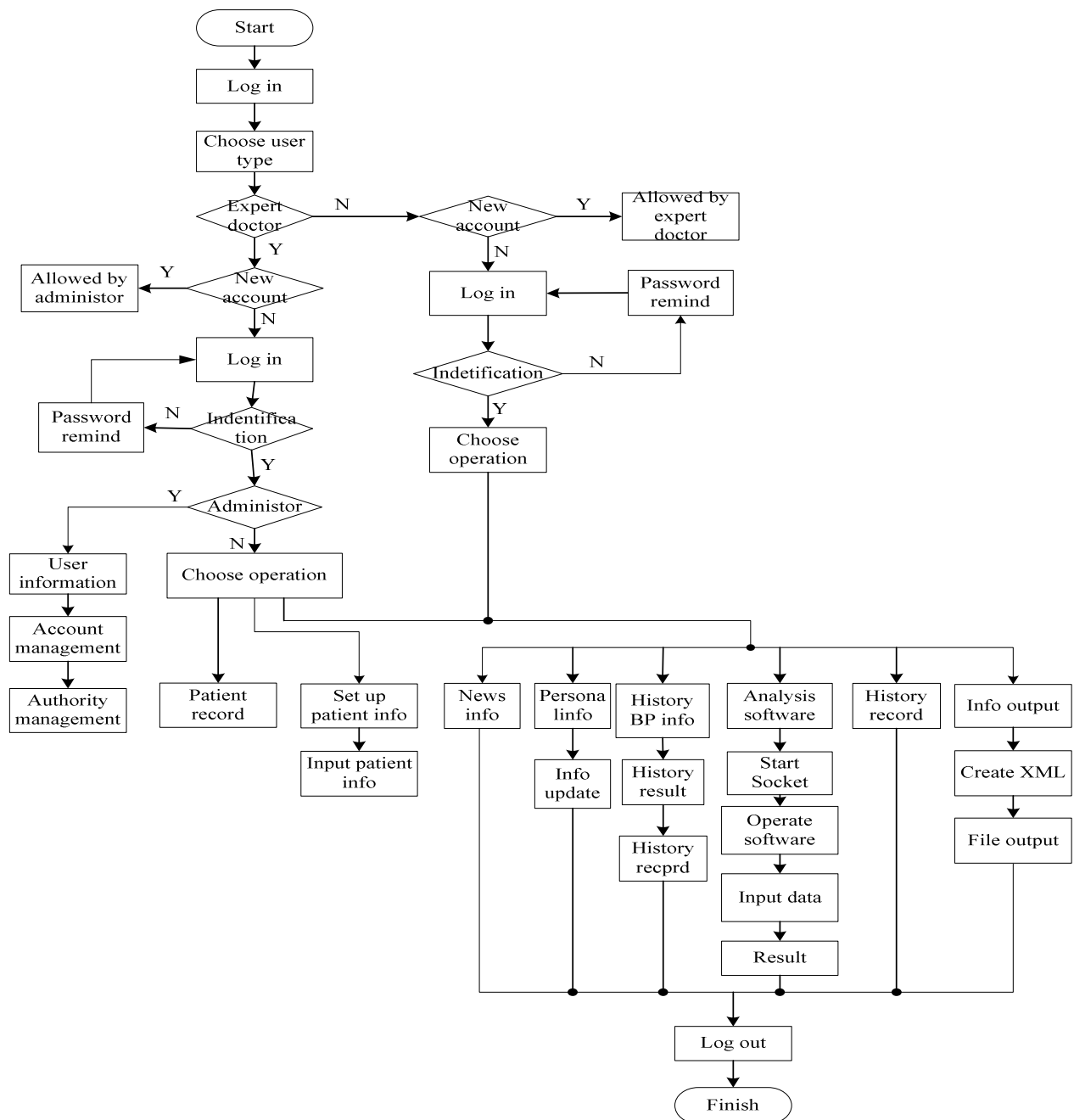


Figure 5.10: The system flowchart for medical staff in the server domain (Version 1) includes 40 operation steps. (Jiang et al, 2009)

The volunteer doctor was asked to check the data at the server unit in the evening each day (after 21:00) or in the morning of the next day. When he found any problem in the BP data of a patient, he recorded his suggestions for the respective patient on the website, and an SMS message was sent to the patient via the server.

The four participants (three patients and one doctor) kept in contact with the researchers to report any problems encountered every day, and their complaints, comments and questions about the system were all recorded.

B.3. Step 3: Design factor identification

The third step of Figure 5.5 is to identify design factors. In this step the researchers from IDE/TU Delft summarised data, identified several key words and generalised design factors. For the summary of data, a “laddering approach” (Burchill & Fine, 1997; Fung et al., 1998; Stufflebeam and Webster, 1980; Chen et al., 2003; Reynolds & Jonathan, 1988;) was applied, being a well-known checklist approach in industrial design that has been applied, for instance, in “Rozenburg’s design cycles” (Hoog & Boeijen., 2008).

Following this approach, data from the interviews with the experts, questionnaires and specification identification were analysed in three steps:

- (1) Gathering all relevant information: All of the outcomes from above sessions (see results section) were recorded, and summaries were made for each part.
- (2) Directing/labelling: Important terms were labelled as “key words or phrases”. For example, one expert mentioned that “Patients consider the comfort of the product in operation”, leading to “comfortable operation” (see results section) being identified as a key phrase.
- (3) Decomposing/classifying: The terms from the previous step were listed and explained in this step. Their depth can be treated as an indication of the complexity of the requirement, also known as elucidatory depth.

B.4. Step 4: Create new specifications

With the identified design factors, new design specifications were established by the research team.

B.5. Step 5: Re-prototyping

A new prototyping was built (Version 2) according to the new specifications.

B.6. Context study, user study and prototype test (Step 2 in the second iteration)

Context and user studies for the second prototype system (Version 2) (in the second iteration) were carried out at the end of 2009.

B.6.1. Laboratory test

A laboratory test targeting technical issues with the second prototype system (i.e., the precision of the measurement device), was carried out. In this test an experimental system was developed that included five elements: 3-V digital power device (with the same two rechargeable batteries), digital oscilloscope, mercury manometer, gas balloon pump, and the PCB board of the

measurement device. Four groups of standardised BP values were chosen (each 30 times) as inputs of the experimental system: 80 mmHg/50 mmHg (SP/DP), 100 mmHg/65 mmHg and 120 mmHg/80 mmHg. All data from the experiment was collected and analysed statistically. For more details of this laboratory test, see the publication (Jiang et al., 2012).

B.6.2. Field test

The new prototype system was tested, again in Daning, Shanghai, at the end of 2009, using the same participants as in the first round of the field test (three patients and one doctor). The participants used the new measurement device for one day, after which they were posed two questions:

- (1) In what ways is the Version 2 system an improvement on Version 1?*
- (2) What improvements are still needed for Version 2?*

All interviews were recorded on video, and the answers, which were in Chinese, were summarised and translated into English by the author.

C Project evaluation and reflection

A meeting was held in April 2010, attended by end-users (patients and doctors), and representatives from external academies, industrial sponsors (Phillips) and government offices, during which the research process (including the approach to identify design factors), the quality of the prototype system (Version 2) and the scientific output (patents, scientific journal articles and conference papers) were evaluated.

5.4.3 Results

In this section the results of “project development and implementation” and “project evaluation and reflection” are presented.

B. Project development and implementation

B.1. Step 1: Initial prototype development (Version 1)

The initial prototype system has been described in section 5.4.2.B

B.2. Step 2: Context and user study

B.2.1. Outcomes of experts’ interviews

Textbox 5.2 presents a summary of the four interviews.

Textbox 5.2: Summary of answers from interviews with experts.

I1:

I think it is necessary to include this kind of system into existing Hospital Information Systems (HIS). SMS can be a useful platform for the sending of information about Blood Pressure. I suggest you use XML as the data type for commercial usage, because it is recognised by most HIS.

In my opinion, additional functions are necessary, such as a time display and a calendar. For medical usage, it is better to store data forever. I don't think a Website is the most appropriate means of access for rural people.

I2:

XML is a frequently used language in server systems, as it can be used to give the highest priority to data security. MySQL should be chosen for the database because it is free and is frequently used in HIS.

On the technical side, a Microsoft .NET framework could be used in the software development of the server domain; and as data security is an important issue in software development, a technical standard like Service-Oriented Architecture¹⁵ may be selected to achieve the required data security.

I3:

Mistakes may occur during BP measurements from the wrist, especially during exercise, which makes the measurements unreliable. In such situations, we often wait ten minutes before measuring again. The measurement time of 30s to 1 minute is too short. Comfort in wearing is an important factor for patients. A dynamic measurement approach is often used in clinics. Usually, Blood pressure values need be measured at least three times per day: in the morning, noon and evening. There are two values that are important in the measurement: Systolic Pressure value (SP) and Diastolic Pressure value (DP), which are recorded by the patients.

An alarm system is necessary, using either SMS or voice messaging.

An acceptable margin of error during measurement is 4-5mmHg. Environmental effects such as temperature may affect the accuracy of the measurement.

The choice of battery should take into account price and durability. Additional functions, such as a time display, will add to the value of your system.

Every community health centre has its own database, however a network between them is lacking.

The business model should include local government, industrial companies and users. Users may pay a service fee if they think it is affordable. Our health centre can benefit from government investment. This idea is feasible for implementation in our health centre.

I4:

All monitoring systems need to be certified every two years. Training for users is necessary to help them use this system.

Currently, the central Chinese government is promoting community healthcare. The Internet is considered as a potentially suitable platform, in that it makes the system flexible through the addition of new functions.

Comments

Understand what kind of alarm would be preferred by patients. (I1)

Understand what the patients consider is affordable. (I2)

Understand the role of the patients in the measurement. For example, do they want to know the measurement results? Do they like to choose when to carry out measurements? Do they need any additional functions? (I3)

Understand the medical awareness of patients in issues such as privacy. (I4)

¹⁵ In software engineering, Service-Oriented Architecture (SOA) is a set of principles and methodologies for designing and developing software in the form of interoperable services.

To conclude, the design team summarised the seven main issues that arose out of the field test:

- The physical infrastructure of community-based monitoring is weak in the case study area. While the idea is feasible, many challenges (e.g., a server in CHC) need to be overcome for the realisation of the project.
- Involving different tiers of medical organisations in one platform is challenging, as many have their own Health Information System (HIS). This makes the project very complex.
- The ICT training and education of medical staff is an important issue in the project, and online training may be difficult (To date, the most efficient approach has been via a face-to-face approach).
- The system should be affordable.
- The reliability and durability of the system should be considered.
- Medical ethics should be considered in the system.
- Compared with other measurement sites, such as the upper arm, BP at the wrist is influenced a great deal by body posture.

B.2.2. Outcomes of patient questionnaire

Textbox 5.3 presents the results of the questionnaire given to the patients. The questionnaire comprised two parts: Seven basic questions (Q0) and ten research questions related to requirements (Q1-Q10). The outcomes from this section provide additional indications of the design requirements of the patients. For instance, most participants chose their landline telephone (almost every house has at least one fixed landline phone) as the preferred means of alarm, meaning that a future study to improve voice quality is needed.

Textbox 5.3 Questions and answers from the patient questionnaire (in total 13 participants).

Q0.1: What is your gender and age?

6 male and 7 female; 3 were <50; 8 were 50–70 and 2 were >70.

Q0.2: What is your monthly income?

2 earn <1,000 RMB; 11 earn 1000–2000 RMB.

Q0.3: How long have you had hypertension?

Of the 10 hypertension patients, 2 said <5 years; 6 said 5–20 years and 2 said >20 years. Three had no history of hypertension.

Q0.4: Do you usually use SMS?

The 7 working patients use SMS regularly; the 6 retired people do not.

Q0.5: What is your education level?

6 said >high middle school; 6 said middle school and 1 said <middle school.

Q0.6: Do you have a blood pressure meter at home?

7 have a BP meter at home; 5 own electronic devices; and 2 own mercury sphygmomanometers.

Q0.7: How often do you measure your blood pressure?

3 said 1–3 times per week; 3 said every two weeks; 4 said they only measure BP when they feel ill; 3 said they never measure their BP.

Q1: What kind of alarm would you prefer, if given the choice? (a. Device alarm, b. Fixed

phone alarming; c. SMS)

5 chose a device alarm; 8 chose phone; 1 chose SMS.

Q2: Would you like to decide for yourself when to take your measurements? (a. Yes, b. No, c. I don't care)

46 percent chose option *a.*, 54 percent chose option *c.*

Q3: Should we develop an automatic measurement device? (a. Yes, b. No c. I don't care)

46 percent chose option *a.*; 54 percent chose option *c.*

Q4: What kind of the security level would you prefer? (a. Private; b. Semi-public; c. Public)

6 chose option *a*, 2 chose options *b* or *c*; 5 did not care.

Q5: How would you like to recharge the battery? (a. Dry battery; b. rechargeable battery; c. I don't care)

8 chose option *a*, 2 chose option *b*; 3 chose option *c*.

Q6: What additional functions would you like? (a. None; b. Heart rate measurement; c. time display; d. Calendar)

5 chose option *a*, 2 chose option *b*, 7 chose option *c*; 1 chose option *d*.

Q7: What is an affordable price for the system? (a. free or <100RMB; b. <200RMB, c. <300RMB; d. <500RMB; e. <1000RMB; f. I don't care)

8 participants said they would like to see a price of between 300 and 500 RMB (50 Euros), 2 chose option *c*; 1 chose option *a*.

Q8: Would you mind paying SMS fees for BP monitoring?

(a. Yes; b. No)

11 chose *a*, 2 chose *b*.

Q9: Would you mind paying maintenance fees for the system? (a. Yes, b. No)

6 chose *b*, as long as the cost was reasonable; 7 chose *a*.

Q10: Do you think this kind of system will affect your life physically and physiologically?

(a. Yes, b. No, c. I don't care)

54 percent of participants worry about the influence of the wearable measurement device on their daily lives, 46 percent do not care.

After analysing the above data, the design team generated twelve initial findings:

- Most patients go to CHC/CHP (Community healthcare point) to have their BP measured.
- Both electronic meters and mercury sphygmomanometers are used at home.
- Most of the retired patients would prefer to be given an alarm by landline phone, because they rarely use SMS.
- Most of the participants would want to receive measurement results directly and more diagnosis information through this system.
- Five participants want dedicated devices (only for BP measurement), while eight participants expressed a desire for additional functions.
- Six participants suggest that the time of measurement should be decided by the patients themselves.
- Six well-educated users (>high middle school) were concerned with information security, while the users with lower levels of education (<high middle school) were not (Combining Q1-10 and Q0.5).

- Eight participants stated a preference for rechargeable batteries that needed charging once a week.
- All participants stated a preference for simple operation interfaces, such as one button operation.
- 100–200RMB (10-20 Euros) was considered an affordable price for the measurement devices by most of participants.
- None of the participants objected to paying SMS fees, but would like to see a maximum fee of 10RMB/month.
- Eight participants were concerned that their lives would be affected by the system.

B.2.3. Outcomes of user test (in the first iteration)

Textbox 5.4 presents a summary of the major complaints, questions and comments from the participants during the six-week test period. The list has been compiled from conversations by phone and e-mail.

Textbox 5.4 Summaries of complaints, questions and comments from the user test (P: Patient, D: Doctor).

Complaints

The size of the device is too big, it affects my activities sometimes. (P1, P2, P3)

Measurement takes too long. (P1)

There is some noise during measurement. (P2)

It is not solid enough. The casing broke. (P2)

I don't like the colour. I like red. (P3)

Sometimes it troubles me, as I can't stop my work immediately to take measurements. (P1, P3)

I don't like the appearance; my grandson says it is ugly. (P3)

Questions

Can I decide on the measurement time by myself? (P1, P2)

Is it possible to show me the Blood Pressure values? It would make me more confident. (P2)

Can I record all my blood pressure values so that I can show them to my family? (P2)

Can I meet the doctor working with my case every week? (P1, P3)

Is the measurement correct? I was playing with my grandson this morning when it started to work ... I am afraid something went wrong with the measurement. (P3)

Comments

The website is not fast enough; can you make a faster system? How about making a system for my iPhone. (D)

Make the measurement device like a watch. Add time display. (P1)

Leave the contact information of doctor for me so that we can keep in touch. (P1,P3)

Seven conclusions were drawn from this user test information:

- Three patients were concerned about the comfort of the measurement device.
- Two patients were concerned about the colour and appearance of the measurement device.
- The patients would like to be allowed to contact their doctor.

- All participants said that the device should be a little bigger than a watch, but hoped that it would not affect their lives.
- Patients are concerned about the accuracy of the measurement. They would like to be able to see the values after measurement.
- Patients said the measurement device should be more robust.
- The doctor said that the server system need to be more convenient to access.

B.3. Step 3 Identification of Design Factors

The research group analysed the investigation data, and consequently fourteen key words were highlighted by the design team as important design factors in the project, listed in Table 5.8. The explanations of these factors come from expert interviews [1], a questionnaire applied to thirteen patients [2] and a context study [3].

Table 5.8: Explanations of design factors in the Blood Pressure monitoring case (F: Design factor: [1] outcomes from experts' interviews; [2] outcomes from patients' questionnaire; [3] outcomes from user test).

Item	Design factor	Explanation
F1	Comfortable operation	User comfort in the operation of the system, that it will not (or seldom) affect their lives either physically or physiologically [1,2,3]
F2	Reliability	The ability of the system to perform and maintain its accuracy in routine use [1,2,3]
F3	Low cost/price	The price paid by users should be affordable in relation to their income [1,2]
F4	Accessibility	The extent to which the system is accessible by the users [1,3]
F5	Durability	The ability of the system to endure in different environments [3]
F6	Ease to operate	Simple operation systems and interfaces with which the users can operate the system [1]
F7	Flexibility	The ability of the system to be adapted when external changes occur, such as integration with existing HIS [1]
F8	Personal preference	The unique way in which individuals act or behave when operating a system [3]
F9	Technical feasibility	Technical factors different to related functions, such as data management, transmission [1,2,3]
F10	Appearance	User perception of the appearance of the product, such as size, colour and style [1]
F11	Expandability	Ability to allow new functions to be added [2,3]
F12	Privacy	Security of medical data in the process of management and transmission [1,2]
F13	Measurement standard and policy	Using a standard for measurement that is recognised by experts and organisations [1]
F14	Direct communication	Direct interaction between patients and doctors [3]

	with doctors	

A graphical representation of above design factors with a three layered structure is shown in Figure 5.11, as the principle result of the project concluded by the author.

- The first layer is the “system level” – in this case, a “BP measurement system”.
- The second level, called the “facet level”, comprises three parts: “product-related”, “user-friendly” and “Economic adaptation”. This classification is based on the three constructs mentioned by Rithey (2009) (see section 4.1).
- The third level is the “verbatim level”, in which design factors are presented.

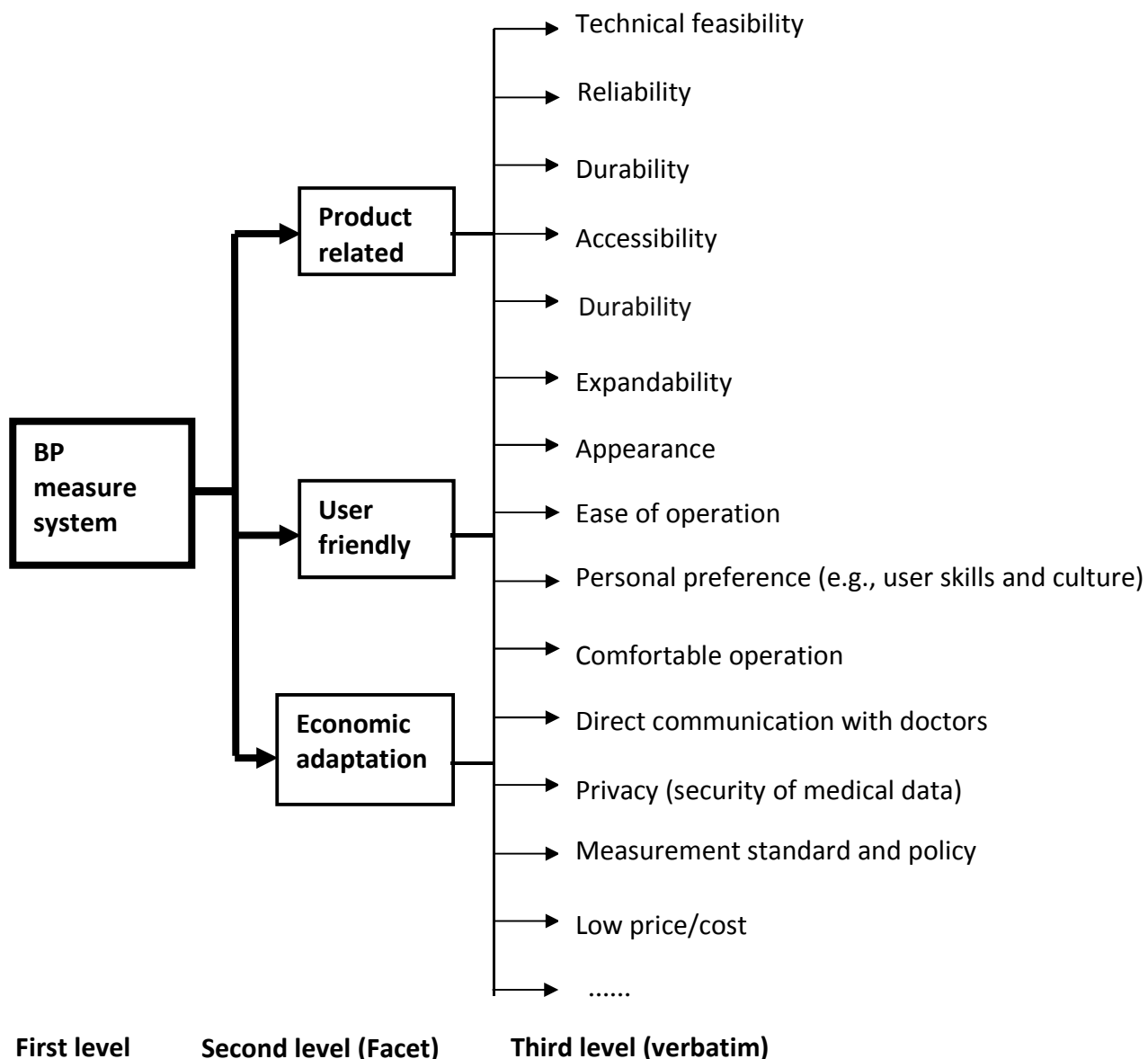


Figure 5.11: Graphical representation of laddering for a Blood Pressure monitoring system.

B.4. Step 4: New design specifications

Table 5.9 shows the design specifications of Version 2, their descriptions and the related design factors.

Table 5.9: Design specifications, their descriptions and the related design factors in the case “Development of a blood pressure monitoring system incorporating ICT” (Version 2. Source: Project report)

Design specification	Descriptions of design specification	Related design factors (from Table 5.8)
Alarm preferences for design target group	Software installed on a PC that allows medical staff to set up different alarm preferences for different patients	F1, F2, F8
Voice alarm	Voice alarms sent automatically to patients via landline or mobile phone, controlled by the system server	F9
Short Message Sending (SMS) alarm	Based on user preference, an SMS message can be sent to users automatically	F4
Measurement adjustment with action status	The protocol in the measurement device can calculate the body posture	F13
Data storage and transmission using XML language	Server software can transfer data into XML format and store it automatically	F11
Coding and Encoding	Coding and encoding SMS information using a special protocol	F9, F13
Software analysis	Analyse BP signals and estimate trend for the following week	F6, F8, F9
Patient access to the database	Patients are authorised to access the database (website) via the Internet on a PC or mobile phone	F6, F7, F14
Feedback	The sever sends feedback to patients by e-mail every day	F12, F14
Battery	Rechargeable batteries as the power source of the measurement device	F3,F5
Interface	Data transmission between the sever and an external device	F8,F9,F10, F11
Measurement intermission	Intermission between two measurements can be decided by the system automatically	F1, F13
Heart rate	Heart rate can be estimated through calculating BP signals	F11

B.5. Step 5: Re-prototyping (Version 2)

Based on the above design specifications, a new prototype system, called “iCare-SHU,” was built at the end of 2009. Several technical innovations were implemented in this system, (Jiang et al., 2010b) including a wearable measurement device for patients (see Figure 5.12) that was designed with fewer electronic components (compared to the existing Omron devices), a simplified Blood Pressure Value estimation protocol; and a service workstation with website access (see Figure 5.13).

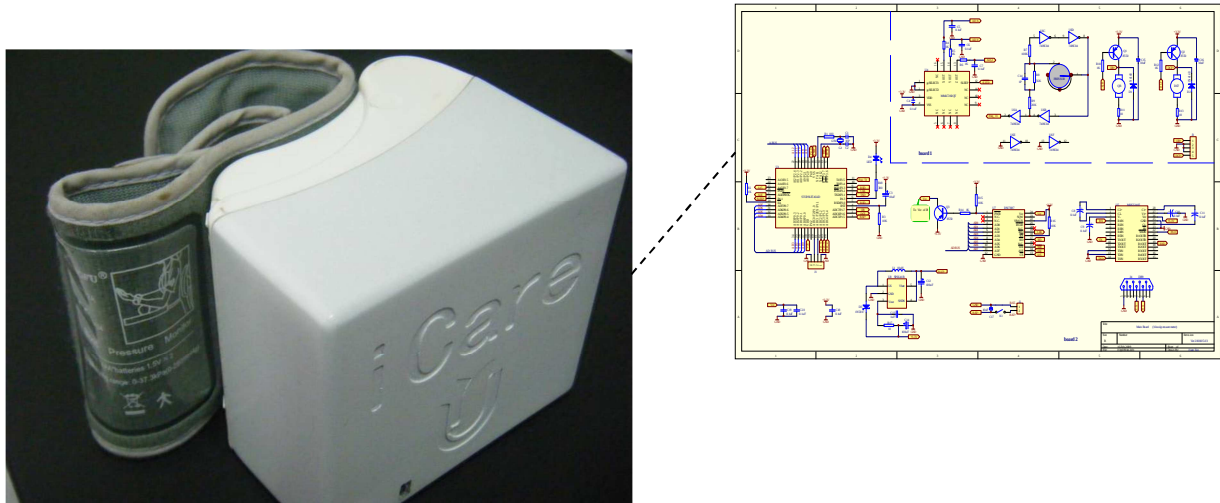


Figure 5.12: The wearable device (user domain) (Version 2)



Figure 5.13: Screenshot of the website for medical staff (Version 2), which shows the values and the trend analysis of the patients' blood pressure

B.6. Context study, user study and prototype test in the second iteration

B.6.1 The laboratory test

The results of the experiment reveal that the limits of the agreement for blood pressure values was clinically acceptable according to the “Golden Standard”, and so may be considered reliable. For more descriptions of the statistic results, see the publication (Jiang et al., 2010b)

B.6.2 The field test

Textbox 5.5 presents a summary of the answers to two questions from the interviews.

Textbox 5.5 Summary of the answers to two questions from the interviews in the second round field study (P: Patient, D: Doctor).

Answers to Question 1: *In what ways is the Version 2 system an improvement on Version 1?*

The one-button automatic measurement function is very useful. It is easy to operate. (P1, P2, P3)

The wireless data transmission function through SMS is useful. It is easy to manage medical data. (D)

Answers to Question2: *What improvements are still needed for Version 2?*

The original type/size of the design is so big that it is still uncomfortable to wear all the time. A decrease in size is needed. (P1, P2, P3, D)

The system should be an open-loop so that other sensors, such as for ECG or blood sugar measurement, can be added to the system in the future. (P1, D)

Technical optimisation is still needed. There is still some distance between the current prototypes and commercial products. Optimisation should include greater accuracy in BP measurement, increased system reliability (a decrease in device measurement and operation mistakes, and aesthetic improvement. (D)

The textbox shows that all participants provided positive feedback about the functionalities of the Version 2 prototype i.e., all patients were satisfied with the one-button automatic measurement function, and the doctor was satisfied with the wireless data transmission function. The respondents also made suggestions for further improvement in the future, including technical optimisation, a reduction in size of the measurement device, and making the system more flexible for the integration of other sensors.

C. Project evaluation and reflection

C.1 Recommendations on the design process from stakeholders

In the evaluation meeting the company managers and the government representatives were satisfied with the prototype system and gave positive feedback about the design process (Figure 5.7). They commended the fact that the approach integrated complementary elements from industrial design (IDE/TU Delft) and biomedical engineering. For example, one company manager stated, “*Compared to the previous biomedical engineering approach,*

the new approach includes user studies by which biomedical engineers can get feedback immediately to improve the prototypes; and compared to the previous industrial design approach, the prototypes can be used to significantly enrich user studies”.

C.2 Reflections on the teamwork

The stakeholders also reflected on the teamwork in the evaluation meeting. All stakeholders (including the R&D team) agreed that the industrial designers had played a complementary role to the Chinese biomedical engineers. For instance, the biomedical engineering students from Shanghai University mainly contributed to the prototype development, while the industrial design students from IDE/TU Delft mainly contributed to the context and user studies. Consequently, it can be stated that teamwork between industrial designers and biomedical engineers may be useful for DIMRC.

Besides the teamwork between industrial designers and biomedical engineers, external support was also recognised as an important complementary factor in this DIMRC case. The medical guidance group, which included physicians, general practitioners and technical developers, was extremely helpful to the research team, from which it can be concluded that the involvement of such as an advisory team may also be beneficial for R&D teams working in DIMRC.

Concrete proposals for the roles and responsibilities of different R&D team members in DIMRC cases will be given in Chapter 6.

5.4.4 Discussion: Comparison of the design factors from the case study and those of previous studies

A comparison of the design factors from the case study (Figure 5.11) and those of previous studies (Tables 5.1 and 5.5) reveals that most of the design factors from the case study are the same or similar to those in Tables 5.1 and 5.5. For example, the factor of “accessibility” (F4) appeared in both Figure 5.11 and Table 5.5; the factors “comfortable and easy operation” (F1 and F6) are similar to “users’ activities skills” stated by Heeks (2006); factors of “reliability” (F2) and “durability” (F5) are similar to “Usability and interoperability” by Rithey et al. (2009); and factors of “personal preference” (F8) and “Measurement standard and policy” (F13) are similar to “Medical staff and patient characteristics” and “care policy” by Calvin et al.(2009).

Besides the design factors that are the same or similar to previous studies, a number of new design factors were also identified in the case study. For example, aesthetics (e.g. size, colour and style) and emotion (families’ attitudes) (F10) are deemed important in DIMRC, but were absent from previous studies. (e.g., Patient 3 complained that he did not like to wear the device anymore because his grandson did not like the look of it). Another new factor was “Direct communication with doctors”. Chinese patients have a strong trust in their doctors, and considered the care provider to be a main

factor in the selection of a healthcare system. (e.g., in the case study, three patients wanted to be able to speak to a doctor from a big hospital face-to-face every week, as they felt more confident when a doctor talked with them about their health situations).

Hence, the results of the case study have suggested that design factors from previous literature related to other design domains can be used to identify design factors for DIMRC, and that the design research should focus on the collection of suitable design factors from other sources for adoption into DIMRC.

5.4.5 Conclusion

There are four objectives in this sub-study (to answer SQ3–6): (1) To verify whether design factors for DIM (Table 5.1) and DfBoP (Table 5.5) can be used in actual DIMRC cases; (2) to test whether an empirical approach to identifying design factors for DIMRC is appropriate for an actual DIMRC case (This approach combined and adapted approaches from industrial design [IDE/TU Delft] and biomedical engineering [See Figure 5.7]); (3) to identify the key team members of an R&D team in an actual DIMRC case; and (4) to explore the roles of industrial design students from IDE/TU Delft in DIMRC practice. The DIMRC case “Development of a blood pressure monitoring system incorporating ICT” was used as a data source.

The results showed that ***(1) Design factors for DIM and DfBoP can indeed be applied as design factors for DIMRC, but the selection and extension of design factors is needed; (2) The design methodology from IDE/TU Delft can be applied to identify design factors for DIMRC. The “prototyping driven IDE approach” is an example of how approaches from industrial design (IDE/TU Delft) and biomedical engineering can be combined and adapted; (3) Industrial design students from IDE/TU Delft played a complementary role to the Chinese biomedical engineering students in the case study, contributing particularly to the user and context studies. They are expected to play important roles in future DIMRC cases, a detailed descriptions of which will be introduced in Chapter 6; (4) The key team members of R&D teams in the case study included industrial designers, biomedical engineers and medical experts. It is recommended that all be appointed as key team members in future DIMRC cases.***

5.5 Results of this chapter: A checklist of design factors for DIMRC

Based on the results of this chapter, a list of design factors for DIMRC is proposed in Table 5.10, combining the results in Table 5.1, Table 5.5 and Table 5.8. A total of 24 design factors are given in this table, listed in the first column. Explanations of each design factor are given in the second column, recorded from sections 5.2 [1], 5.3[2] and 5.4 [3].

Table 5.10: Design factors for DIMRC and their explanations.¹⁶

Design factors	Explanations
Lifestyle (Jiang et al., 2009)	A characteristic bundle of behaviours that makes sense to both others and oneself at a given time and place, including social relations, consumption, entertainment and dress. [2]
Habit (Heeks, 2006)	User behaviours that will influences design results. [2]
Health awareness (Jiang et al., 2009)	Cognitive reactions to healthcare of the rural population in China. [2,3]
Skills (Heeks, 2006)	Education and ability of patients and medical staff in rural China. [2]
Personal manner (Matinez et al, 2005)	The unique way in which a user acts or behaves when operating a system. [3]
Direct communication with doctors (from the case study)	Direct face-to-face interaction between a patient and doctor. [3]
Business model (from Table 4.5)	The profit-producing system that results in multi-win situations in rural China. [2]
Affordability (Rithey et al, 2009)	The amount of money paid buy users for the solution. [2,3]
Medical Insurance (from Table 4.5)	A form of collectivism by means of which people collectively pool their risk, in this case the risk of incurring medical expenses. [2]
Local economic content (from Table 5.5)	Refers to consumption opportunity gained by an entity within a specified local content. [2]
Social impact and social awareness (Wells & Wells, 2007)	Refers to the processes of analysing, monitoring and managing the intended and unintended social consequences, both positive and negative, of planned interventions (policies, programmes, plans, projects) and any social change processes invoked by those interventions. [2]
Local government (Calvin et al, 2009)	Market rule controller and a potential payer in ICT healthcare solutions in rural China [2]
Product policy (Rithey et al, 2009)	A deliberate plan of action to guide product decisions and achieve a rational outcome [2,3]
Building of the team (Wells & Wells, 2007)	Stakeholders in ICT-enabled healthcare in rural China. [3]
Aesthetic appeal and emotion (from the case)	Acceptance of the features of the products' appearance, such as size, colour and style by families and friends. [3]
Comfortable operation (Rithey et al, 2009)	Comfort in use during the operation of the system, ensuring it will not (or seldom) influence lives physically or physiologically. [3]
Ease of operation (Rithey et	Simple operation of the systems and interfaces by the

¹⁶ As factors sometimes repeat in the three sections, double or overlapping factors were removed, i.e., user behaviour, cost, material and advanced technology. In this table, user behaviour may also be referred to as personal manner, cost may also refer to affordability, advanced technology (here, ICT technology) can refer to reliability, durability, flexibility, expandability, usability, privacy, accessibility and ease of operation, and material (here, material means the materials in the hand of the end-users) can refer to comfortable operation.

al., 2009)	users. [3]
Accessibility (Rithey et al., 2009)	The accessibility of the solution to as many people as possible in rural China. [2]
Reliability (Rithey et al., 2009)	The ability of the system to perform and maintain accuracy in routine use. [3]
Durability (Diehl, 2011)	The ability of the system to endure different environments. [3]
Flexibility (Rithey et al., 2009)	The ease of adaptability of the system in the event of external changes, such as synchronization with existing HIS. [3]
Expandability (Rithey et al., 2009)	The ability to allow new functions to be added. [2]
Usability (Diehl, 2011)	Actions that occur between the user and the solution. [2]
Privacy (from the case)	The security of medical data in the management and transmission processes. [3]

5.6 Discussion for this chapter

In this section, some important lessons learnt from this chapter are discussed.

5.6.1 The benefits of the checklist to biomedical engineers

As mentioned in Section 5.1, biomedical engineers prefer to use checklists from previous literature (e.g., ISO documents) to identify design factors when engaged in medical device R&D projects. The most commonly used checklists are promoted by the International Standards Organisation (ISO). For instance, ISO 13,845 is a quality management standard for the design and manufacture of medical devices. IEC 60,601 standards state the requirements for medical electrical equipment, and IEC 62,304 specifies the standards for medical software. A number of design factors relevant to medical device R&D can be derived from these standards, such as the make-up of the design team, materials, protocol control etc. (Higson, 2002). For example, BS2782-11 (part of ISO 13,845) specifies standards for the design of a plastic piping system for a medical device. The design factors listed under this specific topic include framework (apparatus), pressure control and pressure measurement, which are standards that biomedical engineers are familiar with.

However, problems may occur when biomedical engineers work on an unfamiliar topic, e.g., DIMRC. Most biomedical engineers have only limited time to identify design factors, and so they require a reference checklist at the start of product design. Accordingly, one benefit biomedical engineers may draw from this chapter is that they can use Table 5.10 as a reference list, to be read in conjunction with their familiar standards (e.g., ISO standards); and the list may also be used by other R&D team members.

5.6.2 Comparison of design factors for DIM, DfBoP and DIMRC

Table 5.1 lists several design factors for DIM, garnered from previous literature; while Table 5.5 lists 14 design factors for DfBoP; and 5.10 proposes a list of design factors specific for one specific DIMRC case. A comparison of these three tables reveals some notable differences.

Table 5.11 presents a comparison of the results from Tables 5.1, 5.5 and 5.10. All design factors are proposed as design factors for DIMRC in the last column. By comparing the last three columns, it can be found that (1) two design factors, “local government” and “product policy”, are design factors for DIM, but have not been identified as relevant to DfBoP. (2) One design factor, “local economic content”, is a design factor for DfBoP, but has not been identified as relevant to DIM. Finally, (3) two design factors, “direct communication with doctors” and “aesthetic appeal and emotion” are proposed as design factors for DIMRC, but are not design factors for DIM or DfBoP.

The reason for (1) may be that many local governments in developing countries do not pay enough attention to product development for their BoP populations. As mentioned by Simanis (Simanis & Hart, 2008), NGOs play important roles in DfBoP, but more efforts are expected from local governments, such as devising policies to encourage product design specifically for DfBoP. Many developing countries are failing in this aspect (Amir, 2004).

The reason for (2) might be attributed to the fact that the purchasing power of BoP populations is low. Medical insurance systems are relatively undeveloped in most developing countries, when compared to developed countries. For instance, in India many farmers have to pay part, or even all, medical expenses from out of their own pocket, and for this reason it is important to obtain information about the local economic context, such as the average savings of a rural family, etc., for consideration as a key design factor.

The reason for (3) can be understood from the case study in Section 5.3. It was found that Chinese patients in rural regions were eager to communicate with doctors face-to-face, as rural Chinese patients rarely have the chance to speak directly to fully qualified doctors (e.g., specialists from big hospitals). Their desire to obtain advice directly from skilled doctors led to the addition of “Direct communication with doctors” as a design factor.

Table 5.11: A comparison of design factors for DIM (Table 5.1), DfBoP (Table 5.5) and DIMRC (Table 5.10). ✓ indicates the appearance of the design factor in the respective table. A description of all design factors can be found in Table 5.10.

Design factors	DIM Design and development of ICT-enabled Medical device and system	DfBoP Design for the Base/Bottom- of-the-Pyramid	DIMRC Design and development of ICT-enabled Medical device and system for Rural China
Lifestyle	✓	✓	✓
Habit	✓	✓	✓
Health awareness	✓	✓	✓
Skills	✓	✓	✓
Personal manner	✓	✓	✓
Direct communication with doctors			✓
Business model	✓	✓	✓
Affordability	✓	✓	✓
Medical Insurance	✓	✓	✓
Local economic content		✓	✓
Social impact and social awareness	✓	✓	✓
Local government	✓		✓
Product policy	✓		✓
Building of the team	✓	✓	✓
Aesthetic appeal and emotion			✓
Comfortable operation	✓	✓	✓
Ease of operation	✓	✓	✓
Accessibility	✓	✓	✓
Reliability	✓	✓	✓
Durability	✓	✓	✓
Flexibility	✓	✓	✓
Expandability	✓	✓	✓
Usability	✓	✓	✓
Privacy	✓	✓	✓

The second added design factor was “aesthetic appeal and emotion”. Rural Chinese patients take into account the opinions of their families when deciding whether or not to use a medical measurement device. This design

factor is completely new, having not been mentioned before in previous literature related to rural China. In the case “Providing blood pressure monitoring by ICT”, one elderly patient stopped using the measurement device because his grandson did not like it. The attitudes of other members of Chinese society should also be considered in DIMRC, meaning that it is important to carry out an ethnographic study for rural Chinese users in DIMRC. A deeper description of this factor is given in Section 6.4.6.

5.6.3 Teamwork

Chinese biomedical engineers may benefit from obtaining knowledge from industrial designers (from advanced design institutes) when attempting to identify design factors for DIMRC. As team players, biomedical engineers are used to cooperating with other engineers, such as electrical engineers and mechanical engineers (King & Fries, 2009); however Chinese biomedical engineers have little experience in working with industrial designers. A lesson learnt from the case study of “Development of a blood pressure monitoring system incorporating ICT” was that knowledge from industrial design engineering may complement the skills of biomedical engineers in identifying design factors. For example, industrial designers may offer advice or suggest concepts to biomedical engineers when creating prototypes, as industrial designers have a deeper understanding of user needs; while biomedical engineers may provide suggestions/ideas about the technical feasibility of product concepts before industrial designers launch user studies, based on their deeper technical background. Consequently, it is recommended that Chinese R&D teams include industrial designers (e.g., educated or trained at advanced design institutes) in their number.

5.7 Conclusion and recommendations

This chapter had two objectives: (1) To generate a checklist of important design factors for DIMRC (Design and development of ICT-enabled Medical device and system for Rural China); and (2) to identify possible contributions from IDE/TU Delft to help Chinese biomedical engineering students identify design factors. To achieve these two objectives, three sub-studies were carried out in this chapter. In the first sub-study (section 5.2), a literature analysis was carried out to identify design factors relevant to DIMRC; in the second sub-study (Section 5.3), 14 design factors for DfBoP (Design for Base/Bottom of the Pyramid) were identified through a study of 24 student design projects from IDE/TU Delft; and in the third sub-study (Section 5.4), an DIMRC case “Development of a blood pressure monitoring system incorporating ICT” was analysed to investigate (1) design factors in an actual DIMRC case, and whether design factors for DIM (Design and development of ICT-enabled Medical device and system) and DfBoP can be used in an actual DIMRC case; (2) whether or not design methodologies from IDE/TU Delft can be applied to help Chinese biomedical engineering students identify design factors, and in what ways; and (3) to explore potential roles for industrial designers in R&D teams operating in DIMRC.

Combining the results from Section 5.2, 5.3 and 5.4, a **reference list of design factors for DIMRC was proposed in Table 5.10, which includes the following 24 design factors: lifestyle, habit, health awareness, skills, personal manner, direct communication with doctors, business model, affordability, medical insurance, local economic content, product policy, building of the team, aesthetics and emotion, comfortable operation, ease of operation, accessibility, reliability, durability, flexibility, expandability, usability and privacy.**

The results of this chapter also showed that the knowledge and insights garnered from IDE/TU Delft were useful for Chinese biomedical engineering students in identifying design factors in the specific case “Development of a blood pressure monitoring system incorporating ICT”. At least two conclusions can be drawn: (1) ***Teamwork with industrial design students from IDE/TU Delft was useful in the case; and (2) Delft Design Methodology (DDM) may be adapted (i.e., combined with King’s approach) towards a new approach for Chinese biomedical engineering students to identify design factors.***

Based on the results in this chapter, three recommendations are proposed for the three key stakeholders in DIMRC (Chinese government, academia and companies). Adoption of these recommendations would, in all likelihood, lead to Chinese biomedical engineers augmenting their skills and experience in identifying design factors in the future.

Recommendation 5.1 (for universities and companies): Table 5.10 may be useful as a reference checklist for biomedical engineers to identify design factors for DIMRC. Biomedical engineers are expected to be able to apply these factors in conjunction with existing standards (e.g., ISO standards).

Recommendation 5.2 (for universities): It may be useful for Chinese R&D teams to obtain more support from IDE/TU Delft (or similar institutions) when faced with a need to identify design factors.

Recommendation 5.3 (for universities and companies): External support from a medical guidance group may also be useful, involving physicians, general practitioners, technical experts, etc.

Chapter 6 Exploring design methodology for DIMRC¹⁷

The last chapter contained an investigation and identification of design factors. The focus of this chapter is design methodology. See Figure 6.1.

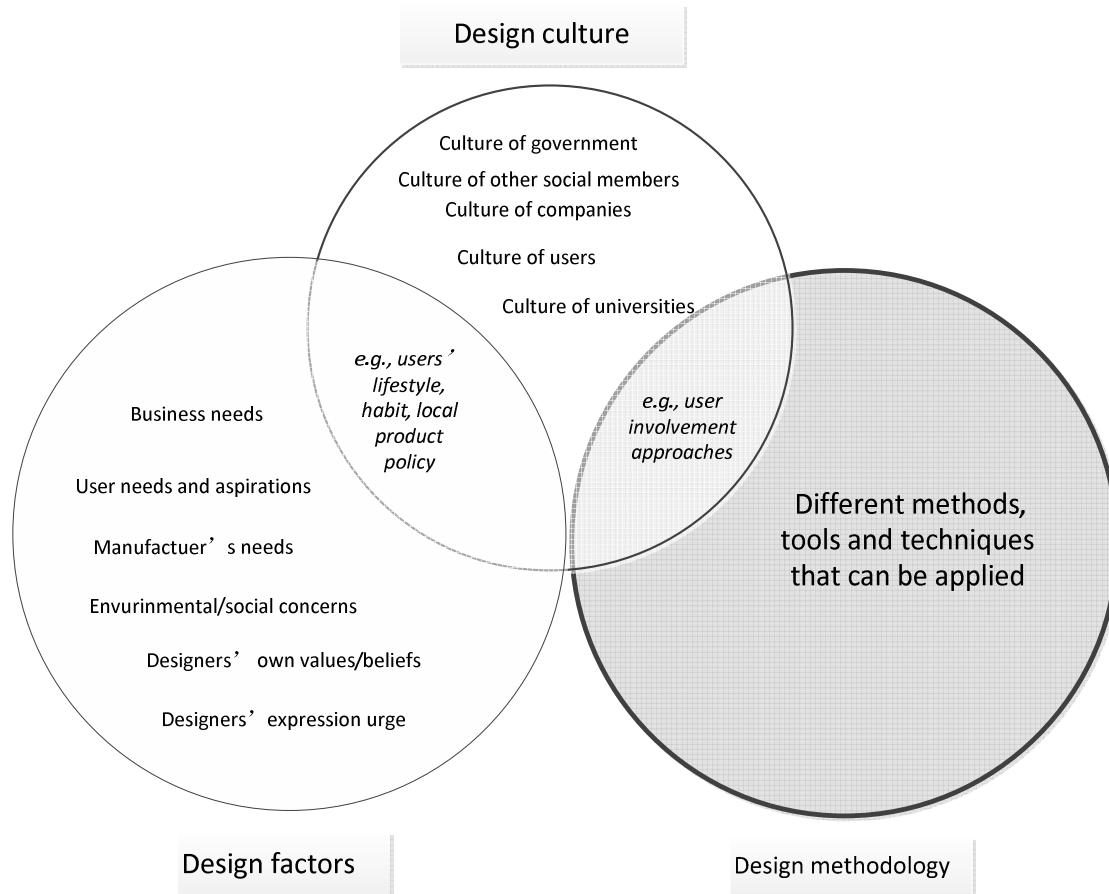


Figure 6.1: In this thesis, three educational areas are investigated for DIMRC (Design and development of ICT-enabled Medical device and system for Rural China); and this chapter focuses specifically on “design methodology” (shaded section). An overlap exists between “design methodology” and “design culture”, in that user involvement approaches, as part of a “design methodology”, are also used for investigating “design culture”.

¹⁷ 本章中文名称：探索 DIMRC 的设计方法。This chapter is based on following publications:

J. Jiang and J. Flexman (2007), Shanghai University club uses technology to fight poverty. Engineering in Medicine and Biology Magazine, IEEE, 26(12):10-11.

J. Jiang & P. V. Kandachar (2009), Four domain model: a new possible innovation model for Design for Base of the Pyramid (DfBoP), ICED 2009, Stanford, USA.

J. Jiang & P. V. Kandachar (2008), New Market, New Challenge, New Opportunity (1) – Overview of China rural healthcare & Design methodology, Proceedings of 30th Annual International IEEE Engineering in medicine and biology Conference, Vancouver, British Columbia, Canada, Page 1579–1582.

J. Jiang, A. Freudenthal & P. V. Kandachar (2009), Exploring insight of user needs, the first stage of Biomedical Engineering design, Chapter 4 in the book “Advanced Biomedicine”, Ed. C.A. Barros de Mello, In-Tech publishing, ISBN 968-953-307-013-1.

6.1 Introduction

6.1.1 Definitions

According to Irny & Rose (2005), a methodology is generally a guideline system for solving a problem, with specific components such as phases, tasks, methods, techniques and tools. Almost every discipline has its own definition of “design methodology”, for example: (1) in semiconductor engineering, “design methodology” is defined as a comprehensive set of specific engineering rules, methods, and procedures that are used to design and implement integrated circuits, subsystems, or systems; (Ref: 1994 National Technology Roadmap for Semiconductors: <http://www.rennes.supelec.fr/ren/perso/gtourneu/enseignement/roadmap94.pdf> [accessed on 16-OCT-2012]); (2) in business management, it is defined as a process by which all possible kinematic chains which have the same numbers of links and joints as the generalised kinematic chain can be synthesised (Yan, 1992); and (3) in product design, it is defined as a systemic process of knowledge comprising the principles, guidelines, best practices and methods relating to product design (Pabini, 2010). In this thesis, definition (3) is used. The term “design methodology” is thus defined herein as follows:

Design methodology is the systemic process comprising design methods that are, can be, or have been applied to product design.

To illustrate with an example, Figure 6.2 shows a possible design methodology for the product design and development of a medical device, which is adapted base on King and Fries (2009). The methodology includes four phases: Research and Development (R&D), qualification and manufacturing, marketing, and sale and retail. There are five sub-steps in the R&D phases. Figure 6.2 shows four linear phases; however the cycle of R&D is iterative.

A design methodology can include multiple design methods, with each applied to various facets of the entire scope of the methodology. In this thesis the term “design method” is defined as follows (Cross, 1999):

Design method is a way of drawing specifications of design solutions that can lead to better design activities.

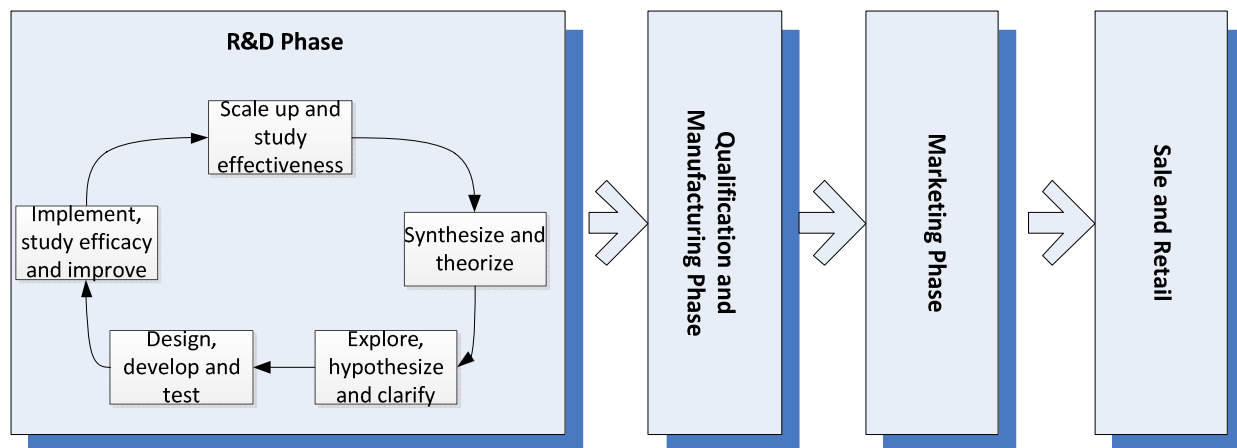


Figure 6.2: A adapted design methodology of product design and development for medical devices based on King’s approach (King and Fries, 2009).

6.1.2 Relevant design methodologies from three literature domains

In Chapter 3, three literature domains relevant to DIMRC were identified: Design for Base/Bottom of the Pyramid (DfBoP), User Centred Design (UCD) and ICT-enabled Healthcare Design (DIM). These literature sources contain rich design methodologies in both the UCD and DIM domains; however there is almost no design methodology specifically for DfBoP. This section a literature analysis will be conducted, identifying four design methodology domains from UCD and DIM.

6.1.6.1.2.1 Literature search of design methodologies from UCD and DIM domains

A number of design methodologies that may be relevant for DIMRC have been developed by scholars in UCD and DIM from four different sciences: social sciences, management and economic sciences, product design sciences and engineering sciences. Each has generated its own insights, and these have already been applied by R&D teams in practical DIM cases. To get a view of existing publication, a literature analysis was done. An Internet search throughout in the field of “Design methodologies for ICT-enabled medical device- and system development” was carried out through the search system Google scholar (<http://scholar.google.com/> [accessed on 16-OCT-2012]) and from Year 2000-2010. Following journals and databases were chosen in the literature search: Journal of Medical Internet Research, International journal of medical informatics, Health informatics journal, and IEEE publication database. By reading related journal paper, conference proceedings, and project reports, frequently used design methodologies were concluded. They were divided into four clusters of methodologies.

Table 6.1 provides four clusters of methodologies in these four sciences, including their focuses, benefits and references.

Table 6.1: Clusters of methodologies from four sciences, focus, benefits and references.

Design methodology clusters	Focus	Benefits/Purpose	References
Living lab design methodologies (<i>social scientists</i>)	User-centred design and open innovation, co-creation, exploration, experimentation and evaluation of innovative ideas	• Involvement of users in development/Adapting to local contexts • Community-people partnership • Overcome sustainability challenges	<i>Maritz et al., 2007; Fourie, 2007; Lynne et al., 2002</i>
Entrepreneurial design methodologies (<i>management and economic scientists</i>)	Cooperation between local government and non-governmental organisations (NGO) and local community, Innovations happen in the community	• Consider a community as a target user unit • Win-win sustainable business model • Involvement of multiple stakeholders	<i>Minkler & Wallerstein, 2008; London, 2007;</i>
Holistic system thinking design methodologies (<i>engineers</i>)	Combine knowledge inputs from society, economic, technique and management domains	• Empower business professionals • empower ICT deployment in developmental context	<i>Alter, 2008; Petkov & Petkova, 2008; Andrew & Petkov, 2003</i>
Product design methodologies (<i>product designers</i>)	Develop appropriate socio-technical systems	• Start the study by identifying user needs	<i>Pauhl & Betiz, 1980; Hekkert & van Dijk, 2001; Miller, 2001</i>

The first cluster is about Living Lab (LL) design methodologies, which was initially developed by social scientists but has been increasingly adopted by other scientists and technology developers. These methodologies foster the co-creation, exploration, experimentation and evaluation of innovative ideas, scenarios, concepts and related technological artefacts in real-life use cases. According to Fourie (2007) and Lynne et al. (2002), the main advantage of LL is its multi-contextual sphere in which the co-creation of, for example, an ICT product and service development, takes place. By using design methodologies from the LL cluster R&D teams establish long-term relationships with the inhabitants of the real-world context in a way that will ensure active participation by the latter in the R&D process (Maritz et al., 2007).

Entrepreneurial design methodologies are developed by researchers from economic and management sciences. The concept of this cluster is based on community-based research (Minkler & Wallerstein, 2008), which means that the investigations and implementations of DIM projects are mainly carried out within communities. Cooperation between local governments, non-governmental organisations and local communities is emphasised in these methodologies, which have also been applied for transferring ICT solutions from developed to developing countries (London, 2007).

The third cluster has been devised by engineers: holistic systems thinking design methodologies. The core idea of this is to view “problems” as parts of an overall system, rather than reacting only to a specific part, outcome or event. Without a systems approach there is a risk that solutions may contribute to the development of unintended consequences. (Alter, 2008; Petkov & Petkova, 2008; Andrew & Petkov, 2003)

The final cluster comes from product designers, whose focus is on product and service. Some existing design methodologies include “phase models of the product design process” (Pauhl & Beitz, 1980), “vision in product design (VIP)” (Hekkert & van Dijk, 2001) and the “fish trap model” (Miller, 2001).

6.1.2.2 Design methodologies from IDE/TU Delft

The Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft) has overseen the development of a number of product design methodologies by Cross (1999), Roozenburg & Eekels (1995), Miller (2001), etc.

In this chapter, one particular design methodology from IDE/TU Delft – the Delft Design Methodology (DDM) – has been chosen. The DDM is one part of a design guide called the Delft Design Guide (DDG), which is taught in several bachelor and master student courses within IDE/TU Delft. DDM integrates the design methodologies developed by scholars at IDE/TU Delft in different periods:

- The methodology of Pauhl & Beitz (1980) is from the 1980s, when the main focus of product design research was related to the interaction between human and product (Simon, 1969);
- The methodology of Roozenburg & Eekels (1995) is from the 1990s, when a particular point of focus in product design research was User-Centred Design (John, 1997); and
- The methodologies of Hekkert & van Dijk (2001) and Miller (2001) are from the 2000s, when systemic thinking in combining the user, product and environment was a main factor of concern (Brown, 2009).

A digital version of the DDG is available at:

http://wikid.eu/index.php/Delft_Design_Guide (accessed on 16-OCT-2012)

6.1.2.3 Delft Design Guide

There are three parts to the DDG (Hoog & Boeijen., 2008). The first part presents the definitions and background of DDM. In this part some previous investigations about product innovation processes and product design processes from IDE/TUD Delft are introduced, such as “phase models of the product design process” (Pauhl & Beitz, 1980), “vision in product design (VIP)” (Hekkert & van Dijk, 2001) and the “fish trap model” (Miller, 2001).

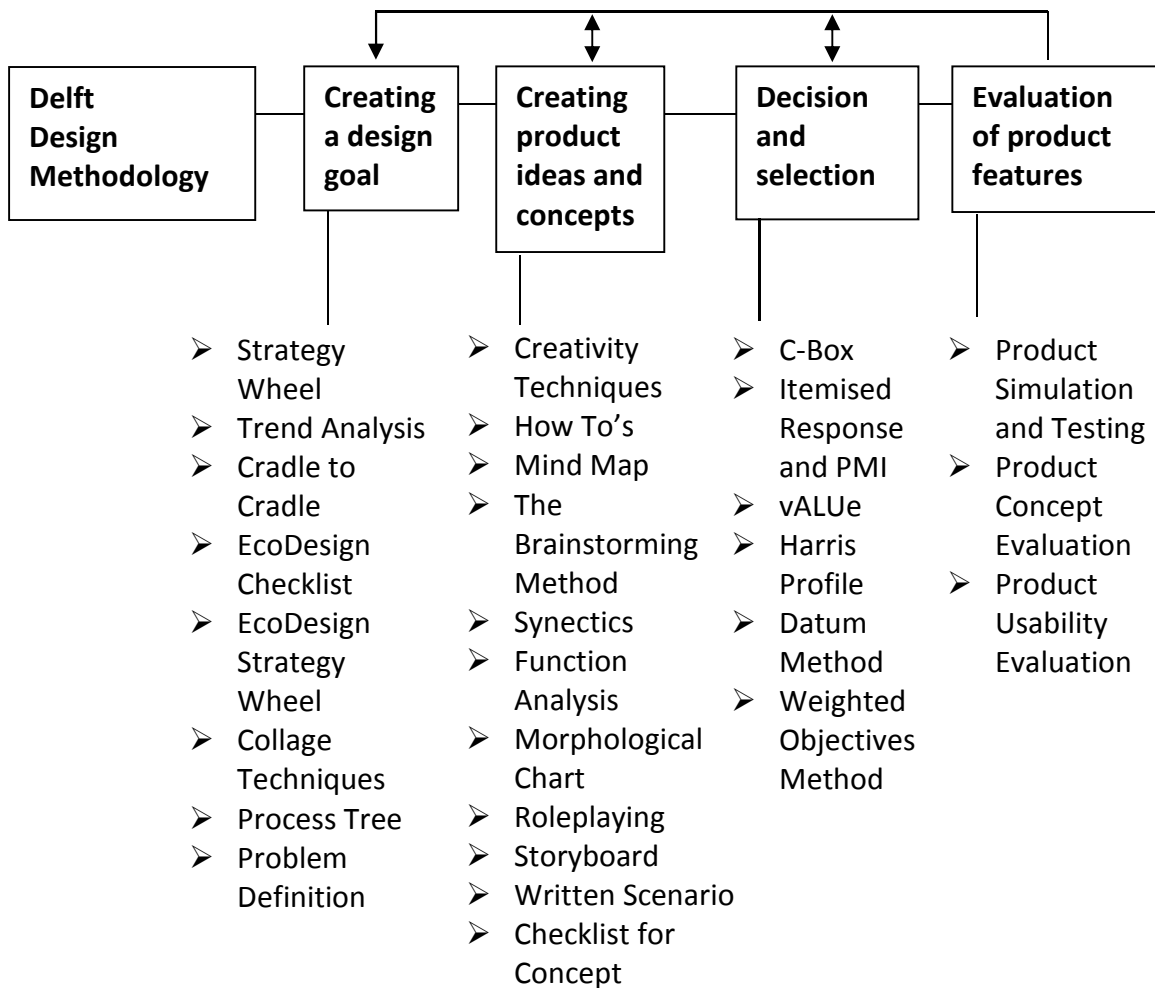


Figure 6.3 The DDM process and some example design methods (Hoog & Boeijen., 2008).¹⁸ This methodology is applied as an “iterative process”, which is composed of four steps: creating a design goal, creating product ideas and concepts, decision and selection, and evaluation of product features. There are several design methods in each step, such as strategy wheel, trend analysis etc. A detailed description of these methods are given at [http://wikid.eu/index.php/Delft Design Guide](http://wikid.eu/index.php/Delft_Design_Guide) (accessed on 16-OCT-2012).

The second part presents a description of the DDM as an iterative process that is divided into four steps: creating a design goal, creating product ideas

¹⁸ Figure 6.3 is a high level design process. Each step in Figure 6.3 includes several sub-steps. For example, Figure 5.4 provided a process to identify design factors. This process is one part of ‘creating product ideas and concepts’.

and concepts, decision and selection, and evaluation of product features. Each step includes a number of design methods (See Figure 6.3), which have been generated by summarising the most frequently used methods from student projects at IDE/TU Delft. The DDM wiki is continuously updated with the addition of new methods. See http://wikid.eu/index.php/Delft_Design_Guide (accessed on 16-OCT-2012).

The final part of DDG is about competences in design, in which design deliberations and tips (e.g., teamwork and design) are presented, with the intention being to aid students in developing their competences and skills.

6.2 The objective and methodology of this chapter

As no specific design methodology for DIMRC could be traced in literature, the objective of this chapter is to ascertain whether existing general design methodologies from literature can be applied or adapted (if needed) for DIMRC.

The research question of this chapter is therefore:

Can existing design methodologies be applied for Design and development of ICT-enabled Medical device and system for Rural China (DIMRC)?

As a special focus, the Delft Design Methodology (DDM) from IDE/TU Delft (Faculty of Industrial Design Engineering, Delft University of Technology) has been adopted as the candidate design methodology, leading to a parallel research question for the chapter:

How can existing knowledge and insights from IDE/TU Delft (DDM) be applied for the design methodologies and methods for DIMRC in actual DIMRC cases?

There are six sub-research questions under the two research questions:

SRQ1: Which existing design methodologies from literature may be relevant to DIMRC?

SRQ2: Can existing design methodologies from IDE/TU Delft be applied for DfBoP (Design for Base/Bottom of the Pyramid)?

SRQ3: How can design methods from the chosen design methodology from IDE/TU Delft be applied and combined by an R&D team in actual DIMRC cases?

SRQ4: Who should be the key members of an R&D team in future DIMRC cases?

SRQ5: What roles may be played by industrial designers from advanced design institutes to benefit the R&D team in future DIMRC cases?

SRQ6: What should be the roles of all members of the R&D team in future DIMRC cases?

To answer above sub-research questions, four steps are followed in this chapter:

- (1) General design methodologies that may be relevant to DIMRC are investigated. From various existing design methodology clusters, one design methodology from Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft), being the Delft Design Methodology (DDM), has been chosen following a literature analysis (Section 6.1.2). SRQ1 is answered in this step.
- (2) DDM is adapted for Design for Base/Bottom of the Pyramid (DfBoP). The adaptation is carried out by studying 24 student DfBoP cases. (For details of the methods, see Section 6.3.2) SRQ2 is answered in this step.
- (3) Design methods from DDM are combined and applied to identify design opportunities in rural Shanghai in an actual DIMRC case. The research objective of this case is to identify an empirical approach for biomedical engineers to identify design opportunities. This empirical approach is developed by combining existing design methods from literature and personal experiences. Industrial design students from IDE/TU Delft and biomedical engineers from Shanghai University worked as a team in this case. (Section 6.4) SRQs3–5 are answered in this step.
- (4) Based on the lessons learnt from two actual DIMRC cases from Sections 5.4 and 6.4, the roles and responsibilities of team members in Chinese R&D teams will be identified and discussed in Section 6.5.2. SRQ6 will be answered in this step.

By combining the results of these four steps, the two main research questions of this chapter will be answered.

6.3 Adapting Delft Design Methodology for Design for Base/Bottom of the Pyramid (DfBoP)

In this section, 24 DfBoP student projects from IDE/TU Delft will be collected and analysed to identify a common methodology suitable for DfBoP. The most successful of the 24 cases will be studied to identify elements of the common methodology. SRQ2 will be answered in this section.

6.3.1 Introduction

Several researchers have explored design methods, tools and techniques for DfBoP. For example, in “Base/Bottom of the Pyramid Model 2.0,” Simanis & Hart (2008) provides a toolkit for DfBoP with several tools (See Section 3.4.1); while Kandachar & Halme (2008) proposes several design methods and techniques for DfBoP (See Section 3.2.1). Despite the obvious focus on DfBoP, no author to date has proposed a specific design methodology for DfBoP.

Accordingly, the aim of this section of the thesis is to explore and propose an empirical design methodology for DfBoP through a study of past cases.

As a pioneer in DfBoP, IDE/TU Delft launched research in the field with the establishment of student design projects from 2003 onwards; and by the end of 2011, more than 150 DfBoP student projects had been carried out, most of which were MSc graduation projects. These are real world projects, generally conducted in cooperation with entrepreneurs and/or NGOs, and all of the student designers had been trained at IDE/TU Delft and had been taught to use design methodologies from IDE/TU Delft (such as DDM). The graduation reports have been used as a data source in this chapter, in which DDM is most often cited as the design methodology used, although the design methodologies of individual companies were used in some of the projects. Some students state specifically that the research methodology used is “Delft Design Methodology”, while others note that they used methods or definitions from DDM e.g., written scenarios, checklists for concept generation, etc.

6.3.2 Method

An “In depth study of external cases” (in which the author did not participate) was used as the method in this sub-study, in which the research process includes four steps: (1) establishment of criteria for case selection; (2) data collection; (3) data analysis; and (4) results generation.

A Case selection criteria

To select suitable DfBoP cases from IDE/TU Delft, two criteria were employed:

- All design activities in the project should have been published in detail, e.g., descriptions of problem definitions, methods, results, evaluations and reflections.
- DDM should be stated as the selected or referred design methodology in the project.

Because the first requirement is exactly same with the requirements of case selection in Section 5.3, the outputs from Section 5.3: Twenty-four DfBoP cases, were directly used to judge the second requirement.

B Data collection

All the cases that met the two criteria were identified. By searching TU Delft master thesis database, the published material (MSc theses) related to each were read, and the design activities executed in each case were collected and summarised.

C Data analysis

Firstly, the selected cases were noted as either *success* or *failure*, according to the definition of Heeks, an expert in the area of ICT4D, who came up with a definition of *success* for ICT projects in developing countries (Heeks, 2006):

“Success: Most stakeholder groups attain their major goals and do not experience significant undesirable outcomes.”

Other cases were defined as *failure*.

Secondly, both groups were analysed separately.

For the *successful* group:

- (1) The method sections of the publications (MSc theses) were read for a second time, and the four words/phrases with the highest occurrence rate within the publications were identified (using Visual Basic for Applications for Microsoft Office [Salton et al., 1975]).
- (2) The supervisors (researchers at IDE/TU Delft) of each *successful* project were presented with the four words/phrases identified in part (1), and were asked the following questions: a) Were these four words/phrases important in these projects? b) Do you know of any existing models that emphasise these four factors?
- (3) Three experts in design methodologies at IDE/TU Delft were presented with the four words/phrases identified in part (1), and were asked the question: Do you think these four words/phrases are important in DfBoP?
- (4) One *successful* case, being the “Adoptable stove”, was selected and studied in more detail to devise a design methodology for DfBoP. In this step, the technique “High Frequency Words in Context” (HFWC) was used, see Section 5.2.3.C.
- (5) Finally, the chapters in the “Adoptable stove” case that contained the highest occurrences of the words/phrases identified in Step 4 above were studied in more detail, and were defined and explained by the author of this thesis in a summary of the related chapters.

The “Adoptable stove” project was launched in 2005 as a collaborative project between Philips and IDE/TU Delft, and was based on a green burning technology that had been developed by the company. Seeking a way of penetrating emerging markets, Philips assigned a student from IDE/TU Delft with the task of redesigning the stove for rural India.

The student designer (Ideler) lived in rural India (outside Bangalore) for six months to study and understand the local context, after which she generated the design concept for India. The prototype was built in the Netherlands, and the student returned to India to carry out user tests and to build the business model. By the end of 2010 (at the time of the data analysis of this sub-study) the product was being manufactured and sold in India.

For the failure group, the supervisors of three failure cases (Safe drinking water [item 21, Table 5.2]; Screening device for oral cancer [item 8, Table 5.2]; and Cooking in rural China [item 20, Table 5.2]), as well as one company mentor (Support tool for China [item 7, Table 5.2]), were shown the new design methodology (Figure 6.2), and asked two questions: a) In your opinion, what issues were ignored that resulted in the failure of the project?; and b) In what stage of the new model could these ignored issues be included?

D Results generating

After the data analysis, a design methodology was proposed, and descriptions of all elements were identified.

6.3.3 Results

A Data collection

Twenty-four DfBoP student design cases from Section 5.3 fulfilled the second selection requirements. They have already been listed in Table 5.2 (See Section 5.3.3.).

B Data analysis

According to the definition of *success* in section 6.2.2, the following four cases were classified as *successful*: solar lighting (item 3, Table 5.2); personal water purifier (item 4, Table 5.2); Adoptable stove (item 10, Table 5.2) and Tricycle for disabled entrepreneurs (item 11, Table 5.2). The other twenty cases were classified as *failure*.

i Analysis of the successful cases

(1) Identifying four high-frequency words

By using Visual Basic for Applications for Microsoft Office, the four words with highest frequency were identified: reality, mind, production and realisation.

The definitions of these four words were:

- Reality: the designers' experience in real design contexts. In all four cases, students lived with local people, talked to them and observed their daily lives. This helped the student designers to build a complete picture of user needs.
- Mind: the brain activities of designers, used in the generation of design concepts.

- Production (of prototypes): creating prototypes as part of the design process.
- Evaluation (of prototypes): testing and evaluating the prototypes.

(2) Interviews with the supervisors of the successful cases

These four words were confirmed as key words in the design process of their DfBoP projects by the four supervisors of the successful projects.

(3) Interviews with three experts in design methodology at IDE/TU Delft

The three experts in design methodologies confirmed the importance of these four words in DfBoP.

(4) Identifying elements of the model

Figure 6.4 provides an overview of the design activities collected from the MSc thesis of the “Adoptable stove” case. In total, 23 design activities were identified and put into four categories (The four most frequently used words were defined as the four categories in this step).

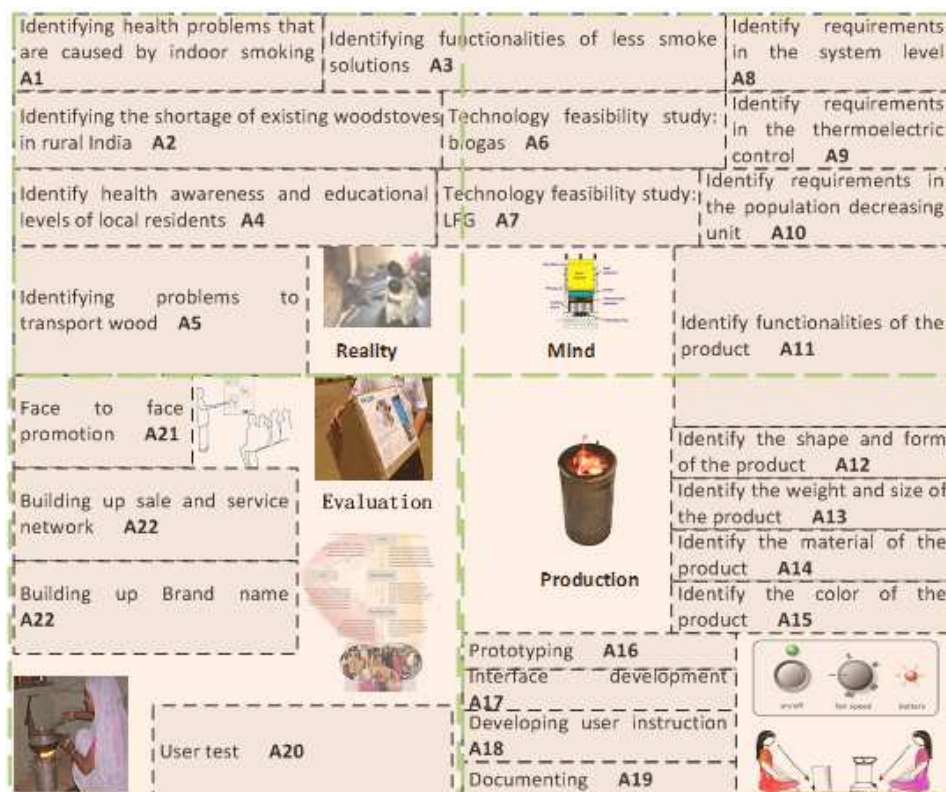


Figure 6.4: An overview of design activities in the “Adoptable stove” project (Ideler, 2008) (A: design activity in this project)

Table 6.2 provides description of elements in the project.

Table 6.2: Four categories, elements and descriptions of elements in the stove project (A: Activity) The four most frequently used words were defined as the four categories in this step.

Category	Elements	Descriptions of elements in the project	Activity
Reality	Description of the situation	Observe the lifestyles of local residents	A1, A2
	Problem identification	Identify the problems with the current situation	A4,A5
	Present products	Identify the weakness of current solutions	A6,A7
	New requirements	New product-related requirements	A3
Design Mind	Idea generation	Generate a new design idea	A3,A6,A7
	Design brief	Formulation of the design idea	A8
	Design criteria	Define the criteria of requirements for the design idea	A9,A10
	Product functionality	Define the functions of the concept	A11
Production of prototypes	Product documentation	Record the functions and define technical protocols	A11
	Technical development	Develop all technical protocols	A12,A13, A14,A15, A17, A18,A19
	Prototyping	Build the prototype	A16
Evaluation of prototypes	User test	Pilot the prototype	A20
	Business development	Set up the business plan	A22
	Brand name and sales	Set up a sales network and brand name	A21,A23

ii Analysis of the failure group

The interviews with the three supervisors and one company mentor in the projects classified under “failure” revealed three possible causes for the failure of their projects. One supervisor said that *“The student faced problems when identifying user needs in the project ... he did not spend enough time getting to know the local culture,”* while another said that *“The student faced problems in creating a business model in the project”*. The company mentor claimed that *“The design suits Western people, but is difficult getting it accepted by poor consumers in developing countries ... the stakeholder organisation is not strong enough”* etc.

Based on these given reasons, three issues that had possibly been ignored were proposed by the student designers in DfBoP projects were identified, referring to issues that are frequently ignored or overlooked by researchers and practitioners in the design field.

- Issue 1(I1): It is unclear and confusing for designers to understand how to assess the current situation and how to identify problems (e.g., user needs, product needs).
- I2: It is difficult for designers to involve users in the generation of ideas.
- I3: Designers have difficulty in developing business models.

C Results generation

By combining the four categories and the identified elements in Table 6.2, a new design model has been devised (See Figure 6.5), known as the “Four Domain Model,” in that it combines the four domains of product design. The descriptions of the domains are:

- Reality: This domain begins with a description of the situation and the identification of the problem. Once information about the currently used/available products or services are collected and analysed, the requirements for new products are identified.
- (Design) Mind: Based on the requirements and methodologies, a new product idea is generated and the idea is formulated and detailed.
- Production (of prototyping): Prototype development is carried out in this domain, during which the properties of the product are decided upon, including shape, material, colour, etc.
- Evaluation (of prototyping): The last domain covers the testing and evaluation of the project, including user tests. A business model is created to build the brand of the new product on the market.

Three possibly ignored issues are indicated in Figure 6.5. I1 occurs during the step from “situation description” to “problem definition” (in the domain of “Reality”); I2 occurs in the “idea generation” phase (in the domain of “Mind”); and I3 occurs in the “business development” step (in the domain of “Realisation”).

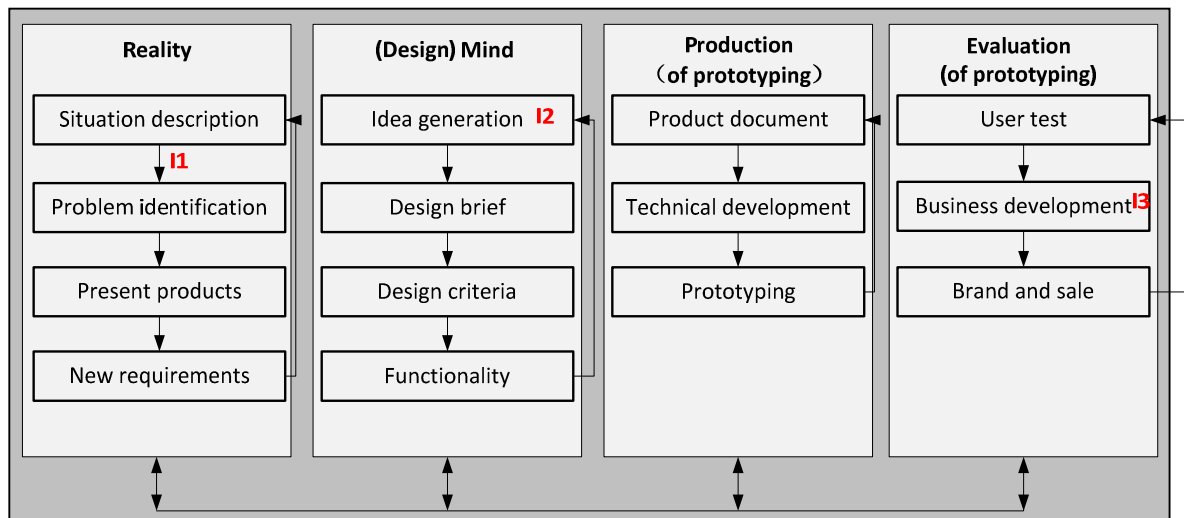


Figure 6.5: The new model is composed of four domains, being: reality, mind, production and evaluation. There are fourteen steps, and all steps within one domain are iterative. The four domains (bottom arrows) are also iterative, and lack a clear starting point. I1, I2 and I3 indicate a possibly ignored issue.

6.3.4 Discussion

A The success rate of applying DDM

Delft Design Methodology (DDM) was applied to all 24 DfBoP student cases analysed in this sub-study. The results showed that four out of the 24 cases were deemed *successful*, which is similar to the success rate of general student design projects from IDE/TU Delft.¹⁹ From this it can be understood that there is no significant difference between DfBoP cases and general product design cases at a macro level.

B The adaptation of DDM at the micro level

The adaptation of DDM for DfBoP should be at a micro level. As claimed by the author of the “Adoptable stove” project: “*Much attention needs to be paid to adapting existing design methodologies and methods to ensure user comfort*” (Ideler, 2006). To understand just how DDM may be adapted, the “Four Domain Model” was compared to DDM in this section. A comparison of the two reveals that most elements in the “Four Domain Model” can be found also in DDM. For example, the elements “design brief, design criteria, product document, prototyping, user test” are same as elements in DDM; however some elements in the “Four Domain Model” are special, for example four elements in the “domain of reality”: “situation descriptions, problem identification, present products and new requirements” are categorised under one element in DDM – “problem identification”. This result concurs with a previous research from IDE/TU Delft by Kandachar (Kandachar et al.; 2008), who claimed that special attention should be paid to the domain of reality.

¹⁹ According to the definition of success (see page 182), the *success* rate of general student design projects in IDE/TU Delft is about 10%. This number is estimated by researchers from IDE/TU Delft (Roozenburg, 2009).

The “Four Domain Model” is an iterative process in which any of the four domains can be chosen as a starting point. DfBoP student projects often start from different domains; for example, the “Adoptable stove” case (item 10, Table 5.2) started from “user test”; the “solar lighting” case (item 3, Table 5.2) started from “technical development”, etc. For this reason, the “Four Domain Model” can be considered as more flexible than DDM.

6.3.5 Conclusion

The objective of this sub-study was to explore an empirical methodology for DfBoP. As the Delft Design Methodology (DDM) was used as the referred methodology, the research question in this section was ***Can DDM be applied for DfBoP (Design for Base/Bottom of the Pyramid)?*** To achieve the above objective, 24 student projects carried out between 2006 and 2009 at IDE/TU Delft were chosen and studied. In all cases, the students had used DDM as the design methodology.

The results showed that ***DDM can be applied for DfBoP cases at the macro level, but adaptation is required at the micro level if a DfBoP case is to be successful.*** The new model, called the “Four Domain Model”, reflects how students adapted DDM (see Figure 6.3), and brings to light three issues that are often ignored by student designers from IDR/TU Delft that seem to be related to the failure of DfBoP projects. These three issues are: (1) It is unclear and confusing for designers to understand how to assess the current situation and how to identify problems (e.g., user needs, product needs); (2) It is difficult for designers to involve users in the generation of ideas; and (3) Designers have difficulty in developing business models.

6.4 Adapting Delft Design Methodology to identify design opportunities in an actual DIMRC case

6.4.1 Introduction

In previous section DDM was applied and adapted by industrial design students from IDE/TU Delft for 24 DfBoP student cases. These cases were analysed, and as a result an empirical model for DfBoP was proposed. In this section design methods from DDM will be further applied and combined by a R&D team in an actual DIMRC case: “Exploring design opportunities for rural Shanghai”. The major objective of this section therefore is to explore whether or not design methods from DDM can be applied and combined to identify design opportunities in actual DIMRC cases. Other objectives of this section include identifying modes of teamwork between industrial designers and biomedical engineers, and identifying the roles of the different team members.

SRQs3–6 will be answered in this section. See Section 6.2.

A Background of exploration of design opportunity

Scientists and technologists have come up with two main industrial innovation models for healthcare: technical-oriented innovation, and market (user)-oriented innovation (Robert & Tomas, 1998). In technical-oriented innovations, the success of a healthcare project (e.g., in medical devices, telemedicine and record management, etc.) depends on a technological development (one example of a technical-oriented innovation is the Positron Emission Tomography [PET]. The PET device was developed after the development of nuclear medicine imaging techniques). In market (user)-oriented innovations, on the other hand, success depends on satisfying market and user requirements. Today, market (user)-oriented innovations are applied in both industrial design schools (e.g., IDE/TU Delft) (Hoog & Boeijen., 2008) and in biomedical engineering schools (King & Fries, 2009).

Currently over 90 percent of product innovations are market (user)-oriented (Henry et al., 2006), some elements of which are presented in Figure 6.6, which is composed of two rows and six steps. The first row (the first three steps) relate to the exploration of design opportunities, including user context research, needs analysis, design and the generation of opportunities. The second row is related to strict product development, including design concept generation, prototyping, etc. The activities in the second row are based on the research outputs of the first part. Other steps, such as user test and market development, are not included in Figure 6.6, in that these steps are not related to this section, although they are important in market (user)-oriented innovation.

The aim of exploring design opportunities (the first row in Figure 6.6) is to identify, define and clarify the design objectives and sub-objectives, and the relationships between them, through a process of exploration and investigation. Commercial companies use this process to explore new market opportunities, while in IDE/TU Delft, exploring design opportunities falls under the “creating design goal” phase of the Delft Design Methodology (DDM). It is often considered as an important topic in DfBoP (Kandachar & Halme, 2008).

B Background of the case “Exploring design opportunities for rural Shanghai”

The aim of the project “Exploring design opportunities for rural Shanghai” is to identify opportunities for ICT-enabled healthcare solutions in rural Shanghai. The project was sponsored by Philips Medical Systems and Applied Technologies, and the preliminary research for the project was carried out in 2003 and 2004. The research team in the project included students from three academic stakeholders: IDE/TU Delft, the Public Health Department at Erasmus University (Netherlands) and the Biomedical Engineering Institute/Shanghai University (China). The author of this PhD-thesis also worked as a team member, and the team was supervised by a business manager from Philips and a professor from Shanghai University.

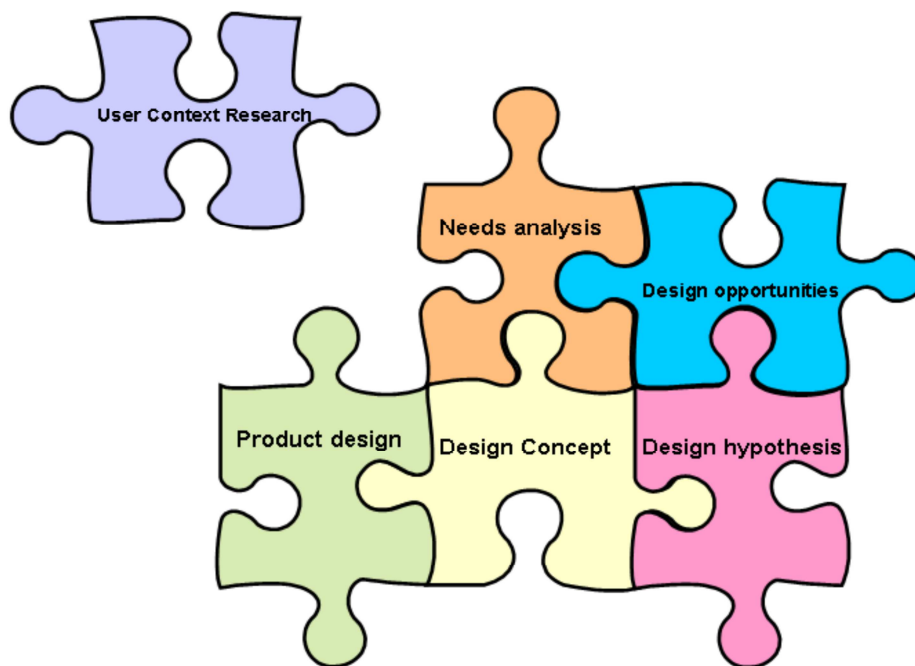


Figure 6.6: Some of the elements in market (user)-oriented innovation. The exploration of design opportunities is often considered as the starting point of this process .

C Definitions of design methods used in the case study

The five methods used in the case study were: brainstorming, observation, interview, persona and questionnaire, which are also included in the Delft Design Methodology (DDM) (Hoog & Boeijen., 2008). These methods are conducted as follows:

Brainstorming (Osborn, 1963)

Brainstorming is the mental process of developing and organising ideas, and is often conducted in a workshop. In healthcare design, the participants of a brainstorming group could be from medical organisations (hospitals), government offices (healthcare policy), industrial companies (product manufacturers), academic institutes (universities) and even end-users (community). Brainstorming is an important source of user information, especially for those designers who lack local knowledge and experience.

Observation (Douglas, 1976)

Observation gives designers a first-hand experience of the end-users, including their lifestyles, habits and living environments. Observation provides designers' with the opportunity to compare outputs from design trips and real feelings in the local context. The results of observations may be recorded through the taking of notes, photographs and videos, which constitute first-hand information for future analysis.

Interview (Campion et al, 1994)

An interview is a conversation between two or more people (the interviewer and the interviewee) where questions are asked by the interviewer to obtain

information from the interviewee(s). Interviews are the most important tool for helping a designer to understand how the user thinks, such as “How can the user be satisfied?” An interview can be in the form of a chat, a question and answer session, and even a group discussion.

Persona (Jenkinson, 1994)

Persona is a tool for the obtaining of key user information for designers. It can be used to draw together the varied needs, preferences, wishes and requirements into a “model” of the user, which can be used to guide designers when identifying user needs. The contents of persona are related with the design tasks. For example, if a designer wants to design a device for the measurement of blood pressure, for which the end-users are high blood pressure patients, the persona might include the patients’ age, gender, family medical history, diet, and other factors that might affect blood pressure.

Questionnaire (Foddy, 1994)

A questionnaire is a research tool consisting of a series of questions and other prompts for the gathering of information from respondents. A questionnaire may be used to gather basic information from stakeholders, social and economic information about users, or opinions of current solutions. Questionnaires are often used in a quantitative method.

6.4.2 Methodology

To achieve the research objectives, the research approach “study of the author’s own project” (in which the author participated) is used, according to which the design case “Exploring design opportunities for rural Shanghai” is used as a data source. The research process is composed of three phases: (1) Project preparation: all of the design activities in the project are planned in this phase, during which an important preparatory task on the way to achieving the research objectives was carried out – proposing the research approach for the case; (2) Project development and implementation: the project was developed and implemented. Data was recorded during the case to answer SRQs 3–5; (3) Project evaluation and reflection: data from the case was evaluated in this step, and reflection was given.

A Project preparation

The research team organised a workshop in June 2005, during which managers from Philips and biomedical engineering professors from Shanghai University engaged in a brainstorming session. The student from IDE/TU Delft was in charge of communicating with all participants, and developed an approach to the case that was based on the application and combination of design methods from DDM. This approach was introduced in the workshop, and was finally selected as the approach for the case.

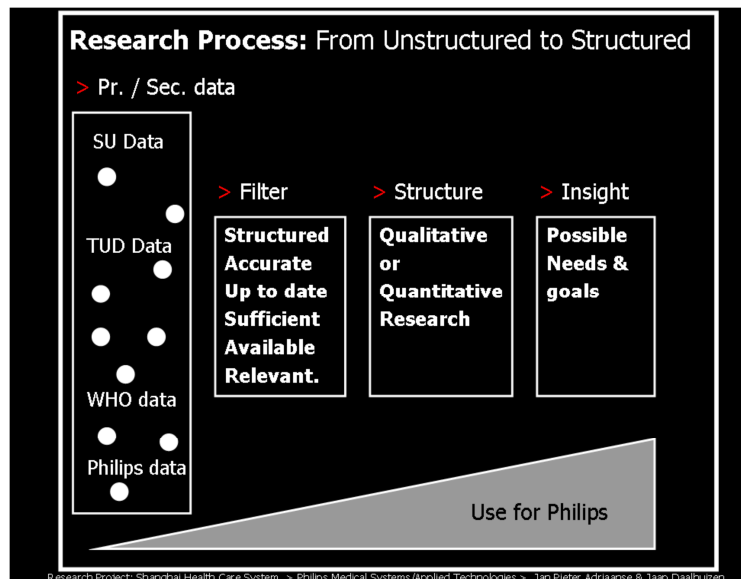


Figure 6.7: An approach was proposed at the beginning of the case study that underwent development as the project progressed.

This approach was named “from unstructured to structured,” being that the core goal was to help industrial designers to structure useful data from a number of information sources. Figure 6.7 shows the approach, which is composed of four steps: (1) pre-work to collect secondary data from literature and research organisations, including TU Delft, Shanghai University, Philips and World Health Organization (WHO); (2) filter sufficient data relevant to the topic; (3) structure data through qualitative or quantitative research. The methods and tools noted in section 6.4.1 B were used in this step; and (4) obtain insights about possible user needs and design opportunities.

B Project development and implementation

The four steps in this section are described below.

B.1 Pre-work

This step involved the brainstorming of three stakeholders: academicians from TU Delft and Shanghai University, a non-governmental organisation (<http://www.sfic.org.cn> accessed on 16-OCT-2012) and an industrial company (Philips). The research team obtained secondary data through discussion, reading the reports of the stakeholders and a literature analysis (e.g., data from the World Health Organisation [WHO]).

B.2 Filtering the data

This step involved a team discussion (brainstorming). The research team read relevant publications from which they extracted any appropriate data. The criteria for data selection included: (1) The data should not pre-date 2003; (2) The data should be about Shanghai, or regions close to Shanghai (e.g., the Jiangsu or Zhejiang provinces).

B.3 Structuring the data

B.3.1 The qualitative research

To structure the data from previous step, a qualitative research was carried out of Chongmin Island, rural Shanghai, in August 2005. The students from IDE/TU Delft designed the research activities, while the students from Shanghai University were the executors in this step. BME students went to villages in Chongmin where they lived with three local families, observed their lives, and interviewed five different residents: one elderly person, one farmer, one factory worker, one housewife and one young person (13 years old). For a more detailed description of this qualitative research process, see Appendix C.

B.3.2 The quantitative research

The objective of the quantitative research was to verify the findings of the qualitative research by administering a questionnaire among rural residents. This step involved students from IDE/TU Delft, who designed the questionnaire, and students from Shanghai University, who administered the questionnaire in five different areas in rural Shanghai (Jinshan, Qingpu, Fengxian, Nanhui and Songjiang) in August 2005. In all, 300 questionnaires were sent to each area, and were collected the following day.

The questionnaire contained 48 questions, divided into three sections:

- Basic personal information (6 questions): Name, gender, age, address, contact phone number and e-mail.
- Basic health information (10): medical history, patient history.
- Healthcare requirements (32): The respondents were asked to rate their response to the given questions using a five-point Likert scale. They were given five choices of answer: “strongly agree”, “agree”, “neither agree nor disagree”, “disagree” and “strongly disagree”, which were marked respectively “5”, “4”, “3”, “2” and “1”. Table 6.3 presents the question topics and their descriptions.

For a more detailed description of this quantitative research, see Appendix C.

B.4 Generating design opportunities

The results of the questionnaires were entered into a digital database and were analysed statistically. Following this step, the results were used to identify a number of design opportunities through a team discussion, which were then submitted to the company (Philips). The company evaluated the design opportunities, and took the decision to “Go, or no go”. For a more detailed description of this step, see Appendix C.

Table 6.3: Topics of questions and their descriptions, relevant for healthcare requirements

Topic of Questions (number of questions)	Question descriptions
Treatment of common diseases (4)	Fever, cold, stomach and intestinal diseases
Cancer (6)	Lung cancer(2), breast cancer(2), esophageal cancer, cervical cancer
Heart disease and Cerebrovascular diseases (2)	Immediate treatment and prevention
Chronic diseases (6)	High blood pressure, high blood sugar and high blood fat
Nutrition (1)	Nutrition detection for children under 1 year old
Injury, poisoning & external causes (2)	Care and treatment
Tuberculosis (3)	Prevention, detection and treatment
Diseases of the respiratory system (2)	Diagnosis and treatment
Low cost/safe medical service (3)	Current three types of low cost medical service are insufficient
Pregnancy & birth (3)	Pre-natal care, birth care and post-natal care

C Project evaluation and reflection

An evaluation meeting to discuss the research approach in this project (Figure 6.7) was set up at Philips in September 2005, involving local (Shanghai) stakeholders, including researchers from Shanghai University and Philips, representatives from Shanghai government, etc. In addition, an internal reflection meeting of the research team was held in September 2005, during which two topics were discussed: (1) Verification of the research process to identify design opportunities in rural Shanghai; and (2) teamwork for DIMRC.

6.4.3 Results

B Project development and implementation

B.3.1 Five personas for the qualitative research

Five personas were proposed as results in this step. Figure 6.8 shows one persona, that of an elderly person from Chongmin Island. The persona contains basic information, as well as details of living conditions, and the awareness and needs of the subject.

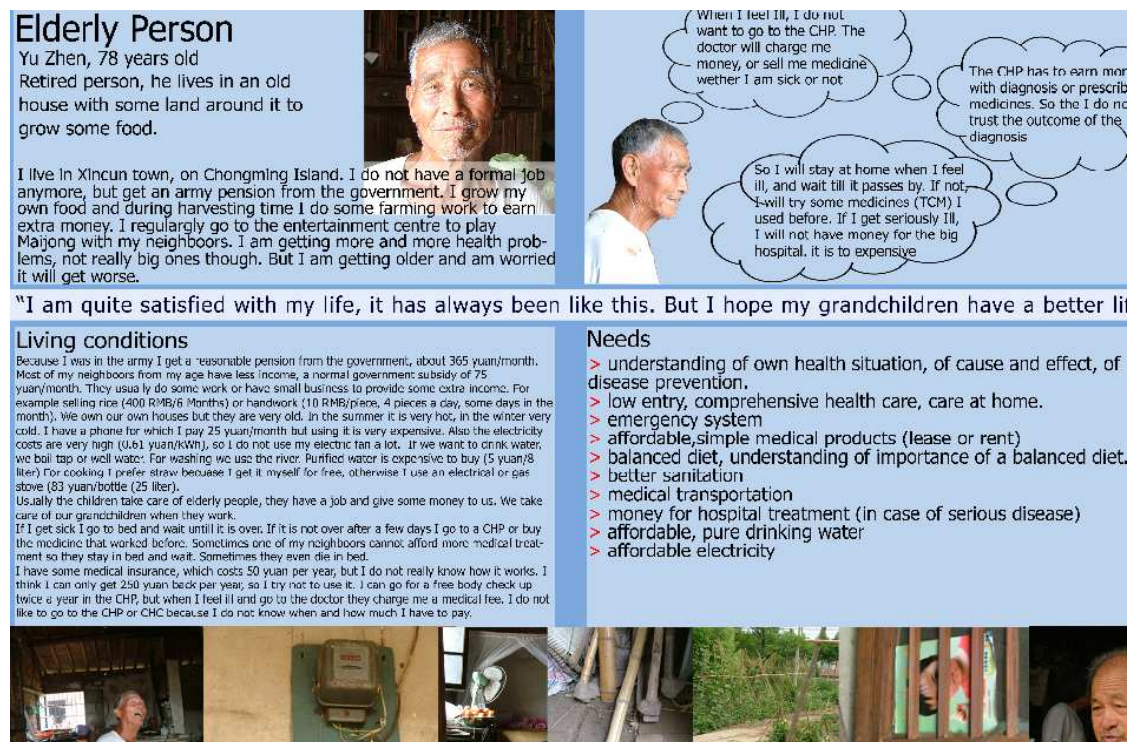


Figure 6.8: A persona of an elderly person in Chongmin (Jiang et al., 2010).

B.4 Generating design opportunities

Table 6.4 shows the results of user needs, garnered from the questionnaire, the directions for solutions and the design opportunities in the case study. For a more detailed description of these results, see Appendix C.

Table 6.4: The results of needs, directions for solutions and design opportunities identified in the project.

Needs	Directions for solutions	Design opportunities for Philips
Chronic disease treatment	Diagnosis and treatment	ICT-enabling tools
Affordable medical cost	Governmental policy	None
Safe living conditions	Governmental policy, physiological parameters monitoring & analysis	Production materials, manufacturing, ecodesign advanced technology
Pregnancy & natal care	Care	Telemedicine, medical materials & equipment, interface, advanced ICT technology

The above design opportunities were submitted to Philips, and after discussion, it was decided to pursue ICT technology for pregnancy care. As a result, the “Temperature CT for pregnancy care” project was launched in 2006. See “About the author” in the Appendix.

C Project evaluation and reflection

The approach to identifying design opportunities received positive comments during the evaluation. In particular, a biomedical engineering professor at Shanghai University said, *“The methods and tools used in the case are attractive for biomedical engineers, and they can be helpful in DIMRC”*, while a manager from Philips called the approach *“reasonable”*. In 2009, the above approach was described by the author as follows: (a) practice being a user yourself; (b) identify information sources; (c) conduct a qualitative research; (d) conduct a quantitative research; (e) conduct a needs analysis; and (e) define a primary goal. For more details about the approach, see Appendix C.

Furthermore, three additional lessons about teamwork were defined during the internal reflection meeting. These three lessons were:

C.1 Government officers as key team members

It may be useful to involve government officers as key team members in R&D teams for DIMRC. In the case, the support of the Shanghai local government officers (city, town and village levels) was essential for the research team in the field studies, such as administering the questionnaire in five rural regions. In this process government officers from Shanghai municipal government are considered as key persons to scale up our research. They arranged to scale up our user research through local administration interventions, which was very effective and efficient. A “top-down” approach was used in the case: firstly, the research team contacted the Shanghai municipal government; secondly the officers of Shanghai municipal government passed on the requirements of the field studies to the local town and village administrations; and finally, all of the field studies were assigned by the local government administrations, such as the interviews and questionnaires. The roles and responsibilities of government officials in the R&D teams will be described in Section 6.5.2.

Chinese universities may be useful agencies to introduce relevant government officers to R&D teams. Currently a number of professors from Chinese universities are also working as employees for local municipal governments, and they have strong personal relationships with relevant government officers (as opposite for outsiders who are likely to face more problems when trying to motivate government officers in China). In the case a professor from Shanghai University was invited as the supervisor. He also worked as vice-chairman of Shanghai Federation Of Industry & Commerce (a government department). He accompanied us when talking with the coordinator of Shanghai Rural Healthcare, and to invite the coordinator to join in the R&D team. This approach worked efficiently in the case.

C.2 Teamwork between industrial designers and biomedical engineers

The second lesson relates to the need for teamwork. In the selected case study, industrial design students from IDE/TU Delft and Chinese biomedical engineering students worked together as key actors. An industrial design

student from IDE/TU Delft developed the approach “from unstructured to structured” due to his rich knowledge of design methods and tools from DDM; while the Chinese biomedical engineering students were responsible for executing the field study and carrying out the data analysis. The students of the two academic institutions played complementary roles in identifying the user needs.

C.3 Approaches to involving rural Chinese people

The third lesson from the case is about how to involve people from the local rural community in the research team. It was found that the local community were reluctant to talk with strangers, and so to encourage them to speak openly, the research team used two approaches: (1) some informal workshops were organised by the research team, to which members of the community were invited. The team prepared tea and gave out gifts (lamps, supplied by Philips) to the participants. The technique worked very well. After half an hour of free discussion, the participants agreed be interviewed and to fill out the questionnaire; (2) the research team lived for a period in the village, during which they were able to gain the trust of the local people.

Rural Chinese people tend to become nervous and are reluctant to talk in the presence of government officials, making difficult to get useful information from them. The respondents provided the research team with only limited answers when in such a situation. For example, one of the most frequent replies during the interviews was: *“I am happy with my life. Everything is ok. I do not need any help.”* Once the government officials left, the respondents provided the research team with more in depth information.

6.4.4 Discussion

A Relating to previous chapters

The above three lessons verified, changed and improved three conclusions from previous chapters.

The first lesson is related to governmental support. In the initial framework for DIMRC (Figure 1.5) Chinese governmental support was suggested as being fundamental to the success of an DIMRC project, but after reviewing this case study, it was ascertained that their level of involvement should be extended from a supporting to organising role. In the case study, all research activities during the field studies, such as interviews and the administration of the questionnaires were arranged by local government offices. The results of the case study also provided an indication of the benefits to be gained in obtaining the help of local government offices, e.g., the benefit of a “top-down” approach in the organisation of field studies (See Section 6.4.3.B). This is a new insight that has to date not been covered in previous literature.

The second lesson is related to design culture. In Chapter 4 it was claimed that *“Chinese R&D teams have fewer opportunities to co-design with end-users,*

and therefore their practical ability in user research is weak” (See Section 4.6.1). This sub-study has verified this conclusion. In this case study, Chinese biomedical engineers (as part of R&D teams) were lacking in the necessary knowledge and skills to carry out a study of user needs on their own, however these knowledge and skills can be provided by industrial designers from advanced design institutes.

The third lesson is related to teamwork. In Chapter 5 it was concluded that, *“It may be useful for Chinese biomedical engineers to cooperate with industrial designers from advanced design institutes as a team”* (See Section 5.6.3). This sub-study has verified this conclusion. In the case study, the industrial design students from IDE/TU Delft played an important role in the team, and worked well with the local biomedical engineering students from Shanghai University (See Section 6.4.3.B).

B Selecting and combining methods and tools from DDM

In the case study, the industrial design students from IDE/TU Delft developed an approach to exploring design opportunities for rural Shanghai. In this approach, methods and tools from DDM were selected and combined, such as brainstorming, observation, persona, etc., and the results verified the suitability and efficiency of the approach.

To the best of the author’s knowledge, this is the only approach focusing on exploring design opportunities for DIMRC, and for Chinese biomedical engineers in particular. There are at least two benefits to this approach:

- This approach expands upon existing design methodologies related to biomedical device and system design, such as that of King (King & Fries , 2009). (See Figure 5.3) In existing design methodologies, the exploration of design opportunities is usually mentioned as part of the early stage of the design process, however design steps, methods and tools for the purpose are not introduced. In this respect, Appendix C may be considered as adding to the knowledge of existing methodologies for biomedical engineers.
- This approach can also be an example of how knowledge may be transferred from industrial design to biomedical engineering. In Chapter 4 it was claimed that industrial design was not emphasised in the cycle of R&D in DIMRC, and one important reason for this is that many engineers (including biomedical engineers) do not understand the potential contributions of industrial designers to DIMRC, and this approach shows what may be possible.

That said, further optimisation of the approach is required, and in this regard, Appendix C can be merely considered as a first version.

6.4.5 Conclusion

Design opportunity exploration is an important issue in Design and development of ICT-enabled Medical device and system for Rural China (DIMRC). The Delft Design Methodology (DDM) provides several methods and tools, but these are not well known, and are seldom used by Chinese biomedical engineers in DIMRC. There were three objectives explored in this sub-study: (1) investigate whether design methods from DDM can be applied and combined for use in an actual DIMRC case; (2) explore the roles of industrial design students from IDE/TU Delft in an actual DIMRC case; and (3) analyse the teamwork of Chinese R&D teams in actual DIMRC cases.

A study of the author's own project "Exploring design opportunities for rural Shanghai" was used as the prime method in this sub-study. The research process was composed of three phases: (1) Project preparation (2) Project development and implementation; and (3) Project evaluation and reflection.

The results of the case showed that: (1) ***An approach to identify user needs was proposed, and methods and tools from DDM were applied and combined in this approach.*** This approach included five steps: (a) identification of key words related to user needs as the principle; (b) pre-work in user needs identification; (c) collection of user context information; (d) information analysis; and (e) identifying design opportunities. For details about the approach, see Appendix C; (2) ***An industrial design student from IDE/TU Delft was the methodology developer in the research team in this actual DIMRC case, and industrial designers can be expected to play the same role in future DIMRC cases;*** (3) Based on experiences from the case study, it may be advised that ***biomedical engineers, industrial designers and government representatives be appointed as the key team members of Chinese R&D teams in future DIMRC cases. Chinese universities may play as agencies to invite local governmental officers into R&D teams.*** The roles and responsibilities of these key members will be described in Section 6.5.2.

6.5 Discussion for this chapter

In this section, some lessons learned from this chapter are discussed.

6.5.1 Can DDM be used for DIMRC?

This question was explored through an analysis of two actual DIMRC cases: "Development of a blood pressure monitoring system incorporating ICT" (Section 5.4) and "Exploring design opportunities for rural Shanghai" (Section 6.4). As a result, an approach to identifying design factors that combined DDM and King's approach was proposed in Section 5.4; and an approach to identifying user needs and design opportunities in which methods and tools from DDM were selected and combined, was proposed in Section 6.4.

These two examples provided a strong indication that DDM may well be applied or adapted (if necessary) for DIMRC.

In this, the following two aspects are relevant:

- (1) Answering the research question for this chapter, existing design methodologies may be applied or adapted (if necessary) for DIMRC, and Delft Design Methodology (DDM) can be considered a good example of such a methodology.
- (2) Knowledge from IDE/TU Delft (Faculty of Industrial Design Engineering, Delft University of Technology) may be used to develop design methodologies and methods for DIMRC. Chinese R&D teams can benefit from DDM if the knowledge from IDE/TU Delft could be transferred by some means, like for instance, as a manual, or by collaborative projects between Chinese & Dutch engineers etc.

6.5.2 The roles and responsibilities of team members

SRQ6 will be answered in this section.

Teamwork for DIMRC has been already discussed in Chapter 5 (See Section 5.6.2), which concluded that industrial designers from IDE/TU Delft, Chinese medical experts and Chinese biomedical engineers had all played important roles as team members in the case “Development of a blood pressure monitoring system incorporating ICT”. Other stakeholders, such as business managers and ICT-technology developers should also be considered as potential team members. Teamwork in DIMRC was further investigated in this chapter. From the case “Exploring design opportunities for rural Shanghai”, it can be clearly concluded that government officials also played an important role in the success of the case study, particularly in matters related to public relations and in the facilitation of field studies. In summary, four players should be considered as key team members in R&D teams for DIMRC: industrial designers (e.g., from IDE/TU Delft), biomedical engineers, government officials and medical experts. Their roles and responsibilities should be:

- Industrial designers: Industrial designers should be developers of integrative approaches, providers of existing design methodologies/methods/tools, organisers of context/user studies, and participators in product development. They should take responsibilities in business strategy analysis, design idea and concept generation, business model development, etc.
- Biomedical engineers: Biomedical engineers should be the executors in product development. They should take responsibility in the materialisation of design, prototype building, manufacturing, engineering etc.
- Government representatives: Government representatives act as consultants to the R&D team. They should take responsibility in

matters of public relations, policy and financial matters, and in facilitating the field study.

- Medical experts: Medical experts should act as advisors in matters related to medical issues in product development. They should take responsibility for all medical issues, such as patient safety, medical ethics etc.

Teamwork was a must in both DIMRC cases. For instance, without industrial designers, the R&D teams would lack the knowledge and skills to select and combine suitable design methods in both cases; without the support of government officials, the research activities related to the application of the DDM could not have been implemented in rural China in the “Exploring design opportunity for rural Shanghai” case; and without the support of medical experts, the research team could not have set up any experiments or adapted DDM in the “Development of a blood pressure monitoring system incorporating ICT” case. In short, multidisciplinary cooperation is vital for DIMRC.

6.5.3 Three Chinese initiators and organisers of DIMRC projects

From Chapters 5 and 6 it can be noted that three Chinese stakeholders should take on roles as initiators and organisers in DIMRC projects: the Chinese government, companies and the academia, who should work together during the initial stages of DIMRC projects. By combining the outputs from Chapters 5 and 6, and from the previous studies of the author of this thesis, the ideal roles and responsibilities of the three Chinese stakeholders were ascertained as:

- Chinese government: The Chinese government should be the major investor in DIMRC projects. It should provide more subsidies to medical device companies and provide grants to universities. It is recommended that government officials be involved in R&D teams, in that they can provide support in many issues, such as policy matters, the organisation of field studies, the provision of medical certification, etc.
- Chinese companies: Chinese companies should be the technology and market developers. It is recommended that they be in charge of developing and marketing ICT technologies, the manufacture of products, and everything related to the business side of the project.
- Chinese universities: Chinese universities should be the knowledge developers for DIMRC. A deeper knowledge of ICT technologies and relevant design skills should be developed in universities. At the same time, Chinese universities should explore and prepare new DIMRC project activities, such as organising stakeholder networks, conducting user research, etc.

Besides the three Chinese stakeholders, foreign universities and companies were also involved as initiators and organisers in the two actual DIMRC cases in this thesis: in both cases, Philips was the initiator and sponsor, and IDE/TU

Delft was one of the organisers. This means that foreign stakeholders can also be involved as organisers and initiators in DIMRC cases, which is an issue that will be elaborated in Chapter 7.

6.5.4 Knowledge contribution to DIMRC from IDE/TU Delft

At the beginning of this thesis it was mentioned that a particular focus of research would be learning from best practices and the transfer of knowledge from IDE/TU Delft to Chinese biomedical engineers (See Section 2.6), while knowledge from other advanced design institutes will be added into the educational solution in the future. The two actual DIMRC case studies (“Exploring design opportunity for rural Shanghai” and “Development of a blood pressure monitoring system incorporating ICT”) have shown just how IDE/TU Delft may contribute to DIMRC, which will be defined in this section.

To demonstrate the concrete contributions, a frequently used biomedical device and system design methodology (King’s approach, described in detail in Chapter 7. See Figure 7.3) will be followed to illustrate how industrial designers from IDE/TU Delft can contribute to the biomedical engineering discipline in different steps. See Table 6.5.

Table 6.5: A frequently used biomedical device and system design methodology (King’s approach) defining the tasks to be undertaken by biomedical engineers, and possible contributions of industrial designers from IDE/TU Delft.

Steps	The task of biomedical engineers	The possible contributions from industrial designers, for instance from IDE/TU Delft
Setting up a stakeholder network	Assemble R&D teams	Organising a suitable stakeholder network, communication with other stakeholders
User research	Identify user needs	Provide design methods, tools and techniques to obtain insights into user needs
System level design concepts	Provide the overall design goal at the system level	Provide systemic thinking, including design culture and other issues
Outline design	Identify design factors, and design specifications	Provide design methods, tools and techniques to identify design factors
Detailed design	Provide concrete design assignments, hardware and software protocols	Ergonomics
Prototyping	Hardware and software development, integration and validation	X
Testing and evaluation	Test prototypes through user tests and evaluate the design	Provide methods, tools and techniques for field studies
Decision	“Go, or no go” decision by R&D teams	X

In Table 6.5., Columns 1 and 2 provide the different steps and tasks to be taken by biomedical engineers when following King's approach (King, et al., 2009), as described in previous literature. Column 3 illustrates the possible contributions that may be made by industrial design engineers, such as those of IDE/TU Delft, in every step. The contents of Column 3 were gathered from two real DIMRC cases.

Table 6.5 reveals that knowledge from IDE/TU Delft can mainly contribute to the early stages of King's approach, such as in the setting up of a stakeholder network, user research and outline design. In these steps, IDE/TU Delft has a rich knowledge of design methods, tools and techniques that can be applied or adapted by biomedical engineers (or through teamwork with industrial designers). Knowledge from IDE/TU Delft may also be useful in the testing and evaluation stages, providing methods, tools and techniques for the involvement of the end-users in the field studies. Chapter 7 will present a more detailed description of this aspect.

6.6 Conclusion and recommendations of this chapter

Previous literature has provided a number of design methodologies for Design and development of ICT-enabled Medical device and system , such as Living Lab design methodologies, Entrepreneurial design methodologies, etc. These methodologies have been sourced from various scientific disciplines, e.g., social sciences, economics, product design, etc., however previous literature is lacking in any design methodologies specific to the subject of Design and development of ICT-enabled Medical device and system for Rural China (DIMRC). Accordingly, the key aim in this chapter was to investigate whether existing design methodologies could be applied for DIMRC.

To this end, a design methodology from the Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft), namely the Delft Design Methodology (DDM), was chosen as a suitable methodology. This methodology had been applied in 24 student DfBoP cases and adapted for the DIMRC case "Development of a blood pressure monitoring system incorporating ICT". The design methods of this methodology were applied and combined in the DIMRC case "Exploring design opportunities for rural Shanghai".

The results of these studies showed that:

- ***Existing design methodologies (e.g., Delft Design Methodology [DDM]) were found to be applicable for DIMRC. For example, DDM was adapted into a "Prototype-driven IDE approach". Design methods from DDM were applied and combined to form a "From unstructured to structured" approach.***

Besides the main objective, this chapter also sought to answer a parallel research question: *How can existing knowledge and insights from IDE/TU Delft be applied to create design methodologies and methods for DIMRC in actual DIMRC cases?* To answer this question, two actual DIMRC cases were analysed. The results showed that:

- *Knowledge and insights from IDE/TU Delft were useful to Chinese biomedical engineers in developing design methodologies and methods in two actual DIMRC cases. For the transfer of such knowledge, one possibility is through teamwork with industrial designers from IDE/TU Delft. Industrial designers were the methodology developers in both cases.*

Based on the studies in this chapter and in Chapter 5, four recommendations for applying or adapting existing design methodologies for DIMRC are proposed.

Recommendation 6.1 (for universities): Chinese universities may benefit from teaching students design methodologies and methods from IDE/TU Delft, of which the Delft Design Methodology is a prime example: http://wikid.eu/index.php/Delft_Design_Guide accessed on 16-OCT-2012

Recommendation 6.2 (for universities): Chinese universities should provide students with more teamwork opportunities for DIMRC. For instance, Chinese universities should consider setting up international cooperative projects, allowing students to work with companies developing and manufacturing medical devices. Multidisciplinary cooperation should also be encouraged in Chinese education.

Recommendation 6.3 (for government): The municipal government officers should be more open to be key members of R&D teams. They should and would benefit from establishing a special department to help outsiders (who have no personal relationships with governmental officers) organise field studies in rural China.

Recommendation 6.4 (for companies): Chinese companies should pay more attention to user needs in research, with social research being afforded particular importance by the R&D teams of companies working in the field of DIMRC. Such R&D teams also need to work closely with members of the Chinese academia involved in the design of medical devices.

PART 3

PART 3: RESULTS

This is the third and final part of the thesis, in which all of the data collected in the previous parts is combined and synthesised (Chapter 7) into a conclusion (Chapter 8). Figure 7.1 shows the structure of this thesis, in which Part 3 is clearly defined.

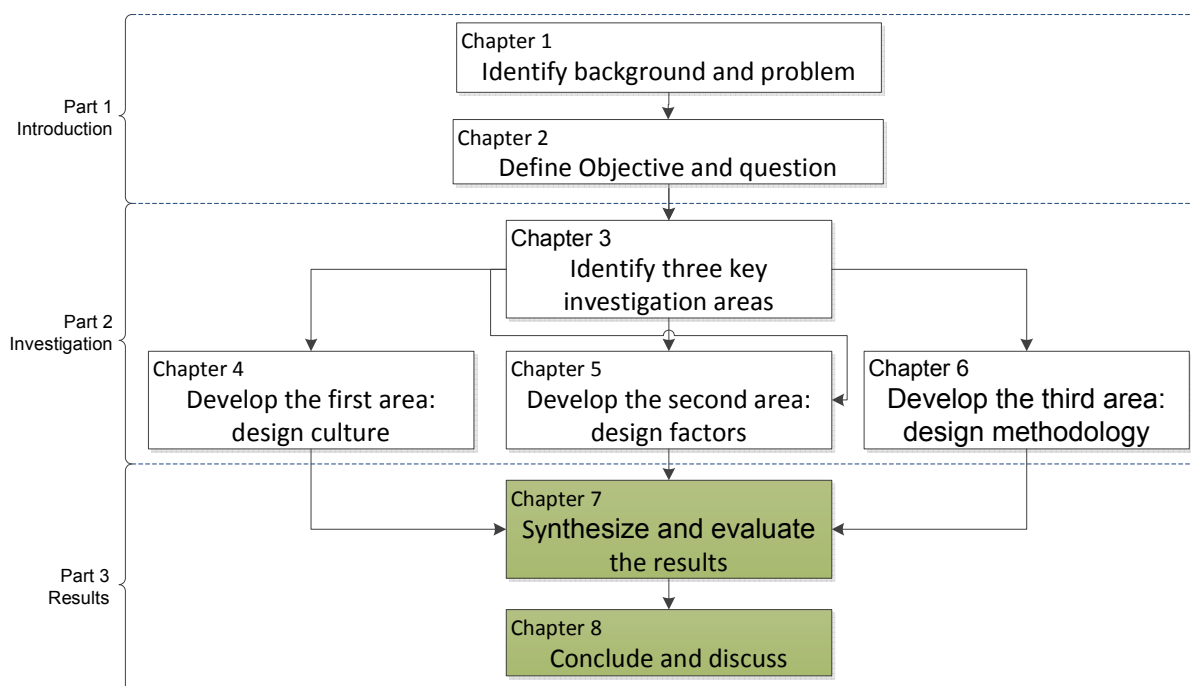


Figure 7.1: The Structure of this thesis. Part 3 comprises Chapters 7 and 8.

Chapter 7 Results of this thesis²⁰

The first part of this chapter provides a framework of DIMRC. A detailed description of the elements of this framework can be found in previous chapters, including (1) three Chinese stakeholders, i.e., Chinese government, companies and academia, as essential organisers and initiators; (2) the 14 recommendations proposed for these three stakeholders; and (3) the four disciplines (industrial designers,²¹ biomedical engineers, government representatives and medical experts) proposed as key members of Chinese R&D teams. Based on these progressive insights, a new and modified framework for DIMRC will be introduced in Section 7.1.

The second part of this chapter proposes an educational module for biomedical engineering education in Chinese universities. This module is intended to be an educational solution for the augmentation of the design competences of Chinese biomedical engineers (as well as other Chinese R&D team members). Integrative approaches²² will be applied within the module.

7.1 The new version of the framework for DIMRC

At the beginning of this thesis, an initial framework for DIMRC was presented (Figure 1.5), in which three conditional elements for DIMRC were indicated: (1) support from the Chinese government: in the form of grants to universities and financial subsidies to companies for DIMRC; (2) knowledge to be provided by universities: the generation of scientific knowledge about how to provide successful DIMRC; and (3) market exploration by companies: commercial companies need to contribute to the commercialisation of products. Based on these three elements, it was proposed that concrete DIMRC projects should be launched by companies and/or universities. This framework has been further improved and refined in this thesis. Based on the research results from Chapters 1–6, a new version of the framework for DIMRC is proposed in Figure 7.2. The structure of the new framework builds on the initial framework in Figure 1.5, which includes three blocks: (1) initiators and organisers, (2) concrete DIMRC projects; and (3) a knowledge base for DIMRC.

²⁰ 本章中文名称: 结果。

²¹ In this chapter, industrial designers refer to product designers with extensive skills and experience in the integration of design knowledge from multiple disciplines, such as social sciences, engineering sciences and business sciences. They possess the skills to solve complex design problems, e.g., DIMRC, through integrative approaches.

²² In this thesis the term integrative approach refers to a design approach that integrates multidisciplinary design issues, including diverse requirements of materials, manufacturing, context of product use, considerations of usability, identity and marketing, etc. Integrative approaches are often taught in advanced design institutes, such as IDE/TU Delft, Industrial Design at TU Eindhoven and the Stanford Product Design Programme. Recently (Year 2009), the “World’s Best Design Programs” were listed in Business Week Magazine http://images.businessweek.com/ss/07/10/1005_dschools/index_01.htm (accessed on 16-OCT-2012), among which can be found the Strategic Product Design programme of IDE/TU Delft.

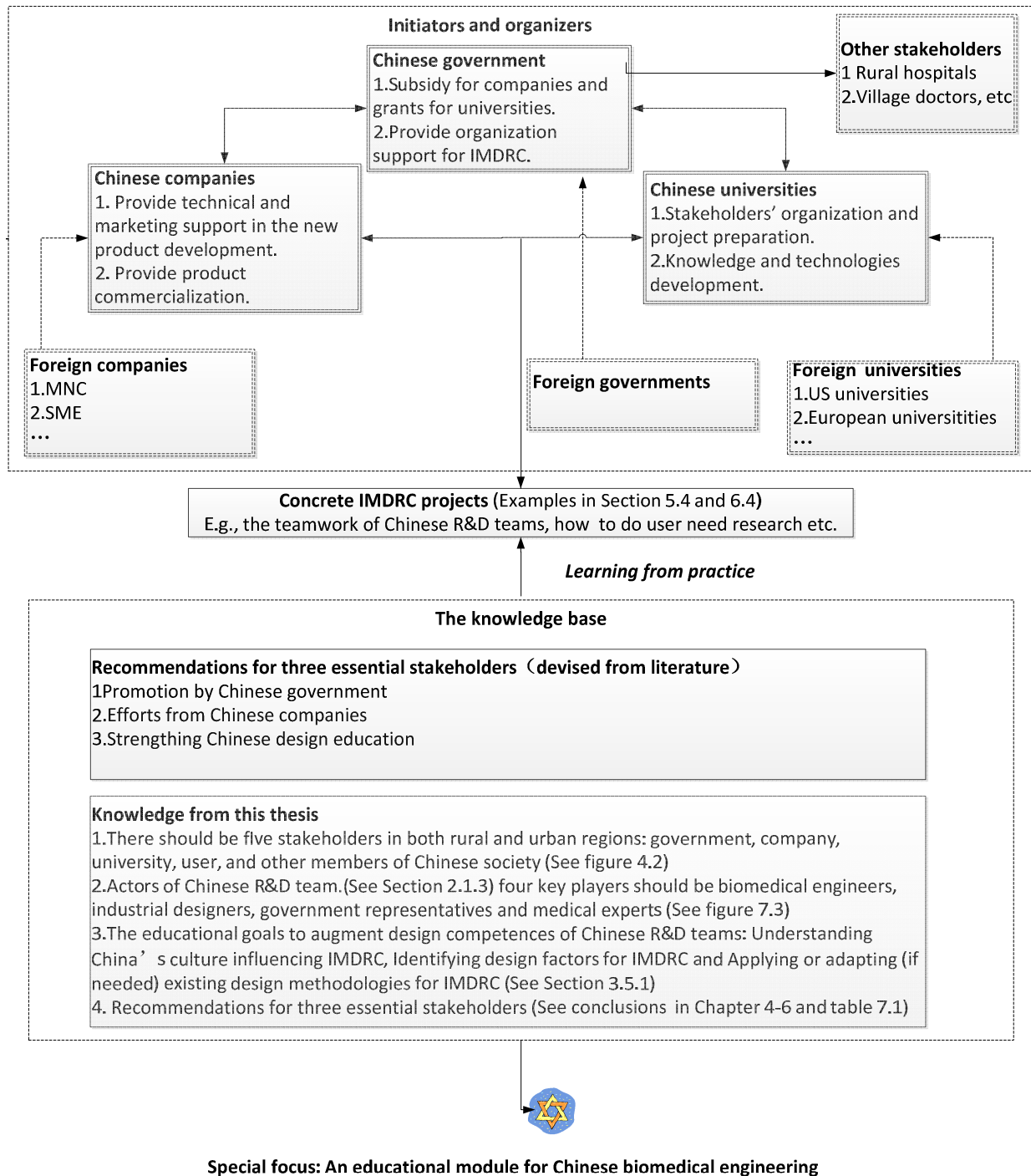


Figure 7.2: The new framework for Design and development of ICT-enabled Medical device and system for Rural China (DIMRC). The framework comprises three blocks: initiators and organisers, concrete DIMRC projects, and a knowledge base. It also shows how foreign entities – companies, governments and universities – can be involved in this process. This framework is expected to be useful as a guide for researchers and practitioners work towards DIMRC.

In Figure 7.2 it is indicated that DIMRC projects need input from two directions, needing to be well organised by the three essential initiators and

organisers, while also requiring practical knowledge and support of a knowledge base for DIMRC. This knowledge base should be under constant development and improvement based on experience. An educational module for Chinese biomedical engineering is presented as a special focus of the knowledge base in Section 7.2.

7.1.1 Initiators and organisers

The first block of Figure 7.2 relates to initiators and organisers. This block includes three essential Chinese stakeholders, with optional support coming from foreign partners. The Chinese initiators and organisers for DIMRC projects should be the Chinese government, companies and universities, who, working in cooperation, should define the initial stage of DIMRC projects, e.g., the project preparation phase. See Section 6.5.2.

The roles and responsibilities of the three stakeholders are proposed as:

- Chinese government: The Chinese government should be the main investor in DIMRC projects, providing more subsidies to medical device-producing companies and more grants to universities. It is recommended that government officials be involved in project R&D teams given their ability to provide support in many issues, such as policy matters, financial aspects, the organisation of field studies, medical certification and approval, etc.
- Chinese companies: Chinese companies should be the technology and market developers. It is recommended that they be in charge of developing and commercialising ICT technologies, manufacturing products and all business aspects.
- Chinese universities: Chinese universities should be the knowledge developers for DIMRC. A deeper knowledge of ICT technologies and design should be further developed in universities. At the same time, Chinese universities should explore and prepare new DIMRC project activities, such as organising stakeholder networks, conducting user research, etc.

Foreign partners may participate in this block in cooperation with the three main Chinese stakeholders. For instance, an international cooperation could include academic cooperation (e.g., international academic conferences, staff exchanges, student internships, etc.), governmental cooperation (e.g., setting up joint grants), or industrial cooperation (e.g., setting up Sino-foreign equity joint ventures). Sino-foreign international cooperation has already started in many sectors, such as agriculture, water management, etc. (Xie et al., 2011); however international cooperation for DIMRC is still lacking. It is the expectation of the author that foreign partners such as TU Delft, Philips, and Dutch and European medical organisations, etc., can play important roles in DIMRC in the future.

Other stakeholders, such as rural hospitals, village doctors and patients themselves, can also play an important role in DIMRC. In the current Chinese medical system (see Chapter 1) these institutions are led by local government, and as such are considered as a subsidiary of the central government.

7.1.2 Concrete DIMRC projects

This section opens a discussion of practical issues related to concrete DIMRC projects. This thesis has explored a number of issues, such as the composition of Chinese R&D teams, a design approach to identifying user needs, etc., through an analysis of two actual DIMRC cases: “Development of a blood pressure monitoring system incorporating ICT” (Section 5.4) and of “Exploring design opportunities for rural Shanghai” (Section 6.4).

Some practical lessons were learnt from these two cases. For example, the results of Section 5.4 showed that industrial designers, medical experts and biomedical engineers played important roles in the R&D phase of DIMRC, while the results of Section 6.4 showed that Chinese farmers were reluctant to talk with strangers and foreigners. This kind of knowledge of practical issues can be incorporated into a knowledge base through learning from experience.

7.1.3 The knowledge base for DIMRC

The third block in Figure 7.2 refers to the knowledge base for DIMRC, and lists the knowledge Chinese R&D teams should possess if they are to develop more and better DIMRC applications. The knowledge base has been compiled from two sources in this thesis:

- (1) Previous literature (Section 2.3) provided recommendations of three essential stakeholders: the Chinese government, universities and companies. The recommendations included:
 - Promotion by the government. Chinese government should guarantee a system and mechanism for DIMRC. Essentials of the guarantee should include:
 - Acceleration of the establishment of an enterprise- and market-oriented technological innovation system that combines manufacturing, education and research as a whole.
 - An improvement of the market environment for technical innovation, accelerating the development of entrepreneurial risk investment, and improving technical advice, technology transfer and other intermediary services.
 - The establishment of a favourable fiscal and tax regime; and financial and government procurement policies that support independent innovation should be implemented.
 - The ability to make good use of global scientific and technological resources, continuing to introduce advanced technologies from

foreign countries, and participate in international scientific and technological exchanges.

- o Strengthening the protection of intellectual property. Ineffective protection of intellectual property rights is having a major effect on technological innovation in China, where the intellectual property protection system needs improvement. The public, society as a whole and enterprises need to work together.
- Efforts from Chinese companies. Chinese companies should pay attention to three issues to improve their R&D environment:
 - o Improvement of institutional capacity, e.g., setting up workshops for R&D teams.
 - o Provision of more financial incentives to R&D facilities, e.g., bonuses to R&D teams if a patent is published.
 - o The creating of a culture of innovation, e.g., providing R&D teams with opportunities to take risks, and to demonstrate new products and processes to encourage their adoption.
- Strengthening Chinese (industrial and engineering) design education to augment the design competences of Chinese students: This can be done by providing supplementary courses and training from other disciplines, both nationally and internationally, e.g., learning advanced design knowledge from IDE/TU Delft. This has been discussed in more detail in Section 2.6.

(2) Knowledge of DIMRC was learnt from Chapters 3–6.

- The main stakeholders for DIMRC should come from both urban and rural regions. The stakeholders from urban regions should include Chinese universities and companies, while in rural regions they should be hospitals, doctors and patients. Some stakeholders are a part of both regions, i.e., local Chinese government and other members of Chinese society (e.g., patients' families). Figure 4.2 shows the relationships among these five major stakeholders.
- Chinese R&D teams: teamwork is a must in DIMRC, in which four players should be considered as key members of R&D teams: biomedical engineers, industrial designers, government officials and medical experts. Their roles and responsibilities should be as follows:
 - o Industrial designers (See footnote 21, page 206): Industrial designers should lead the development of integrative approaches, while also bringing existing design methodologies/methods/tools to the table, and organising context/user studies and participating in product development. They should take responsibility in strategy analysis, idea design and concept generation, business model development, etc.

- o Biomedical engineers: Biomedical engineers should lead the product development and should take responsibility in the materialisation of designs, prototyping building, manufacturing, engineering etc.
- o Government representatives: Government representatives should take a consultant role during product development. They should be responsible for public relations and assist in the organisation of field studies, and should lead in all matters related to policy and finance.
- o Medical experts: Medical experts act as advisors in medical issues during product development. They should take responsibility in all medical issues, such as patient safety, medical ethics etc.

The involvement of above four actors in different steps of the design process for DIMRC will be discussed in next section.

- Three educational goals were identified in the augmentation of the design competences of Chinese R&D teams (See Chapter 3). They were: (1) understanding China's cultural influence in DIMRC, (2) learning to identify design factors for DIMRC, and (3) applying and adapting (if needed) existing design methodologies to actual DIMRC projects. These three blocks have been explored in detail in this thesis, leading to the following results:
 - o 14 important aspects in China's design culture that influence DIMRC were identified (See Chapter 4), including "cooperation among different Chinese companies is not strong", "Usability design for DIMRC is not tailored to different regional cultures", etc. Table 4.4 lists the details of these factors.
 - o 24 important design factors for DIMRC were identified (See Chapter 5): lifestyle, habits, health awareness, skills, personal manner, direct communication with doctors, business model, affordability, medical insurance, local economic content, product policy, building of the team, aesthetics and emotion, comfortable operation, ease of operation, accessibility, reality, durability, flexibility, expandability, usability and privacy. Table 5.10 presents explanations of these factors.
 - o Four design methodology domains relevant to DIMRC were identified (See Chapter 6): "The Living Lab approach (LL)", "Entrepreneurs approach", "product design science approaches", and "holistic system thinking approach". The "Delft Design Methodology (DDM)" is a product design science approach that can be applied for DIMRC. Two example design methodologies for adapting DDM to DIMRC can be given as "a Prototyping driven IDE approach" and "From unstructured to structured". The adaptation processes were described in Sections 5.4 and 6.4,

and these two example methodologies will be introduced in detail in Section 7.2.

- Recommendations for three essential Chinese stakeholders: In previous chapters a total of 14 recommendations were provided for the Chinese government, universities and companies. See Table 7.1.

Table 7.1: Recommendations for the three essential Chinese stakeholders: Chinese government, universities and companies. Recommendations are categorised into five different colour-coded sections: Grey relates to the training of Chinese students with skills in co-design; red is about strengthening academic-industrial cooperation; orange denotes strengthening user research and investments for rural healthcare; green is about improving the design awareness of Chinese society; and white is about referring to a checklist of design factors. Recommendations sharing the same colour are proposed to be done together.

Item	Target group	Recommendation	Mentioned in section
1	Chinese universities	Courses relating theoretical fundamentals of new product development should be provided to Chinese biomedical engineering students. Chinese biomedical engineering institutes should adapt and adopt the curriculum design from Western industrial design universities, such as IDE/TU Delft. Students should also spend some time in rural China carrying out observational research, as well as in (Chinese) companies doing practical work.	4.7
2	Chinese universities and companies	External support from specialists in hospitals, universities and companies is also useful in the identification of design factors for R&D teams in DIMRC.	5.7
3	Chinese universities	Chinese universities may teach students design methodologies from IDE/TU Delft. One example may be the Delft Design Methodology.	6.7
4	Chinese universities	Chinese universities should provide students with more teamwork opportunities for DIMRC.	6.7
5	Chinese universities	Academia-industrial collaboration courses (e.g., the course “Project Advanced Products” at IDE/TU Delft) may be useful for Chinese universities.	4.7
6	Chinese companies	Chinese companies should strengthen cooperation with Chinese universities to include R&D knowledge exchanges and the establishment of academia-industry collaborative projects, both at staff and at student levels.	4.7
7	Chinese government	Chinese government should create a better system and mechanism to encourage academic-industrial collaboration and to protect intellectual property.	4.7
8	Chinese universities	Chinese R&D teams may benefit from the support of IDE/TU Delft or similar institutions, e.g., through	5.7

		cooperation projects, when they need to identify design factors. It would be helpful to learn from educational courses from IDE/TU Delft and incorporate them into Chinese design education. Knowledge from IDE/TU Delft should be integrated into Chinese design education for the identification of design factors. One suitable resource is the Delft Design Guide. (Ref: http://wikid.eu/index.php/Delft_Design_Guide [accessed on 16-OCT-2012])	
9	Chinese companies	The Chinese companies should create a design-oriented company culture, for example, emphasising the importance of user research regarding different regional cultures (e.g., usability for users, price, emotional support for users).	4.7
10	Chinese government	The Chinese government should increase awareness of the importance of industrial design among all stakeholders in Chinese society, while enacting design policies for new product development, regarding DIMRC.	4.7
11	Chinese government	The Chinese government should provide more subsidies for Chinese DIMRC manufactures and should stimulate them to make medical devices and systems affordable for local rural hospitals, CHCs and CHPs. The government also should make DIMRC services affordable for rural patients, and encourage staff and students from universities, as well as companies, to spend time in rural China understanding the needs of the rural Chinese.	4.7
12	Chinese companies	Chinese companies should pay more attention to user need in research. Social research should be one task of the R&D team in DIMRC.	6.7
13	Chinese government	The Chinese government should more effectively support academic research for DIMRC. One idea would be to set up a special department to help organise field studies in rural China.	6.7
14	Chinese universities and companies	Table 5.10 may be used as a reference checklist for biomedical engineers to identify design factors for DIMRC. By following this checklist, biomedical engineers will be able to supplement those factors with other existing formats (e.g., ISO standards).	5.7

In Table 7.1, the 14 recommendations are clustered and coded with five different colours, and there are some correlations among the recommendations with the same colour. For instance, Items 1, 2, 3 and 4 all refer to training Chinese students with skills in co-design: Item 1 is about the education of co-design between biomedical engineering students and users;

Item 2 is about cooperation between biomedical engineering students and companies; Item 3 is about the education of the co-design methodologies in universities; and Item 4 is about teamwork within R&D teams. These four items are all shaded in the same colour (grey) in the table, indicating that they should all be carried out at the same time.

7.2 The educational module for Chinese biomedical engineering students

A new framework for DIMRC was introduced in the first part of this chapter, (Figure 7.2) in which the lack of design competences was considered as a barrier to the creation of suitable DIMRC applications under the government strategy of “Created in China” (See Section 2.2). Providing a solution for the augmentation of design competences of Chinese R&D teams, therefore, was identified as the main research objective of this doctoral thesis (See Section 2.6).

As another intended result of this thesis, this section will introduce an educational module for Chinese biomedical engineering education in DIMRC, suggested as one possible solution to augmenting the design competences of Chinese R&D teams (The reasons for choosing this approach will be given in Section 8.1.3).

7.2.1 Background to the Educational Module

A What is this part?

This part describes an educational module for the strengthening of Chinese biomedical engineering education in Design and development of ICT-enabled Medical device and system for Rural China (DIMRC). This part focuses only on the R&D phase of DIMRC and is proposed as a supplement to the course being currently taught in biomedical engineering education in Chinese universities now, not a substitute.

B Who should read this part?

The prime target groups in this section are ***Chinese biomedical engineering professors, senior Chinese biomedical engineering undergraduate students and Chinese graduate students***. Secondary target user groups include:

- (1) ***Fresher Chinese biomedical engineering students***. If the reader belongs to this group, please first read up on the development of ICT-enabled medical devices and systems before reading this document. One recommended book is: “Design of Biomedical Devices and Systems” (King & Fries, 2009). Available at: <http://www.crcpress.com/product/isbn/9781420061796;jsessionid=P4Bc+6FZ7LOYc2Vfob5t0w>** (accessed on 16-OCT-2012)

- (2) **Other Chinese researchers or practitioners, e.g., physicians and social workers, without a biomedical engineering background.** If the reader belongs to this group, please first read (1) about the development of ICT-enabled medical devices and systems; and (2) about the roles and responsibilities of biomedical engineers. One recommended book is: “The Biomedical Engineering Handbook” (Brozino, 2000). Available at: <http://www.amazon.com/Biomedical-Engineering-Handbook-Electrical/dp/0849383463> (accessed on 16-OCT-2012).
- (3) **Foreign researchers or practitioners who have interests in DIMRC.** If the reader belongs to this group, please first obtain some knowledge about China, in particular rural China, medical devices and systems in rural China, and ICT in rural China. For example, read Section 1.1, Section 1.2, and Appendix A. Secondly, please develop some personal expertise in biomedical engineering, and if needed, read some basic books on the subject.

C How to use this part?

This part can be used as DIMRC-related course material by Chinese biomedical engineering students in a university course, e.g., a course on medical instrument design (e.g., first year MSc course in biomedical engineering, Shanghai University). This document may also be used as training material in student projects for DIMRC, such as graduation projects. Other researchers or practitioners can use this document as a source of reference for DIMRC.

7.2.2 Definitions used in Educational Module

Design and development of ICT-enabled Medical device and system for Rural China (DIMRC): Designing and developing medical products/systems that are supported by Information and Communication Technologies (ICT) to resolve health problems in rural China (For more descriptions, read Section 1.6.)

Research and Development (R&D): The creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society; and the use of this stock of knowledge to devise new applications. In general the R&D process is iterative and includes several steps, such as explore, hypothesise, clarify, design, develop, test, implement, improve, scale up, etc. (OECD, 2008) (For more descriptions, read Section 2.1.3).

Design culture: The attitudes, values, goals and practices of different stakeholders that influence product design. Design culture is the study of the interrelationships between design artefacts, in all their manifestations, the work of designers, production of a design (including advertising and distribution) and their consumption (For a detailed description, see Section 4.1.1).

Design factor: Aspects of designs that should be considered to satisfy various stakeholders, such as user needs and aspirations, the needs of manufacturers,

businesses, environmental and social concerns, designers own beliefs, values and urge for expression, etc. (Section 5.1.1 provides more detail).

Design methodology: The systemic process comprising design methods that are, can be, or have been applied for product design (Pabini, 2010) (For more details, see Section 6.1.1).

Design method: The way to define specifications of design solutions, which can lead to better design activities (Nigel, 2006) (More on this can be found in Section 6.1.1).

7.2.3 The adaptation of King's approach

There are several design methodologies and models that are used by Chinese biomedical engineers to design and develop biomedical devices and systems, e.g., V-model (Rottier & Rodrigues, 2008), the ISO 13845 medical device standard (Ref: http://www.iso.org/iso/catalogue_detail?csnumber=36786 [accessed on 16-OCT-2012]), King's approach (King & Fries, 2009), etc. King's approach is a systemic design process, created specifically for biomedical engineers, and consisting of six steps. See steps 1–6 in Figure 7.3 (For more details, see Section 5.1.2).

King's process is widely taught in biomedical engineering institutes around the world, including China. The process has been widely applied in biomedical device and system development; however the results of Chapter 3 reveal that Chinese R&D teams (including biomedical engineers) often face three challenges in this process when designing and developing DIMRC applications: (1) understanding cultural influence; (2) identifying design factors; and (3) applying and adapting design methodology (For more details, see Section 3.5.1).

It is these three challenges that have been the focus of this thesis, having been investigated in detail in Chapters 4–6. The results of these chapters were used as three educational blocks to improve King's approach. See Step 0 in Figure 7.3.

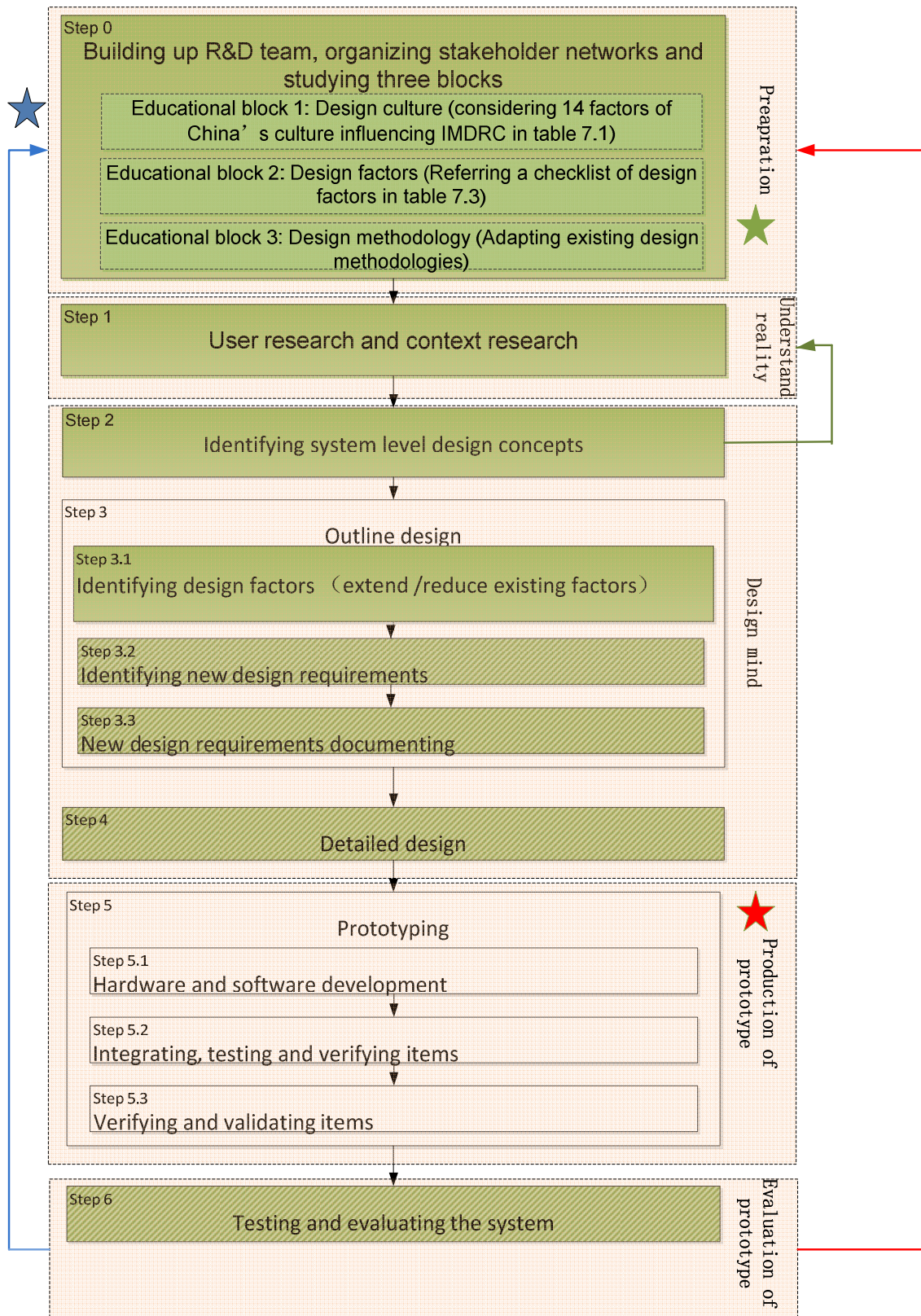


Figure 7.3: The proposed design approach for DIMRC has been adapted from King's approach, and is presented as an integrative approach (Integrated with different design issues, i.e., design culture, design factors and design methodology. For further discussion, see Chapter 8). The green sections show four steps with major improvements. Steps 1, 2 and 3.1 are significantly improved. The shaded parts are slightly improved steps. All steps have been

improved by studying the three educational blocks in step 0. The different steps are also divided into five domains: Preparation, Understand reality, Design mind, Production of prototypes, and Evaluation of prototypes. In practice, this approach can be used in three different types of projects, meaning that there are three different potential uses of this process in practice, which are shown different colours. (Possibility 1 in green; Possibility 2 in blue; and Possibility 3 in red. The star refers to the starting point of each possibility). All three possibilities are iterative. For further descriptions on the three possibilities, see Table 7.4.

7.2.4 The proposed design approach for DIMRC

Figure 7.3 proposes a design approach for DIMRC based on an adaptation of King's approach. There are two significant changes to the original approach.

Adaptation I: A new step

A new step, "Step 0: Building up R&D teams, organising stakeholders and studying three educational blocks", has been added. This step is in the early stages of the design process. Knowledge integration is emphasised in this step through teamwork and a study of the three educational blocks.

- (1) R&D teams: Because DIMRC is a complex task, multidisciplinary teamwork is vital for DIMRC. Many different individuals should be involved in a R&D team, including project managers, industrial designers (defined in footnote 21, page 206), biomedical engineers, electrical engineers, marketing managers, etc. (For more introductions about these individuals, see Section 2.1.3). Among these, four players should be considered as key members of R&D teams for DIMRC: industrial designers, biomedical engineers, government officials and medical experts; and their roles and responsibilities are introduced in Section 7.1.3.

These four key actors should be involved in different steps in Figure 7.3 (See Table 7.2). Table 7.2, relating the experiences of actual DIMRC cases, illustrates that biomedical engineers should be involved in the entire R&D cycle; industrial designers and medical experts should be involved in the entire cycle, except for step 5 – prototyping; and government officials should be involved in steps 0, 1 and 6. (For more discussions of these results, see Sections 5.6.4 and 6.5.1).

Table 7.2 Four key members in the R&D team for DIMRC and their involvement in different steps of Figure 7.3. X indicates the involvement of that particular team member. The results are based on the lessons learned in Chapters 5 and 6.

R&D Team member	Step 0	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
Industrial designers	X	X	X	X	X		X
Biomedical engineers	X	X	X	X	X	X	X
Government officials	X	X					X
Medical experts	X	X	X	X	X		X

Furthermore, based on results of previous chapters (e.g., Table 6.8), Table 7.3 provides the possible contributions from industrial designers, government officials and medical experts to biomedical engineers in the team.

(2) Three educational blocks: While the R&D team is being put together, three educational blocks should be studied by the R&D team: design culture, design factors and design methodologies for DIMRC. The three educational blocks will be introduced in detail in Section 7.2.5. By studying the three educational blocks, several steps of the design process for DIMRC can be expected to be improved by the R&D team. A total of three steps are affected (shaded in green in Figure 7.3):

- Improvements are expected in Step 1: Context and user research. By studying the educational block “design methodologies”, the R&D team can be expected to obtain design methodologies/methods/tools for the creation and execution of user studies (See Section 6.3). By studying the educational block “design culture”, the R&D team can be expected to learn the best ways of communicating with Chinese farmers (See Chapter 4).
- Significant improvements are expected in Step 2: Identifying system level design concepts. By studying the educational block “design culture”, the R&D team is provided with 14 design factors of China’s culture that influence DIMRC (See Textbox 7.1). The R&D team should consider these both before and during Step 2 “identifying design concepts in the system level”.
- Significant improvements are expected in Step 3.1: Identifying design factors for different items. By studying the educational block “design factors”, the R&D team is provided with a checklist of design factors for DIMRC as a start point. The R&D team is expected to use these design factors at the outset, and during the design process, the R&D team is expected to extend (or reduce) design factors. For a more detailed description about this improvement, see Section 7.2.5.

Table 7.3 The possible contributions from three team members (other than biomedical engineers) in different steps of Figure 7.3. X denotes no contribution by the team member in that step.

Steps	The task of biomedical engineers	Possible contributions from industrial designers, for instance, from IDE/TU Delft	Possible contributions from medical experts	Possible contributions from government officials
0	Creating R&D teams and organising a stakeholder network	Establishing suitable, communications with different stakeholders	Introducing suitable stakeholders from the medical domain (e.g., hospitals)	Introducing suitable stakeholders
1	Identifying user needs and design opportunities	Selecting and combining design methods, tools and techniques to obtain insights of user needs in a field study	Providing secondary user and context information	Organising field studies in rural regions through a “top-down” approach
2	Providing the overall design goal at the system level	Providing and applying systemic thinking, including design culture and other issues	Providing professional knowledge and suggestions based on personal experience	X
3	Identifying design factors and design specifications	Providing and executing design methods, tools and technique to identify design factors	Providing professional knowledge and suggestions based on personal experience	X
4	Providing concrete design assignments, hardware and software protocols	Ergonomics, CAD, fast prototype approach, etc.	Providing professional knowledge and suggestions based on personal experience	X
5	Hardware and software development, item integration and validation	X	X	X
6	Prototype testing and design evaluation	Providing and executing co-design methods, tools and techniques for user testing	Providing medical standards, evaluating the design	Evaluating the design

Besides the three major improved parts, some minor improvements are also expected in other steps, i.e., in Steps 3.2, 3.3, 4 and 6 (shaded green in Figure 7.3). These improvements result from the significant improvements to Step 3.1 (extend/reduce new design actors), and include: (1) the R&D team is expected to identify and document new design requirements after extending (or reducing) design factors (improvement to Steps 3.2 and 3.3); (2) the R&D team is expected to get new detailed design ideas by analysing new design requirements (improvement on Step 4); (3) the R&D team is expected to test the prototypes through multi-activities, such as user tests during field studies, technical lab tests; and evaluation meetings involving all stakeholders (improvement to Step 6).

Adaptation II: Five domains

The second adaptation in Figure 7.3 involved the division of Steps 0–6 into five domains: Preparation, Understand reality, Design mind, Production of prototype and Evaluation of prototype. These domains are sourced from the “Four Domain Model” (Figure 6.3).

The “Four Domain Model” is a design model developed in this thesis that reflects how design students from IDE/TU Delft successfully design products for Base/Bottom of the Pyramid populations (BoP: those populations who live at the base of the economic pyramid, defined in Section 3.1.1. Most Chinese farmers can be considered as BoP). The descriptions of the four domains are (For more information, see Section 6.3):

- Understand reality: Industrial designers analyse the usage contexts through interventions.
- Design mind: The brain activity of industrial designers in the generation of design concepts.
- Production of prototype: Creating visual prototypes in the design process (simple product interfaces or product appearance models. These are different from prototypes made by biomedical engineers in Figure 7.3. Biomedical engineers go deeper into technical development).
- Evaluation of prototype: Evaluating and testing the prototype.

The most important feature of the “Four Domain Model” is that the four domains are accessed iteratively (See Figure 6.5), in that most DfBoP cases have no predefined starting point. For this reason, the iterative process may be better suited and more flexible than linear approaches. In Figure 7.3 it is proposed that the design process for DIMRC is not completely linear, as in practice there are three different possibilities in using the design process for DIMRC. See Table 7.4.

Table 7.4 Three possibilities in using the design process in Figure 7.3 for DIMRC, and the benefits of each possibility.

Item	Project type	Possibility to use the process	Benefit
1	Market research (e.g., identifying design opportunities for commercial companies)	Step 0–1–2–1–2 ... (iteration of Steps 1 and 2)	R&D teams can conduct theoretical tests of design concepts in user and context studies
2	Design a novel product	Steps 0–1–2–3–4–5–6–1–2–3–4–5–6... (iteration of Steps 1–6)	R&D teams can gradually improve the designs through iteration. The number of iterations depends on the time schedule.
3	Re-design based on existing products	Steps 5–6–0–1–2–3–4–5–6–1–2... (the first iteration does not conclude Steps 1–4)	R&D teams can use existing products as an initial prototype. The time of product development may be shortened by developing existing prototypes.

Table 7.4 lists three possibilities in the use of the design process in Figure 7.3, each targeting three different types of design project in practice: (1) Market research projects, e.g., if a medical device company wishes to identify opportunities for applying a new ultrasound technology for rural China, R&D teams will be assigned to carry out a market research; (2) Complete product design projects, e.g., if a medical device company has a new ultrasound technology and they plan to develop a new device for rural China, R&D teams may be assigned to develop the device; and (3) Re-design based on existing products, e.g., if a medical device company has already developed an ultrasound device, but plan to make it more affordable for rural China, R&D teams may be assigned to re-design the device.

Possibilities 1 and 3 were identified from two of the authors' own DIMRC cases in this thesis: (1) Possibility 1 was identified from the case "Exploring design opportunities for rural Shanghai". In this case, two iterations were made (Steps 0–1–2–1 ... See Section 6.4); and (2) Possibility 3 was identified from the case "Development of a blood pressure monitoring system incorporating ICT". In this case, two iterations were made (Steps 5–6–0–1–2–3–4–5–6 ... See Section 5.4). Possibility 2 was identified from a student DIMRC case from IDE/TU Delft (Item 7, Table 5.2), in which the approach was used to develop a support tool for Chinese village doctors. In the case, two iterations were carried out (Steps 0–1–2–3–4–5–6–1–2 ... Ref: van Groot, 2006). The design processes of all three possibilities received positive evaluations from the stakeholders involved in the projects. In the following section, the three educational blocks will be explained in detail.

7.2.5 Three educational blocks

A Educational block 1: Design culture

The first educational block (of Step 0, Figure 7.3) is related to China's cultural influence on DIMRC, involving five stakeholders: the Chinese government, Chinese universities, Chinese companies, end users (rural hospitals, medical staff and patients) and other members of Chinese society (e.g., patients' families etc.). For a detailed description of the relationships among these five stakeholders, see Figure 4.2. There are 14 important factors in China's design culture influencing DIMRC (Chapter 4), see Textbox 7.1.

Textbox 7.1: 14 important factors in China's design culture that should be considered while identifying system-level design concepts. The factors are categorised under five headings: cultural influences from the government, universities, companies, end users and other members of Chinese society.

Cultural influences from end users
Usability design for DIMRC should be tailored to different regional cultures.
Affordability (in DIMRC) is not solely dependent on cost, as it depends also on different regional cultures and emotional experience.
Emotional support, e.g. the style of the product is important in DIMRC. Suitable emotional support should be provided for the various regional cultures.
Cultural influences from Chinese universities
Chinese students have little opportunity to work in DIMRC with people from other disciplines.
Chinese students have little practical experience in working with users in DIMRC.
Chinese industrial design education currently emphasises product appearance and modelling in DIMRC.
Design methodologies in Chinese biomedical engineering institutes are not sufficiently advanced for DIMRC.
Cultural influences from the Chinese government
The Chinese government does not provide an efficient environment for encouraging the exchange of R&D knowledge between companies and universities, including DIMRC.
The Chinese government has not provided an efficient protection mechanism for intellectual property, including DIMRC.
The Chinese government encourages reimbursements for DIMRC services used by rural patients from the public medical insurance.
Cultural influences from other members of Chinese society
Most Chinese people think design is part of the art discipline, including DIMRC.
Cultural influences from Chinese companies
Cooperation in R&D among different Chinese companies is not strong enough.
Chinese companies lack a design-oriented culture of independent thinking and innovation, which is the case also for DIMRC.
The knowledge exchange between Chinese companies and universities is still poor.

In considering above factors in Steps 0–2, Chinese biomedical engineers have raised some design questions that will be helpful for them both before and during the identification of system-level design concepts, and will assist them in the creation of their R&D team and when organising user research. Example questions include: How can the R&D team (located in the university) work efficiently with companies? What kind of ICT tools are accepted by local end users (village doctors and patients)? etc.

Table 7.5 provides some examples of the questions regarding cultural influence addressed by the R&D team in the case “Development of a blood pressure monitoring system incorporating ICT”, the development process of which was introduced in Section 5.4.

Table 7.5: Some example questions in the case “Development of a blood pressure monitoring system incorporating ICT” considering factors of design culture. These example questions were raised both before and during the identification of system-level design concepts.

Factors of design culture from Textbox 7.1	Example questions	Steps in which the question was raised
Four factors of cultural influence from Chinese university	What kinds of external support are still needed for the R&D team? For example, will the R&D team need professional project management support from companies?	Building up the R&D team (Step 0)
Three factors of cultural influence from the Chinese government	How can support be obtained from the government offices in charge of the public medical insurance system?	Organising stakeholders (Step 0) and identifying system level design concepts (Step 2)
Three factors of cultural influence from Chinese end users	What kinds of user interfaces are most acceptable for users in this region? (Table PC, mobile phone, laptop) What kinds of business models are most accepted by users in this region? What kind of social and emotional support is needed for the application of ultrasound detection in the region?	User research (Step 1) and identifying system level design concepts (Step 2)
One factors of cultural influence from Chinese companies	How to involve partner companies in the design phase with their resources, knowledge and technologies?	Organising stakeholders (Step 0)
Three factors of cultural influence from other members of Chinese society	How to protect intellectual property when the design concept is used in field studies?	Identifying system-level design concepts (Step 2)

The questions in Table 7.5 influenced the R&D team while making decisions regarding the creation of the R&D team, organising stakeholders (Step 0), carrying out user and context research (Step 1) and identifying system-level

design concepts (Step 2). For example, the mobile phone was the most popular user interface in the region, leading the R&D team to explore the possibilities of mobile phone-based applications during the user research. A more detailed description of these decisions can be found in Section 5.4.

Advanced design institutes offer courses to help students understand local design culture. Some example courses at IDE/TU Delft include student group projects, individual final year graduation projects and internships. Chinese biomedical engineers could take part in such courses to acquire the suggested knowledge.

B Educational block 2: Design factors

The second educational block is related to design factors. A particular problem faced by biomedical engineers related to design factors is that they lack sufficient knowledge of design factors to generate a checklist for a new topic, e.g., DIMRC. They normally use previous literature as a source of design factors for DIMRC, however no accessible overview of design factors exists for DIMRC (For more descriptions and explanations, see Chapter 6).

The results of previous chapters have led to the creation of a checklist of 24 design factors (Chapter 5). See Table 7.6.

Table 7.6: Design factors for DIMRC and their explanations, categorised under three headings: user aspect, economic aspect and technical aspect (Section 5.3).

Aspect	Design factors	Explanations
User	Lifestyle (Jiang et al., 2009)	A characteristic bundle of behaviours that makes sense to both others and oneself at a given time and place, including social relations, consumption, entertainment and dress.
User	Habit (Heeks, 2006)	User behaviours that will result in design results.
User	Health awareness (Jiang et al., 2009)	Healthcare cognitive reactions of the rural population in China.
User	Skills (Heeks, 2006)	Education level and ability of patients and medical staff in rural China.
User	Personal manners (Matinez et al., 2005)	The unique way an individual user behaves when operating a system.
User	Direct communication with doctors (from the case)	The direct interaction between patients and doctors (face-to-face).
Economic	Business model (from Table 4.5)	The profit-producing system that results in multi-win situations in rural China.
Economic	Affordability (Rithey et al., 2009)	The price paid by users for the solution.
Economic	Medical Insurance (from the case)	The form of collectivism by means of which people collectively pool their risk, in this case the risk of incurring medical expenses.

Economic	Local economic content (from the case)	Refers to the consumption opportunity gained by an entity within a specified local content.
Economic	Social impact and social awareness (Wells & Wells., 2007)	Referring to the processes of analysing, monitoring and managing the intended and unintended social consequences, both positive and negative, of planned interventions (policies, programmes, plans, projects) and any social change processes invoked by those interventions.
Economic	Local government (Calvin et al., 2009)	Market rule controller and a potential payer in ICT healthcare solutions in rural China.
Economic	Product policy (Rithey et al., 2009)	A deliberate plan of action to guide product decisions and achieve a rational outcome.
Technical	Building of the team (Wells & Wells, 2007)	Stakeholders in ICT-enabled healthcare in rural China.
Technical	Aesthetic appeal and emotion (from the case)	A products' features of appearance, such as size, colour and style, and its acceptance by families and friends.
Technical	Comfortable operation (Rithey et al., 2009)	Users feel comfortable with the operation of the system, and the feeling that it will not (or seldom) influence their lives physically or physiologically.
Technical	Ease of operation (Rithey et al., 2009)	The simple operation systems and interfaces by which users operate the system.
Technical	Accessibility (Rithey, 2009)	The degree to which the solution is accessible to as many people as possible in rural China.
Technical	Reality (Rithey et al., 2009)	The ability of the system to perform and maintain accuracy in routine use.
Technical	Durability (Diehl, 2011)	The ability of the system to endure different environments.
Technical	Flexibility (Rithey et al., 2009)	The ease at which the system can be adapted when external changes occur, such as synchronising to changes in the HIS.
Technical	Expandability (Rithey et al., 2009)	The ability to allow new functions to be added.
Technical	Usability (Diehl, 2011)	Action that occurs between the user and the solution.
Technical	Privacy (from the case)	The security of medical data in the process of management and transmission.

Chinese biomedical engineers can use above design factors as a starting list, and by considering these factors, they can come up with several concrete design questions that can help the R&D team identify design requirements. Textbox 7.2 provides some questions from the case “Development of a blood pressure monitoring system incorporating ICT”. These questions were identified through the consideration of design factors found in previous literature (See Section 5.4).

Textbox 7.2: Some questions identified in the case “Development of a blood pressure monitoring system incorporating ICT”.

USER ASPECTS
How often do rural patients need to use a blood pressure monitoring system? (Lifestyle) What kind of ICT tools do village doctors use currently? (Habit) What is the level of education and skill of village doctors? (Skill) What length of time of an operation is preferred by village doctors, such as for hypertension homecare? (Easy to use) What size of blood pressure monitoring system is preferred by village doctors? (Comfortable use)
ECONOMIC ASPECTS
Who should own the patient data in the system? (Business model) How much are rural patients willing to pay to use a blood pressure monitoring system? (Affordability) What special function for this system is suggested by local government? (Local economic content)
TECHNICAL ASPECTS
Can wireless communication technologies be used? (Accessibility) Can the patient information be integrated into the existing medical information system in hospitals, e.g., by USB? (Flexibility) Can different measurement sensors be integrated into the system? (Expandability)

By considering questions in textbox 7.2, design requirements were identified (Step 3.2). Other steps in Figure 7.3 (Steps 3.3–6) were also carried out by the R&D team. For more descriptions, see Section 5.4.

Of course, different design factors should be assessed for every DIMRC project, and so Chinese R&D teams should acquire capabilities in the identification of design factors by themselves. To learn such capabilities, Chinese biomedical engineers could follow at least two approaches: (1) engage in teamwork with qualified industrial designers (e.g., designers from IDE/TU Delft); and (2) attend courses at advanced design schools (e.g., IDE/TU Delft), and take part in student group projects, individual final year graduation projects and internships.

C Educational block 3: Design methodologies

The final educational block is related directly to design methodologies for DIMRC. The results garnered in Chapters 5 and 6 suggest that existing design methodologies, methods, tools and techniques (e.g., Delft Design Methodology, DDM) may be applied for DIMRC.

To illustrate the adaptation, this block also provides two design approaches developed in this thesis. They are (1) the “Prototyping driven IDE approach”, and (2) “From unstructured to structured”.

Prototyping driven IDE approach (Figure 5.7)

The “Prototyping driven IDE approach” is a design methodology for identifying design factors for DIMRC (See Figure 5.7), integrating complementary elements from industrial design (IDE/TU Delft) and biomedical engineering approaches. The advantage of this methodology is that R&D teams can build their own design factor library and tailor design factors to actual DIMRC projects by removing or enhancing some of the design factors in the design process. This approach was applied in an DIMRC case “Development of a blood pressure monitoring system incorporating ICT”. The evaluation results for the case showed the approach to be promising in that case. For more information about the implementation of this approach in the actual DIMRC project, see Section 5.4.

In this chapter the approach has been further identified as “Possibility 2” (Table 7.4) in using the design process in Figure 7.3. (Step 5–6–0–1–2–3–4–5–6 ...)

This approach follows the following sequence of activities:

- Step 5+6: Initial prototype development. Based on existing products on the market, the first generation prototype system (Version 1) should be built up within a short timeframe. The initial prototype system should also be tested.
- Step 0: Preparatory work. Obtaining an existing checklist of design factors as the start. Chinese R&D teams can use the checklist of design factors in Table 7.3 as a point of reference.
- Step 1: Context and user study. By using the first generation prototype system (Version 1), research activities related to the identification of design factors should be established through a user study.
- Step 2: Identifying design concepts at the system level. After analysing data from Step 1, the system-level design concepts should be identified.
- Step 3: Outline design. New design factors may be generated and some design factors from Step 0 may be reduced. Explanations of the new design factors should be provided, and the new design requirements should be identified and documented.
- Step 4: Detailed design. Based on the new design requirements, some detailed design concepts at the item level should be developed.
- Step 5: Re-prototyping. A new prototyping system (Version 2) should be created according to the results of Step 4.
- Step 6: Testing and evaluation. The new prototype should be tested and evaluated.

From unstructured to structured (Appendix C)

“From unstructured to structured” is an approach for identifying design opportunities. This approach was learnt from the case “Identifying design

opportunities for rural Shanghai” in which it was found by the biomedical engineers to be efficient, acceptable and understandable. The target group for this approach are fourth year biomedical engineering bachelor students in China who are about to design medical devices addressing healthcare issues in rural China. This approach could be implemented in the “medical design” course for biomedical engineers at Shanghai University (See Section 7.3). The core aim is to help readers structure useful user and context data from a number of sources in an approach comprising six steps. These can be summarised as follows:

- (1) Practice being a user yourself. Imaging you are the target user and that you will be observed, asked questions and interviewed. What kind of conversation would be welcomed by you? What kind of questions would be welcomed by you?
- (2) Identifying information sources. If you are going to work with an unfamiliar user group, it is a good idea to get some ideas and fundamental information from local partners, who may be industrial companies, educational facilities or non-governmental organisations. Your partners will provide you with an overall picture of the users and will give you the first idea of their conditions. The information should be systemic and statistical, but sometimes lacks detail.
- (3) Qualitative research. Interacting with the users. First of all, observe the user’s actions, from which you will get the insight of both the experienced and inexperienced users. Secondly, talk with the users, interview them and take notes. Thirdly, write down their stories, and create personas if necessary.
- (4) Quantitative research. Through qualitative research you will have already gained a lot of information about users. Sometimes this is structured for your projects, but sometimes you will have to prove them through quantitative research, such as questionnaires. At the same time, it may also be helpful to expand your information through a quantitative research of different opinions.
- (5) Needs analysis. You have enough user information, but you should identify the relationship between user needs and product needs (solutions). The simplest approach to this is to compare user needs and the existing solutions through a needs analysis.
- (6) Define your preliminary goal, which is the start of the concept design. You should write down your design tasks in this step. These tasks may be totally new products, new functions for existing products, etc.

For more descriptions of this approach, see Appendix C.

The two approaches, “Prototyping driven IDE approach” and “From unstructured to structured,” are only suggested approaches. They are only examples, and have not been tested on other DIMRC cases. Developing them into general methodologies will take a long time and a great deal of effort,

however readers may decide to use these two approaches as points of reference.

Chinese biomedical engineers are also expected to apply and adapt (if needed) existing design methodologies and methods in their own DIMRC projects, which can be done in at least two ways: (1) developing a close working relationship (teamwork) with qualified industrial designers (e.g., designers from IDE/TU Delft), who can take on the role of methodology developers; and (2) attend courses at advanced design schools (e.g., IDE/TU Delft) to obtain such capabilities.

7.3 Integration of the educational module into the current Chinese biomedical engineering education system

To illustrate the possible integration of the educational module (Section 7.3) into the current Chinese biomedical engineering education system, we use the example of the Biomedical Engineering Institute at Shanghai University. (<http://www.ci.shu.edu.cn/swyx08.htm> [accessed on 16-OCT-2012]). See Figure 7.4.

Figure 7.4 describes the educational programme at the Biomedical Engineering Institute in Shanghai University. It is divided into three phases: Bachelor phase (Years 0–4), MSc phase (Years 5–7.5) and PhD phase (year 7.5–10.5). In the first three years of the bachelor phase, all Chinese biomedical engineering students take the same courses to gain engineering skills and basic medical clinic skills, such as C++ programming, information technology, electrical component, anatomy, etc. In years 3–3.5 students choose their research directions and the related elective courses, which, for medical device design (Option 2), include medical electronics (Wang, 2000), biomedical engineering device design (Wang, 2005), etc. In years 3.5–4 students choose their bachelor graduation projects.

The graduation projects in the MSc and PhD phases are very long (MSc 2 years, PhD 2.5 years). Upon entering the institute, a Chinese MSc or PhD student chooses a supervisor, who will coach him/her for the duration of his/her studies. In China, the supervisor is usually referred to as “Boss” by the students.

The educational module detailed in Section 7.2 could be implemented in the blue sections of Figure 7.4. There are three options for integrating the module into existing biomedical engineering courses:

(1) Adding the module into the bachelor period in Year 3–4. In this period, bachelor students are taught design knowledge relevant to the design and development of medical devices. The knowledge should be broad, but not too deep. Hence, in this period knowledge of user and context research (from the

educational module) could be emphasised. For example, some methods and tools in user research, e.g., brainstorming, interviews and questionnaires, could be taught to bachelor students in the course “medical design” in Year 3–3.5. Knowledge about working in a team could also be imparted to bachelor students in their graduation project in Year 3.5–4.

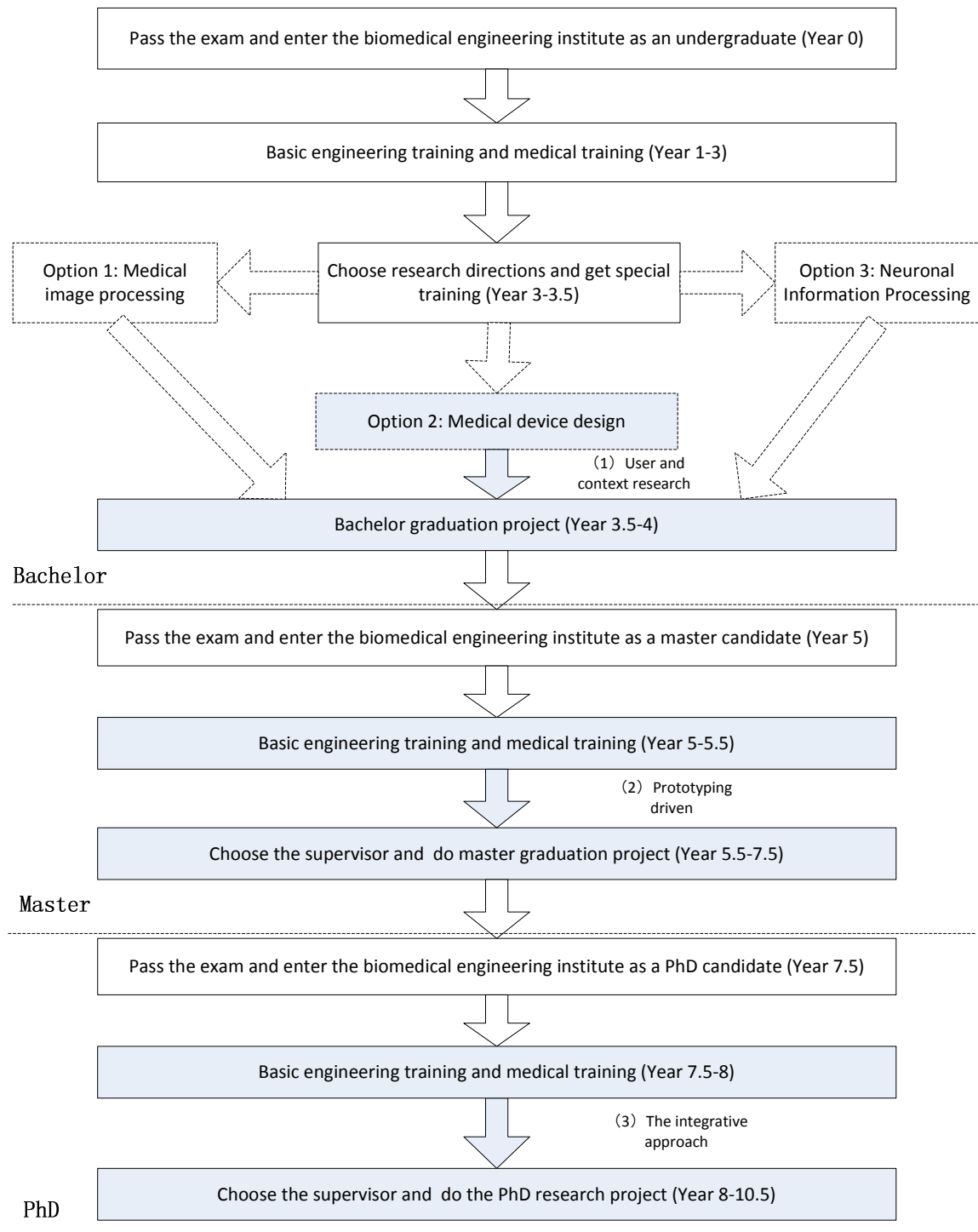


Figure 7.4 The current educational programme at the Biomedical Engineering Institute of Shanghai University. The educational module could be integrated into the blue parts.

(2) Adding the module into the MSc period in Year 5–7.5. In this period, MSc students are taught how to design and develop parts of medical devices (e.g., software, or a sensor part of a medical device). In this period, knowledge of prototyping (from the educational module) could be emphasised. For instance, knowledge about the identification of design factors (i.e., “Prototyping driven approach”, the reference checklist of design factors) could be taught to MSc students in the course “Biomedical engineering device design” in Year 5–5.5. Knowledge could also be applied in the MSc graduation project in Year 5.5–7.5.

(3) Integrating the module into the PhD period in Year 7.5–10.5. In this period PhD students are taught to design and develop complete medical devices, and are involved in government-funded research projects, and so in this period, knowledge of integrative approaches (from the educational module) could be emphasised. For instance, a design process for DIMRC (Figure 7.3) could be taught as an example in the course “Advanced biomedical engineering device design” in Year 7.5–8. PhD students are also expected to adapt existing design processes (e.g., King’s approach) by themselves in their own projects.

If the implementation of the educational module in Shanghai University is successful, the module can be introduced at other biomedical engineering institutes in China. Currently, more than 300 Chinese universities have biomedical engineering departments (all over China), and medical device design is an important topic for these institutions (See Chapter 2). The educational module could be a complementary course material for them or could act as a guide for biomedical engineering students, or it could be used in graduation projects.

However, to achieve the above goal, many other steps have to be taken. Scientific papers related to this educational module should be published in journals indexed by SCI (Science Citation Index), as research outputs indexed by SCI draw the attention of Chinese biomedical engineering professors. A book about DIMRC and this educational module could also be written, with Chinese biomedical engineering professors invited to write different chapters. Such cooperative research activities could help in the implementation of the recommendations of this PhD thesis throughout China.

7.4 Evaluation of the framework and the educational module

To test whether the framework and the educational module would be useful for Chinese biomedical engineering education, an evaluation study was carried out in July 2012 using a questionnaire. A biomedical engineering professor from a Chinese university and a senior biomedical engineer from a Chinese medical device company participated in the evaluation study.

Firstly, a summary of this thesis and all of Chapter 7 (Except for Section 7.4) in Chinese were sent to the two participants by e-mail, and they were asked to

read the material. Secondly, they were asked to send any questions they may have about the material, for instance, if they did not understand certain sentences, to the author of the thesis, who answered their queries via MSN. Finally, once all queries had been answered satisfactorily, the participants were sent a questionnaire that included the following questions:

- Q1: Is the framework for DIMRC complete? Is there anything missing?
- Q2: Would this educational module be useful for medical device design in the current biomedical engineering education system? Why?
- Q3: In what biomedical engineering courses could this educational module be applied? At what stage of biomedical engineering education?
- Q4: How could the educational module be improved?

The answers to the above questions were collected from the respondents in early August 2012. Textbox 7.3 shows the answers from the two participants

Textbox 7.3: Answers to the questionnaire to evaluate the framework for DIMRC and the educational module. P1: Participant 1 (Chinese biomedical engineering professor); P2: Participant 2 (Biomedical engineer from a Chinese medical device company).

Q1: Is the framework for DIMRC complete? Is there anything missing?
P1: The framework is interesting. As the funding providers, Chinese governments play important roles in DIMRC; however at the organisational level, your framework does not provide recommendations about how Chinese universities and companies should work with governments. P2: The framework is interesting, but I am still missing the information about how Chinese companies should work with Chinese universities and governments.
Q2: Would this educational module be useful for medical device design in the current biomedical engineering education system? Why?
P1: It is useful. Our department does not have such a guide to product design. P2: I am not sure whether the education module is really useful in education. I think at least the guides of design culture are useful.
Q3: In what biomedical engineering courses could this educational module be applied? At what stage of biomedical engineering education?
P1: This guide is suitable for graduate students. We could create a new course about medical product design. This guide could be used for that. P2: The module could be used in the third year of bachelor studies. You should choose some suitable universities, which should have strong backgrounds in biomedical engineering and mature communication channels with local governments and companies. Also, they should have enough funding.
Q4: How could the educational module be improved?
P1: I am wondering what will happen if students use this module in concrete educational cases. P2: Safety part (IEC 60601), EMC/FCC part, OSHA, FDA ... A designer should be involved in these parts, or should cooperate with relative specialists to turn design works to reliable products.

The results presented in Textbox 7.3 showed that both participants provided positive feedback regarding the framework and the educational module, stating that the framework was interesting and that the educational module could be applied to senior undergraduate and graduate students. They did, however, state that there was room for improvement in the details, i.e., both participants wanted to know more about how Chinese governments, universities and companies could work together in concrete DIMRC cases at an organisational level. P1 wondered what will happen when students use the educational module in the educational cases; while P2 suggested the addition of more information about the safety aspect of medical device design, etc.

In the next chapter, the above results will be discussed.

7.5 Conclusion

This chapter presents the two main results from Chapters 1–6:

(1) **A new framework for DIMRC (Figure 7.2):** This new framework is a modification and improvement to the initial framework in Figure 1.5. The new framework is composed of three blocks.

(i) **Organisers and initiators:** This block includes three essential Chinese initiators and organisers in DIMRC projects, supported by foreign partners, being the Chinese government, Chinese companies and Chinese universities. These three essential stakeholders should all take part in the project preparation phase of DIMRC projects.

(ii) **Concrete DIMRC projects:** This block includes practical issues learnt from actual DIMRC cases, e.g., the roles and responsibilities of different members of Chinese R&D teams.

(iii) **A knowledge base for DIMRC:** This block lists the knowledge Chinese R&D teams should possess to achieve more and better DIMRC applications, e.g., recommendations for the three Chinese initiators and organisers. Recommendations for the Chinese government, universities and companies were also presented in this block. The knowledge in this block was garnered from previous literature and case studies.

(2) **An educational module for Chinese biomedical engineering education in universities, with the purpose of augmenting the design competences of biomedical engineers for DIMRC:** Figure 7.3 presents the design process provided in this module, which builds on existing well-known biomedical engineering design approaches to device design. Two adaptations were added:

(i) **A new step:** Step 0: Building up R&D teams, organising stakeholders and studying three educational blocks, was added. This step takes place in the early stages of the design process. Knowledge integration and expansion is

emphasised in this step, through teamwork and the study of three educational blocks (design culture, design factors and design methodologies). R&D teams should have four key members for DIMRC: industrial designers, biomedical engineers, government officials and medical experts.

(ii) Five domains: the second adaptation is that Step 0–6 was divided into five domains: Preparation, Understand reality, Design mind, Production of prototype and Evaluation of prototype (See Figure 7.3). These five domains are not linear in that there are at least three different possible iterations of the five domains in practice. See Table 7.4.

Both the framework and the educational module were evaluated by one biomedical engineering professor from a Chinese university and one senior biomedical engineer from a Chinese medical device company (See Textbox 7.3). The feedback shows that the educational module is useful for Chinese biomedical engineering education, and the framework is helpful for DIMRC researchers. Furthermore, two issues were specially marked to investigate in future: (1) safety issues, (2) Concrete roles and responsibilities of three essential stakeholders (Chinese companies, universities and government).

The educational module is expected to be implementable into the current biomedical engineering syllabus in China, however many other steps have to be taken to augment the influence of the Chinese biomedical engineering education system in its totality, e.g., publishing more SCI journal papers. Both results were evaluated by a biomedical engineering professor and a senior biomedical engineer from a Chinese medical device company, who both provided positive feedback.

In next chapter, the framework and the educational module, and their evaluation results, will be discussed.

Chapter 8 Discussion, conclusion and future research needs

The previous chapter brought together two major results of this thesis: (1) A revised framework for Design and development of ICT-enabled Medical device and system for Rural China (DIMRC); and (2) An educational module for Chinese biomedical engineering education. How these results answer the main research question, as well as other relevant issues, will be discussed in this chapter.

8.1 Discussion

8.1.1 Correlations between the integrated results of Chapters 2–6 and Chapter 7

In this section the correlations among Chapters 2–7 will be discussed. See Figure 8.1. (Chapter 1 offers only a background introduction to DIMRC, and so is not included in Figure 8.1).

The objective of this thesis was to deliver the first step in the attainment of a long term objective: The augmentation of the design competences of Chinese R&D teams. After augmentation, it can be expected that Chinese R&D teams will be able to develop more and better applications to improve healthcare for people in rural China.

To this end, the main research question in this thesis was formulated as:

What design competences are needed for Chinese R&D teams to design and develop ICT-enabled Medical devices and systems for Rural China?

While attempting to answer this question, it became clear that to meet the long-term objective, the attainment of design knowledge and insights are essential for Chinese R&D teams. This thesis has therefore looked into learning from the experience of an expert institute, namely IDE/TU Delft, and to provide supplemental training to Chinese biomedical engineers (see Section 2.6). Accordingly, a parallel research question for this thesis has been formulated: ***How can knowledge and insights from advanced design schools, e.g., (predominantly) the Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft) be made useful for Chinese biomedical engineering students regarding DIMRC?***

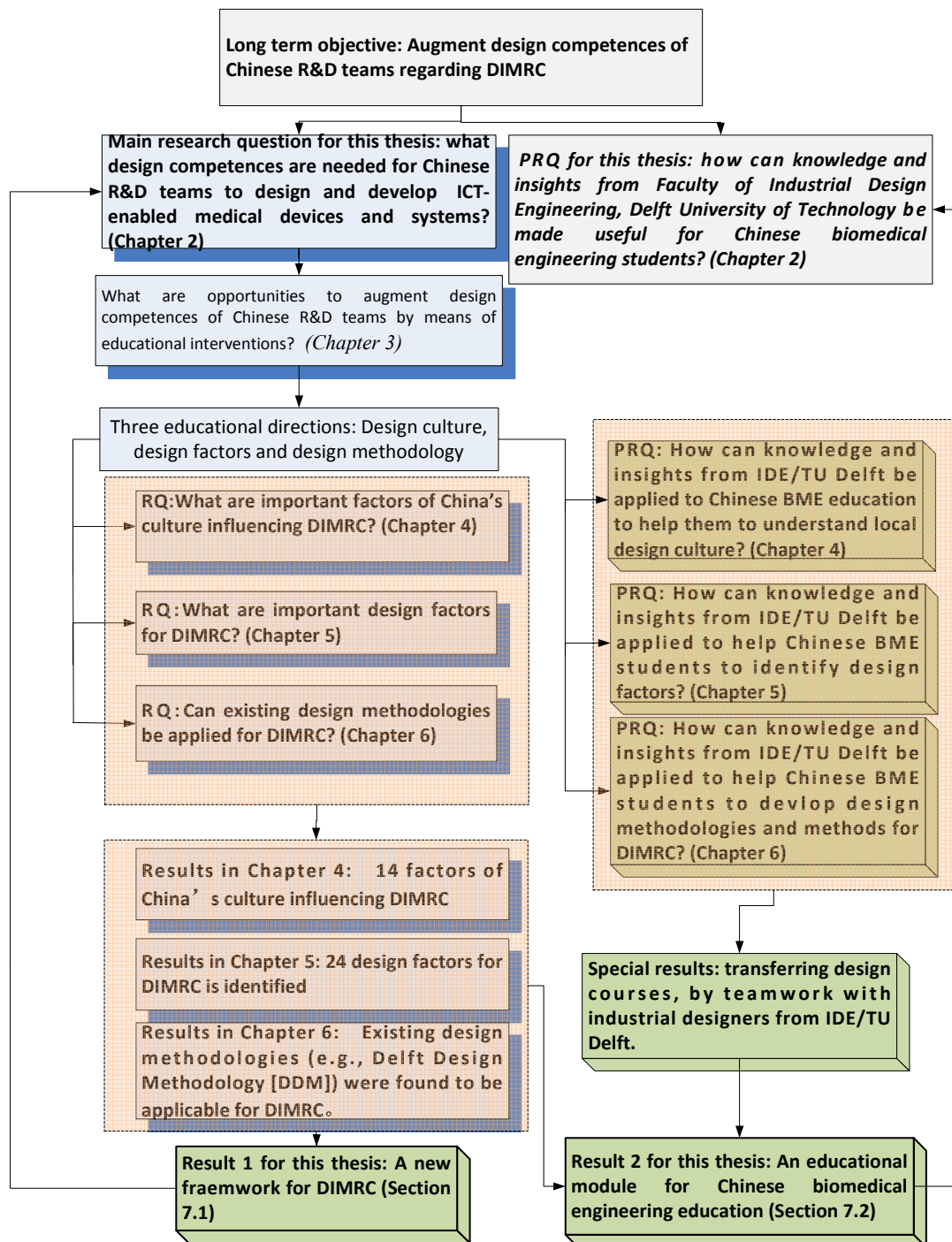


Figure 8.1: The correlation between the results of the thesis in its entirety and the results of each chapter. RQ: Research question; PRQ: Parallel research question.

To answer the main research question and the parallel research questions, a literature analysis was carried out in Chapter 3, revealing that: (1) there were 23 problems that Chinese R&D teams were likely to face in the augmentation of their design competences; (2) existing design models from literature cannot be used directly as the educational solution to solve these problems for DIMRC; and so a new educational solution was required. To develop the new model, three main challenges were identified that needed to be addressed in education (Malkin, 2007):

- (1) understanding local design cultures
- (2) identifying design factors
- (3) applying and adapting (if needed) existing design methodologies.

These factors were examined in detail in Chapters 4–6. The sub-research questions for Chapters 4–6 were:

- Research question for Chapter 4: *What are the important factors of China's design culture that influence DIMRC?*
- Research question for Chapter 5: *What can be considered important design factors for DIMRC?*
- Research question for Chapter 6: *Can existing design methodologies be applied or adapted (if needed) for DIMRC by Chinese R&D teams?*

Several sub-studies were carried out in Chapters 4–6 to answer the above research questions. The research methodology was based on data from literature, interviews and design cases, and the garnered data revealed that:

- ***There are (at least) 14 factors of China's culture that should be considered in DIMRC. Chinese R&D teams should consider these factors both before and during the devising of design concepts.***
- ***A checklist of 24 design factors for DIMRC was identified, which can be expected to be useful as a source of reference for Chinese R&D teams in their actual DIMRC projects.***
- ***Existing design methodologies, (e.g., Delft Design Methodology [DDM]) were found to be applicable for DIMRC.***

The above results defined some important content for inclusion in the three educational areas. Furthermore, Chapters 4–6 aimed to garner design knowledge and insights from IDE/TU Delft that might be useful to Chinese biomedical engineering students in helping them to understand the contents of the three educational areas. Accordingly, three parallel research questions were defined for Chapters 4–6:

- Chapter 4: *How can knowledge and insights from IDE/TU Delft be applied to the design education of Chinese biomedical engineers, in order to help Chinese biomedical engineering students understand China's design culture for DIMRC?*
- Chapter 5: *How can knowledge and insights from IDE/TU Delft be applied to help Chinese biomedical engineering students identify design factors for DIMRC?*
- Chapter 6: *How can the existing knowledge and insights from IDE/TU Delft be applied as design methodologies and methods for DIMRC in actual cases?*

The results in Chapters 4–6 showed that:

- ***Some educational modules at IDE/TU Delft, i.e., student group projects, individual final year graduation projects and internships,***

can be considered as potential approaches to helping Chinese biomedical engineering students understand the local design culture.

- *Knowledge and insights from IDE/TU Delft helped Chinese biomedical engineering students to identify design factors in two DIMRC cases. At least two possibilities were explored for Chinese biomedical engineers: (1) teamwork with industrial design students from IDE/TU Delft; and (2) applying and adapting (if needed) DDM. These opportunities may be achieved through the participation of Chinese students in courses at IDE/TU Delft.*
- *Knowledge and insights from IDE/TU Delft were useful in helping Chinese R&D teams to identify design methodologies for DIMRC. This may be achieved by developing designs as part of a team with industrial designers from IDE/TU Delft. In such an approach, industrial designers can be the methodology developers.*

To answer both the research questions and the parallel research questions in Chapters 4–6, several sub-research questions were asked. Table 8.1 provides an overview of the three research questions [RQ], the three parallel research questions [PRQ], and the several sub-research questions [SRQ] in Chapters 4–6.

It can be seen in Table 8.1 that the same SRQs were repeated in different chapters, i.e., “Who should be the key members of the R&D team in future DIMRC cases?” and “What roles should be played by industrial designers from advanced design institutes to benefit the R&D teams in future DIMRC cases?”. The reason for the repetition is that in this exploratory research, the research questions in this investigation were formulated gradually after learning from different actual DIMRC cases (in Chapters 5 and 6), and for this reason the same sub-questions were repeated. The results of Chapters 5 and 6 were combined in the final answer to the research questions. For instance, the results of Chapter 5 indicated that industrial designers, biomedical engineers and medical experts were the key members of Chinese R&D teams, while the results of Chapter 6 showed that industrial designers, biomedical engineers and government officials were the key members. Accordingly, as a final answer it was ascertained that industrial designers, biomedical engineers, medical experts and government officials were all key R&D team members within the scope of this thesis.

The results of the research questions and the parallel research questions were used to devise an educational module for Chinese biomedical engineering education, i.e., the “design culture” block of the educational module was developed based on the results of Chapter 4; the “design factor” block of the educational module was developed based on the results of Chapter 5; and the “design methodology” block of the educational module was developed based on the results of Chapter 6.

Table 8.1: An overview of the questions in Chapters 4–6. RQ: Research Question; PRQ: Parallel Research Question; SRQ: Sub-Research Question; DIMRC: Design and development of ICT-enabled Medical device and system

Chapters Questions	Chapter 4 (Design culture)	Chapter 5 (Design factors)	Chapter 6 (Design methodologies)
Research question (What)	RQ: What are important factors of China's design culture that influence DIMRC?	RQ: What are important design factors for DIMRC? <i>SRQ1: What important design factors for DIM (Design and development of ICT-enabled Medical device and system) can be found in literature?</i> <i>SRQ2: What are design factors for DfBoP (Design for Base/Bottom of the Pyramid)?</i> <i>SRQ3: Can design factors for DIM and DfBoP garnered from previous studies be used directly in an actual DIMRC case?</i>	RQ: Can existing design methodologies be applied for DIMRC? <i>SRQ1: What existing design methodologies from literature might be relevant to DIMRC?</i> <i>SRQ2: Can existing design methodologies from IDE/TU Delft be applied for DfBoP (Design for Base/Bottom of the Pyramid)?</i>
Parallel research questions (How)	PRQ: How can knowledge and insights from IDE/TU Delft be applied to the design education of Chinese biomedical engineers, in order to help Chinese biomedical engineering students understand China's design culture for DIMRC?	PRQ: How can knowledge and insights from IDE/TU Delft be applied to help Chinese biomedical engineering students to identify design factors for DIMRC? <i>SRQ4: What roles should be played by industrial designers from advanced design institutes to benefit the R&D teams in future DIMRC cases?</i> <i>SRQ5: Who should be the key members of the R&D team in future DIMRC cases?</i> <i>SRQ6: Can design methodology from IDE/TU Delft be applied to identify design factors for DIMRC in an actual case?</i>	Parallel RQ: How can existing knowledge and insights from IDE/TU Delft be applied to help Chinese biomedical engineering students to develop design methodologies and methods for DIMRC? <i>SRQ3: How can the chosen design methodologies and methods from IDE/TU Delft be applied in an actual DIMRC case?</i> <i>SRQ4: Who should be the key members of the R&D team in future DIMRC cases?</i> <i>SRQ5: What roles should be played by industrial designers from advanced design institutes to benefit the R&D teams in future DIMRC cases?</i> <i>SRQ6: What should be the roles of each member of the R&D team in future DIMRC cases?</i>

The results of Chapters 4–6 were also used by the author to develop a new framework for DIMRC, as can be seen in Figure 7.2; and this new framework contributes to answering the main research question of this thesis, while the proposed educational module for Chinese biomedical engineering education contributes to answering the parallel research question.

8.1.2 Reflection on the research approach of this thesis

The previous section offered a description of the research questions in this thesis. Integrative approaches were used in this thesis to answer research questions (As DIMRC is a wicked problem). In detail this thesis started out by identifying three literature domains relevant to DIMRC, namely “Design for Base/Bottom of the Pyramid”, “User Centred Design” and “Design and development of ICT-enabled Medical device and system”(Chapter 3). In these three domains publications integrate knowledge from multidisciplinary, including social sciences, economic and management sciences, design sciences, engineering sciences, medical sciences etc. Then three investigation areas were identified at a high level (through a literature analysis, in Chapter 3): “design culture”, “design factors” and “design methodologies”. To explore these three areas in more detail, knowledge from advanced design institutes (IDE/TU Delft was used as an example. Knowledge to solve wicked problems are provided in these advanced design institutes.) was combined into exiting knowledge repository of Chinese biomedical engineering education. For instance, DDM (as a design methodology with integrative approaches) was combined with King’s approach to identify design factors (Chapter 5). As a result, a new framework for DIMRC and an educational module for Chinese biomedical engineering education were proposed, which were evaluated by a Chinese biomedical engineering professor and a senior Chinese biomedical engineer from a Chinese medical device company.

The positive evaluations of both the framework and the educational module indicated that above research approach may be effective at a macro level; however at least two improvements are necessary at a deeper level.

- (1) More Chinese biomedical engineering institutes and experts involved in medical device design need to be involved in the investigations. In this thesis, only the knowledge garnered from IDE/TU Delft and the Biomedical Engineering Department at Shanghai University was taken into account, which is limited and does not cover all important issues for medical device design. For instance, one evaluator suggested including safety design in the educational module (See textbox 7.3), however this subject is not currently on the curriculum of Biomedical Engineering at Shanghai University and so has been totally ignored in the two DIMRC cases. This may be resolved through the integration of the knowledge of other experts into the research process.
- (2) More DIMRC cases, including cases from educational institutions other than IDE/TU Delft, need to be studied. In this thesis only two DIMRC cases were put under the microscope; and in addition, only limited research issues were investigated in the two cases, with focus being on “design

factors” and “design methodologies and methods”. Other issues, such as the organisational processes of DIMRC projects, the management of the R&D teams, etc., were only touched upon. This was one of the criticisms raised during the evaluation study (See Textbox 7.3) – that the educational module did not address the organisational issues of DIMRC, however this shortfall may be resolved through a study of more DIMRC cases.

The above reflections bring to light some future research needs, which will be listed in Section 8.3.

8.1.3 Reflection on the new framework for DIMRC

A Comparison to the initial framework for DIMRC

In Figure 7.2 a new framework for DIMRC was presented, which was developed based on a previous framework that had been developed by the author of this thesis, and that had been published in an academic journal (See Figure 1.5, Section 1.6). The new framework features two improvements over the initial framework for DIMRC.

- (1) The correlations among the three essential Chinese stakeholders (Chinese government, universities and companies) was clarified and extended. In the initial framework, only Chinese companies and universities were considered as organisers, while the Chinese government was considered as the investor and initiator. In the new framework all three stakeholders were considered as initiators and organisers, and the government was still considered as the investor. It was evident in the case “Exploring design opportunities at rural Shanghai” that the three stakeholders should all work together in the initial stages of DIMRC projects. In that case, government officials were involved as organisers, which made it easy to set up field studies in five rural regions. For more information about this lesson, see Section 6.4. Foreign partners (e.g., foreign universities, MNC, foreign governments) may also be able to take part in organising DIMRC projects in cooperation with the three essential Chinese stakeholders. For instance, IDE/TU Delft played an organising role in the case “Exploring design opportunities for rural Shanghai”, and the students from IDE/TU Delft provided complementary knowledge regarding methodologies.
- (2) In the initial framework the knowledge base was still unspecified; while in the new framework some details were developed, including knowledge garnered from literature and the case studies.

Figure 8.2 sets out the improvements detailed above.

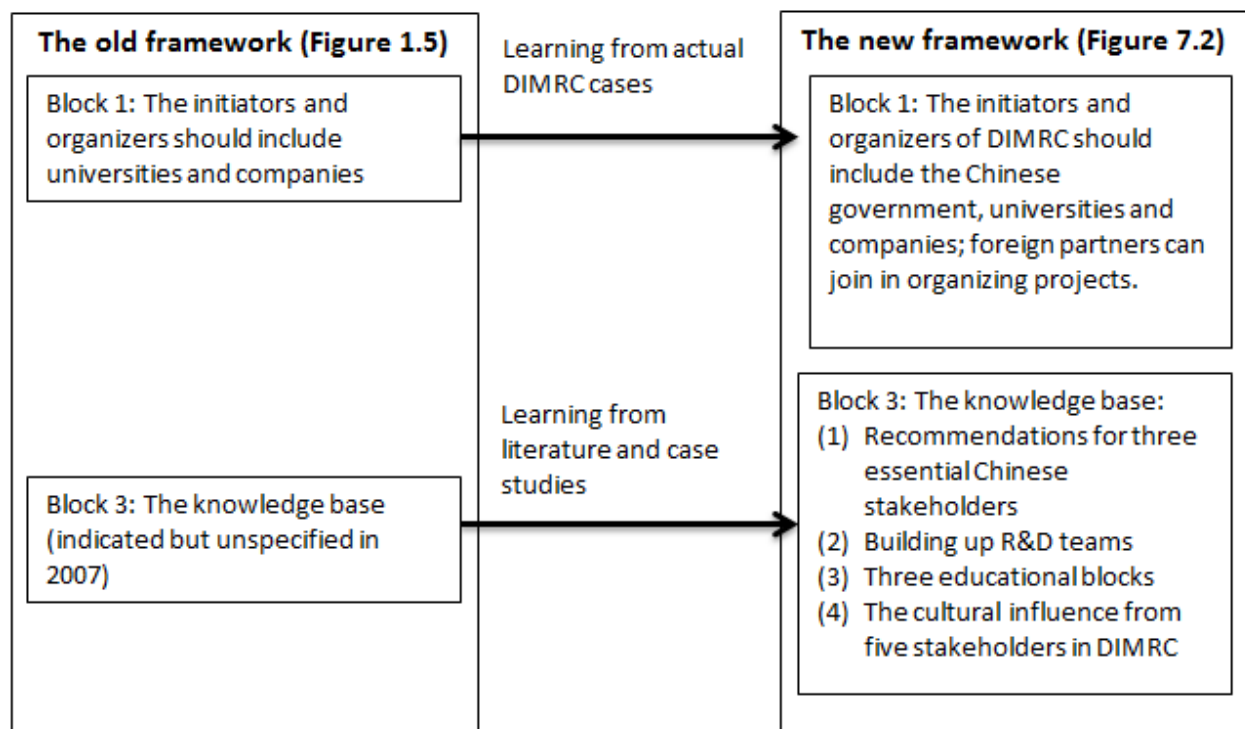


Figure 8.2: A schematic model depicting the old framework prior to this PhD investigation (Figure 1.5), and the new framework for DIMRC developed during the investigation (Figure 7.2).

B Comparison with previous studies

Although academic literature specific to DIMRC is still limited, scholars have provided hundreds of frameworks that may be deemed relevant to Design and development of ICT-enabled Medical device and system (DIM) in developing countries. For instance, Simanis & Hart (2008) proposed an ICT design framework for R&D teams from Indian NGOs that defined how R&D teams should involve local residents from villages during the product design process; Van Reijswoud (2009) proposed a theoretical framework to guide more effective and appropriate design and the implementation of ICT in low-income developing countries, in which he divided appropriate ICT design and development into two perspectives: the content and the design process – content referring to culture, environment, organisation, economy and political climate.

The general frameworks noted above have already been validated in many developing countries, such as India, Uganda, South Africa, Tanzania, etc., however they have to date not even been tested in China, for two possible reasons:

- (1) The presence of NGOs (Non-Government Organisations) in rural China operating in the domain of healthcare is marginal; but in many of the frameworks found in literature, professional NGOs have an important role to play. For example, in Simanis' framework, most R&D team members

come from NGOs; while in van Reijswoud's framework, NGOs are the investors and technical developers in ICT projects. In China, different to other developing countries, there are almost no professional NGOs relevant to ICT4D, which means that knowledge and experience of previous frameworks cannot directly be applied for DIMRC. At least some adaption is needed to address this.

- (2) The rich and powerful Chinese government: Compared to other developing countries, the Chinese government (both central and local) is both richer and more powerful, and only rarely can DIMRC projects be carried out without governmental support. Hence one key issue for DIMRC should be to define how to involve the Chinese government, which again is not something that has been paid much attention in previous literature, particularly, how to work with stakeholders under such a powerful government.

Therefore, as knowledge has developed for rural China, the most innovative aspect of the new framework in this thesis has been the strengthening of the roles of the Chinese government and the removal of NGO involvement. The Chinese government has been identified as the essential initiator, organiser and investor in DIMRC projects, and specific recommendations for the government have been provided, including the inclusion of government officials as key members of R&D teams.

Naturally, the new framework from this thesis and the frameworks from previous literature bear similarities at the micro level. For example, both the new framework and Van Reijswoud's framework emphasised the design process, and identified design culture as an important aspect of the design contexts. However, a comparison of the old (the three frameworks noted above) and new reveals a number of differences, which in Table 8.2 are listed alongside the similarities, with an explanation of the expected benefits to DIMRC.

By observing the results of Table 8.2, it can be concluded that old frameworks from literature might be useful for DIMRC but adaptation would be needed.

Table 8.2: Some similarities and differences between the new framework from this thesis and three older frameworks from literature, and arguments for the differences.

The new framework The old frameworks	Similarities	Differences	Arguments for the differences
Simanis' framework	Teamwork is a must in the design process.	The new framework identified different team members, their roles and responsibilities, e.g., governmental officers were identified as key members.	Involving governmental officers as the organisers is an efficient way to organise research activities for DIMRC. (See Chapter 6)
Van Reijswoud's framework	Emphasise the design process as a circle.	The design process for DIMRC has at least three different start points and orders. (See Figure 7.3)	There are at least three concrete possibilities for DIMRC projects in practice. (See Chapter 7)

8.1.4 Reflection on the educational module for Chinese biomedical engineering education

This section will discuss issues relevant to the educational module (Section 7.2).

A The integrated design process in the educational module

In the beginning of this thesis one important problem statement in current Chinese biomedical engineering education was presented: knowledge and skills of integrative approaches is lacking in Chinese biomedical engineering education. (See Section 2.2.3) We aimed for the educational module to include knowledge and skills of the integrative approaches. The results showed the integrative approaches can be found in three aspects of the educational module:

- (1) Design methodologies from Design and development of ICT-enabled Medical device and system (DIM) and Design for Base/Bottom of the Pyramid (DfBoP) were integrated. As illustrated in Section 7.2, the design process for DIMRC combined King's approach and the "Four Domain Model". The King's approach is an approach for DIM, and the "Four Domain Model" is a common model about how IDE students conduct DfBoP projects.
- (2) Three educational blocks (Design culture, design factors and design methodology) were combined in the educational module for Chinese biomedical engineering education. These three blocks were expected to be considered at the same time in an integrative approach.

- (3) The educational module for Chinese biomedical engineering education combined several design issues from existing design models. These design issues include design culture, mindset, methodology, design team, and so on. To illustrate this, we will compare the educational module and four existing design models from literature: Sanders' model (Sanders, 2009), the "knowledge chain model" (Holsapple & Signh, 2001), the "Base/Bottom of the Pyramid model 2.0" (Simanis et al, 2008) and the "ICT change for healthcare model" (Aarts et al, 1998). These four design models were introduced in detail in Chapter 3. These are existing design models most relevant to DIMRC. Table 8.2 shows the results of comparison. The columns of Table 8.3 are the four design models and the educational module, while design issues are listed in the rows. These design issues are from the four existing design models.

Table 8.3: Comparison of the coverage of design issues in the educational module and issues in the four design models. An X denotes that the design issue is covered.

Design issue \ Design model	Education module developed in this thesis	Sanders' model	Knowledge chain model	Base/Bottom of the Pyramid model 2.0	ICT change for healthcare model
Design culture	X	X		X	
Design mindset	X	X			
Design methodology	X	X	X		X
Design method	X	X		X	
Design tools/techniques	X	X		X	
Design factors	X				X
Design team	X			X	X

Table 8.3 reveals that many design issues from the four existing design models were covered by the educational module. When compared to the four existing design models, it is apparent that the educational module covers more design issues that are relevant to DIMRC, and in this respect, the educational module may be considered as more suitable as the educational solution for DIMRC than the other four design models.

B The knowledge contributions from IDE/TU Delft to the educational module

As a special focus in this thesis, knowledge and insights from the Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft) were expected to be useful for Chinese biomedical engineering students for DIMRC. Three knowledge contributions from IDE/TU Delft to the educational module were found:

(1) The Delft Design Methodology (DDM) from IDE/TU Delft was used to develop new design approaches for DIMRC. In the educational block “design methodologies,” two design methodologies were proposed: a “Prototyping driven IDE approach” (to develop and identify design factors in actual DIMRC projects) and “From unstructured to structured” (to identify user needs in actual DIMRC projects). These two methodologies were adaptations of DDM: (i) “Prototyping driven IDE approach” integrated two design approaches, i.e., DDM from IDE and King’s approach from BME; (ii) in “From unstructured to structured,” design methods based on DDM were applied and combined. Chinese biomedical engineers may apply and adapt (if needed) these two approaches (as well as other design methods and tools from DDM) into their future DIMRC cases, either through teamwork with industrial designers from IDE/TU Delft, or by joining training courses at IDE/TU Delft. Furthermore, Chinese biomedical engineers may also learn other knowledge from the Delft Design Guide, e.g., design deliberations and tips (e.g., teamwork and design), which may help augment the design competences of Chinese biomedical engineers for the future.

(2) Predominantly, knowledge extracted from DfBoP (Design for Base/Bottom of the Pyramid) by IDE/TU Delft was used to develop the educational blocks “design factors” and “design methodologies”. For instance, 14 design factors for DfBoP were found also to be applicable for DIMRC; and the DfBoP “Four Domain Model” was used to develop the design process for DIMRC (see Figure 7.3).

As one of the earliest design schools to research DfBoP, IDE/TU Delft had up until 2012 executed more than 150 student DfBoP projects. In this thesis, 24 of these student projects were analysed to identify the design factors and design methodologies for DfBoP.

(3) Two actual DIMRC projects – “Exploring design opportunities in rural Shanghai” and “Development of a blood pressure monitoring system incorporating ICT” – were studied, in which students from IDE/TU Delft worked as part of R&D teams. Several of the lessons learned were used in the educational modules, such as the need for teamwork in DIMRC, stakeholder involvement, etc.

Besides IDE/TU Delft, knowledge from other advanced design institutes may also be useful to optimize the framework and the educational module. This knowledge will be explored in the future.

C Is the educational module useful to solve likely design problems in DIMRC?

In Section 3.4, 23 problems that Chinese R&D teams may face in DIMRC were identified through a literature analysis, and an analysis was made of whether the educational module offered solutions for the resolution of these problems.

First, the 23 likely problems were presented, after which the educational module in Section 7.2 was read carefully, and each potential problem was compared to the “methodology block” in the educational module. The aim of the comparison was to explore whether any potential methods within the educational module could assist in resolving the problems, and as a final stage, all of the potential methods identified were recorded and presented.

The results of the comparison showed that the educational module may either directly or indirectly have the potential to tackle all of the 23 identified problems. For example, problems related to user information and local context, such as identifying medical needs, lifestyle, awareness and skills; and problems in the development of local content and services, ICT infrastructure, physical assessments, management design factors, medical will and appropriate technology might be solved if R&D teams apply and adapt (if needed) the approach “From unstructured to structured”. Other likely problems might be solved if R&D teams apply and adapt (if needed) methods from DDM.²³ For instance, problems in developing the macro and local economic environment might be solved if R&D teams apply and adapt (if needed) the method “trends analysis” from DDM; while problems in developing sustainability and creating a business model might be solved if R&D teams apply and adapt (if needed) the method “MET matrix” from DDM.

Compared to other existing design models, such as that of Sanders (Sanders, 2009), the “knowledge chain model” (Holsapple & Singh, 2001), the “Base/Bottom of the Pyramid model 2.0” (Simanis & Hart, 2008) and the “ICT change for healthcare model” (Aarts et al., 1998), the educational module covers all of the potential problems identified in Section 3.4, while the four existing models cover individually only parts of those problems.

8.1.5 Innovative aspects of this thesis

Compared to previous studies in the field of “ICT medical device- and system development for developing countries” from literature, three innovative aspects have been achieved in this thesis:

- (1) The topic of “Design for rural China” is new. China is one of the biggest industrial manufacturers in the world. (This statement was described in the beginning of this thesis, see Chapter 2). “Product design” is not emphasized in current China society (see Chapter 4). More specifically, (until 2012) Chinese governmental organizations has not published any formal design policies; industrial designers are rarely involved into R&D teams in Chinese companies (see Chapter 4); and there is almost no knowledge integration between industrial design and biomedical engineering in the Chinese education system, etc. Therefore, this thesis pioneers the topic of “Design for rural China”.

²³ In the educational module, DDM is advised as reading material for biomedical engineers. DDM includes a number of design methods for product development, some of which may play a role in solving likely problems.

- (2) This thesis describes the potential roles of industrial designers (See footnote 21: the definition of industrial designers) in “Created in China”. As described in Chapter 4, most Chinese politicians, researchers and practitioners have not understood “what industrial designers should look like” and “what industrial designers can do in actual R&D activities”. By learning from two actual DIMRC cases, this thesis indicates how industrial designers may work with other engineers and medical experts. The potential roles of industrial designers in Chinese R&D teams were proposed.
- (3) This thesis pioneers the possible roles and responsibilities of Chinese governmental officers regarding DIMRC. Chinese government is a powerful government, and Chinese governmental organizations played important roles in DIMRC (See Chapter 2). By learning from two cases, this thesis provide some indications in this issue: e.g., Chinese universities could be useful agencies to invite governmental officers; Governmental officers could be the one who organise field studies and scale up the research.

8.1.6 Interventions of this thesis for improving healthcare in rural China

As mentioned at the beginning of this thesis, there are many challenges to improving healthcare in rural China, such as providing a better public medical insurance system, training more and better skilled medical staff to work in the rural communities, providing affordable and advanced medical devices and systems, etc., however the particular focus in this thesis is on providing design knowledge and insights for Chinese R&D teams to design and develop suitable ICT-enabled medical devices and systems (DIM), which is only one improvement to the problems of healthcare in rural China.

Nevertheless, this thesis is expected to lead to more social impacts in the near future that will go a long way to improving healthcare in rural China. The expected social impacts include:

- (1) More Chinese managers and scientists with an understanding of the importance of research in DIMRC. Currently, many managers and scientists from Chinese companies still believe DIMRC is only about simplifying existing medical devices and making them cheaper,²⁴ and so treat it purely as a technical development topic. By reading this thesis, they may be able to understand the true complexity of DIMRC. Research is necessary in the R&D process for DIMRC, including technical, user and financial investigations, among others. Accordingly, more human

²⁴ This conclusion was firstly achieved by the author in 2007 while working for Philips. In 2012 he spoke with two managers, one principle scientist and one senior biomedical engineer from three Chinese medical device companies. He ascertained that there was no need to change this conclusion.

resources and investments are needed for the R&D teams engaged in DIMRC.

- (2) Industrial design could play a more important role in DIMRC. Chapter 4 revealed that the currently awareness of industrial design is very weak in Chinese society, and so by reading this, people from different walks of life in Chinese society e.g., government officials, academicians, business managers, etc. would obtain a deeper understanding of the opportunities that are open to qualified industrial designers²⁵ in DIMRC. Accordingly, industrial design could play a more important role in DIMRC, e.g., as key members of R&D teams; and Chinese universities could adapt knowledge from industrial design into the current medical device design education curriculum, etc.
- (3) More international cooperative research projects could be launched between China and Holland for knowledge generation. Most recent Sino-Dutch cooperation projects have been focused on high-technology development and transfer, such as LED lighting (<http://www.rnw.nl/english/bulletin/tu-delft-opens-beijing-campus> [accessed on 16-OCT-2012]), green agriculture technology, new sustainable industrial materials (http://www.most.gov.cn/tztg/201203/t20120318_93206.htm [accessed on 16-OCT-2012]) etc. However, as time goes by, Chinese universities and companies will become more skilled in advanced technologies, and then the biggest challenge for the R&D teams will be how to develop products or systems to meet local requirements using these high-technologies. This thesis presented an example of DIMRC to show the feasibility of Sino-Dutch cooperation projects. We expect Chinese government officials to read this thesis and appoint more PhD projects in a similar vein.

Besides the above three aspects, it is expected that more and more Chinese universities and companies will begin to get involved in DIMRC projects after reading this thesis, and it is hoped that DIMRC will become an important topic in universities and medical device companies and universities all over China.

8.2 Conclusion

The delivery of healthcare in rural communities has always been a complex problem for the Chinese government, and several factors have impeded its implementation, including a shortage of fully trained medical personnel, a lack of medical equipment and facilities, etc. To address this this, the government in 2002 proposed the launch of “Design and development of ICT-enabled Medical device and system for Rural China (DIMRC)” (Wen, 2004). Studies of the author of this thesis prior to 2007 indicated that adequate DIMRC solutions required the collaborative effort of different stakeholders, such as

²⁵ In this chapter, the term “qualified industrial designers” refers to product designers who have extensive skills and experience in integrating design knowledge from multiple disciplines, such as social sciences, engineering sciences and business sciences. They possess skills to solve complex design problems, e.g., DIMRC, through integrative approaches.

the Chinese government, companies, universities etc., as several challenges were not being addressed, including efforts to raise the design competences of Chinese R&D teams, promotion from Chinese government, etc.

As a critical step to developing successful DIMRC, this thesis has sought to clarify the design competences that are needed in Chinese R&D teams to address the government's "Created in China" strategy. Two research questions were asked: (1) ***What design competences are needed for Chinese R&D teams to design and develop ICT-enabled medical devices and systems for rural China?*** and (2) ***How can knowledge and insights from advanced design institutes, e.g., (predominantly) the Faculty of Industrial Design Engineering, Delft University of Technology (IDE, TU Delft) be made useful for Chinese biomedical engineering students regarding DIMRC?***

There are a number of approaches to this, such as providing design education in Chinese universities, providing design manuals to the Chinese government and commercial enterprises, however in this thesis the focus was on providing advanced design knowledge in the education of biomedical engineers. To this end, design knowledge from IDE/TU Delft was found to be an entrance as well as a promising source for the strengthening of the design competences of Chinese biomedical engineering students, and so two joint DIMRC projects between IDE/TU Delft and BME at Shanghai University were set up and studied as case studies.

The results of these two DIMRC cases, as well as the results of other sub-studies of this thesis (e.g., literature analysis, interviews and studies of student cases from IDE/TU Delft), were applied to develop a new framework for DIMRC, as well as an educational module for Chinese biomedical engineering education. The two research questions were answered in both the framework and the educational module. Table 8.4 presents the main points of the answers to the research questions.

Table 8.4 reveals that Chinese R&D teams need knowledge and skills in a minimum of four aspects: teamwork, stakeholder organisation, design process and design content, which can be obtained by biomedical engineers either by working with qualified industrial designers or joining educational courses at IDE/TU Delft.

Table 8.4: The key words and descriptions of the main results from the framework and the educational module for the two research questions.

Research questions Key words of answers	What design competences are needed for Chinese R&D teams to design and develop ICT-enabled medical devices and systems for rural China?	How could knowledge and insights from advanced design institutes be made useful for Chinese biomedical engineering students regarding DIMRC? (IDE/TU Delft as an example)
Teamwork	Chinese R&D teams should have the necessary knowledge and skills to establish and work within multidisciplinary teams (Team compositions and the roles and responsibilities of team members described in Section 7.2.4).	(1) Biomedical engineers can work with qualified industrial designers, who can be the organisers and manages of Chinese R&D teams. (2) Biomedical engineers can join educational courses at IDE/TU Delft, which provide practical experience to students on multidisciplinary teamwork.
Stakeholder organisation	Chinese R&D teams should have the necessary knowledge and skills to organise different stakeholders and maintain efficient communication with them (Stakeholders for DIMRC described in Section 7.1.1).	(1) Biomedical engineers can work with qualified industrial designers, who have skills in organising stakeholders. (2) Biomedical engineers can join in educational courses at IDE/TU Delft, which provide practical experience to students in organising stakeholders.
Design process	Chinese R&D teams should possess the necessary knowledge and skills to implement integrative approaches during the R&D process (Figure 7.3 presented an example of an integrative approach for DIMRC).	The proposed design approach for DIMRC in this thesis (Figure 7.3) integrates King's approach from BME with Delft Design Methodology (DDM). Biomedical engineers can learn design methods and techniques from DDM.
Design contents (Three educational blocks: "design culture", "design factor" and "design methodology")	Chinese R&D teams should possess the necessary knowledge and skills to use references from the content of these three blocks (Some content references from the three blocks were described in Section 7.2.5). Chinese R&D teams should be able to identify the contents of the three blocks in their own DIMRC projects.	Biomedical engineers can learn methods and techniques to identify the contents of the three blocks by joining educational courses at IDE/TU Delft.

The framework for DIMRC and the educational module were evaluated by a biomedical engineering professor and a senior biomedical engineer working in the sector, both of whom gave a positive assessment. They thought the framework was helpful for DIMRC researchers, and that the education module was useful could be applied in current Chinese biomedical engineering education; however, the findings of this thesis are not yet complete, as some knowledge is still missing, e.g., knowledge from institutes other than IDE/TU Delft could also benefit the education module, as well as the addition of a safety design aspect. Accordingly, both the framework and educational module have scope for further improvement.

8.3 Recommendations for future research.

Because this investigation is iterative, the results of this thesis are only the outputs of the first iteration. To achieve the long term objective of this thesis: “Chinese R&D teams should be able to design and develop appropriate DIMRC products”, many other iterations are needed. For instance, as mentioned in figure 2.3, there are also other possible approaches, such as developing manuals for governments. These approaches were not investigated in this thesis, but they are expected to be studied in the future. This section introduces some future research opportunities in the next iteration.

8.3.1 Exploring other design issues

In textbox 7.3 two evaluators provided two possible future investigation directions: the concrete roles and responsibilities of three essential stakeholders (Chinese universities, companies and government), and safety issues. Hence two research questions are planned to be answered specifically in the future.

- (1) “How can the three essential stakeholders play efficient and effective roles in DIMRC?”. In this thesis the potential roles and responsibilities of three essential stakeholders were proposed. However, the concrete contributions of three essential stakeholders in each concrete step of product development were not described, and teamwork between them were not explored. These issues are expected to be studied in other actual DIMRC cases in next research iteration.
- (2) “How can patient safety be addressed in DIMRC?” “Patient safety” is an important issue in medical device- and system development. This issue includes technical safety (e.g., the medical measurement should be safe, the data transmission should be safe.), usability safety (e.g., decreasing the operation errors.) and risk management methods. In this thesis only the technical safety was partly discussed (See Section 5.4), while usability safety was not investigated. In the future DIMRC cases we plan to set up experiments to explore this issue.

Besides above two questions, some other possible research questions may also be explored, such as “What is the most efficient approach for teamwork?”, “How can DIMRC projects be scaled up from a pilot project?”.

8.3.2 Continuous improvement of the educational module

In the evaluation, both respondents mentioned that the education module was lacking in some areas, with one participant singling out safety design in particular as an issue. To understand what knowledge is still missing and to improve the module, three activities are proposed for future studies:

A Inviting more experts to evaluate the education module

More Chinese biomedical engineering professors and senior biomedical engineers from Chinese medical device companies are planned to be invited to evaluate the educational module. By obtaining input from experts from different fields of expertise in the design and development of medical devices, more information will be garnered on what is missing from the module and how it may be further improved.

B Learning from other advanced design schools

Other advanced designed schools, such as the Art Centre College of Design, Carnegie Mellon University, etc., should be visited and their design knowledge and insights should be studied to understand how the educational module proposed in this thesis may be improved.

C Implementation of the educational module

As a next step, the education module is planned to be tested in Shanghai University, the results of which may help in the identification of any other missing knowledge. If the implementation of the module in Shanghai University is successful, it will be introduced to other biomedical engineering institutes in China, from where more testing results could be collected to help improve it as a continuous process.

8.3.3 Continuous Improvement of the framework for DIMRC

Besides improving the educational module, two activities are expected to improve the new framework for DIMRC (See Figure 7.2):

A Learning from more concrete DIMRC projects

In the evaluation study, both respondents stated that details related to the organisation of DIMRC projects were lacking in the study, which may be addressed through the creation of more concrete DIMRC projects. One such area that needs to be addressed is care of the elderly in rural China, who suffer from a lot of medical problems, such as chronic disease (e.g., hypertension), physiological problems and loneliness. While homecare is a feasible solution, the problem is that there is no existing homecare

infrastructure that can provide the full range of necessary support, including instrumental, financial and emotional support.

The results of this thesis can be used to launch such a homecare platform for the elderly, especially in regards to the design methodology part (IDE-driven prototyping approach). In the last year, a research group proposed a design methodology that was a “community-based co-design” for elderly care, which includes four design methodologies: community-based research, action research, usability and safety design, and prototype-driven engineering. The methods and tools from this thesis were included in the new methodology.

Led by Dr. Adinda Freudenthal, the research group is applying for grants to conduct pilot projects on the way to the creation of a “healthcare platform for aging society”. The methods and tools from this thesis related to “community-based co-design” will be validated and developed in pilot projects. For more information, visit <http://io.tudelft.nl/onderzoek/projecten/community-based-co-design-for-homecare/> (accessed on 16-OCT-2012).

B Connecting the framework with other existing knowledge bases

Expanding the knowledge of the framework can also be achieved by creating a network with other knowledge bases. Currently, the framework contains the knowledge areas explored in this thesis, such as recommendations for the Chinese government, companies and universities; creating R&D teams, etc. In the future this framework will be connected to other existing knowledge databases, such as that of the Continua Health Alliance, (<http://www.continuaalliance.org> [accessed on 16-OCT-2012]), which is a knowledge database in which smart technology is used to keep patients, caregivers and healthcare workers connected and empowered to manage health and wellness at any time, and from anywhere. More than 100 industrial enterprises, including GE and Philips, have been involved in developing the standards for the database, and while the knowledge maintained by the Continua Health Alliance is mainly related to homecare, it can also contribute to our framework, especially in the organisational aspects of DIM projects.

Abbreviations

BME	Biomedical Engineering
BoP	Base (Bottom) of the pyramid
BP	Blood Pressure
CCR	Concept-Context Relationship
CDR	Concept-Designer (or R&D team) Relationship
CFR	Concept-Function Relationship
CHC	Community Healthcare Centre
CHP	Community Healthcare Point
CMR	Concept-Manufacturer Relationship
CUR	Concept-User Relationship
DfBoP	Design for Base/Bottom of the Pyramid
DDG	Delft Design Guide
DDM	Delft Design Methodology
DP	Diastolic Pressure
DIM	Design and development of ICT-enabled Medical device and system
DIMRC	Design and development of ICT-enabled Medical device and system for Rural China
GE	General Electric
GO	Government
HFE	Human Factors Engineering
HFWC	High Frequency Words in Context
IC	Integrated Circuit
ICT	Information and Communication Technology
IDE/TU Delft	Faculty of Industrial Design Engineering, Delft University of Technology
IDV	Individualism versus Collectivism
LGT	Local Growth Team
ITAA	Information Technology Association of America
LL	Living Lab approach
LTO	Long- versus Short-term Orientation
MAS	Masculinity versus Femininity
MDD	Medical Device Directive
MDG	Millennium Development Goals
MNC	Multi-National Companies
MRI	Magnetic resonance imaging
NGO	Non-governmental organisations
PDI	Power Distance Index
PET	Positron emission tomography
R&D	Research and Development
REESE	Research and Evaluation on Education in Science and Engineering
SME	Small and medium enterprise
SP	Systolic Pressure
SPECT	Single-photon emission computed tomography
UAI	Uncertainty Avoidance Index

UCD	User Centred Design
VD	Village Doctor
WHO	World Health Organisation
WWW	World Wide Web

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Appendix A: Visit report - Rural Chongming (Shanghai, China)

This Appendix is one part of a project report, “exploring design opportunities for rural Shanghai”, sponsored by Philips Apptech, Shanghai. The co-authors of the report are: Mr. Zhou Pan, Miss. Jing Zhang, Mr. Jiehui Jiang and Mr. Nalin W. (Year 2006)

Background

Chongming island is a typical rural area, 50km from Shanghai. As one of biggest islands in China (Land area of the island is 1411 km²) by the end of 2006, domicile population in Chongming island amounted to 699,800, with a drop of 1408 as against the previous year. More than 80% Chongming people is rural population and the average income of rural people is RMB 6786/year (1.7 Euro/day) in 2006. (Ref: <http://www.cmx.gov.cn> [accessed on 16-OCT-2012])

The medical resources in Chongming are limited, compared to urban Shanghai. There is only one two-tier hospital in the island. Unlike other areas of China, the natural growth rate of population in Chongming is below 0%. In 2006, the birth rate of Chongming was 5.93‰, but the death rate was 8.33‰ and the natural growth rate was -2.4‰. The mortality rate of children under five years old in Chongming (0.14‰) was higher than the average rate in rural China (0.08‰) and the death rate of Infectious Disease and Cancers in Chongming was also much higher. (For example, the death rate of tuberculosis in Chongming was 30% higher than in other regions in rural China)

Living environment and lifestyle in rural Chongming (Example of Nanqiao Village in SanXing town)

Nanqiao village is in the west of Chongmin, as shown in Figure 1. The village is about 3 km² which is composed of farm areas (80%) and living areas (20%). There are about 1200 people living in this village and most of them are farmers.



Figure 1: Nanqiao village location in Chongming map (Map source: Google)

In figure 1 Nanqiao Community Health Point (CHP) is located in the village (The sign “A”). It is about 4.8 km from the Sanxing Community Healthcare Center (CHC, the yellow point), about 15.6 km from Chongming County hospital (the third tier in the rural medical system, the green point), and about 109.2 km from Ruijin hospital (Big hospital in urban Shanghai, the red point). It takes about eight hours from Nanqiao village to Ruijin hospital by bus and boat. The travel expense is about 60 Yuan. (which is three days’ income for a farmer in Nanqiao village).

Normally, five to ten people (three generations) live together as one family. For example, in one family visited by the authors five people live together:

- **Grandfather:** 56 years old
- **Grandmother:** 54 years old
- **Farther:** 32 years old
- **Mother:** 31 years old
- **Son:** 5 years old

They all live in one small house, which was built by the grandparents at the time of their marriage (Figure 2). The grandfather is in charge of a small farm (In 1957, Chinese central government assigned a farm to every farmer. These

farms belong to the government but farmers can use them for free.), and the father works in a factory in Chongming.



Figure 2: A typical living house in Chongming

An open closet is 300 M away from the house. (Figure 3) This kind of open closet was built by the local government 20 years ago and it is still used now.



Figure 3: A typical open closet in rural Chongming

To understand their daily lives, the authors lived with them for one week and recorded their schedules:

Common schedules of grandfather (August 16th, 2006)

This is a schedule of the grandfather, 56 years old, who lives in Nanqiao city, Chongming, rural Shanghai. (Figure 4)



Figure 4 Photo of grandfather and his grandson

He gets up at 6:30 when the sun just goes up. His wife has prepared breakfast for him. He listens to his radio and has his breakfast. After 30 minutes, he finishes his breakfast and leaves home. He arrives at his farm at about 7:15am. (Figure 5) Before working he is used to smoking. The cigarette that he smokes, named “peony”, is very cheap (2.4 RMB per box/20 branches). He finishes his cigarette and starts his work at about 7:30. He works in the farm until 10:00. He stops his work, goes to the umbrage, has some drink (Boiled water) and smokes again. After a 10 minutes rest, he is back to the farm. He finishes his work at 11:45am. It’s a lunch time for him. He goes back home to have his lunch.



Figure 5 Farm scenes of grandfather

He arrives at his home at 12:00 noon, has his lunch and goes to bed for a two hours sleep. He wakes up until 15:15. He doesn’t work in the afternoon. He chooses some entertainment activities to spend the time. He goes to entertainment hall, which is close to his house. A number of neighbors are there and they are playing MaJiang. He sits down behind a friend of him and watches their play.

He goes back home at about 18:30, and his wife is cooking their dinner. He helps her to cut vegetables and washing dishes. They have their dinner at 19:30. After that, they watch TV there and go to sleep at 21:30.

He spends all of his life in this village and has no any additional income except from farming (Some rural people have retired salary if they have ever worked in a factory). His main income is from his own farms (Rice sold). His average income is 400 RMB per month. His son gives him 400 RMB every month. His biggest worry is about his health care: it is too expensive to go to hospital if he or his wife gets a serious disease.

CHP and village doctors

The authors also visited the Community Healthcare Point in Nanqiao village. There is only one CHP in Nanqiao village and two village doctors work there. It is a three room clinic:

Consulting room: This room is used for the Village Doctor to make basic diagnosis on patients such as body temperature and blood pressure. Commonly a desk is found in the consulting room, and a medical kit and other diagnosis tools are there. (Figure 6)



*Figure 6 Typical medical kits in CHP
(Source: Nanqiao village CHP)*

Transfusion and observing room: This room is used for patient's transfusion. Normally several beds and chairs are available in this space. (Figure 7)



Figure 7 Typical transfusions and observing Room in CHP (Source: Nanqiao village CHP)

Treatment room: This room is for deeper diagnosis and treatments like enswathement and injection. (Figure 8)



Figure 8 Typical treatment rooms in CHP (Source: Nanqiao village CHP)

Two village doctors are in charge of this CHP (60 years old and 58 years old). Each of them work here for three and a half day per week. The working time of this CHP is from 8:00 am to 18:00 pm. Emergency help is also available because both of them live in the village. The education level of these two village doctors is primary school.

CHC and existing medical products (Example of SanXing town)

SanXing town only has one CHC in the town centre, about 20 km away from Nanqiao village. With a permission of director of that CHC, the authors visited it and interviewed doctors there.

Usually all departments of CHC are in one building. The main function of CHC includes disease prevention, diagnosis and treatment; health data management; village doctors education; immunization of infants and so on.

Figure 9 provides an overview about the CHC at Sanxin town. It has its own diagnosis department, treatment department and surgeon department. It has eighteen doctors, twenty nurses and fifty beds. However, medical equipments in the CHC are out of date and average education level of medical staff is only secondary school. Equipments in this CHC include:

- Electrolyte analyzer (Easlyte Plus): second hand
- Semi-automatic biochemical analyzer (Analy Tech-738): it has been used for 7 years now facing elimination because of inaccuracy
- Device for maintaining constant temperature
- Tabletop low speed centrifuge (80-1 Juntan Zhongda Medical Devices Co. Ltd in Jiangsu Province)
- ECG (ECAPS 12 Shanghai Mingqiao Medical Devices Co. Ltd): low quality but still used for 5-15 times/day
- Sonography (B-scanner SSC-370 ALOKA): it has been used for 5-6 years and 10-15 users/day. But it also malfunctions: bad image, electrode oxidization, only one probe
- X-ray: refit by the doctor and has been used since 1968. Its daily use is 15-20 times. It always malfunctions. Up to now, there are 4 cases that people with bone fracture had an X-ray but the equipment did not detect the fracture.
- Emergency room equipment: automatic stomach pump (SMIC) and medical sucker(SMIC)
- Blood analyzer
- Blood glucose detector



Figure 9 Typical scenes of CHC (Source: Sanxin town CHC)

Appendix B: The interview protocol for Chinese MSc and PhD students at IDE/TU Delft

Interview Notes

Objectives: Exploration insights about the development criteria for each layer

Date and Time:

Attendee:

Recorder: Jiehui Jiang

Part 2: Attendee's introduction

- > MSc department
- > Bachelor institute, department
- > Bachelor Graduation Project

Part 3: Basic Questions

- > Are you familiar with rural china design?
- > Are you familiar with design for healthcare?

Part 4: Research Questions

Cultural layer:

1. What are the design education courses in Chinese universities in your bachelor?

- Academic course about design approach and tool?
- Training and intern in industrial about design design approach and tool?

2. What will the designer do in a design project such as a mobile phone design for Chinese rural market?

- Could you please envision one actual project you experience?
- How many people?
- Is any member from engineering or business?

3. What kind of interaction between designers and users happened in a design project?

- Do you involve users in the design process?
- How to involve? Do you think it is necessary to involve?
- What is the users' attitude in the design process if you will involve them?

4. What is the role of the company in a design project?

- Does industrial company would like to cooperate with academic?
- How do they work with academic?
- What kind of cooperation did happen in your experience?

Mindset layer:

1. What are the important design facts in that case you described?

Methodology layer: What kind of design methodology do they use? "or would like to use"

- Literature you refer
- Any experience framework

Methodology layer:

1. What are the difference between them and DDM? (for those students who have been involved into DDM)
- What are your benefits between Delft Design and original design approach in China?

Method layer:

1. What kind of generative methods do they use in a design project?
- Observation
 - Organized interview
 - Questionnaire
 - Brainstorm ...
 - Creative design? Multidisciplinary team management etc.

Tool layer:

1. What kind of design tool do they use?
- Statistic
 - Video camera
 - Do you think current tools are enough to support your design in rural Chinese healthcare?

Comments and suggestions

Appendix C: Exploring Insight of User Needs: The First Stage of Biomedical Engineering Design

Publishing information: J. Jiang, A. Freudenthal and P.V.Kandachar (2009), Exploring insight of user needs, the first stage of Biomedical Engineering design, Chapter 4 in book “Advanced Biomedicine”, Ed. C.A. Barros de Mello, In-Thech publishing, ISBN 968-953-307-013-1.

1 Introduction

1.1 What is design?

Compared with some fundamental sciences such as physics or mathematics, the history of industrial product design is much shorter and original from other subjects. To quote Herbert Simon (Simon, 1969) from his work on science of artificial: “Everyone designs who devises courses of action aimed at changing existing situations into preferred ones.” Design is not fundamental research, which may be defined as a careful investigation or study. The design process needs research to accomplish the design task, but it typically involves the integration of fundamental knowledge, rather than the generation of fundamental knowledge.

On the other hand, design is not only craftsman (Paul and Richard, 2008). Creativity is an important skill in the design process. It is a brain activity as well as hand activity. Design work could be the manufacture of a physical device, and also could be a plan or a study to determine the process. It can range from the physical device level to the complete situation of product or manufacture related activities.

As a result, with the increased attention on interaction between product, user and environment (Hekkert and van Dijk, 2001; Tassul 2006; Hoog etc, 2008), the “product design” has widened from initial “arts, crafts and architecture” to the development of a complex system including aesthetics, ergonomics, economics, manufacture and so on (Roozenburg and Eekels, 1995; Muller, 2001; Roozenburg 2008). For most professional designers, their design activities are focusing on not only strict product development (Embodiment design, manufacture process (Pahl and Betiz, 1980)), but also product related behaviours such as user needs user experience or business model.

1.2 What is biomedical engineering design?

Biomedical engineering design means the design of biomedical devices and systems. As one part of healthcare design, biomedical devices and systems are much more complicated than common consumer products. They are characterized by such factors as usability (hardware and software), mobility and affordability. Right now three kinds of biomedical engineering design can be recognized.

Healthcare devices, examples are:

- Stethoscope
- Blood pressure measurement device
- Blood sugar measurement device
- Defibrillator device
- Portable ultrasound device
- Surgery instruments
- Inject instruments
- Dental instruments

Healthcare service, examples are:

- Development of Computer Aided Design for screening diagnosis
- Development of Electrical Healthcare Records system
- Development of user friendly interfaces for special doctors
- Development of Hospital Information System
- Development of Picture and Communication System
- Development of disease database

Healthcare environment, examples are:

- Optimization of architecture of operation room
- Optimization of water purified system
- Development of indoor pollution filter system
- Optimization of drug delivery system

In certain cases, two issues or all three issues will be involved.

1.3 Role of user needs research in biomedical engineering design

User needs are usually considered as one part of in biomedical engineering design projects. (Paul and Richard, 2008) Each biomedical engineer has his/her personal experience to work with users. These users may include patient, doctor and industrial companies etc. It is an efficient way to prepare a biomedical design project from user needs research. (Wiklund, 1995).

Recently, there are mainly two kinds industrial innovation models for healthcare: technical-original innovation and market (user)- original innovation.(Robert and Tomas, 1998). Technical-original innovations are able to achieve success in medical devices, telemedicine and record management, based on Information and Communication Technology. Nevertheless, market (user) – original innovations are more general because they don't need to wait for the enabling technology development. (Enabling technology means core technologies for industrial innovations, like X-ray technologies for computerized tomography device design. One example is that the idea of Compact Disc appeared at 1980 by Philips and Sony research group, but the product did not appear until 1982, because laser technology was not available in 1980(<http://news.bbc.co.uk/2/hi/technology/6950845.stm>)).

As opposed to technical-original innovations, the key feature of market (user) – original innovations is that it is user-central. (Ronald and Everett, 1980)User needs are considered to be the start point of the innovation process and user's purchasing as the end of the process. The role of user needs research has been emphasized in this model and the interaction between users and engineers (or designers) is crucial. Of course, market (user) – original innovation is not the only one approach for designing a biomedical device and system..

1.4 Why do we write this article?

As biomedical engineer, the first author of this paper has been involved in several biomedical engineering design projects. The subject of "user needs research" was addressed in one of the cases: "Strategy design research for Rural China". After cooperative activities with students from industrial design engineering and market research, he personally found that "user needs research" was an interesting issue in biomedical engineering design. And he started to collect more knowledge about user research and analysed past projects in the stand of industrial design engineering.

He found that the significance of user needs research has been ignored in several cases when he informally analysed the cases from industrial biomedical engineers, academic biomedical staffs and students. Once he talked with biomedical engineers, he would like to ask the question "why will you design this device or system with this technology?" In most cases he got answers such as "increase the accuracy of the device (Reliability)", "cut down the device cost (Affordability)" or "suit for local situation (Usability)" will appear. But once he asked further "How did you prove your design is effective?", the feedback is uncompleted most of time.

As a result, the aim of this paper is to introduce a systemic process on user needs research, which can provide the higher goal with spirit of a professional industrial design.

Besides introduction and methodology at the beginning, this article includes three parts. In section 2 , firstly a case of user needs research of biomedical engineering design, named "Strategy design research for Rural China" will be described detailed; and then some tools and methods will be inducted from the case as one possible approach to conduct user centred research; finally some discussions will be given about user needs research of biomedical engineering design.

This paper is an extension version based on the conference paper "New market, new challenge, new opportunity (2) -User context research" for 30th IEEE EMBS Conference in Canada, 2008

(<http://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=4649474&isnumber=4649055>) and the audios of this paper might be biomedical engineers, or related researchers and designer as well. (Jiehui and Kandachar, 2008)

1.5 Research objective and question

Open innovation includes several different type of innovation and user central innovation is one of them., Here it means involves users in the design process.(Henry etc, 2006) In this methodology, user needs are looked as the start points. The objective of user needs research is to explore insights of user needs, or with the word “Needs identification”. Needs identification is the first stage to develop design opportunities and then result in

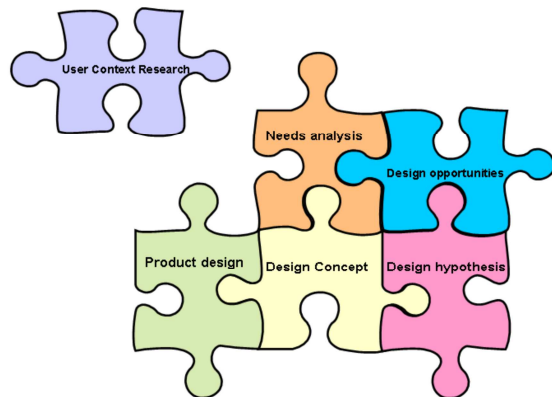


Figure 1: Needs identification related design activities (first raw focus). User context research is often used in the beginning, and after needs analysis, design opportunities are the results of needs identification. Second raw is about concrete product development, and it provides feedback for the first raw, however, it won't be discussed here.

function establishing and design hypothesis. In practice, user context research is frequently-used at the beginning, as presented in Figure 1.

The aim of needs identification is to identify, define and clarify design objectives and sub-objectives, and the relationships between them. In this paper, user context research needs analysis and design opportunities with published case will be discussed and the research question is “How the insights of the user needs were explored for biomedical engineering design?”

2.Methodology: Case study “looking for healthcare design opportunity for rural Shanghai”

This section will introduce a user central design case, which was meant as a first stage in product development: a preparation before the engineering phase of strict product development, Published earlier in EMBC. The major contests of the case come from the published conference paper (Jiehui and Kandachar, 2008).

2.1 Project motivation and research team

China has a largest population in the world (1.3 Billion) and 0.9 Billion is rural population (NBSC,2007).They are composed of 0.75 Billion rural people who live in rural and 0.15 Billion who live in urban as migrant workers (John and Xinmin, 2006). Although their average income increases every year to about 4000RMB/year (US\$1.4/day) at the end of 2006 (NBSC,2007), the income gap between rural and urban is becoming large year by year.

According to the World Bank, there are 4 billion people living on an income less than US\$3 per day and 1 billion living less than even US\$1 per day. This part of the population is often called “Base-of-the-Pyramid” (BoP), referred by Prahalad and Hart (Prahalad and Hart, 2007). And so more than 95% china rural belongs to BoP under this standard (NBSC,2007).

Recently, some Multi National Companies (MNC) such as HP, Intel, Philips and Microsoft have been aware of the design opportunities of this market, as well as some design institutes such as Delft University of Technology (DUT) (Kandachar and Halm, 2008), Illinois Institute of Technology (IIT), Berkley and Standford which are partnering with MNCs for BoP design (Wilson and Wilson, 2006; Jamie and Niels, 2007).

As a result, this project is the strategy part of the research program “Provide healthcare solution for rural China” and the outputs are intended for industrial partners for future healthcare product design such as new business opportunities to sell simplified devices for rural hospitals.

The research team includes students form three academic stakeholders: Delft University of Technology, Erasmus University (Netherlands) and Shanghai University (China), which is sponsored by Philips Medical

Systems and Applied Technologies. Related field work for user context researches are carried out through field study in rural Shanghai, by a student team of Tufdelt and Shanghai Univeristy.(Jiang and Jennifer, 2007)

6.3.2.2 Research Process

For the case, a research process named “From Unstructured to Structured” has been designed by teammate Jan Pieter Adriaanse and Jaap Daalhuizen. (Figure 2)

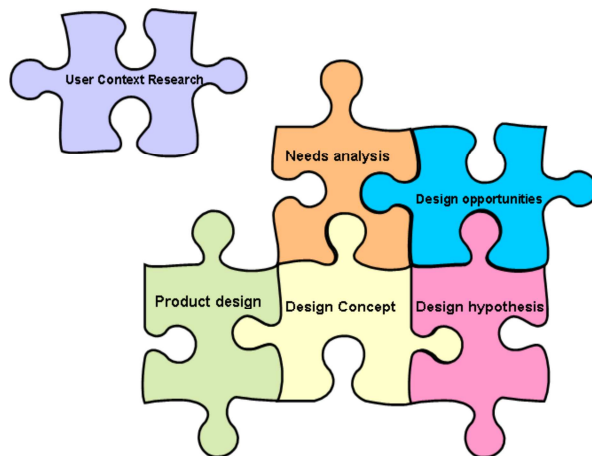


Figure 2: Research Process of User context research in rural Shanghai

In this research process, Primary/Second hand data is collected firstly through related research partners: Shanghai University, Tufdelt and Philips and referred official data: statistic from World Health Organization.(WHO) (Carrin G, etc, 1999) These data are structured accurate up to date, which compose of background knowledge and experienced tool for researchers. Qualitative and Quantitative research will be done to analyse and structure research data and insight on possible needs and goals will be found through this research.

2.3 Research Details

2.3.1 Pre-work and information source identification

In this project, pre-work of user context research was done through Internet and literature rather than practice as a user with a real product. The life style of local people has been understood by designer teams and information comes from three stakeholders: Academics, Non-Government Organization and industrial companies. The tool “*brainstorm*” (workshop with stakeholders, see 6.3.3.4) was used at the beginning.

2.3.2 Qualitative research

After the first step, to gain initial insights on healthcare needs, a qualitative exploratory in Shanghai research has been carried out in Chongmin island, rural Shanghai. The main approach is based upon the observation of the customs, habits and differences between people in everyday situations and four steps are used:

- Seeing through the eyes (*Initial Idea*)
- Unstructured observations (*Problem definition*)
- Diaries (*Data collection*)
- Semi structured interviews (*Interpretation and communication*)

To approach real life of target group, five rules are used for interviews:

- Develop empathy with the respondent
- Make sure the respondent is relaxed and comfortable
- Be personable to encourage and motivate respondents
- Note issues that interest the respondent and develop questions around these issues
- Not be happy to accept brief ‘yes’ or ‘no’ answers.

Target rural people are divided into five types in this research: elderly, farmer, worker, housing women and child. And the output of this step is 5 *personas* (introduced in 3.4).

Personas are archetypal users with specific goals and needs on real market and design research. They each represent a characteristic group of users, like ‘workers’ or ‘farmers’ (Thomas and James, 1995)

Following factors are included in our personas:

- A name
- A photograph
- Demographic characteristics
- Techno graphic characteristics
- Behavioural characteristics

- Barriers and/or challenges
- Specific goals and needs

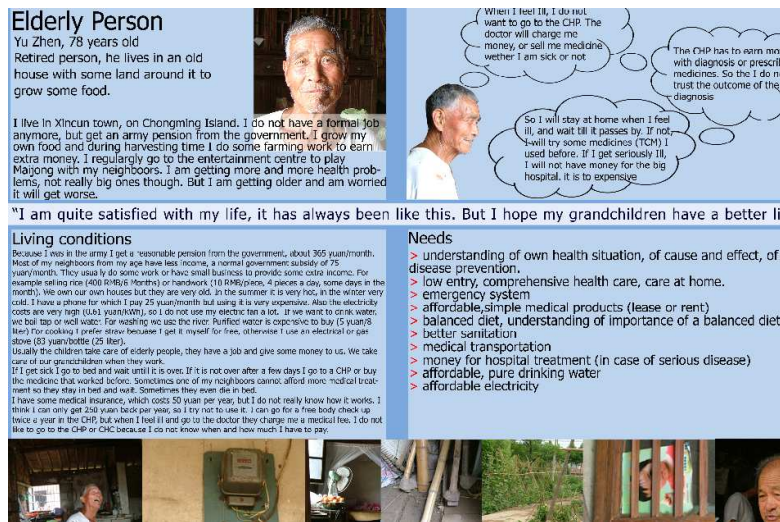


Figure 3: Persona of elderly, Edited by Jan, Jaap and Jiang

Figure 3 shows a finished persona of elderly in Chongmin, which is composed of four parts: Introduction, Living conditions, Awareness and Needs. Pictures are added to help understand contents for readers and a special topic is there: “I am quite satisfied with my life; it has always been like this. I hope my grandchildren have a better life.” And this thought will be considered in an interaction healthcare design for rural China as culture factors. The needs of personas are looked as main outputs for future research and they are recorded as images.

2.3.3 Quantitative research

Quantitative research is used as the third step of this project. Here, the aim of quantitative research in this research is to prove hypothesis. Some hypotheses have been found through persona such as “care at home” for elderly; this hypothesis will be detected by other target elderly group. And then the factor or phenomena can be the evidence for researchers. *Questionnaires* (introduced in 3.4) are designed as quantitative research tools here.

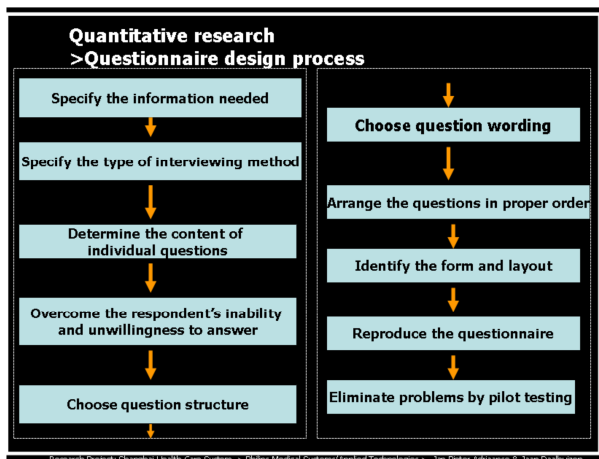


Figure 4: Questionnaire design process

order and layout, totally 64 questions are set up and they are composed of: basic information(6), basic health information(10), health awareness(8), medical insurance(8) and healthcare needs(32). 50 example questionnaires had been tested in Chongmin as pilot test. (10 for every persona) (The work has been carried out by local student teams; also see Figure 6 and 7)

2.3.3.1 Questionnaire design

Three special objectives are confirmed before the design:

- It must translate the information needed into a set of specific questions that the respondent can and will answer;
- Must uplift, motivate and encourage the respondent to become involved in the interview;
- It must minimise response error.

Figure 4 shows the design process of questionnaires in this research. The contents of questions are chosen from qualitative research and they are specified into a type of interviewing method, after a makeup in structure, wording,

Table 1: Respondents of questionnaires

Area	Respondent type	No of feedback	Area totally	Respondent totally	Plan		
Jin Shan	farmer	118	288	farmer	farmer		
	worker	27		632	650		
	elderly	30					
	Housing woman	97					
	child	16		worker	worker		
farmer	135	276	125			150	
worker	19						
elderly	32						
Housing woman	77						
child	13						
Feng Xian	farmer	127	277	elderly	elderly		
	worker	33		148	200		
	elderly	28					
Nan Hui	Housing woman	77	289			437	400
	child	11		child	child		
	farmer	134					
Song Jiang	worker	21	289			77	100
	elderly	22					
	Housing woman	94					
	child	18					
	farmer	118					
Jiang	worker	25	289	77	100		
	elderly	36					
	Housing woman	91					
	child	19					

2.3.3.2 Respondents

Five different rural areas: Jinshan, Qingpu, Fengxian, Nanhui and Songjiang have been chosen as questionnaire areas. 300 questionnaires are sent to each area by team (see Figure 7) and they were back at the second day , so totally 1500 questionnaires were finished.

Table 1 shows the respondents detail of this research, five target groups are separated. In this research, totally 1419 questionnaire are given back and the rate is 94.6%. The highest area is Nanhui and Songjiang(96.3%) and the lowest area is Qingpu. (92%)

For the respondent types, farmer gets a highest rate 44.5% and child is least 5.4%, the real number is acceptable according to plan.

2.3.3.3 Question description

Totally 64 questions are designed in this study, and they will divide into five parts:

- Basic personal information (6): Name, gender, age, address, contact phone and Email
- Basic health information (10): like Infectious disease history, impatient history
- Health awareness (8): like “I will trust Village Doctor more if they have advanced product”
- Medical Insurance (8): like “A good medical insurance will let me approach higher quality health care service”
- Healthcare Needs (32): like “I prefer to monitoring my body vital signals at home (Temperature, blood pressure)” and more details can be found in table 2. (Because the needs is the prime focus in this article I would provide a table of examples, both closed and open examples)

Most of answers of questions are choices and only a little will be formed by respondents themselves. Commonly five choices are given like “Very agree”, “agree”, “no sense”, “not agree” and “reject”., and the result will be imputed into the computer as “5”, “4”, “3”, “2” and “1”.

2.3.3.4 Data analysis

Two steps are used to identify and dismiss of error answered questionnaires,

- Similar comparison: Of 32 questions about healthcare needs, the questionnaire will be ignored if more than 30 answers are same.
- Complete decision: Of totally 64 questions, the questionnaire will be if ignored if more than 12 questions are skipped.

As a result, 1768 questionnaires are remained for next analysis.

To confirm the healthcare needs, all results of 32 questions are inputted into a 32*1768 matrix (Figure 5):

$$\text{Where } S = \sum_{j=1}^{1768} X_{ij}, \quad M_i = S_i / 1768 \quad \text{and} \quad SD_i = \sqrt{\frac{\sum_{j=1}^{1768} (X_{ij} - M_i)^2}{1768}}$$

M of the statistic means the important level of needs for target group and SD means agreement of the M, and the head ten results of M are showed in table 3.

Q5: Early detection for lung cancer

Q6: Treatment for lung cancer

Q7: Early detection for breast cancer

Q9: Early detection for esophageal cancer

Q14: Blood pressure personal care

Q15: Blood sugar measurement

Q16: Blood sugar personal care

Q27: Improvement for Village healthcare points

Q31: Birth care

Q32: Care for new birth

All M of 32 questions are located between 3.7 and 4.5, which means all above healthcare needs are real and agreed by rural people. (3 is the average line)

Table 2: Statistical distribution of respondents

Needs	Needs description	Target Group
Common diseases treatment (4)	Fever, cold, stomach and intestine diseases → Treatment	All
Cancer (6)	Lung cancer(2), breast cancer(2), esophageal cancer, cervical cancer → early detection and treatment	1,2,3,5
Heart Diseases and blood vessel for brain (2)	Immediate treatment and prevention	1,2,3,5
Chronic disease (6)	High blood pressure, high blood sugar and high blood fat → monitoring and personal care	5
Nutrition (1)	Nutrition detection for kids under 1 year old	4
Injury, Poisoning & External Causes (2)	Care and treatment	All
Tuberculosis (3)	Prevention, detection and treatment	All
Diseases of the Respiratory System (2)	Diagnosis and treatment	All
Low cost/safe medical service (3)	Current three types of low cost medical service can't satisfy them	All
Pregnant & Birth (3)	Pregnant care, birth care and mother care for new birth	2,5
1. Farmer; 2. Housing woman; 3.rural worker; 4. Children; 5. Elderly		

Table 3: The results of statistic, top 10 of approved actual needs

	Mean	SD	Order
Q5: Early detection for lung cancer	4.47	0.63	1
Q6: Treatment for lung cancer	4.29	0.87	2
Q14: Blood pressure personal care	4.25	0.77	3
Q15: Blood sugar measurement	4.19	0.71	4
Q16: Blood sugar personal care	4.17	0.82	5
Q9: Early detection for esophageal cancer	4.03	0.69	6
Q31: Birth care	4.01	0.77	7
Q32: Care for new birth	3.96	0.85	8
Q7: Early detection for breast cancer	3.91	0.93	9
Q27: Improvement for Village healthcare points	3.9	0.82	10

	1	2	3		31	32
1	X_{11}	X_{12}	X_{13}		X_{131}	X_{132}
2	X_{21}	X_{22}	X_{23}		X_{231}	X_{232}
⋮	⋮	⋮	⋮		⋮	⋮
1767	X_{11}	X_{12}	X_{13}		X_{131}	X_{132}
1768	X_{11}	X_{12}	X_{13}		X_{131}	X_{132}
Sum	S_1	S_2	S_3		S_{31}	S_{32}
Mean	M_1	M_2	M_3		M_{31}	M_{32}
SD	SD_1	SD_2	SD_3		SD_{31}	SD_{32}

Figure 5: The matrix for data analysis

2.3.4 Needs analysis

Through above three stages, a number of user needs from Qualitative Research. have been confirmed, which consequently were considered as design objectives. Next we clustered the 32 topics (First of all, these objectives have been listed and concluded into three issues “Chronic diseases”, “Cancer” and “Mother and Child”. To explain the procedure of needs analysis, “Mother and Child” will be chosen as the example. Secondly, some objectives about “Mother and Child” will be collected as:

1. Pregnant care
2. birth care
3. mother care after new birth

After analysing local statistic data and videos from field study, we found that more than 70% death of mother and baby happened in the birth process. So birth care was chosen as our major objective for next design steps.

Thirdly, birth care will be focused and sub objectives have been showed:

1. Affordable medical devices
2. Low risk of birth process
3. Safe and clean room environment

Finally, low risk of birth process has been chosen because we found that the problem is still there once 1 and 3 have been improved in a pilot village.

2.3.5 Define preliminary goals and design opportunities

As the last step of user context research, some design opportunities for companies have been submitted as preliminary goals. For example, educational, awareness creation, Information and communication enable tools have been considered as design goals. These opportunities will be evaluated by the investor and decide “Go or no go” for next phase. (Table 4)

3. Results

In this section, we will discuss what we have learned from the case. And some initial results will be given according to Figure 1.

3.1 Principle: four key words of user needs identification

As an approach to help designers/engineers to understand the designing target group (users) and user needs, it can be helpful to focus in research on four key words

- Who: Who are your users? In healthcare product design, users are often including patients and medical staffs.
- What: What characters do your users have? User habits and work/life circumstance are always considered as important inputs for product design.
- Where: Where are your users? It should be very clear before a design. Design a product for an American or design for a Chinese is different, especially for their culture.
- When: When will your users benefit from your design? Sometimes particular using time need particular functions, for instance, design for ambulance.

Above four key words should be addressed through the whole process.

3.2 Pre-work of user context research: practice yourself as a user

Once you start a user research, some pre-work is needed. With the key words of four ‘W’, designers/engineers could write a research proposal to understand users through their experience or special tools such as interview, question and so on. In design practice, before a real user context research, a method called “design trip” (Nigel, 2006) can be used to test your user research proposal. The essential idea of design trip is very simple: you just take a trip through the whole process of using the proposal (it could be your user research plan), making yourself a critically observant user. You may be supervised how much you find out, if you keep yourself enough self-aware and observant. Once this method has been used a few times, more outputs will be received to help you to adapt your proposal and adopt your attitude at the start you had no attitude.

Decide first of all whom your users are and their points of view you are taking: elderly patient, pregnant women, village doctors, etc. You may want to make several mental trips, from different user perspectives. Usually, it is easiest to make a single user’s trip, since you may need special permissions, tools or skills before you take more.

Table 4 : Some design opportunities for rural China healthcare needs

Needs, Concerns	Directions for solutions	Design innovations
Chronic diseases treatment	Diagnosis and treatment	Educational, awareness creation, ICT enabling tools
Affordable medical cost	Governmental policy	Hybrid Business models
Medical Insurance	Health care policy, financing	ICT enabling tools to reach the poor
Safe food	Food monitoring	Educational, awareness, Packaging Materials, ICT
Safe Living Conditions	Governmental policy, Conditions monitoring & displays	Production Materials, Manufacturing, Ecodesigns advanced technology...
Pregnant & Birthcare	Care	Telemedicine, Medical materials & equipment, Interface, advanced ICT technology...

Next, decide the limits and variations to mental trips. It seems a good idea to extend the trip into complicated conditions, which provide you more integrated overall solutions for problems you may meet. For example, if you want do a user context research about blood pressure measurement, you may divide a year into different

seasons; divide a day into different times and with different weather conditions. The extending of trips will properly bring more problems and indications you can't get from a single user trip.

Now you just have to prepare and conduct the real field trip, recording the actions, impressions, ideas and thoughts. Some tools are often used in the real field trip such as paper poster, video camera or recording pen. Through reviewing the records, some improvements will be achieved, which makes you more confident, relaxed and accepted by user groups.

3.3 User context research process

As one part of product design, user context research also follows the characters of product design, like the process of problem solving and reasoning. Others' research and personal experience is the fundamental for designers to build user context research process. A frequently used process in TUDelft is from Thomas. (Thomas, 1961)

In his option, carrying out a user context research project includes five stages:

1. Initial Idea. The initial idea of context research is based on others' research and personal experience in related topic. It means designers can talk with other experienced designers or do literature review in Internet or books to build initial idea about target users.
2. Problem definition. The procedure of problem definition is continuous in the whole user context research process. At the same time, designers should carry out each action with problem such as four "W"s.
3. Data collection. With the problem, some user related data will be collected. The data could be unstructured or structured.
4. Interpretation. Explain the collected data with design words, and find the relationship between user data and product needs.
5. Communication. Document your process, conclude your opinions and present your research results. The evaluation could be done through compare results and initial ideas.

All five steps could be achieved through design tools.

3.4 Data collection tools

Currently, most of tools used for user data collection in product design are coming from social/market science methods, like observation, questionnaire and user scenarios (Heath and Stewart, 2003). These tools are collected and chosen by designers according to local project requirements. Part of frequently-used tools is introduced as follows:

Brainstorm

Brainstorm is the mental process of developing and organizing ideas. Brainstorms often occur as workshops in the above case, and users were often involved into the brainstorms directly. In practice of healthcare design, the participants of brainstorm could be people from medical organizations (hospitals), from government organizations (healthcare policy), industrial companies (product manufactures), education institutes (universities) or even users directly (community). Brainstorm is an important source for user information, especially for those designers who lack of local experiences.

Observation

Observation plays a role in the process of context mapping, and it gives designers first sight scene about users: their life style, their habits and their life environment. The observation provides designers' opportunities to compare outputs from design trips and real feeling in local context, and then improve the shortcomings that previous trip suffered from. (In the case, some added information from rural people in China has been achieved through observation as the beginning)

The results of observation could be recorded through taking notes, photos and video. These records are first hand information for future analysis.

Interview

An interview is a conversation between two or more people (the interviewer and the interviewee) where questions are asked by the interviewer to obtain information from the interviewee. Interview is the most important tool in the above case to help designers understand users' thinking. And the aim is to understand "How can user be satisfied?"



Figure 6: Interviews in the case (Jiehui and Jennifer, 2007)

The interview could be done through chatting, question and even group discussion. The contents of interviews depends on the interview/ observation set up, compared with observation. (Figure 6: Local students are doing interviews with local users in the case)

Persona

Persona is a tool to record some information. In above case, it has been used to draw the together the varied needs, preferences, wishes and requirements into a "model" of users, in order to guide designers for next step actions. The aim of persona is to construct some "stories" from users' lifestyle into one picture. These stories are user scenarios through observation and interview, and that picture is called persona. The contents of persona are related with design tasks. For example, if you would like to design a solution for blood pressure measurement and your target users are high blood pressure patients, the persona might include the patient's age, gender, family disease history, the diet and other information that will affect blood pressure.

Questionnaire

A questionnaire is a research tool consisting of a series of questions and other prompts for the purpose of gathering information from respondents. In this topic, the contents of questionnaire may include basic information of stakeholders, social and economic information about users, or the preference on about current solutions. Questionnaire is often used as quantitative method. (Figure 7: Local students are organizing questionnaires with local users in the case)



Figure 7: Questionnaires in the case (Jiehui and Jennifer, 2007)

3.5 Needs analysis: transform user needs to product needs

The formal start point for the design is the design brief or strategy about new product. Although it is a very important step in the product planning and development process, it lacks of attentions from product directly. A connect is needed to bridge user needs and product design tasks. This connection is achieved through two steps: preliminary goal definition and clarifying objectives.

3.5.1 Preliminary goal definition

As an important step for the clarification of current situation, user context research answered the question "what is the existing situation". But it is still a distance away from the new solution- what is designers would like to generate. In another aspect, when a client, sponsor or company project manager approaches a designer

with a product need, further work is needed. The client does not exactly wish to know what kind of product want or what target customer group needs, what kind of functions could be added into their existing products or what kind of artefact improvement is needed to increase customers' purchasing will. Simply speaking, a "problem" needs a "solution".

Therefore, the start point of "solution development" for designers is to define some preliminary goals, although in this step it is quite rare for a designer to give a complete and clear statement of design objectives. The preliminary goal definition can be considered as a desired end. For example, when you find that "High blood pressure is a serious problem for your target group and the reason is they lack of measurement devices and medical staffs in local", an idea on "design a portable, affordable, assessable self-measurement blood pressure device" may appear in your mind.

The Preliminary goal definition should be very logical and the relationship between user needs and preliminary goal should be pointed out directly. In fact, it is feasible to build logic relationship within two steps in healthcare projects. For another example, lung cancer is an important disease in rural India, while the first reason is the indoor pollution. Through user context research in rural Bangalore, the designer team (Master student from TU Delft and designers from Philips) found that the gas from indoor cooking result in pollution and then the design goal is "Design a non-pollution cooking stove for rural India". Lung cancer->indoor pollution ->design new cooking stove is logic.

3.5.2 Clarifying objectives

Once the preliminary goal is defined, the focus of design thinking will be transferred to products. So it is helpful for designers to have a clear statement of design objectives. Clarifying objectives includes three steps:

1. Make a list of design objectives: To achieve the preliminary goal, the first step is preparing a list of design objectives about the "solution" in your mind. The list can be generalized at random as you think or in discussion with the design team.
2. Order the list with different level objectives: As you make a list of objectives, it should become clear that some are high-level objectives and important. In most of time, as a designer you have to choose high-level objectives and forget some low-level objectives because it is difficult to consider every objective equally. For example, in the case of "Design a non-pollution cooking stove for rural India", safe is the highest-level objective. If you want to control the air pollution within a limited scale, new energy technology is necessary, so it means the product cost is higher than original stoves, which are always using woods. (Wood is free in rural India according to our field study) The aim of ordering the objectives is to help designers locate critical innovation direction and the determination might be from design team and even users.
3. Reality of objectives: This is the last step before the real concept design progress. The high-level objectives than can be detailed and implemented into present product markets in this step. The question about objectives now is becoming "How to achieve the high-level objectives". The often used approach is "*drawing a diagrammatic tree*" and finds variables in the hierarchical diagram. It is not necessary just only a simple tree with the structure of branches, twigs and leaves, which shows the relationship and interconnection among each variable.

3.6 Design opportunities

Design opportunities identification is the last stage of the whole process. After the series of information analysis, some conclusions can be drawn. Some new research activities were added in this stage, such as comparison among existing products in the market.

3.7 Summary of user needs identification for biomedical engineering

This section introduced the procedure for needs identification based on the case, which is as follows:

1. Practice being a user yourself. Imaging you are the target users, and you will be observed, asked questions, and interviewed. What kind of conversation type will be welcomed to you? What kind of questions will be welcomed to you?
2. Identify information source. If you are going to working for an unfamiliar user group, it is a good idea to get some ideas and fundamental information from your local partners. These partners could be industrial companies, educational institutes or nongovernment organizations. You partners will provide you a big picture about users and first sight scenes of their condition. The information is systemic, statistical, but sometimes lacks detail. For biomedical engineering design, two features were found in the case:

- a) Diseases are normally main problems in healthcare issues. (In the case, diseases are also major contexts) In the step of problem definition, diseases are often thought as first element of the needs. It is easy to understand because diseases result in healthcare problems directly. As a result, disease information is often used as the starting of user context research.
 - b) Availability is important in healthcare. This differs from other product types, Users' expectation on healthcare is not only about the product, but also healthcare service by medical staff. (Except in the case of self-care) This means designers should extend their attentions from separate users to the whole eco-healthcare system (device-doctor-patient) and context research should meet this need.
3. Qualitative research. Now you will touch with users. First of all, observe user's actions and then you will get both experienced and inexperienced users' valuable insights. Secondly, talk with users, interview them and take notes about the stories you get from conversation. Thirdly, write down these stories and conclude them into different pictures logically and make personas if necessary.
4. Quantitative research. Through qualitative research you have already gained a lot of information about users, sometimes this is structured for your project, but sometimes you have to prove them through quantitative research such as questionnaires. At the same time, it is also helpful to expand your information through quantitative research with different opinions.
5. Needs analysis. You have enough user information, but you should find the relationship between user needs and product needs (solutions). The simplest approach is to compare user needs and existing solutions through needs analysis. Also two features are found in biomedical engineering:
- a) The balance between reliability, durability and affordability should be found. As a basic topic, healthcare is aware by all governments, and there must be existing solutions for every healthcare issue. And as the designers, your tasks are building new innovations, which are better than current ones. In healthcare issue, there are two dominants: improve the reliability or durability through new technology/material, or decrease the device/service cost. Most of time, designers are just looking for the balance of two.
 - b) Acceptability should also be considered. Here, acceptability is not only for users, but also for healthcare policy maker. The standard about healthcare product/service is higher than many in other domains. For instance: Food and Drug Administration (FDA).
6. Define preliminary goal. The last step of user context research is preliminary goal definition, and it is the start of concept design as well. You should write down your design tasks right now, and they could be completely new products, new functions for existing product etc.

4. Conclusion

Needs identification is the first stage of whole product design, and the aim of it is to understand the insights of target group users. The methodology and process of user context tools are also useful for healthcare issues.

In this paper, a user needs identification project on China rural healthcare design opportunities has been introduced. The research is mainly composed of qualitative research and quantitative research, and the research process is pre-work research → Information source identification → Qualitative research → Quantitative research → Design opportunities. The healthcare needs were verified through quantitative data analysis. This case shows that the process mentioned is efficient for biomedical engineering design but some adaption work are needed.

As a result, there are six steps in the user context research has been proposed: practice being a user yourself, identify information resources, qualitative research, quantitative research, needs analysis and define preliminary goals. And some tools are used including: brainstorm, interview, questionnaire, experiment and so on. User context research methodology is also suitable for healthcare projects, and this chapter provides a case study about rural China healthcare.

Finally, a special user target group: BoP has been discussed in the paper. Some design features and new challenges about user context research have been introduced. However the research in this issue is still undergoing and more adaption and adoption work are needed to design biomedical engineering (healthcare) devices/systems in the future.

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About the author

Jiehui Jiang (1981) currently works at the Faculty of Industrial Design Engineering at Delft University of Technology as a PhD student. He received his bachelor and MSc degrees from biomedical engineering institute at Shanghai University, China in 2004 and 2007 respectively. He is one of the earliest researchers and practitioners focusing on providing Design and development of ICT-enabled Medical device and system for Rural Chinese (DIMRC).

He has been developing medical products and systems when he worked as the MSc candidate and as an intern in the “emerging market group” with Philips. During that time he was also enrolled into DIMRC projects. These projects include:

- ***Design of remote monitoring system for BoP*** (2006): This project was his MSc gradation project (of the author) in Shanghai University in 2007. The goal of this project was to design an affordable patient monitoring system for village doctors, which is used to gather real-time bio-signals, store, display and analyze data, communicating important information between servers and terminals etc. Village doctors can use it for on-the-spot-diagnosis as well as remote specialist consultations in higher-tier hospitals for further medication. Supervised by other researchers and developers from universities and Philips, the author worked as the principle designer and developer with a biomedical engineering student team. His work included identifying user requirements, creating design goals, generating design ideas, developing the prototype system, and testing the prototype system. If so this is very relevant and needs elaboration. *(For more details for this project, see the publication: J. Jiang and J. Zhang (2007), Remote patient monitoring system for China, IEEE Potentials, Issue 3, 2007, ISBN: 0278-6648, Page 26-29)*
- ***Digital tools for village doctors in rural China*** (2006): This project was a MSc graduation project by Marion de Groot executed for IDE/TU Delft in 2006. This project was sponsored by a Dutch company IMPACT. The R&D team of this project included de Groot herself, engineers from IMPACT and biomedical engineering students from Shanghai University. The author of this thesis worked as Chinese co-researcher in this project. He was involved in the field studies in Shanghai. The aim of the project was to develop a digital tool to help village doctors for diagnosis, specialist consulting and communications. This tool was designed and developed as a TV set-box. Information concerning several diseases and the related drug information were stored in the box beforehand. When the village doctors use it for diagnosing and prescribing, it is linked to a TV by a cable. The TV is then used as a computer screen, and a wireless controller is used to operate this system. The interface is simplified and village doctors only need to choose information with “up” or “down” button and make

“Yes” or “No” decisions. (For more details about this project, see the publication: *de Groot (2006), Digital tools for village doctors in rural China, MSc thesis, Faculty of Industrial Design Engineering, Delft University of Technology, Delft, The Netherlands, 2006*)

- **Identify design opportunities for rural China** (2006): This project was a research project conducted by the Philips “emerging market group”. This group consisted of different professionals, e.g., project managers, business managers, biomedical engineers, and industrial designers. The author of this thesis worked as an intern in that project. He was involved in the field studies in Shanghai and in generating design opportunities for Philips. The aim of this project was to help Philips identify design opportunities that apply and possibly require adaptation of existing healthcare technologies from Philips. (For more details for this project, see the publication: *J. Jiang & Kandachar, PV (2008). New market, new challenge, new opportunity (2) - User context research. In G Dumont & H Caliana (Eds.), Proceedings of the 30th Annual International Conference of the IEEE Engineering in Medicine and Biology Society "Personalized Healthcare through Technology", pp. 1583-1586*)
- **The application of temperature CT for early detection of breast cancer in rural China – feasibility study** (2006): This project was a research project conducted by the Philips “emerging market group”. This group consisted of different professionals, e.g., project managers, business managers, biomedical engineers, and industrial designers. The author of this thesis worked as an intern in the project. The aim was to explore whether the temperature CT device can be re-designed as a reliable and affordable device for early detection of breast cancer in rural China. The feasibility study included testing of environmental influences on the reliability of temperature CT measurement in villages, usability study for village doctors, exploring the business model, etc. The author was involved in the field studies and quantitative data analysis.

Besides being involved in DIMRC projects, the author was also a student organizer of international conferences (EMBC in full please 2004, 2007), and an invited speaker at several international conferences.

Publications of Jiehui Jiang

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1. J. Jiang, P.V.Kandachar, A. Freudenthal (2011), Overview of literature relevant to Information and Communication Technology based healthcare design in rural China, *Journal of Emerging Knowledge on Emerging Markets*, Volume 3.
2. J. Jiang, ZZ Yan, J Shi, P.V.Kandachar, A. Freudenthal (2010), A Mobile Monitoring System of Blood Pressure for Underserved in China by Information and Communication Technology Service, *Information*

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