4

Exploring Insight of User Needs: The First Stage of Biomedical Engineering Design

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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 craftsmanship (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 reliability (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 initiated in 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 decision to purchase 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 analyzed 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 analyzed 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 centrered research; finally some discussions will follow about user needs research of biomedical engineering design.

This paper is an extended 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 function establishing and design hypothesis. In practice, user context research is frequently-used at the beginning, as presented in Figure 1.

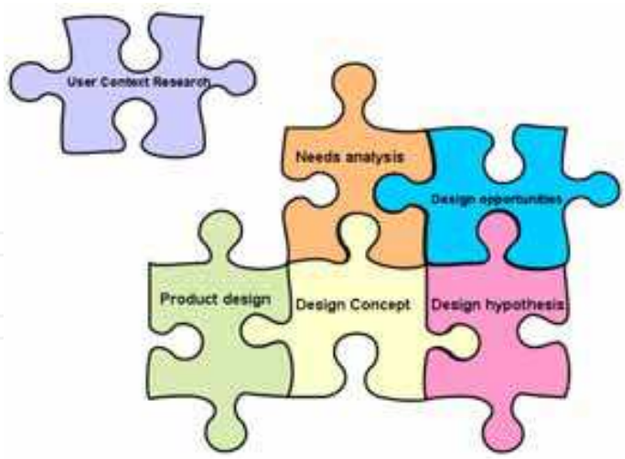

Fig. 1. Needs identification related design activities (first raw focus). User context research is often used in the beginning, and after needs analysis, design opportunities are the results of needs identification. Second raw is about concrete product development, and it provides feedback for the first raw, however, it won't be discussed here.

The aim of needs identification is to identify, define and clarify design objectives and subobjectives, 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 "searching 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 the 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 has increased 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 Hewlett-Packard (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 Tudelft and Shanghai University.(Jiang and Jennifer, 2007)

2.2 Research Process

For the case, a research process named "From Unstructured to Structured" has been designed by teammates Jan Pieter Adriaanse and Jaap Daalhuizen. (Figure 2)

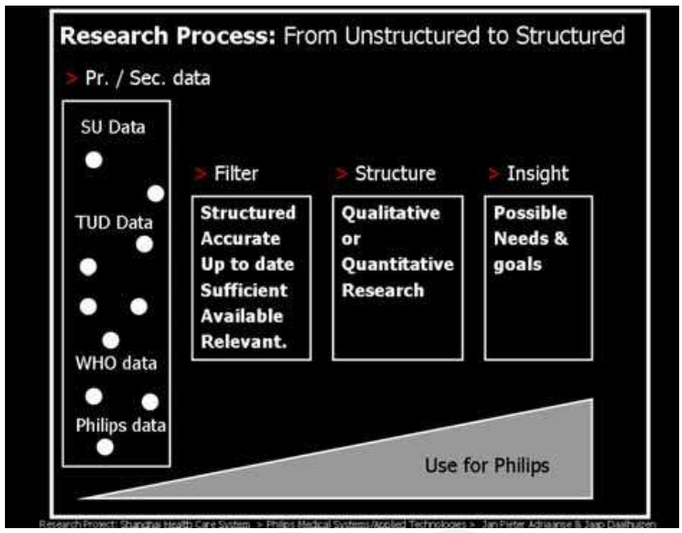

Fig. 2. Research Process of User context research in rural Shanghai

In this research process, Primary/Second hand data will be collected firstly through related research partners: Shanghai University, Tudelft 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 well established tools of for researchers. Qualitative and Quantitative research will be done to analyze 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 reviews rather than practice as a user with a real product. The life style of local people has

been studied by designer teams and information comes from three stakeholders: Academics, Non Government Organization and industrial companies. The tool "*brainstorm*" (workshop with stakeholders, see 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 research in Shanghai was carried out in Chongmin island, rural Shanghai. The main approach was 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 shows a completed 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 section: "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.

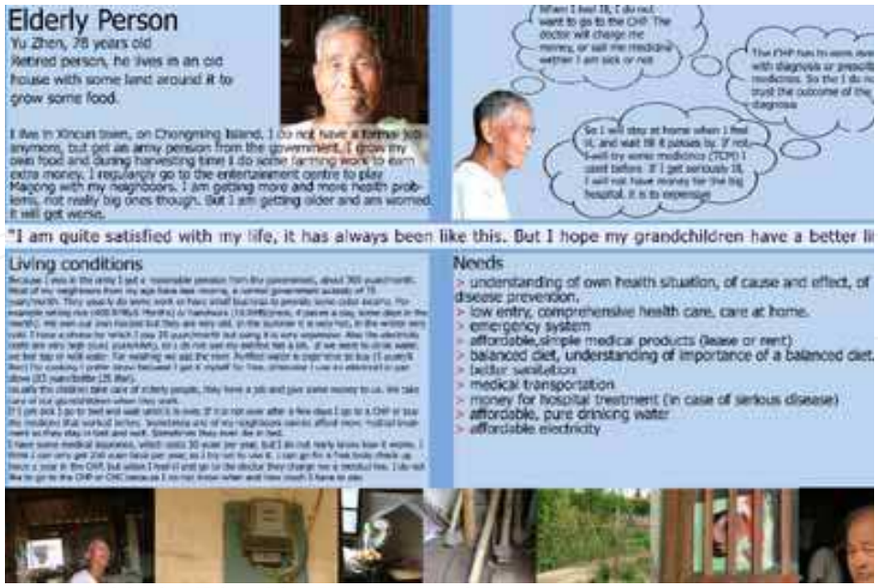

Fig. 3. Persona of elderly, Edited by Jan, Jaap and Jiang

2.3.3 Quantitative research

Quantitative research is used as the third step of this project. Here, the aim of quantitative research in this part 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.

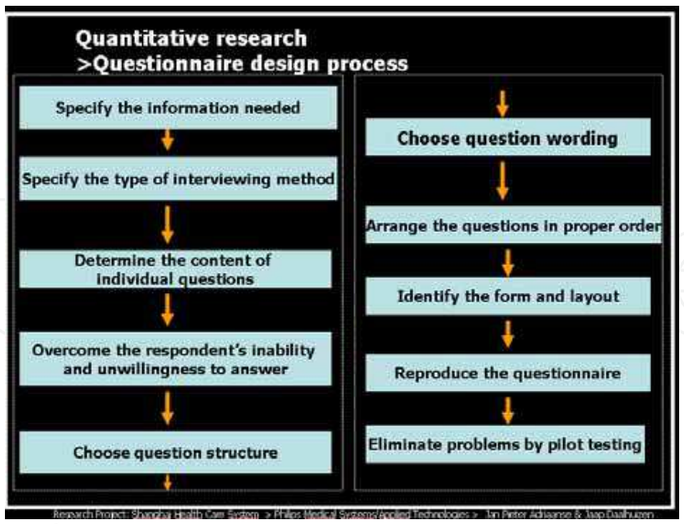

Fig. 4. Questionnaire design process

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, 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 person) (The work has been carried out by local student teams; also see Figure 6 and 7)

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 are divided 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 is 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,

a) Similar comparison: Of 32 questions about healthcare needs, the questionnaire will be ignored if more than 30 answers are same.

b) Complete decision: Of totally 64 questions, the questionnaire will be if ignored if more than 12 questions are skipped.

Area	Respondent type	No of feedback	Area totally	Respondent totally	Plan
Jin Shan	farmer	118	288	farmer	farmer
	worker	27			
	elderly	30			
	Housing woman	97		632	650
	child	16			
Qing Pu	farmer	135	276	worker	worker
	worker	19			
	elderly	32			
	Housing woman	77		125	150
	child	13			
Feng Xian	farmer	127	277	elderly	elderly
	worker	33			
	elderly	28			
	Housing woman	77		148	200
	child	11			
Nan Hui	farmer	134	289	Housing woman	Housing woman
	worker	21			
	elderly	22			
	Housing woman	94		437	400
	child	18			
Song Jiang	farmer	118	289	child	child
	worker	25			
	elderly	36			
	Housing woman	91		77	100
	child	19			

Table 1. Respondents of questionnaires

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):

Where $S = \sum_{j=1}^{1768} Xij$, $Mi = Si/1768$ and $SDi = \sqrt{\frac{\sum_{j=1}^{1768}(Xij-Mi)^2}{1768}}$

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)

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 2. Statistical distribution of respondents

	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

Table 3. The results of statistic, top 10 of approved actual needs

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 analyzing 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).

	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_{i1}	X_{i2}	X_{i3}	……	X_{i31}	X_{i32}
1768	X_{i1}	X_{i2}	X_{i3}	……	X_{i31}	X_{i32}
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}

Fig. 5. The matrix for data analysis

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…

Table 4. Some design opportunities for rural China healthcare needs

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 include 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.

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 talked 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 originating 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.

Fig. 6. Interviews in the case (Jiehui and Jennifer, 2007)

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?"
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 includes 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)

Fig. 7. Interviews 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 development. 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 answers the question "what is the existing situation". But it is still a distance away from the new solution- what 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 TuDelft 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 chose 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", safety 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 introduces 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 differ 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 have 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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Biomedical Engineering can be seen as a mix of Medicine, Engineering and Science. In fact, this is a natural connection, as the most complicated engineering masterpiece is the human body. And it is exactly to help our “body machine” that Biomedical Engineering has its niche. This book brings the state-of-the-art of some of the most important current research related to Biomedical Engineering. I am very honored to be editing such a valuable book, which has contributions of a selected group of researchers describing the best of their work. Through its 36 chapters, the reader will have access to works related to ECG, image processing, sensors, artificial intelligence, and several other exciting fields.

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