

IDENTIFYING STRATEGIC DIRECTIONS FOR DESIGN DEVELOPMENT OF GENERAL HOSPITAL EQUIPMENT FOR THAILAND

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ABSTRACT

The research sets out to achieve a better understanding of the Thai public healthcare sector and Thai medical device industry to identify strategic directions for the Medical Devices Laboratory (MDL), other researchers in related fields, and Thai medical device producers. Base on this strategic platform, the ultimate goal is to enhance the capability of medical device design and development in Thailand, increase the competitiveness of the Thai medical device industry and improve the quality of life of Thai people. Soft System Methodology was adopted, as a rigid structure was not suitable for the fuzzy nature of the research. A series of qualitative research methods were employed to capture requirements from all stakeholders and suggest potential products that matched the capabilities of the MDL and the Thai industries. Although the research intended to explore all possibilities, the results revealed that non-surgical hospital equipment and basic rehabilitation devices held the highest potential. At the end of Year Two, concept designs for a standing frame and hoist were developed. In this paper, the rationale and research methods, and findings are presented and discussed in order to address current challenges that the Thai healthcare practitioners and medical device developers recently faced.

Keywords: Public Healthcare, General Hospital Equipment Design, and Requirement Capture Process

INTRODUCTION

One of the Royal Thai Government's long-term strategic directions was to become the "*Health Tourism Hub of Asia*" (Nuttavuthisit, 2007). Aungkasuvapala, the General Director, Department of Health Service Support, Ministry of Public Health (2002), reported that 632,300 foreign patients sought treatment from 33 private Thai hospitals. Based on his estimation, the revenue was expected to reach 23 billion baht (~367 million pounds) in 2005. Nevertheless, the public healthcare sector and the medical device industry in Thailand depict a contradictory story. According to the Thai Medical Device Association (THAIMED), the majority of medical devices sold in Thailand are imported (Dombrowe, 2002). Thailand Trading Report 2007 produced by Ministry of Commerce Thailand (2007), also revealed that the total import value exceeded ten billion baht (~158 million

pounds). Since most imported devices are relatively highly priced, they are considered unaffordable by a majority of healthcare users. Currently, the medical devices produced in Thailand are restricted to only a small number of categories. Moreover, most of them are dispensable and low valued added devices. Dombrowe (2002) reported that only 16% of the medical device suppliers in Thailand are manufacturers, 50% of which are producing surgical/examination gloves and/or condoms. The author also claimed that the Thai Government has made several attempts to attract international investors to set up production facilities of high-tech medical devices, but this drive has not yielded significant results. This situation presents a pressing need to enhance the capability of medical device design and development in Thailand in order to increase the competitiveness of the medical device industry and improve the quality of life of Thai people. Besides, the medical devices developed domestically are considered more likely to fulfil the requirements of the local users and match Thai lifestyle. However, there has been no previous detailed research that studies the public healthcare sector and medical device manufacturing in Thailand before. Thus, this research aimed to identify strategic directions for the MDL and other researchers in related fields, and the industries.

THE RESEARCH TEAM

The research team comprises of three researchers from three different fields: Product Design, Engineering Design and Biomedical Engineering, and employed by the MDL, the National Metal and Material Technology Center (MTEC). Recently, MTEC, a member of the National Science and Technology Development Agency (NSTDA), Thailand, is under immense pressure due to the government scheme, which forces all national research organizations to deliver more concrete products, techniques or processes in addition to research publications. This is considered a major cultural change, since, in the past 20 years, publications have been regarded as the key contributions and main criteria for career development at MTEC. Consequently, the MDL research team needs to begin taking more proactive roles, e.g. networking with all stakeholders, identifying market opportunities, and creating a product portfolio. Hence, customers' satisfactions were measured alongside experts' opinions in order to determine research success. Even though, these activities are considered common business practices, for MTEC, which does not have any marketing function or business plans for the technologies they developed, these actions are regarded as revolutionary. Although MTEC has developed many skills, technologies, and facilities in related areas, e.g. materials to cure injuries and skin substitution, materials and equipment for post treatment of bone and injuries, and equipment for joint rehabilitation, the expertise is too specialized to leverage to the mainstream directly. Hence, the research group conducted a design-led enquiry as

a means to investigate design strategic opportunities in the public healthcare sector and the medical device industry in Thailand. Since, this research was funded by the government, it was expected that the results should benefit the majority of Thai people and not focus on one specific population sector. Nevertheless, there is no strategic direction at national level. As the role of the national research organization is to support Thai industries, the outcomes should not compete with any existing products provided by local companies or other institutes. Thus, the key challenge was to uncover the latent needs of the healthcare users that had not been recognized by local or global companies. Moreover, this opportunity must match the expertise of the MDL and the Thai industries. A clear design strategy will benefit not only the MDL team but also other developers in related fields.

RESEARCH OBJECTIVES

This research prepares the platform for further extensive research and developments that will be conducted by the MDL. Therefore, it aims to 1) investigate the nature, constraints, current problems and challenges of the public healthcare sector and the medical device industry in Thailand, as well as 2) discover latent requirements of all stakeholders in order to 3) identify strategic directions and potential products that leverage skills and capabilities available within MTEC and the Thai industries, and fulfils the requirements of the local users.

THE MAIN CHALLENGES

Since the medical device is regarded as “*High-stakes Design*” (Wilcox, 2003), it is extremely important to achieve functionally correct and safe designs (Wikilund, 2003). Moreover, it is noted that several marketing rules are not applied to this type of product. For instance, it is purchased due to its function, quality, and performance more than its customer-perceived values, personal desires or different price points. According to its unique characteristics, it is important to obtain a sufficient level of understanding of the clinical issues and address requirements from all stakeholders including healthcare users (providers and receivers), purchasers, and developers/manufacturers (Department of Health & Design Council, 2003). Compared to developed countries, the Thai market was considered “liberal”, as there are no restrictions on the import and sale of medical devices, except for the registration of the products with the Thai Food and Drug Administration: TFDA (Dombrowe, 2002). Although the Thai Medical Device Act 1988 (TFDA, 1988) described the registration process in detail, testing methods were hardly mentioned. Moreover, the literature regarding the public healthcare sector and the medical device industry in Thailand was limited. Even though the Advisory Council for Applied Research and Development: ACARD (1986) identified the potential of developing ‘*Appropriate Technology*’ equipment for

developing countries, the equipment developed with users in developing countries in mind is still rare. This might be because specific knowledge, e.g. an insightful understanding of users and their environments, the level of technology available, local materials and costs, is required (Bothwick, 2003). Recently, most medical design research projects have shifted their focuses to emotional aspects (Desmet & Dijkhuis, 2003; Design Council, 2005) and advanced technologies (Bringley, 2004; Skarlatos, 2005; Chirnside, 2006), the design and development of basic hospital equipment is therefore somewhat neglected. The closest case study, the general purpose hospital bedstead developed by the Royal College of Art (RCA), dates back to 1961.

RESEARCH METHODS

Design-led enquiry was considered suitable for this type of investigation, as *“design starts with the general and works towards the particular”* (Archer, 1991). Due to the fuzzy nature of the project, where the context of the subject area remained unclear and the research problem was underdeveloped, the Soft System Methodology: SSM (Checkland and Scholes, 1995) was employed as a means to plan the research (see figure 1). Moreover, the root definition was generated as a means to describe the research context and plan future actions (see figure 2).

The research structure was conceptually similar to the Delphi technique, which was created to obtain a consensus view on a given subject. Firstly, the preliminary research was carried out in order to develop a better understanding about the sector and explore the broad range of possibilities. Several qualitative research methods were used, e.g. observations, interviews, and questionnaires. The results were collected and analyzed in order to narrow down the strategic directions. Next, the second phase was formed based on the previous outcomes. The main objectives were clarifying all requirements, confirming knowledge gained from the preliminary stage, and obtaining more detailed information. In this stage, further qualitative research was conducted. The major research tools included observations, focus groups and interviews. Finally, the design strategies were specified. Some design solutions were offered and tested with users as a means to verify the strategic directions. Different tools were selected according to different targets and purposes. Observation and questionnaire were chosen due to subjects' limited time availability, while the interview and focus group were used as a means to gain in-depth information and build up relationships with practitioners, which could lead to increasing user involvement in the future. As research and development previously conducted by MTEC hardly involved users, these methods also provided a chance for team members from engineering backgrounds to develop new skills in user research. Since most research in this field emphasized the importance of user involvements or co-design (Foqué &

Lammineur, 1995; Chamberlain & Roddis, 2003; Schechterman, 2003; Gowans, *et al*, 2007), user-empathetic experiments suggested by other researchers (e.g. Torrens, 2000; Wilcox, 2005) were used throughout.

Compared with the general purpose hospital bedstead project, it can be seen that the focuses were significantly different. While the research conducted by the RCA team concentrated on rationalising design and developing rigorous specifications, design processes and evaluation methods (Cousins, 1965), this research aimed at capturing latent requirements and providing strategic directions for research institutes and the Thai industries. Consequently, the research question was relatively broader. Compared with the nation-wide survey, the research methods employed in this case were considered more conventional and the number of subjects was smaller. Nevertheless, an in-depth understanding of user needs was the major concern of both the hospital bed project and this project. Furthermore, both projects aimed to use design as a means to solve identified problems.

STAGE ONE: PRELIMINARY RESEARCH

The structure of the primary research was based on the model of research, strategy and idea-centred activities for NPD (Bruce & Cooper, 2000). However, in this case, requirements from all stakeholders replaced the activities (see figure 3). The list of four key stakeholders was based on the recommendations of the Department of Health & Design Council (2003). The details of the preliminary research are illustrated below:

1. **Healthcare Users:** The research team visited a number of public healthcare units, e.g. male general surgery ward, paediatric ward, and intensive care unit: ICU, in order to observe problems that healthcare practitioners currently face. All observations were documented in great detail, since photographing and video recording were not permitted due to ethical reasons. Many user-empathy experiments, e.g. role plays, were carried out during their visits in order to obtain first-hand experiences. The hospital visits were followed by the questionnaires conducted with healthcare practitioners at Thammasat University Hospital (see Appendix A). The main purpose was to discover user needs. Nurses and their assistants were chosen as the subjects, as they work closely with patients and operate many essential devices. Moreover, many subjects considered their tasks laborious, since one nurse is responsible for at least five patients. In addition, several tasks are performed manually, as most public hospitals cannot afford several devices for the employee's safety. Evidently, nurses and their assistants should be able to identify a device that holds greatest potential. The subjects were also chosen due to the proximity, since several responses needed clarification afterwards. The questionnaire was designed to maximise ease of response, and the number of questions was kept to a minimum.

2. **Purchaser:** An interview with the key decision maker, the Deputy Director of the Sirindhorn National Medical Rehabilitation Center (SNMRC), was carried out due to her strong influence over the purchasing process. Working at a managerial level, she was able to envision the products/services that did not exist, and provide valuable suggestions. In this case, the informal interview was conducted simultaneously with the site visit. Thus, the questions were relatively spontaneous and formed based on activities observed or ideas mentioned by the interviewee. The main purpose was to discover latent needs and problems of healthcare organizations in general.
3. **Designers/Developers:** The MDL team visited several research groups internally and externally, such as the Assistive Technology Center: ASTEC, the Healthy Ageing Research Program (HARP), Chulalongkorn University, and the Human Centered Design Laboratory, King Mongkut's University of Technology, in order to find out their research directions, and determine how to collaborate with them. A number of informal group interview/discussions were conducted during the site visits. These visits also contributed to the network developments. Furthermore, a self audit was carried out.
4. **Manufacturer:** A semi-structured interview was carried out with the owner of the SME medical product business. This interviewee was selected according to his significant experience in this area, as well as his knowledge about the public healthcare sector and medical device industry. Since most Thai businesses are SMEs, he is qualified to comment on the Thai industries. The main purpose was to develop a better understanding about local materials, technologies, and manufacturing processes; examine current capabilities of the SMEs in terms of product design and development, existing problems, constraints, limitations, and key challenges; and obtain his opinion regarding potential products. In addition, current manufacturing processes were observed.

THE PRELIMINARY RESULTS

1. **Healthcare user:** Based on the observations, the team agreed that a number of laborious and time-consuming tasks could be improved, e.g. changing bed linen. Furthermore, many of them involved safety risks for both practitioners and patients, e.g. lifting patients. However, the results from interviews and questionnaires did not concur with the observations. As most subjects operated these medical devices everyday, they were familiar with the procedures and could not identify any difficulties that might lead to a new improvement. The subjects could only suggest the devices that they were familiar with, e.g. infusion pumps. The devices that they liked and disliked were the same type.

The satisfaction and dissatisfaction were dependent on the reliability, ease of cleaning/maintenance, and durability. Besides, they were unable to prioritize the criteria for purchasing medical devices. Consequently, most factors are perceived to be equally important (see Appendix A). Nevertheless, reliability, patient safety and energy efficiency are overriding concerns. Based on several interviews, the subjects showed also concern about affordability. It must be stressed that affordability, in this case, means half the market value. They preferred many disposable items to be replaced with reusable ones, since most public hospitals cannot afford to discard these items. As most users have to maintain imported devices themselves, the ease of maintenance has become one of the most important criteria. Evidently, suggestions from healthcare users were very diverse. They often requested a product to perform a very specific task based on their daily activities, which were dependent on the units they work with – the following quote exemplifies the informal interview feedback:

Q: What are your current problems and how do you deal with them?

“...We do not have enough staff to keep an eye on disoriented patients 24/7. Thus, we have to tie and untie them every four hours to allow blood circulation. We need to secure their hands and feet. We also have to secure their chest. Otherwise, they will be able to lift their bodies up and use their mouth to untie their hands. Currently, we use fabrics from old patient clothes. Although they take time, they will not cause any injury. We tried Velcro before but the edges were too sharp...”

Nurses in the paediatric surgery wards proposed a similar device. Nonetheless, since their patients are generally physically smaller, the restraining tolerance could be lower. Clearly, their ideas need further development, as a restraining device is not the only solution for securing disoriented patients to their beds. Interviews with medical doctors resulted in similar outcomes, as each practitioner required a very specific device for specialized fields only, e.g. an orthopaedic practitioner required an operating table for orthopaedic surgery. Although this research yielded many niche products, most of them could be classified as basic devices intended to make routine jobs easier and less time-consuming. As a result, fundamental equipment which improve/simplify day-to-day tasks that can be applied to all units, e.g. a hoist, holds a strong potential. Moreover, the imported hoists are considered unaffordable to most users.

2. **Purchaser:** From the interview it was noted that currently the main purchasing criterion is affordability. This was due to the lack of the local benchmarks and standards to examine the other qualities.

Q: What products did you recently purchase and what were your purchasing criteria?

“...Every year we give away 5,000 standard wheelchairs to disabled people who cannot afford them. At present, we do not have our own testing procedure and there is no company offering this kind of test. Thus, we have to select the supplier that offers the lowest price. This means we have to buy from the biggest supplier every year, as they have strong bargaining power to keep the costs low. Like this, there is no real competition and only small improvements are made each year...”

The results of the interview with the producer also supported the finding that affordability is the principal purchasing criterion. Governmental standards would benefit the manufacturers, as they did not have to compete purely on price when bidding for orders from the public hospital. The interviewee suggested many potential products to replace the existing ones in order to improve affordability, durability and ease of use. The recommendations included electric wheelchairs, and basic rehabilitation equipment that benefit most patients (both with accident injuries or some disabilities), e.g. standers.

3. **Designers/Developers:** Self audit revealed that the MDL's strongest point is mechanical design; thus the research team decided to focus on the medical device in which mechanism was regarded as critical. Rehabilitation equipment drew a lot of attention from the team, as most of them require practical mechanical design and they were recommended by several research groups. Moreover, MTEC had developed many technologies in relation to rehabilitation and prosthesis, e.g. prosthetic legs and feet. Besides, the rehabilitation equipment could benefit the Thai society, since the majority of the disabled and patients in this field have a very limited income. One researcher strongly recommended a hoist – this device is available as standard hospital equipment in many developed countries, but rarely used by Thai healthcare practitioners. He expressed as follows his concern that physical therapists, nurses and caregivers risked injuring their backs by lifting patients without any support.

Q: According to your experience, which device will benefit the majority of users, and why?

“...I think a hoist is very essential. I was trained as a physical therapist so I know that it is very difficult to lift a patient without any help. Many bedridden patients and disabled persons are overweight due to a lack of exercise, while most carers, their mothers or female domestic workers, are quite small (~ 5 ft). In most cases, when they need to lift a patient from the bed, they have to position themselves on top on the patients and pull them up vertically. That is very dangerous...”

This device could be used to support patients with accident injuries or severe disabilities during their gait training - a rehabilitation programme aimed at assisting patients and the disabled to regain their mobility. In addition, it can be developed for the disabled/bedridden patients in the home environment.

4. **Manufacturers:** According to this research, even the biggest hospital equipment manufacturer in Thailand produces only non-surgical equipment and hospital furniture, e.g. hospital beds. This was possibly due to the lack of the standard parts. Since the main concern was keeping the price low, most producers avoided producing any devices that required expensive imported components. As a result, their products were restricted to the basic devices. Currently, materials used to manufacture medical equipment are limited to stainless steel or coated carbon steel according to their durability and chemical resistance. Most parts are manually formed using standard metal sheets or tubes, as the production volume is regarded as too small to bear the cost of mould fabricating. It was observed that existing processes were considered labour-intensive. It can be concluded that their strengths lie in the production of general devices that require manual assembling. Most manufacturers could not compete globally due to the lack of resources and ability to handle requirements of international agencies. The lack of local standards also affected the product categories. Most producers are confined to non-surgical devices, since they cannot bear the testing costs abroad. As the number of medical device producers is relatively low, the number of their component suppliers is even lower. Compared to the case study of a traditional British manufacturer (Barnes & Bruce, 2000), Thai producers were far behind in terms of applying a systematic approach in to the NPD process. At present, ideas were generated based purely on intuition rather than user research – as a leading Thai manufacturer reported:

Q: How do you get a new idea for your new product?

“... I like to try new technologies. I have my own factory so I can try anything I want. I have ordered a new 2-way controller from China. I am really excited about it although it does not work as well as I hope. I need to do a bit of modification – swap these switches around...”

The requirements collected from all stakeholders were relatively diverse. Several techniques, e.g. mind mapping, were employed to help the researchers visualize an overall picture and enable the team to convert scattered requirements into certain groups (see figure 4), which were then translated into the model (see figure 5). A rich picture was created in order to express the situation, as the research context became clearer (see figure 6). Both

rich picture and root definition were continuously compared with the real situation and updated based on new data gathered. In this way, the unclear research problems were clarified. Due to the preliminary research, the team managed to identify two devices that hold very high potential, a hoist and a standing frame, and satisfy most of the criteria. Firstly, they are standard devices, which can be used by many types of healthcare users and hospital wards. Secondly, there was no hoist or standing frame producer in Thailand. Hence, developing these products would not lead to any competition with the local industry. Moreover, they can be produced using existing manufacturing processes, local parts and available technologies. In addition, these devices leveraged the expertises and technologies developed by MTEC. Developing hoists and standing frames for local production was considered to have high potential for economical and social impacts on the public healthcare service in Thailand, since 53% of imported medical devices were general medical and diagnostic devices (U.S. Commercial Service 2007). Besides, these devices will become more affordable. Furthermore, they can be tailored to user requirements and constraints in Thailand.

STAGE TWO: USER RESEARCH

The second stage of the research was focused on the users and developers, as the team needed to confirm previous results, clarify user requirements in detail, and explore possibilities further. Subsequently, the team re-conducted the user research by visiting a number of rehabilitation units, e.g. Department of Physical Therapy, Faculties of Associated Medical Sciences, Chiangmai University, and Prostheses Foundation. During the visits, further observations, user empathetic experiments, focus groups (15 participants) and interviews with healthcare practitioners (10 participants) were carried out. Moreover, telephone interviews were conducted with several disabled persons (three participants) who owned similar devices. These interviews allowed the researchers to gain insightful information about the user experience and explore the potential for creating devices for the home environment. The team also visited Srisangwal School for the Disabled to investigate the potential of adapting both devices for school environments – a group interview was conducted with five participants. Visual presentation (see figure 7) of the results was also created together with the textual descriptions.

THE PRINCIPAL FINDINGS

Hoists are designed to assist caregivers in handling patients with locomotive difficulty, especially bedridden patients (Department of Labor and Industries, 1999). Nonetheless, only a small number of hoists are available to care givers in Thailand and most of them were not in use. In many cases, they were out of order due to

maintenance problems. According to the interviews and observations conducted in various places, manual patient handling is considered as a common practice, even though it has been regarded as a high-risk activity. The barriers to using hoists are varied. Firstly, the cost of imported hoists is still too high for most public hospitals. Secondly, overcrowded and space-limited public hospitals make hoists inconvenient to use – as identified from the results of the focus groups shown below. Although using hoists can lead to safer patient handling and reduce injuries related to patient handling, many healthcare practitioners would not consider using it unless the whole procedure takes less than five minutes. Since the speed of the machine is fixed, due to safety standards, the only way to save time is to simplify the operating process. In many cases, the decision not to use hoists is down to an improper attitude towards health and safety. The focus group revealed that this device is regarded very useful in rehabilitation units, e.g. bearing the patients' weight during their gait training.

Focus Group Topic: Please discuss your positive and negative experience of using a hoist.

"...We tried a hoist for a week and found out that it was not practical. This was mainly because of the slow speed. You need to attach many straps onto a patient. This could take up to 10- 15 minutes. Sometimes our patients arrive at the same time. When there are 20 people waiting in a queue, we cannot use the device.

Moreover, the harness is too big for Thai people. Thus, it does not hold the patients in a correct posture..."

Lesser problems occurred in the home environment. This might be because there was only one caregiver (usually one of their parents or a domestic worker) who was not trained as professional healthcare practitioners. According to the telephone interviews with several disabled persons, hoists were considered extremely useful – A paraplegic interviewee aged 50 commented:

"... I think a hoist is very necessary. Even though I have a sliding board, it is still difficult to move from my wheelchair to a bathing chair. I still need two people to lift me up. This device will be very useful for those whose beds cannot adjust to their height. It should be foldable in order to save storage space..."

Their requests were that it should be portable and assist the individual to get in/out of a car, especially a taxi. The process of obtaining this type of product is rather unusual. As most global companies do not want to deal with individual orders, many disabled search for assistive devices via the internet and have them made to order by local producers. This situation expresses a pressing need for hoists specially designed for home-use. The research results can be summarized into five key user requirements as follows:

1. Retail price should be targeted to be no more than half of the imported product price, which means ~15,000 baht (~£240) for a manual-operation device, since average monthly income per household is 17,787 baht (~£280) per month (National Statistical Office, 2006). According to interviews with the healthcare users, this price is considered affordable. Some interviewees suggested that this amount is considered reasonable for a charity to support. A higher price would make it difficult to target the charities, as more money spent on one device means that less people are supported.
2. The equipment can be operated by one person, preferably with minimal training (such as parents)
3. This device must be foldable in order to reduce the cost of distribution and storage space. It would be more desirable if it can assist the user to get in/out of a car and be stored in the car boot.
4. The product must be produced using local materials, standard parts and existing processes in order to minimize manufacturing costs, and to ensure that the product will benefit the Thai medical device industry. Consequently, the ease of maintenance can be increased. The special characteristics, e.g. flexible production line, should be promoted as a means to achieve personalised products. For example, the harness can be tailored to match the user's body shape in order to overcome identified problems.
5. Due to the time pressure at the public hospital, it was requested that time used to operate this machine must be less than six minutes (manual handling standard time is three minutes).

Standing frames are assistive technologies employed by patients with mild to severe disabilities such as spinal cord injury and brain trauma. According to the interviews, standing frames are used at the beginning of most standing or walking programmes in rehabilitation. In this case, sit-to-stand standers are selected, as many physical therapists suggested that it outperforms other standers in many areas. By aiding a natural symmetrical standing posture, it can improve patient's self-esteem and social development, especially for children. The focus group agree that being in the upright standing position also allows other rehabilitative programs and social activities to be performed:

Focus Group Topic: Please discuss your positive and negative experience of using a standing frame.

"...It is really useful. By bearing the patient's weight, it frees up our hands. Like this, we can ensure that the patient stands in the "Neutral Posture", because if he starts off wrongly, he will stay that way. However, it does not provide any support on the side. Thus, he may lean towards the side where the foot is stronger."

The focus group results and experience obtained from using the imported sit-to-stand stander revealed that existing machines do not match the size of Thai people. Since the device does not fit properly, it cannot provide many of its intended benefits. It was reported that, at SNMRC, a sit-to-stand stander serves approximately two patients per hour. Despite its intensive use, there is no commercial production of sit-to-stand standers in Thailand. Moreover, the high cost of imported standers makes them unaffordable for both public hospitals and disabled people. Subsequently, most patients cannot continue a standing program at home. Several physical therapists stressed that regular training is crucial for children, as their chances of regaining their abilities are relatively higher than adults. (Based on the interviews, most adult patients have stopped their rehabilitative programs since they left hospital, as they lose their motivation.) As a result, most parents are willing to invest in assistive devices: a wheelchair and a tilt table. In spite of the limited benefits of these devices for physical rehabilitations, a tilt table is more affordable and available for users, as it can be manufactured locally. In this case, sit-to-stand stander for children (6 – 11 years old) is chosen, because these targets hold a strong potential to regain their physical capabilities. Furthermore, there are several substitute products for smaller children.

The school visit confirmed the strong potential of the targets. Nevertheless, the physical therapists at school pointed out that teenagers (12 – 15 years old) could benefit from similar devices. Firstly, these students do not receive regular training (due to their weight/size and a lack of suitable equipment). Compared with other types of stander, a sit-to-stand stander is much easier to use. Thus, if the device is designed to be operated by the disabled, it will encourage them to exercise regularly. Standing for 10 minutes every hour was strongly recommended by physical therapists. The interviewees proposed a combination of a sit-to-stand stander and a desk. In this way, the students can get frequent exercise. Nevertheless, the main challenge is transferring the user from wheelchair to the standing frame. It was noted that increasing mobility by adding wheels could encourage the users to use this device. In this case, the operating time was not as crucial. Generally, the main adjustments, e.g. foot rests, are pre-set. Therefore, the physical therapists only have to fine-tune the setting. Many requests were based on existing product evaluation, e.g. all adjustment levers should be replaced with knobs. The principal findings can be summarized into five key user requirements as follows:

1. The device can be operated by one person, preferably with minimal professional training. It would be more desirable if the device can be operated by the disabled and encourage self-propelling.
2. The product can be produced using local materials, standard parts and existing processes. It would be preferable if all functions are mechanical and imported materials/parts are not required. In this way, the

ease of maintenance and modifiability can be improved. The special characteristics, e.g. manual assembling, should be promoted as means to achieve personalised products. For example, the supports on both sides can be provided as an add-on feature in order to overcome identified problems.

3. All adjustments must be easy to make, and time used to fine-tune should be kept to a minimum.
4. Since a local prone stander costs ~25,000 baht (~£400), this device should not cost more than 50,000 baht (~£800). Moreover, this product has the maximum lifespan of six years.
5. The main challenges are transferring users between wheelchairs and standers, and making the whole process as user friendly as possible.

STAGE THREE: STRATEGY VALIDATION

The methodology employed to find out strategic design directions was considered successful, as the opportunities identified drew much interest from other research groups. Moreover, the hoist is chosen as a pilot project for a consortium, which comprises of the MDL team, the Department of Physical Therapy, Faculties of Associated Medical Sciences, Chiangmai University, and the Department of Biomedical Instrumentation, Faculty of Science, Rangsit University. At present, the insightful information obtained from the design-led enquiry has been analysed and concepts have been developed (see figure 8 – 9). Several virtual analyses, e.g. Finite Element Analysis, have been performed. Although the detailed design is underway, certain parts are considered patentable – one design patent application is in progress. In addition, the user tests are scheduled to carry out at SNMRC and the Department of Physical Therapy, Chiangmai University.

CONCLUSION

The research results demonstrated that the design-led enquiry and SSM approach employed to investigate the public healthcare sector and medical device industry was considered successful, as it managed to develop a better understanding about the sector from all points of view, identify potential products and provide a strategic direction for the research team to go forward. Moreover, it stimulated interest in medical device design and development, brought in new partners and established the research network with the industries. In addition, the design approach, which includes observations and user empathetic experiments, helped break through the barriers associated with current practice. Constructive questioning alone would not lead to new ideas for improvement, as the subjects could comment and make suggestions about existing products only. Most detailed

requirements were obtained through informal discussions about possible design solutions. During this project, the MDL team also discovered many barriers preventing development in this area:

1. **Improper attitude:** Many healthcare practitioners do not pay enough attention to making their procedures safer. They may not accept a new practice unless it is easier and more convenient to execute.
2. **Lack of standard parts:** Being unable to obtain standard parts in Thailand delays the progress in product developments in this field, as well as increasing the production cost. Thus, it is important to invest in the infrastructure otherwise the medical device development in Thailand cannot be improved.
3. **Limited materials and manufacturing processes:** Targeting the domestic market only results in limited production volume. This prevents a number of materials, techniques and manufacturing processes to be developed, as it is more difficult for the industry to reach a point of breaking-even.
4. **No national strategy:** Although the government realizes that the research and developments in medical devices are essential, there is no concrete strategy for research institutes. Without the national strategy, research and developments are diverse and not likely to reflect the needs of the whole nation.
5. **Lack of Quality Measurement:** Without local standards and publicly published testing methods from the TFDA and Thai Industrial Standard Institute (TISI), it is difficult to encourage producers to explore new product opportunities. Moreover, the institute could provide the purchasers with systematic criteria.
6. **Lack of good examples:** Publications/exhibitions in this area are insufficient, especially those designed for developing countries, as there are only a few showcases published or presented annually. Hence, it is difficult to obtain knowledge regarding medical device design development.

To overcome the identified problems, the strategic directions for the MDL in the next few years are identified as:

1. **Product Opportunities:** Essential non-surgical equipment which can be used by many healthcare users (in hospital, home or school environments) can be developed. In this way, the capabilities in terms of design and manufacturing can be developed based on existing knowledge and expertise. Moreover, demands for local products, and supplies from related industries could be increased. This situation could lead to further developments in other product categories. Although design simplicity is the key to maintaining affordability, emotional aspects should be addressed in the future, which can help expansion beyond domestic markets.
2. **Design Strategy:** Currently, labour-intensive production is employed as this is the pervasive industrial condition. However, these flexible processes can be promoted as competitive advantages, as they support

the emerging mass-customisation trend. Besides, Thai products cannot compete in terms of technology. By involving users in the personalisation processes, emotional aspects can be explored and addressed.

3. **Capability Development:** Currently, design professionals in the area of design strategy and development are still scarce. This situation can be improved through collaborations of the MDL team, the users, the industries and local universities. By involving design students in the projects, they can gain new knowledge and familiarise themselves with this area. In addition, user involvement will ensure practicality and may change some conservative current attitudes. Furthermore, by working closely with users and producers, more progressive practices, such as action research and co-design, could be employed.

This research also uncovered several issues that global companies should take into consideration:

1. **Necessity comes first:** The public healthcare sector in Thailand is not as advanced as those in the developed countries. Thus, most users require standard devices that are more affordable and durable. Nevertheless, aesthetic and emotional aspects should also be taken into consideration, as they have a psychological impact on users and can help open up a new market, e.g. medical devices for home use.
2. **Holistic approach:** Every aspect should be planned from cradle to grave. For example, affordability is applied to the total cost including cost of purchasing, maintenance, energy consumption, etc.
3. **Unexplored opportunities:** There are many market opportunities that remain unexplored, e.g. clinics for the elderly. Despite their limited budgets, these organizations have access to external funding.
4. **User involvement:** Emotional aspects/user experiences are not emphasized as much as when developing medical devices for developing countries. Nevertheless, this research confirms that the design and development of standard equipment does require user involvement as much as other products. Moreover, this design-led methodology is appropriate for capturing user latent requirements.
5. **Service Design:** Design can be used to increase the quality of service and improve safety issues as well. For example, equipment training and service schemes can be transformed into continual learning processes. In this way, both producers and users can develop a better understanding of each other.

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BIOGRAPHY

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APPENDIX A: QUESTIONNAIRE & FINDINGS

The questionnaires were conducted with 30 nurses and assistants as part of the preliminary research. In this case, the questions and answers were presented together – answers are shown in italics. The numbers given at the end of each choice, and those shown in the tables are the percentage of the samples choosing the particular answers.

Section 1: Personal Information

1. Gender: Female (87%) Male (13%)
2. Age: Under 26 (13%) 26-30 (67%) 31-35 (7%) 36-40 (0%)
 41-45 (0%) 46-50 (7%) 50-55 (0%) 56 and above (0%)
 Not stated (6%)
3. Experience: Under 1 year (6%) 1-5 years (47%) 6-10 years (27%) more than 10 years (20%)
4. Department: *General Surgery Ward (40%) And Paediatric Ward (60%)*

Section 2: Personal Opinion Regarding Existing Medical Devices

5. Please select the types of medical equipment that you have to prepare, use and/or maintain regularly

(You may select more than one answer.)

- Diagnostic equipment (67%) Therapeutic equipment (27%) Life supporting equipment (40%)
- Medical monitors (60%) General hospital equipment (87%) Clinical cleaning devices (67%)
- Anesthetic equipment (0%) Medical Laboratory equipment (20%) Other, please specify: _____ (0%)

6. Please specify the equipment that you satisfy the most: *Infusion Pump, Blood Pressure Monitor, Syringe Pump, Defibrillator, Oxygen Saturation Monitor, Electrocardiogram (EEG or EKG), Thoracic Suction, etc*

Reasons: *Ease of use, Convenience, Safety, Reliability, Accuracy, Time & Workload Reduction, etc*

7. Please specify the equipment that you satisfy the least: *Infusion Pump, Blood Pressure Monitor, Defibrillator, Oxygen Saturation Monitor, Electrocardiogram (EEG or EKG), Restraining Device, etc*

Reasons: *Inaccuracy, High Maintenance, Frequent Malfunction, Short Lifespan, Difficulty of Cleaning, Causing Injury (often due to unmatched size), Large Size & Bulky Shape, Heavy Weight, etc*

8. Please give your personal opinion on the following statements: (5 = totally agree; 4 = agree; 3 = neither agree nor disagree; 2 = disagree; 1= totally disagree)

Statements	5	4	3	2	1
1. Equipment I regularly use is easy to operate	14%	73%		13%	
2. There is sufficient amount of equipment	14%	14%	29%	29%	14%
3. Existing equipment is efficient and reduces time and workload	29%	37%	20%	14%	
4. Equipment made in Thailand is as good as imported ones	13%	29%	44%	14%	

9. Please rank the following criteria according to the importance (5 = the most important; 4 = important; 3 = neither important nor not important; 2 = not important; 1= not important at all)

Criteria	5	4	3	2	1
5. Safety	92%	8%			
6. Accuracy & Reliability	92%	8%			
7. Ease of Use	62%	38%			
8. Preventing & Minimising Human Error	77%	23%			
9. Workload Reduction	54%	38%	8%		
10. Time Saving	70%	30%			
11. Energy Saving	85%	15%			
12. Painlessness	92%	8%			
13. Made in Thailand	62%	24%	14%		
14. Reasonable Price	62%	30%	8%		
15. Durability and Ease of Maintenance	76%	24%			
16. Attractiveness	30%	15%	40%	15%	
17. Other, please specify_____	15%				

10. Please rank the following tasks according to the degree of improvement required (5 = the most critical; 4 = critical; 3 = neither critical nor not critical; 2 = not critical; 1= not critical at all)

Tasks	5	4	3	2	1
1. Preparing equipment, e.g. sterilising devices	15%	47%	38%		
2. Monitoring/Measuring, e.g. blood pressure		24%	38%	30%	8%
3. Collecting samples, e.g. taking blood samples	14%	24%	38%	24%	
4. Curing/Nursing, e.g. giving medicines		30%	30%	40%	
5. Taking care of patients, e.g. changing clothes	8%	8%	46%	30%	8%
6. Assisting medical doctors		8%	46%	38%	8%
7. Giving anesthesia	8%		46%	38%	8%
8. Operating equipment	24%	38%	15%	15%	8%
9. Cleaning & maintaining equipment	15%	24%	46%	15%	
10. Other, please specify_____					