Chapter 11

Implementing a Design Methodology: Concept for a Head Positioning Device for Hospital Beds

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Introduction

This chapter reports on the learning experience in a six-week Medical Device Design course in the Division of Biomedical Engineering at the University of Cape Town (UCT). The six participants were academics from the University of Lagos and the University of Ibadan in Nigeria, comprising five engineers (civil, mechanical, industrial and systems engineering) and a radiologist. The course facilitators consisted of two junior and one senior faculty members from UCT. The design process was guided by that of Zenios et al. (2015).

The general steps followed in the design process are needs finding and needs screening, concept generation, concept selection, and prototyping. This chapter describes the convergence towards initially two and then one concept which met a medical need, was technically feasible within the available time, and had a reasonable likelihood of commercial viability. A head positioning device for hospital beds was selected as the focus of the course

Needs finding

"How do you identify an important unmet medical need where there is good clinical, scientific, and market knowledge to suggest that a solution to the need will be feasible and will have a reasonable likelihood of commercial viability?" (Zenios et al., 2015)

The participants had an interest in identifying needs that were relevant for Nigeria. Table 1 gives some general facts about this country and its health system.

DOI: http://dx.doi.org/10.15641/0-7992-2544-0
https://openbooks.uct.ac.za/bmeafrica

Table 1. General facts about Nigeria	
Classification	• Lower-middle-income country
Administrative Structure	• 36 federal states • 774 Local government areas • One federal capital (Abuja)
Population & GDP	• 186 million people and gross GDP of 405.1 billion USD. (World Bank, 2016)
Health facilities	• Over 34,000 health facilities
Ownership of health facilities	• 23,028 (67%) government owned, 11,395 (33%) private (Makinde et al., 2014)
Distribution of health facilities	• 30,345 (88%) primary • 3,993 (11.6%) secondary • 85 (0.25%) tertiary (Makinde et al., 2014)

Inventory of skills

Not only the interests, but also the available skills, of the participants were assessed with a view to ensuring that the course project would be matched to the capabilities of the team. In the first session, the course instructors helped the team through the process of formulating a personal inventory – skillsets that each one brings to the table. This helped everyone become familiar with available skillsets and experience.

Observation and problem identification

The team visited a tertiary health facility in Cape Town - Groote Schuur Hospital - to interact with clinicians, caregivers and patients on order to establish what the users needed. One insight gained from a nurse was the occupational hazard associated with the set-up of manually operated hospital beds. She always had body pain after work whenever she had to set up the beds because over time, the beds had become stiff and required considerable effort to adjust to required settings.

Needs statements

Back in the classroom, the team had to learn how to translate a problem into a clinical needs statement that is accurate, broad in scope and not tied to specific solutions. This was initially difficult for engineers whose minds have been wired to think of solutions to problems. The team however learned to identify the user's needs and not a specific solution. Some similarities

were observed between the medical needs in South-Africa and that of Nigeria that helped in developing broad needs statements as shown in Table 2.

Needs screening

"After the winnowing of many needs, a rigorous follow-on process of screening and specification is required before you begin inventing" (Zenios et al., 2015)

Disease state fundamentals

Disease research was done for the scope of patients covered by the needs statements to provide a foundation for understanding the underlying disease state. Such research insight helps in the appraisal of available treatment options, market size and type, as well as the key stakeholders. It helps in clearly defining the clinical, technical, and commercial feasibility of the project. Information was obtained from medical textbooks, peer-reviewed articles on clinical presentation and clinical outcomes, and economic data relating to the relevant health conditions. The radiographer "breathe assist" lights and the head positioning device did not require research in disease fundamentals as their use would be generic and not particular to any kind of disease. These needs were prioritised.

Table 2. Needs statements

	Project title	Needs statement
1	Development of battery-powered infant operating table	Surgical team needs a way to maintain an optimal operating room temperature that is comfortable for the team and prevents infant hypothermia in areas without reliable power supply.
2	Development of enteral feeding device	Nurses and caregivers need an easier, affordable and more efficient way to feed patients with eating difficulties because hospital wards are short-staffed.
3	Development of real-time blood pressure monitoring device	Health professionals (and individuals) need a way to measure blood pressure accurately and reliably because of the morbidity and mortality rates associated with high blood pressure.
4	Development of radiographer "breathe assist" device	Radiographers need a way to fix the patient in the standard radiographic position and reduce breathing artifacts during X-ray examination for good quality images at first exposure, reducing unnecessary repeat scans and errors in reporting.
5	Development of head positioning device	Hospitals need a way to position patients in a required posture on standard (non-adjustable) beds because of a shortage of inclinable (adjustable) beds.
6	Development of a bubble continuous positive airway pressure device	Health Professionals need a way to help patients with respiratory distress syndrome to overcome breathing difficulties with a view to reducing morbidity and mortality because existing technologies are expensive and inefficient.

Stakeholder analysis

A careful identification of stakeholders is an important step in the biodesign process. Stakeholders affect the innovation directly or indirectly. They can determine to what extent the solution to an identified need is implemented or even accepted.

In trying to identify the stakeholders, the group first had to determine who is the "user". In some instances, this wasn't very obvious. For example, it initially appeared patients were the users of the head positioning device. However, after a more careful deliberation, it was concluded that the actual users were the nurses and caregivers. These caregivers could decide to use the device to manage patients or reject it.

Another lesson learned about stakeholder analysis is the importance of ensuring that no stakeholder is left out. Since their decisions, actions or inactions will affect the success of the product, failure may result if critical stakeholders are omitted. But then how do we define the key stakeholders? The concepts of Business to Business (B2B) and Business to Customer (B2C) sales models assisted in the identification of the stakeholders. In the B2B model, products or services are sold to other businesses. In B2C on the other hand, products are sold directly to consumers. For the head positioning device and the radiographer "breathe assist" device, the main stakeholders identified are shown in Table 3.

Table 3. Stakeholders for two projects that were prioritised

	Need	Stakeholders
1	Radiographer breathe assist device	• Hospitals • Radio-diagnostic centres • Radiographers • Radiologists • Patients • Equipment manufacturers • Medical insurance companies • Health Professional bodies • Regulatory authority • Policymakers
2	Head positioning device	• Hospitals • Government • Nurses • Caregivers • Patients • Patients' relatives • Medical insurance companies

Market analysis

In order to design an innovative product, market analysis at the initial stage of biodesign innovation is very important. Market analysis is a holistic assessment of market size, market dynamics and competition for a new product. The population of people (patients) and the number of hospitals, health workers, manufacturers, private organizations and government agencies that would use the product provided a basis for estimates. The national health budgets (for previous years and the current year, and future estimates), government policies and procurement processes in the health sector, and import and export statistics from national chambers of commerce, were used to determine the market dynamics for the product. To assess the market competition, the pros and cons of the existing solutions in the context of affordability, technology, ease of use, maintenance, durability and stakeholder requirements, were reviewed.

Some of the key findings for the head positioning device were that the ratio of hospital beds to the population size is inadequate in Nigeria, despite recent growth (US. Commercial Service, 2016), and that existing solutions are pricey, not portable, or have a fixed angle. For the radiographer "breathe assist" device, no suitable solution was available, despite the large number of routine and diagnostic chest X-ray examinations taking place in Nigeria annually.

Needs filtering

Filtering needs poses a challenge especially when multiple needs criteria appear equally important. A consensus scoring process was used to determine the most important need components. While needs filtering was somewhat subjective, it allowed for consensus critique of the different ideas. The needs filtering stage helped the team outline the criteria that any design solution should satisfy for that need. This information was then used as the starting point for the generation of preliminary solution concepts. The head positioning device was selected as the focus of a conceptual design. Table 4 shows the application of needs filtering for the head positioning device.

Table 4. Needs filtering template for head positioning device

	Head Positioning Device						
	Weighting (1-3)						
	Market size	Patient impact	Provider Impact	Design Feasibility	Effect on patient's condition		
	1	2	3	2	3		
Need	Rating (Score1= low to 5=high)					Total score	Rank
Affordability	2	3	5	4	1	34	6
Durability	3	4	5	2	4	42	2
Sterilization	4	5	5	1	4	43	1
Maintenance	1	1	4	3	3	30	8
Portability	5	2	5	3	1	33	7
Ease of use	4	3	4	2	3	35	5
Ergonomics	3	4	4	2	4	39	3
Adjustability	3	4	5	3	2	38	4
Non-dependence on electricity	3	2	2	3	1	22	10
Low requirement for technical expertise	2	3	4	3	1	29	9

Head positioning device

Hospital beds can be equipped with devices that allow a range of postures for patients. The WHO (2000) defines a hospital bed as one that is regularly maintained for the accommodation and full-time care of a succession of inpatients and is situated in wards or a part of the hospital where continuous medical care for inpatients is provided. The number of hospital beds determines the capacity for health care delivery to inpatients in hospitals (Pantzartzis, Edum-Fotwe & Price, 2017).

Standard hospital beds cannot be adjusted for angular positioning of the body. Manual hospital beds are adjustable and use a hand crank mechanism for Fowler's angulation, i.e. when the head of the bed is elevated (Fowler, 1900). Semi-electric hospital beds make use of both an electric motor and manual control to give angle adjustment, to the head and foot sections, and the height of the bed respectively. Fully electric hospital beds feature electric motor controls that raise the head, foot and height of the bed frame with a push of a button (Green, 2002; McKee & WHO, 2004; Catalano & Coolidge, 2006).

Three patients have been estimated to die daily in Nigeria due to a shortage of hospital beds (Akuki, 2017). The majority of hospital beds in Nigeria are basic non-adjustable beds. Lagos University Teaching Hospital has 761 beds with only five ICU beds while University College Ibadan has 850 beds with 12 adjustable beds (Shobowale et al., 2015; Somotun et al., 2017). The "no bed space syndrome" in the emergency section of Nigerian hospitals can be attributed not only to insufficient infrastructure, but also to the limited number of adjustable beds for patients who must be managed in specific positions. Poor national health budget, added to the high cost of adjustable medical beds, as well as space limitations, make acquisition of adjustable beds difficult in a low-resource economy. It therefore appears reasonable to develop ways by which non-adjustable medical beds in the hospitals can function like adjustable medical beds.

The design goal was a mechanically operated medical device that would be portable, adjustable and affordable, and could be mounted on a standard hospital bed to give angulation to body posture. It would be manually operated for use in rural areas and where there is unstable power supply. This would enable healthcare providers to manage critically ill patients who have respiratory challenges or need to be positioned at different angles during the course of treatment for other reasons. The device would be safe, easy to operate and portable.

Concept generation and selection

Concept generation was meant to produce design ideas; it begins with ideation and brainstorming. It is interesting to reflect on how difficult it was to defer judgment and critical thoughts until later. Ideas were quickly shot down based on "how good" or "not good" they were. Sometimes discussions wandered off in different directions, but they eventually came back on course. This affected the productivity and flow of the discussions. But as soon as team members began leveraging each other's ideas to make new suggestions, the ideation process began to take shape. Team members had to learn to listen more than talk during this process.

The concepts were scored and ranked based on the design requirements of the device, to inform the final component of the biodesign process before prototyping, namely concept selection.

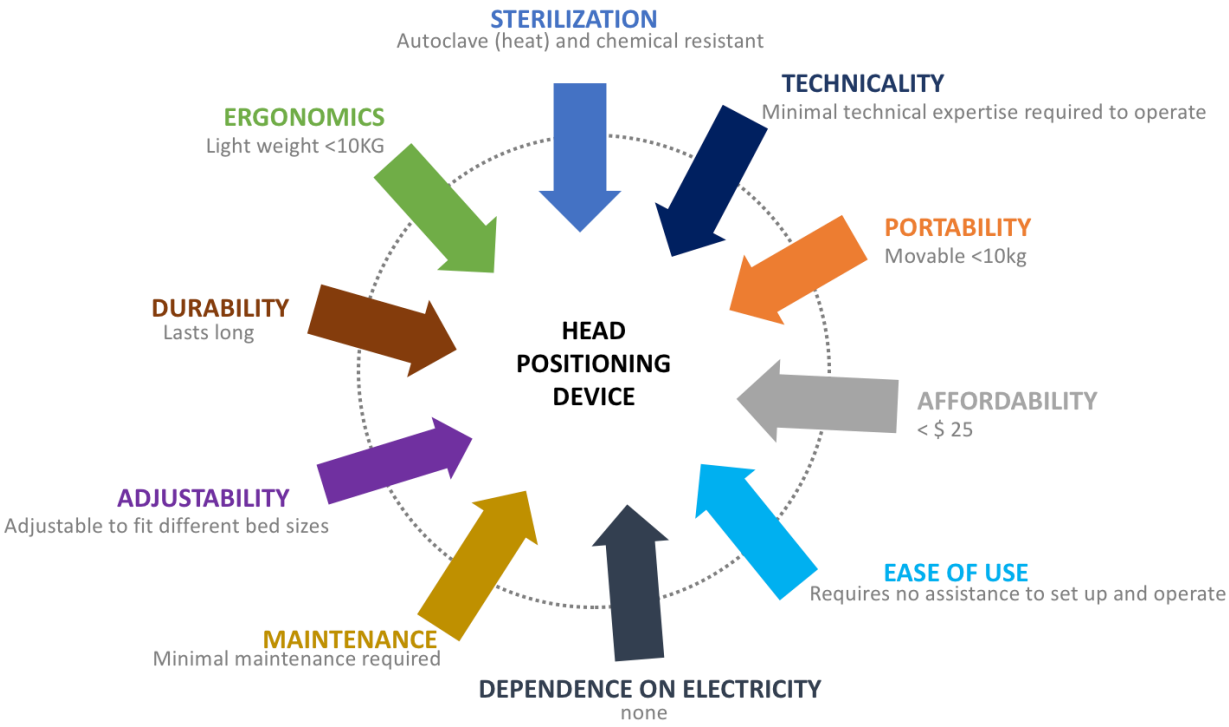

Figure 1: Needs specification for the head positioning device.

During the ideation process, different designs of the head positioning device were considered. Different crank-shaft, lever and screw mechanisms with rotary, oscillating, linear and reciprocating components were considered. The designs were manual, semi-automated or fully automated. Material types considered included steel, aluminium, plastic, wood, alloys, and composite.

Each design idea was carefully assessed based on the outcome of the needs screening and filtering. The design concept that was selected, most satisfied the design specifications.

Other requirements

Additional information was sought related to reimbursement, regulatory requirements, and business models in the Nigerian market space.

Reimbursement

Some leading questions the team tried to answer were:

- Will the existing health care payment infrastructure in Nigeria be able to accommodate a solution to the need for a head positioning device for use on basic hospital beds if such a solution becomes available?

- Who pays (or reimburses) for this device? Will the target market segment be large enough to make the production of this device financially viable?

To answer these questions, further research was done about the healthcare payment infrastructure in Nigeria. The key findings were:

- Over 90% of Nigerian people still pay for health care out-of-pocket (Adewole et al., 2015) and the National Health Insurance Scheme (NHIS) serves less than 10% of the population (Adewole & Osungbade, 2016).
- There is a shortage of hospital beds in Nigeria (US. Commercial Service, 2016).
- Normal hospital beds cost $100 – $150 while adjustable hospital beds cost $250 – $300.
- No existing portable device is available for adjusting the patient's head on regular hospital beds.

Given the statistics, a compelling value proposition exists for hospital management and clinicians to adopt the proposed device. This head positioning device would serve the purpose of making regular beds useable as inclinable hospital beds for managing patients in various Fowler positions. A compact, portable, strong, lightweight and ergonomic design would make it easy for caregivers to set up and stack away when not in use. Components that are both heat and chemical resistant would make the device easy to clean and to maintain high clinical hygiene standards. The device should be affordable for primary, secondary or tertiary hospitals in a low-income economy.

Regulatory

Obtaining regulatory authorization is the first major hurdle that manufacturers of medical devices must overcome to be successful at the commercialisation stage of products (Theisz, 2015). In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) has guidelines for registration of medical devices. The guideline stipulates that "…no medical device shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of ACT CAP F33 (LFN) 2004 (formerly decree 19 of 1993) and the accompanying Guidelines" (NAFDAC, 2018). In this research, it was found that products with US Food & Drug Administration (FDA) approval or CE marking will be approved by regulators if the stipulated guidelines are followed.

The closest device approved by the US FDA is a manually adjustable hospital bed. According to the FDA, it is "a device intended for medical purposes that consists of a bed with a manual mechanism operated by an attendant to adjust the height and surface contour of the bed. The device includes movable and latchable side rails." (US. FDA, 2017). Both the FDA and CE classification classifies this device as Class I as shown in the side-by-side comparison of Table 5.

Table 5. Manual adjustable hospital bed – FDA and CE classifications (US.FDA, 2017)		
	FDA	**CE**
Common name	Manual adjustable hospital bed	Manual adjustable hospital bed
Product type:	Medical device	Medical device
Classification panel	General hospital	-
Device class	Class I	Class I
	Reason(s) Minimal potential harm to patients -typically, simple in design -adequate experience where predicate device exists	*Reason(s)* Relatively low-risk devices that do not enter the human body
	Class I sub classification (a) Exempt device	*Class I sub classification* (a) general low-risk device
	Requirements for exempt device Exempted from premarket clearance. Clinical trials not required. Proof of safety and/or efficacy not required. Must meet the following "general controls": • Establishment registration with FDA. • Medical device listing. • General FDA labeling requirements. • Compliance with quality system regulation	*Requirements for general low-risk device* Certification by the manufacturer. Does not require notified body certification.
Regulatory branch	General hospital devices branch	Not applicable Certification by the manufacturer
Regulation number	21 CFR 880.5120 (US.FDA, 2017)	-
Class number		
Submission type	510(k) exempts	Certification by the manufacturer
Physician review panel	Division of Anesthesiology, General Hospital, Infection Control and Dental Devices, Office of Device Evaluation (ODE), Center for Devices, Health (CDRH) of the FDA	-
Product code:	FNJ	N/A

Business model

A business model is a systematic approach that illustrates how a product will generate revenue and deliver value to customers. It provides a clear view of the revenues, costs, profits, financing, intended customer base and the business enterprise delivering the value (Teece, 2010; Zenios et al., 2015). There are nine common types of medical technology business models in the medical device industry, namely: disposable, reusable, capital equipment, service, fee-per-use, over the counter, prescription, and physician-sell. The head positioning device falls into the reusable category. The product is intended to have repetitive use before wearing out, a moderate life-span and low cost. Table 6 is a business model canvas that summarizes the building blocks such as customers, route to market, value proposition and finance.

Table 6. Business model canvas for head positioning device

<table>
<tr><th>Key partners</th><th>Key activities</th><th>Value proposition</th><th>Customer relationships</th><th colspan="2">Customer segments</th></tr>
<tr><td rowspan="3">Ministry of Health. Hospital management. Healthcare professionals. Medical device outlets and stores. Hospital bed manufacturers. Distributors. Advertising agencies. Marketing services.</td><td>Production
Maintenance
Servicing</td><td rowspan="3">Conversion of plain hospital bed into inclinable hospital bed. Portability. Convenience/Usability. Ease of maintenance and sterilization. Cost reduction. Reduction in occupational hazard. Reliability and risk reduction. No need for electricity.</td><td>After sales service. Training on the use and maintenance of the product.</td><td colspan="2" rowspan="3">Government hospitals. Private hospitals. Health clinics.
Variations: Business-to-Business, Business-to-Government.

Decision-Makers: buyers</td></tr>
<tr><td>Key Resources</td><td>Channel Stores

Phone / mail/ website
Retailers
Distributors</td></tr>
<tr><td>Patents
Brand
Production facilities</td></tr>
<tr><td>Cost structure</td><td>Production
Distribution
Marketing
Branding</td><td>Maintenance
Variable costs</td><td>Revenue Streams</td><td>Asset sales</td><td>Maintenance Fee</td></tr>
</table>

Conclusions

The chapter has described the design methodology followed in a medical device design course, with the concept for a head positioning device as an illustrative example. Further work would require the design of the device and selection of suitable materials, prototyping, and testing in a laboratory and a clinical setting.

Prospects for the head positioning device

The head positioning device would be new to the market. It was conceived as a solution to the acute shortage of medical beds suitable for managing patients who require angular positioning during treatment or recovery. The most common regular hospital beds are flat and patients are often managed at angular positions using pillows; this leads to patient discomfort and physical strain on caregivers. Medical beds that are semi- or fully automated are available to adjust patient positions; however, in low-resource economies, they are considered pricey and, in most cases, have to be imported. Thus, the proposed portable device can be used to enhance regular hospital beds for use in managing patients who require specified angular positions.

Insights on team design

Team members learned the importance of managing communication and interpersonal dynamics in the team effort. In a shared leadership setting where members have divergent opinions on how things should be done, it becomes critical for both the mentors and team members to be able to carefully navigate potential conflict areas. Openness to constructive criticism and the contributions of others makes it easy for better ideas to emerge from team brainstorming and interaction.

Acknowledgments

Research reported in this publication was supported by the Fogarty International Center of the National Institutes of Health under award number D43TW009374. The design team wishes to express profound appreciation to the Principal Investigator and Co-Investigators of this grant.

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