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USING QFD AS A METHOD TO DEVELOP FUNCTIONAL MEDICAL PRODUCTS FOR CHILDREN WITH CANCER

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ABSTRACT

Quality Function Deployment (QFD) is a recognised method of translating customer needs into appropriate technical requirements to inform ergonomic design development. This paper details how QFD has been used to develop a tactile advanced product for a medical application. The project has undertaken innovative experimental and industrial research which has led to the design of a child-focused “Wiggle Bag” which will be used to safely harness and reduce infection at the site of a venous catheter placed in the chest wall of long-term child cancer sufferers. Children with cancer regularly have long term central venous catheters inserted through their upper chest wall to deliver medication. They can result in medical issues, particularly infections or accidental removal, but also discomfort for the children, particularly when sleeping. The research uses an inductive approach, triangulating various research strategies including questionnaires, focus groups and interviews from parents, carers and medical personnel. QFD was used to bring together the key findings from the primary data analysis to establish design criteria and inform the product development. The outcome of the research was a functional product ergonomically designed for maximum comfort and safety, with the added unique selling point of having antibacterial properties.

Keywords: medical products, functional textiles, cancer, textiles, QFD

INTRODUCTION

The project uses quality function deployment (QFD) to undertake innovative experimental and industrial research contributing to the design of a child focused “Wiggle Bag”, which will be used to safely harness and reduce infection at the site of a catheter tail in the chest of long-term child cancer sufferers. The papers details the development of a QFD to aid the product development process by synthesising data collected from a variety of sources and enabling the interdisciplinary team to agree a set of technical requirements. Thus, balancing academic enquiry with practical application.

BACKGROUND

Cancer in childhood is rare; however, through exceptional clinical and scientific research, treatment is successful for most children (Cancer Research UK, 2016). Treatment usually involves the use of intensive chemotherapy at some stage which can only be administered intravenously through central venous catheters (lines) placed through the neck or under the collar bone into the major veins adjacent to the heart (Macmillan, 2016). There are not many sites available to place these catheters and considerable skill is required to insert them, including the need for tunnelling under the skin and sophisticated catheters, with several external openings, or incorporating a subcutaneous “cuff” which helps to keep the catheter in place (the most commonly used is the “Hickman line”). As they may be needed for prolonged periods of time their care is paramount, mainly to avoid infection which usually requires their removal and replacement. Use of the lines requires a very strict guideline involving non-touch technique; when undertaken rigorously the risk of infection is minimised (Department of Health, 2016). Another complication, which is more likely in children than adults, is the risk of displacement or accidental complete removal. Replacement of the catheters can be distressing and increasingly difficult. Children also are embarrassed by the appearance of these tubes attached to their neck or chest which may also cause discomfort, particularly when sleeping.

A device which could safely contain these fine bore tubes in place and reduce the risk of infection in young patients between 2-4 years old poses a considerable challenge to improve the quality of care during this traumatic period of their lives. Meeting this need is paramount to make the period of cancer chemotherapy less distressing, whilst at the same time allowing medical and nursing staff easy access to the catheter to give treatment (sometimes overnight). A holding device which could have a built-in antimicrobial fabric would help to prevent external contamination; and the risk of infection. This could also help reduce pressure on parents to feel responsible for the management of the catheters because they are present with their children, including sleep-overs, during treatment. Their vigilance in preventing very young children from chewing on the intravenous lines or preventing accidental removal through snagging of the loops of tubing external to the skin could be lessened and allow them to feel less pressured. Having a better level of comfort for the children with full mobility, when the device is not being used, would also be a bonus. Older children are able to take some responsibility for themselves but infection and accidental removal are still major risks. However, they certainly are more likely to want an aesthetic look or even concealment of their central venous catheters!

MATERIALS AND EXPERIMENTAL METHODS

The theoretical framework which underpins this study used an abductive logic within the philosophical approach of interpretivism and the epistemology of constructivism. This enabled the researchers to determine the best approach to construct knowledge from competing interpretation within the data set collected to best inform the design (Bryman and Bell, 2015). Muratovski (2016) identified that in “design research” it is paramount that a balance is created between academic inquiry and practical application to ensure a successful outcome. Due to the cross-disciplinary nature of this project (medical/wellbeing, textiles/apparel) and the stakeholders (academic and an external charity) it was essential to resolve epistemological and methodological differences to discover and agree a set of principles to inform the development of the product criteria (Stember, 1991; McLeish and Strang, 2014). In establishing these boundaries a shared understanding was created

between the various stakeholders regarding the technical requirements for the product design. An interpretive constructionist philosophy was deemed important to the project as it allowed data collection methods to be employed that are primarily qualitative. This allowed the team to gain a deeper understanding of impacting issues through the synthesizing of a cross-section of views based on a specific group of carers, patients and medical personnel. Due to the timeframe of the project (five months) an inductive approach was adopted. This approach allowed a small research sample to be selected and was largely associated with product development in context (Saunders et al., 2016).

The research design involved the use of an expert panel (carers of patient, patients) and was influenced by individual perspectives and personal experiences. The research constructed knowledge to inform design research using the model of quality function deployment (QFD). This allowed data collection from various sources (literature, focus group and informal interviews) to be synthesised leading to the development of an agreed set of technical requirements (Mauzer, 1994). One of the key concepts of QFD is the union of the process to balance innovative ideas regarding product and component technologies with customer demands forming a priority for design and technical features. (Chen et al., 2000; Cango & Trucco, 2007). The first section of the QFD process which was utilised in this study, was split into three stages: capturing the consumer requirements, determining importance and translating these into technical requirements.

Prior to conducting any research involving human participants, market research was conducted which established five alternative products which were available on-line and in the US market. Each product was evaluated to assess the differences in approach to design and a mini-wear trial was conducted to establish comfort values and compare design characteristic. To aid with the understand of the complex issues surrounding the homecare of children with cancer and the challenges associated with the care of the central venous catheters an exploratory focus group was formed with parents of children with cancer and an adult patient. Due to the sensitivity of this research, the focus group was facilitated by the researchers and the questions were delivered by a representative of a local charity trust. Ethical considerations were a high priority throughout the data collection process; all interviews were recorded with permission of the participants. The data from the focus group was consolidated with information obtained from the medical profession, charity and market research and synthesised into a focused design brief and set of technical requirements, through the QFD. The research and initial product design is presented within this paper.

RESULTS

The five products currently available on the market were evaluated for design characteristics, comfort and presented to the focus group for analysis (Figure 1). The first product (A), whilst recognised for its aesthetic print was deemed unsuitable for small children due to risk of strangulation. It would not meet the legal requirements for sleepwear and poses a high risk of snagging to the Hickman line. The Gus Gear product (B) fitted the body snugly and was easy to adjust. However, the child during wear complained that it restricted movement, and that the metal clasps were uncomfortable to lie on. Parents at the focus group commented that the flap containing the lumen would be difficult to access and felt that the product was bulky, heavy and the metal clasps would be uncomfortable during sleep. Product (C) from Health Fully Healing, was very complex to fit and during fitting, the mocked Hickman Line was snagged accidentally. The child however, preferred

the looser fit of this harness and commented that it was soft when lying on front, but uncomfortable on when lying on the back (probably due to lack of cushioning around the lumen area). Parents at the focus group commented on the poor aesthetics of this harness, one participant stated that it resembled body armour and would have concerns regarding the child overheating. Product D (careAline) was the preferred product by the child for comfort, “this one is just right, it is very soft”. In the design the Hickman line wrapped around the body sandwiched inside the harness. However, the fitter had to watch the Youtube clip to establish how to correctly thread in the line, which was deemed rather tricky. The child commented that comfort was good when lying on their front and back and the lumen only pressed into her when lying on her side. The parents at the focus group felt that this product had the potential to restrict breathing (this was found not to be the case in wear) and could increase perspiration. They thought that the product would slip down during wear and it would not be comfortable for the child. In the main they appeared unconvinced that wrapping the line around the body was the optimum position. The final product (E) Bundiebaby resembled a baby vest, the child that participated in the trial had the torso measurements of a 4 year old and commented that she didn’t like this one. It was very time consuming to fit primarily due to the amount of poppers. In terms of comfort the child commented that it was only practical to lie on her back since the plastic poppers hurt her everywhere else. This was not presented at the focus group due to unavailability.

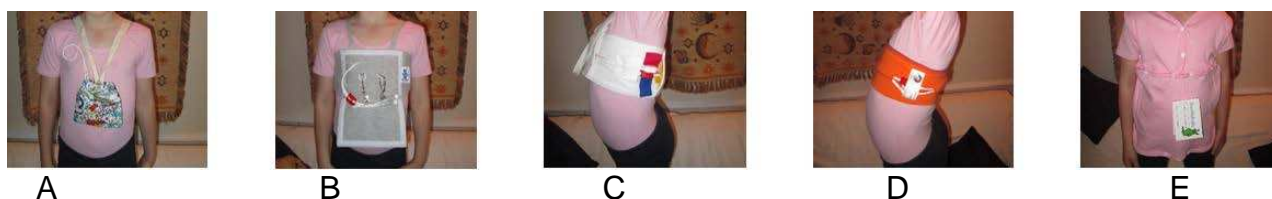


Figure 1 – competitor products

Primary data collection

The sampling criteria for the focus group (March 2015) is illustrated in Table 1. Due to the sensitivity of the research, the first criterion was extended to include an adult cancer patient who expressed interest in the project. The discussion was based around 8 initial themes (general, user issues, H&S, market, design, infection, and technical requirements). The aim was to enable the researchers to gain understanding/knowledge regarding the experiences/views to reduce the humanistic complications in the management of central venous catheters. Three participants contributed to the focus group, a further three individuals completed the questions electronically and three further surveys were conducted with representatives from the medical profession (Table 2). The selection for the participants was purposive and arranged by the charity using their extensive network. The availability of medical personnel governed the selection of participants, the approach was somewhat opportunistic/convenient, based on their expert knowledge in cancer care.

Table 1 – Criteria for carer focus group/questionnaire

Criteria for participation in focus group	
1	Experienced carer of cancer patient (aged 1-16) with central line
2	Type: Peripheral venous cannula around chest
3	Demographic (Yorkshire/midlands)
4	Experience of nightcare and round the clock treatment

Table 2 – Sample of medical personnel and data collection type

Email questionnaire	Consultant nurse at UK hospital – experience of caring for children with cancer
Interview	Senior IV nurse at UK hospital – extensive experience of IV care across all sectors
Email questionnaire	Ex – nurse with extensive experience of cancer care.

The data was synthesised and used to define the design criteria for the product. Table 3 illustrates the main themes extracted. The priorities in terms of design were: comfort, functionality, and aesthetics. The design brief was constructed based directly on the data extracted. It was concluded that the product should be non-medical and should not interfere with the open wound in skin of the chest wall of the children. It had to be interchangeable for use on the left and right side of the upper chest for both Hickman and Portacath type of central venous catheters. Comfort was of a high priority for the selected age group (2-4 years). It was ascertained that the product should be designed to reduce movement/friction of the line and reduce the potential of snagging during the night-time routine. A key focus was to take the weight of the lumen, from the open wound and have a dignity function in relation to the young patient. Finally the product had to meet legal and appropriate standards for H&S, comfort, functionality and be aesthetically pleasing.

Table 3: Focus group findings

General	Can require access to the line 30/40 times a day in the early stages	Home care averages ½ times a day for standard treatment	The Hickman line is permanent for up to two years	Portacaths are inserted when required and last a maximum of 7/8 days	
Routine	Night-time routine is more difficult. Parent and child are often disturbed during sleep. Long Hickman line – risk of snagging as child moves during sleep.	Quite often the parent sleeps with child for comfort and heightens the risk of snagging the line. Discomfort of lumen area as child rolls over, may lead to bruising due to sensitive skin.	Often buy child oversized clothes so line is not trapped. Older babies trap dangling line in nappies etc. difficult during toilet training.	Difficult to keep ends dry during showering and daily cleaning.	Keeping lines clean is a priority, some children use the end as a comforter. All the time there is a need to look at hygiene due to danger of contamination and infection
Experience	Any design needs to be age appropriate.	Health and safety is primary concern followed by functionality Comfort and aesthetics	For a baby comfort is a higher priority than functionality.	NHS do not offer any functional pouch or bag for user	Cost: there would be no limit, people would find a way to afford it if it helps in anyway.
Function	Controls baby temperature. Allows body to breath and wicks away moisture.	Lightweight and not bulky. Smooth material for comfort.	Easy to clean and washable/quick drying or disposable.	Easy to access the Hickman line.	Has some anti-microbial properties. Hypo-allergenic.
Design	Minimum fabric. Stable in wear.	No hard fastening or itchy Velcro.	Reduces the chance that the line will get trapped or snag.	Fits torso, snug and secure	Avoid wrapping around body, do not restrict breathing
Priority	No risk of strangulation	Comfort, functionality and accessibility, aesthetics are important for age range in this order.	Very sensitive skin – avoid tapes	Anything to aid sleep and comfort would be welcomed	Safety is of a high importance, anything to aid with the dignity element must not interfere with medical aspects, it must be a well-being product.

Discussion and QFD

The data obtained during the primary research was synthesized into a set of 16 user requirements (Figure 1, orange column). The first stage of the QFD was to agree on these as a team, in terms of language and to rank them on a scale of 1-5 in terms of importance (green column). This required a judgement and compromise within the team in relation to

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which user requirements took priority. The team devised and agreed a set of 29 technical requirements (purple row), and established whether a positive or negative attribute was desirable (grey row). The final task was to establish the strength of the inter-relationship between the user and technical requirements. At each individual intersection (beige area) a numerical grade of 0 (no relationship), 3 (weak relationship), 5 (medium relationship) and 9 (strong relationship) was given to indicate the strength. The relationship grade was then multiplied by the parent/carer priority rank (green column) to provide the data displayed in the beige matrix (QFD). The value of each technical requirement was totalled to rank the importance of each technical requirement. The highest priority according to the data displayed was the location of the harness, followed by the function and then style line.

			Breathability	colour / visual appearance	Design	Styleline	Snug fit	Ajustability	Antimicrobial	Quality fabric	Wear and tear	Flamability (nightwear)	Sizing BS 7231	Neck opening	Drawcords reduce stragulation	Risk of blood restriction	Hanging loops	Fasteners	Location of harness	Reduce the weight of hanging lumin	Comfort	Snagging reduction	Durability	Quick release	Wicking	Lightweight	Low bulk	Minimum fabric	Placement of pocket	Low impact protection	accessibility	
User requirements	Rank	%	^	^	^	^	^	^	^	^	^	^	^	V	V	V	V	V	^	^	^	^	^	V	^	V	V	V	^	^	^	
product to be comfortable	5	9.09	45	0	15	25	45	45	15	25	0	15	25	15	45	45	45	45	45	25	45	45	15	0	45	25	25	15	25	45	25	
Dignaty	5	9.09	0	25	45	45	25	15	0	25	15	0	25	25	0	0	0	25	45	0	15	15	25	0	0	0	15	15	0	0	15	
easy access (parent)	4	7.27	0	0	36	36	20	12	0	12	12	0	12	0	36	0	36	36	36	20	36	20	0	20	0	0	0	0	36	0	36	
Quick release (medical staff)	3	5.45	0	0	15	27	15	9	0	9	0	0	9	0	27	0	15	27	27	15	0	15	0	27	0	0	0	0	27	0	27	
Suitable for day and night	5	9.09	45	15	45	25	45	15	0	15	25	45	25	25	45	45	25	45	25	45	45	45	25	25	45	25	25	25	45	25	45	
Washable	4	7.27	0	0	12	0	0	12	20	36	20	20	0	0	0	0	0	12	0	0	12	0	12	0	0	0	0	0	0	0	0	
Disposable	2	3.64	10	0	10	10	6	6	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Reduce risk of pulling	5	9.09	0	0	45	45	45	25	0	25	25	0	45	15	45	25	45	15	45	45	45	45	15	25	0	0	0	0	45	15	25	
Prevent against	2	3.64	18	0	18	10	18	6	18	10	6	0	0	0	6	6	0	6	10	18	6	10	0	0	10	0	0	0	6	0	0	
Health and saftey	5	9.09	45	0	45	45	45	25	25	25	25	45	25	25	45	45	45	25	45	45	15	25	0	45	25	0	0	0	45	25	25	
Functional	4	7.27	36	0	36	20	20	36	36	36	36	36	20	20	36	36	36	36	36	36	20	20	36	20	12	36	12	20	20	36	20	36
Desirable to wear	2	3.64	10	18	18	18	6	10	10	10	6	0	6	10	18	18	10	10	18	10	18	18	6	0	10	18	18	6	18	10	10	
cost	1	1.82	5	5	9	3	0	5	9	5	5	9	3	3	0	0	3	5	5	0	3	3	5	3	5	0	0	3	0	3	0	
Protection from lumin	3	5.45	0	0	15	15	9	0	0	15	9	0	0	0	0	0	0	0	15	0	27	0	0	0	0	0	9	0	15	27	0	
Age appropriate	4	7.27	12	20	20	36	12	36	0	20	20	36	36	12	36	36	36	36	36	36	20	36	20	20	20	20	20	12	20	20	36	
Medical value	1	1.82	9	0	3	0	5	0	9	5	3	3	0	0	9	9	9	5	5	5	5	3	3	0	0	3	0	0	0	3	3	5
Sum	55	100	235	83	387	360	316	257	142	273	213	209	231	150	348	265	305	328	393	268	326	300	143	177	199	100	132	96	321	193	285	

Figure 1 – QFD Matrix

This data enabled the team to focus specifically on the design of the fit of the product, as opposed to developing a new material. The fit of the product on the user, appeared to be more important than the placement of the pocket. This was a surprise since in the original discussions the placement of the pocket had been of primary concern. When all the data was synthesised comfort was the most prominent factor. This enabled the team to conduct

initial trials regarding comfort of other products available on the market which informed the design of what has become known as the “Wiggle Bag”. Initially there was some reservation regarding wrapping the central venous line, around the body, yet initial trials showed this to be the most comfortable position for wear. The size of the pocket was initially thought to be important to provide impact protection, but the technical requirements showed this to be lower down on the priority scale. This changed the design from a bulky pocket, to a disposable belt bag that was relatively flexible (Figure 2).



Figure 2 - Final Prototype

The general features of the QFD are synthesized under the four parameters identified to be of importance to the parent/carers (Table 4). It was interesting that health and safety, in terms of regulations, were not the most important design criteria, comfort during wear ranked the highest cumulative followed by functionality. This was perhaps evident from some of the other products on the market, which had not considered strangulation from long attached cords, or loose fasteners. Whilst the charity was highly focused initially on aesthetics this was much lower down the list for user requirements. The material selected was therefore considered in light of the requirements and whilst anti-bacterial properties were lower on the list of desired criteria they were included to differentiated the final design from others on the market.

Table 4 – Technical requirements

Regulations		Comfort		Function		Aesthtics	
Drawcords stragulation	348	Location of harness	393	design	387	visual	83
Hanging loops	305	Styleline	360	Placement of pocket	321		
Snagging reduction	300	Fasteners	328	Snug fit	316		
No blood restriction	265	Comfort	326	accessability	285		
Sizing BS 7231	231	Breathability	235	Quality fabric	273		
Wear and tear	213	Wicking	199	hanging lumin	268		
Flamability (nightwear)	209	protection	193	Ajustability	257		
Quick release	177	Antimicrobrial	142	Durability	143		
Neck opening	150	Low bulk	132				
		Lightweight	100				
		Minimum fabric	96				
Reguations total	2198	Comfort total	2504	Function total	2250	total	83

CONCLUSIONS

The outcome of the research was a functional product ergonomically designed for maximum comfort and safety, with the added unique selling point of having antibacterial properties. The paper details the value of aligning views and translating these into an agreed set of technical parameters within the design team. This process aided the

development team in finding an optimum solution to reduce the humanistic complications in the management of central venous catheters, which has the potential to reduce the discomfort for the children, particularly when sleeping. The product was designed to benchmark three important things comfort, functionality and aesthetics ensuring patients dignity during wear. Prototypes have been produced at the University and the harness has met with the enthusiastic approval of Little Heroes Cancer Trust.

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