

INTEGRATED DESIGN IN THE OPERATING ROOM: REVIEW AND ANALYSIS OF MEDICAL PRODUCT DEVELOPMENT

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1. Introduction

This paper is drawn from a multi-phase programme of research investigating 'Integrated Design in the Operating Room'. The research aims to improve the integration and usability of equipment in the operating room for healthcare providers whilst rationalising the process of its development for manufacturers. It recognises the need to create design strategies and an information resource based on an holistic picture of the development and implementation of medical technologies and products for the operating room. The programme builds upon the research report published by the Department for Trade and Industry, 'The Operating Room of the Year 2010' [Rosin and Kemp 1999] by concentrating on integration in the operating room.

The programme will lead to the creation of a sustainable resource, which will help unify the diffuse community of users involved with the operating room. This community consists of many organisations, including healthcare providers, manufacturers, regulatory and standards bodies. Examples of users within this community include purchasers, clinicians and designers. The resource will function as a design information system and enable knowledge management, whilst supporting technology through a library of digital models of medical products. Information will be available to aid design strategies and multidisciplinary aspects of design including ergonomics, interoperability, evaluation, biomaterials and the environmental impact of equipment at all points in its lifecycle.

The holistic approach taken to this research lends support from various high-profile sources. The final report from the Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary [Kennedy 2001] recognised that the quality of care is dependent on systems, facilities, and clinical staff. The importance of all those involved in healthcare, which includes surgeons, nurses and doctors, as well as non-clinical staff such as managers, is recognised by both this research and in the Bristol Royal Infirmary report. In April 1999, the National Institute for Clinical Excellence (NICE) began operating with the role of providing professional, robust and reliable guidance on current 'best practice' and technology. NICE recognises that the pace of scientific and clinical discovery makes it increasingly difficult for individuals to stay at the forefront of knowledge across the wide range of conditions they have to handle. The philosophy of NICE is consistent with this programme. However, NICE focuses mainly on disease or condition specific technology, for example asthma inhalers or hearing aid technology, and does not address the operating room environment issues covered in this programme.

The initial aim of the programme, and the focus of this paper, was to review and analyse medical product development for equipment found in the operating room environment. Particular attention was paid to investigating design methodology, internal and external communication to both the design team and company, how the complexity of medical design was tackled, and the extent of operating

room experience amongst the design team.

2. Methods

2.1 Literature review

The research commenced with a comprehensive literature review of medical supply networks and medical product development. The review began by concentrating on the operating room but was expanded to cover relevant papers on medical design in general due to the scarcity of published material. For similar reasons, the review of supply networks was further expanded from the medical industry to other heavily regulated industries, for example the aeronautical industry. Reports were written to summarise the reviews of medical supply networks and medical product development, which were reviewed by the Advisory Group, as described below.

2.2 Research design

The process of medical product development was analysed in the spectrum of companies supplying operating room products and services. A multiple case study method [Yin 1984] was used for this study. Data was gathered in many different forms, for example, from web-sites, brochures and publications. Semi-structured interviews were the primary method of data collection used to understand the design process through discussion of innovative products, product evolution and service provision examples in the companies. The interviews were conducted with managers and designers and where possible the same products were discussed with all the staff from each individual company.

Companies that fitted the remit for the research were approached and invited to participate in the study. For those that agreed to take part, staff and at a least one product to be discussed were identified for inclusion in the study. Staff members were selected from the design team at management and designer levels. Each member of staff to be interviewed was then sent identical descriptions of the research and their role within it. Subsequently, each participating member of staff was interviewed separately by two researchers. All of the interviews were of a semi-structured format which was repeated consistently. Both researchers made written notes over the course of the interview, which was also recorded on audio tape so that a full transcription could be produced.

The notes made by the researchers were compiled, analysed and compared. Discrepancies were discussed and the audio recording and transcription were used to clarify anomalous issues. An interview summary was subsequently produced to which the unresolved issues were added, together with any further questions, which was fed-back to the interviewee. The feedback technique was developed from the knowledge of a similar method [Heller 1969]. This allowed the data for each subject to be clarified and validated. Broader analysis was then undertaken by analysing all of the data from the entire study in a number of ways. For example, data was compiled in a semi-quantitative manner into a spreadsheet for mathematical analysis, and diagrammatic analysis proved to be a powerful tool to understanding the data.

2.3 Advisory group

An Advisory Group was formed to both provide guidance and to contribute information and data to the research. The group was composed of a wide spectrum of expertise and included academic staff from the Universities of Manchester and Northumbria with specialist knowledge of ergonomics and physiological measurement. A senior theatre nurse and a consultant medical physicist provided clinical and healthcare knowledge. Industry was represented by a managing director of a small, private, medical company, and a senior designer from an international, public, medical company. The Advisory Group met quarterly during the course of the research and was involved more frequently through reviewing reports and documents.

3. Results

Data was gathered from interviews in seven different organisations, from sixteen interviewees, discussing ten products in detail with a plethora of products discussed in passing. Four additional organisations contributed to the research as part of the Advisory Group. The seven organisations involved in the interview process included public and private companies varying in size from small to medium enterprises, up to large multi-national companies. The organisations also represented a breadth of capabilities including consultancy, manufacturing and distribution with most companies fulfilling several roles. Nine of the interviewees were classified as designers, and seven as design managers. The products discussed in the study were extremely varied, ranging from operating tables to implants and the instruments required for implantation.

3.1 Design process

Four of the seven (57%) participating organisations used a documented project management protocol which usually included procedural flowcharts, for the products discussed, and one (14%) further organisation used a bespoke structured design brief to manage projects. Two (29%) of the organisations had no documented procedure. Alarming, in one of the organisations with a documented protocol a senior, long-standing member of the design team was unaware that it existed.

3.2 Consultations and design factors

All of the organisations stated recognition of user input to the design process, but the range of users recognised to be important varied significantly. Furthermore, the intended inclusion and frequency of user input into the design process was often not realised in practice. The role of surgeon input was universally recognised and addressed. The predominant mode of direct surgical input to the design process was at management level rather than at the designer level in the organisations. When asked to rank the three most important design factors for a product, none of the staff interviewed produced the same ranked list for the same product. No organisation involved in the study provided evidence of a generic checklist of holistic design factors relating to the operating room to consider as part of the design development.

3.3 Operating room experience

Attitudes towards operating room experience were investigated and all of the interviewees considered that such experiences would be beneficial when designing operating room equipment. The frequency of operating room experience for the designers and managers is shown in Table 1. Most designers had no direct experience of the operating room or had only been to theatre once or twice. The managers in the study had largely been exposed to the operating room environment at least twenty times, and often hundreds of times.

Table 1. Operating room experience of the staff in the study

Experience (visits)	Designers	Managers
0 – 2	89%	14%
3 – 20	0%	0%
20 +	11%	86%

3.4 Evaluation

Surgical appraisal and commercial sales were common to all the managers (100%) as the two main criteria for evaluating a product and its success. Both of these criteria together were only voiced by five of the nine (56%) designers. Only one organisation (14%) appeared to use patient input in the design process, yet personnel from two organisations (29%) described how the patient was involved in product evaluation. Patients, surgeons and clients were the only user groups stated as being used in the evaluation process despite other user groups contributing to the design process.

4. Discussion

This research examined the medical industry and in particular the operating room, and the diversity of the organisation and products found in this environment is remarkable. The choice of organisations invited to contribute reflected this diversity, and consequently the products used as examples in the research. The variation in company size and product type explains many of the difficulties described by the contributors to the research in identifying routes to market and purchasers within healthcare providers. Similarly, the purchasers' experience of difficulties in obtaining information about all the companies and products available for a particular application, makes informed purchasing decisions about one solution versus another extremely difficult to make.

4.1 Design process

The medical product design process was of interest in the research, in particular how the complexity of medical design was tackled and how the design brief recorded and communicated the importance of design factors to the design team. Four of the seven organisations participating in the study used a documented project management protocol and one further organisation used a structured design brief. Three of the organisations had either, no documented project management protocol, or, key members of the design team were unaware that a protocol existed. However, these companies were commercially successful and obviously managed without such documentation. Nevertheless, to comply with increasingly stringent regulations in the medical industry, organisations should develop documented protocols which are recognised and employed by staff. Documents such as these would also help with the training of new staff, improve design efficiency and reduce the possibility of design errors occurring.

Medical product design is extremely complex and this research investigated whether this complexity led to solutions that concentrated on specific design factors at the expense of an holistic approach. The findings from this study have supported that theory. None of the organisations described the use of a generic design brief or list of design factors to aid a holistic approach to either the design process or the construction of individual design briefs. A poor correlation was found between the importance of particular design factors described by managers and designers in the same design team, when asked to name and subsequently rank the key design factors for a particular product. Clearly, understanding of the salient features of the design brief differed amongst members of the design team as a whole. Thus, the accuracy of the design brief and internal communication of it to and from the design manager and designers must be improved. This will improve the design process and other benefits will also be reaped, for example, by using the design briefs to reinforce brand and company philosophy, emphasising favoured design factors. The larger medical companies were observed to have a high turnover of staff on projects and a well-defined design brief will maintain design consistency through the life of the project.

4.2 Consultations and design factors

All of the personnel involved in the research recognised the importance of user input to the design process, but the range of users stated to be important varied significantly. Furthermore, the actual inclusion and frequency of user input into the design process was often not realised in practice. The importance of surgical input to the design process was universally recognised and addressed. However, the predominant mode of direct surgical input to the design process was at management level rather than at the designer level in the organisations. The inefficiency of communication of important design factors from management level to the design team has already been demonstrated in this study. Hence, useful design information is being lost in communication from the surgeon to the designer via the manager. Studies have demonstrated (Shaw 1985, Glen and Lord 1996) a strong correlation between user input to the design process and commercially successful medical products, and this emphasises the importance of effectively communicating user input to the design team

4.3 Operating room experience

All of the persons involved in the study believed that exposure to the operating room environment was, or would be, beneficial to the design process. Many reasons were given why this experience was important but those repeatedly cited as most beneficial were communication and awareness of the

operating room environment. Most of the designers who had contact with surgeons in meetings, via the telephone or documents, generally found difficulties in communicating with them. They believed that time spent with a surgeon in the operating room would give them greater knowledge of surgical procedure and the difficulties experienced by surgeons in the pressurised environment of the operating room, consequently allowing them to communicate more effectively. One of the managers in the study, with the experience of literally hundreds of visits to the operating room, stated that the only benefit from operating room experience was understanding surgeon mentality and improving one's ability to communicate effectively. However, most of the managers also cited awareness of the operating room environment to be important to the design process.

A remarkable observation from the research was that persons either had minimal experience of the operating room or substantial experience, with none of the subjects falling in between these extremes. If minimal experience is defined as two or less visits to an operating room in use, then approximately 90% of the designers fell into this category. Similarly, if substantial experience is defined as twenty visits or more to an active operating room, then all but one manager had substantial experience by this definition. It was not necessary in this study to define experience between these two extremes. Operating room experience was thus found to be related to rank in an organisation. As the managers believed that operating room experience was valuable it was surprising that they had not exposed their design staff to the environment more frequently. It is difficult to gain, but the frequency with which managers had done so, strongly suggests that opportunities do arise to give greater exposure of the operating room to the wider design team. If design managers want to improve the knowledge base on which the design process draws they must make greater efforts to give all members of the design team operating room experience.

4.4 Evaluation

Surgical appraisal and commercial sales were the two main criteria expressed by all the managers for evaluating a product and its success. Both of these criteria were voiced by approximately only half the designers. This again emphasises poor communication of important design measures across the design team. Personnel from only one organisation in the study described using patient input in the design process, yet two organisations used patients in product evaluation. Patients and surgeons were the only user groups used in product evaluation, as stated by all of the organisations in this study, despite many other users groups contributing to their design processes. The role of the patient as a user in the operating room is an interesting issue and will be discussed in a later paper. The role of the patient in general medical design has previously been studied and was considered to be paramount (Yen 1988).

4.5 Recommendations

All of the companies involved in this study are commercially successful, or have attracted substantial financial backing due to their intellectual property rights and innovative products. This research and analysis has used simple measures to identify elements of the design process, that could be improved in many medical companies. The methodology of the design process can be improved through documenting the project management protocol and clearly identifying design factors of importance to the design process. Communication of the design process and design brief to the entire design team could be improved in many instances, as could communication of user information and product evaluation criteria. The extent of operating room experience in design managers was found to be excellent and a credit to both them and their organisations. However, this was not reflected amongst the designers and this should be addressed. As these companies are successful and represent organisations that are willing to become involved in research, it can be assumed that the study findings and recommendations would have even greater relevance and impact in the wider medical field.

5. Conclusions

- Approximately half of the contributing organisations used a generic documented process for project management. None of the organisations described the use of a generic design brief to aid either, the design process, or, construction of individual design briefs. Therefore, about

fifty percent of medical companies in this arena would benefit substantially from formalising the design process.

- All of the contributors acknowledged the importance of user input to the design process, but often failed to use their input in practice. The users considered to have relevance to the design process varied widely, although the importance of surgical input was universally recognised. Surgical input to the project was predominantly at managerial level as opposed to designer level. Therefore, companies should develop from simply acknowledging the value of user input, to actively embedding it in the design process to reap commercial benefits.
- The importance and inclusion of design factors for particular products differed between managers and designers in the same design teams. Communication between the design team members needs to be improved, particularly in identifying the importance of various factors in the design process.
- Almost all the designers had none or very limited experience of the operating room in use. Conversely, almost all the managers had extensive experience of the operating room and recognised the importance of this experience to design activity. Thus, exposure to the operating room environment is currently linked to rank in a design team. Therefore, greater efforts should be made by organisations to expose all of the design team to the operating room environment in order to improve the design knowledge base.
- All of the managers involved in the study included surgical appraisal and commercial success as criteria to evaluate products against, compared to approximately half of the designers. Communication amongst the design team with regard to the evaluation criteria should be improved. User groups that are considered important in the design process should be involved in the evaluation process.
- Many user groups were considered important to the design process, but only patients, surgeons and clients to the evaluation process.

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