This article has been published in the International Journal of Health Care Quality Assurance. Year: 2006, Volume: 19, Issue: 6 Page: 500 - 515

User involvement in healthcare technology development and assessment: Structured literature review

Syed Ghulam Sarwar Shah* and **Ian Robinson**

Centre for the Study of Health and Illness, School of Social Sciences and Law

Brunel University, Uxbridge, Middlesex, UB8 3PH, United Kingdom

* Corresponding author

Tel +44 1895 265 463

Fax +44 1895 237 573

Email Sarwar.Shah@brunel.ac.uk

Abstract

Purpose – Medical device users are one of the principal stakeholders of medical device technologies. User involvement in medical device technology development and assessment is central to meet their needs.

Design/methodology/approach – A structured review of literature, published from 1980 to 2005 in peer-reviewed journals, was carried out from social science perspective to investigate the practice of user involvement in the development and assessment of medical device technologies. This was followed by qualitative thematic analysis.

Findings – It is found that users of medical devices include clinicians, patients, carers and others. Different kinds of medical devices are developed and assessed by user involvement. The user involvement occurs at different stages of the medical device technology lifecycle and the degree of user involvement is in the order of design stage > testing and trials stage > deployment stage > concept stage. Methods most commonly used for capturing users' perspectives are usability tests, interviews and questionnaire surveys.

Research limitations/implications – We did not review the relevant literature published in engineering, medical and nursing fields, which might have been useful.

Practical implications – Consideration of the users' characteristics and the context of medical device use is critical for developing and assessing medical device technologies from users' perspectives.

Originality/value – This study shows that users of medical device technologies are not homogeneous but heterogeneous, in several aspects, and their needs, skills and working environments vary. This is important consideration for incorporating users' perspectives in medical device technologies.

Paper type: Literature review.

Keywords: User involvement, Medical devices, Medical devices users, Healthcare technology, User perspective, Technology development and assessment, Medical device lifecycle

Introduction

Medical devices users are one of the primary stakeholders of medical device technologies. Therefore, knowledge of their needs and their involvement in medical device development and assessment (MDD&A) are important. Devices that meet the needs of users enhance safety (Kaye, 2000; Chiu et al., 2004), while non-consideration of user needs has serious consequences (Stone and McCloy, 2004) - for example, the occurrence of medical device errors (Amoore and Ingram, 2002; FDA, 2003; Baker et al., 2004; Bennett et al., 2005), which are very important from users' view point (Samore et al., 2004). In addition, understanding of users' needs is important as it determines the success or failure of technology development (Cahill et al., 1994; Shaw, 1998) and the quality of the product (Keiser and Smith, 1994). Development of better products requires in-depth consideration of all the users and their activities, actual daily working environment, functional limitations, innumeracy and skills (Ostrander, 1984; Wilkins and Holley, 1998; Rockwell, 1999; Green et al., 2000; Staccini et al., 2001; Kittel et al., 2002; Kaufman et al., 2003). Since user requirements affect all aspects of device development, therefore acquiring them has to be done properly (Tsai et al., 1997) and through the involvement of actual users in technology development and assessment (Brockhoff, 2003), which results in the production of more successful medical devices (Biemans, 1991; Shaw, 1998; Lin et al., 2001).

The aim of this literature review was to investigate the practice of user involvement in MDD&A. In particular, the objectives were to find out answers to the following questions:

- What kinds of medical devices are developed and assessed by user involvement?
- What types of medical device users are involved in MDD&A?
- What is the extent of user involvement at different stages of the medical device technology lifecycle?
- What methods are used for capturing user perspectives in MDD&A?

Methodology

The Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) is research collaboration between five leading UK universities in healthcare technology assessment and a cohort of industrial partners. It is sponsored by the Engineering and Physical Sciences Research Council (EPSRC), United Kingdom to support the healthcare technology sector and its user communities by creating methods to assess value from concept through to mature product and by engaging with regulatory bodies at home and abroad (MATCH, 2005). One project within this programme is targeted at the engagement with users and it aims to develop formal methods for evaluating the users' perspectives and for engaging with the community (MATCH, 2003). The project comprises three teams i.e. healthcare, engineering and ergonomics, and social science. This survey reports from the social sciences perspective.

An extensive structured review of literature published in social sciences was conducted from January 2004 to April 2005. Literature in healthcare, engineering and ergonomics disciplines was not surveyed by the authors of this study since it was conducted by other panel (Bridgelal Ram et al., 2005). However, a few studies from the other disciplines might have been included in this study due to their availability on bibliographic databases searched in this study. These studies (Mulholland et al., 2000; Dutt et al., 2002; Garmer et al., 2002a; Garmer et al., 2004; Liljegren and Osvalder,

2004) have been omitted from analysis. The process of literature review was adapted from Beverley et al. (2004) and Bruce and Mollison (2004). Key words used were: device users; end-users; medical device; medical device users; needs assessment; new medical technology; user centred product; user criteria; user input; user interests; user involvement; user needs; user needs assessment; user needs research; user participation; user perceptions; user perspective; user requirements; user requirements elicitation; user studies and user survey. Searches were conducted across the following online bibliographic databases: Blackwell Synergy, Ebscohost, Emerald, International Bibliography of the Social Sciences (IBBS), IEEE/IEE Electronic Library, Ingenta, JSTOR, Kluweronline, Medical Device Link, ProQuest, Sage publications, ScienceDirect, Social Science Information Gateway (Sosig), SpringerLink.

The inclusion criteria for articles included studies that reported user involvement in MDD&A and were published from 1980 to 2005 in English language. Studies where there was no user involvement during any stage of the medical device lifecycle were excluded from the review. Three reviewers that included a full time research fellow and two social science PhD students (interns for a three month period) reviewed the selected articles. A data extraction template was developed in spreadsheet in-house, which had columns for nine variables (Appendix A).

For data extraction purpose, the medical device lifecycle was divided into five stages i.e. concept stage, design stage, testing and trials stage, production stage and deployment stage, which were based on stages of the product lifecycle reported in the literature (Cooper and Kleinschmidt, 1986; Rochford and Rudelius, 1997; WHO, 2003). Details of the used stages are given in Table I.

"Take in Table I".

The process of article identification, short-listing, reviewing and data abstraction comprised three phases. The first phase comprised searching as per search terms and quick reading of titles and abstracts leading to identification of relevant articles. The second phase included careful reading of abstracts of identified articles and short listing of the most promising articles. The third phase involved thorough reading of the short listed articles and data extraction on the template. After completion of the data abstraction process, the data was cleaned and crosschecked. Upon crosschecking of the data, it was found that 28 articles were reviewed more than once. The data abstracted from these articles by different reviewers was compared and no significant difference was found when reviewer had processed the same article. This confirmed the reliability of the abstracted data and helped to validate the process.

Descriptive statistics and qualitative thematic analysis (Ritchie and Spencer, 1994) were used for analysing the data, which was divided into different themes i.e. types of medical devices developed and assessed, types of medical device users involved, extent of user involvement by different stages of the medical device development cycle and methods used for capturing users' perspectives.

Results

We reviewed the social sciences literature related to user perspectives elicitation for development and assessment of medical devices, and other products to have a broader picture. Here we present data from 24 studies that reported user involvement in the development and assessment of medical device technologies (Table II).

"Take in Table II".

The findings of qualitative thematic analysis along with descriptive statistics of these studies are as follows.

Types of medical devices developed and assessed by user invovlement

The review revealed that a variety of medical devices was developed and assessed by involving users of medical device technologies (Figure 1). The device ranged from syringes to neuromagnetometer and included the devices that are used by various types of users.

"Take in Figure 1".

Types of medical device users involved in medical device development and assessment

It was found that a wide range of medical device users was involved in the process of MDD&A. The users included clinicians, patients, carers, family members and persons with different disabilities and impairments (Figure 2).

"Take in Figure 2".

Extent of user involvement by stage of the medical device lifecycle

In 50% (n=12) of the studies, users were involved in one stage of the medical device lifecycle and in the remaining studies (50%, n=12) the users were involved in more than one stage of the lifecycle. In terms of single-stage involvement, this was highest in the deployment stage in 20.8% (n=5) of the studies, followed by design stage in 16.7% (n=4), testing and trials stage in 8.3% (n=2) and concept stage in 4.2% (n=1) of total studies. The user involvement in more than one stage was in the combination of two stages, three stages and four stages of the medical device lifecycle. Two stages combinations were between design stage and testing and trials stage; concept and design stages; and testing and trails and deployment stages. The user involvement in each of the two stages combinations was in 8.3% (n=2) studies. Three stages combination for user involvement was between concept, design, and testing and trials stages in 12.5% (n=3) followed by design, testing and trials, and deployment stages in 4.2% (n=1) studies. Four stages combination for user involvement was between concept, design, testing and trials, and deployment stages in 8.3% (n=2) studies. The extent of over all user involvement in each stage of medical device technology lifecycle was highest in design stage (58.33%, n=14) and the lowest in concept stage (33.33%, n=8), which is shown in figure 3.

"Take in Figure 3".

Methods used for capturing users' perspectives

Methods used for involving the users and capturing their perspectives in the medical device technology lifecycle were usability tests in 33.3% (n=8); interviews in 25% (n=6); questionnaire surveys in 20.8% (n=5); discussions and simulations each in 8.3% (n=2); design sessions, focus groups (Delphi method), human factors approach, observation, task analysis, use experiment, user and producer seminars, users' feedback and video recording each in 4.2% (n=1) of the studies. These methods are mapped against the medical device lifecycle stages where they were used (Table III).

"Take in Table III".

Usability tests, interviews, questionnaire surveys and user-producer seminars were used in all four stages of medical device lifecycle where the users were involved.

However, usability tests, interviews and questionnaire surveys were the most commonly used methods for involving users and capturing user perspectives at various stages of the medical device lifecycle. The interviews were mainly semi-structured and face-to-face. Other methods were used at one or two stages of the lifecycle such as the use of design sessions during the design stage, use of focus groups (Delphi method) during the deployment stage and the use of 'discussions' during the concept and design stages.

Discussion

This review has revealed that various types of medical devices are developed and assessed by user involvement. These devices when grouped together based on their use mainly include assistive devices, surgical devices and devices used for drug administration. This does not imply that these are the only medical devices that can be developed and assessed by involving the users. There might be other types of medical devices that are developed and assessed by user involvement but were not identified in this review. This might have happened due to the nature of databases selected for this review.

Medical devices are divided into different classes according to the EC classification (EC, 1993; EC, 2001) and the USA classification (FDA, 1997). Information regarding the class of medical devices identified in this review could not be ascertained from the reviewed studies. It is therefore not possible say that such and such classes of medical devices can be developed and assessed by involving the users. The review has shown that different types of medical device users can be involved in the development and assessment of medical device technologies. However, some of the users might be easily available while others would not. The latter category might include the elderly and disabled users (Marshall et al., 2002) and clinical consultants, particularly in highly demanded clinical specialities such as cardiac surgeons or consultants working in the accident and emergency departments. In this case, their surrogates called as 'user surrogates' may be involved. For instance, the participation of representatives of physicians working in the emergency department in the sessions for joint application development, since they had worked with the physicians and were aware of physicians' needs (De and Ferratt, 1998a; De and Ferratt, 1998b). However, the decision regarding the use of user surrogates must be made after consideration of possible advantages and disadvantages (Bradley et al., 1983; Herbert and Salmon, 1994; Cook and Woods, 1996; Gotzsche et al., 1996; Tsevat et al., 1998; Moinpour et al., 2000). Moreover, user involvement in MDD&A is dependent on regulatory approval since there are ethical and legal issues involved (McGregor and Brophy, 2005).

None of the studies reviewed mentioned financial implications of involving the users. There was also no mention of the financial remuneration given to the users for participating in the research. This however does not imply that there are no costs associated with the user involvement. The users might participate on volunteer basis but there might be other costs involved in the process of user involvement in MDD&A, which however need to be studied.

The review has revealed that the users are involved at all stages of medical device technology lifecycle except the development stage. This was probably because users have nothing to do at this stage as this stage relates to full-scale manufacturing supported by business and commercial rationale. Kaulio (1998) identified three

interfaces of user involvement i.e. specification, concept development and prototyping in new product development process where the actual user involvement takes place during design stage. Gyula (2001) found that user involvement was higher in the beginning stage and market stage. However, we have found that user involvement occurs during four out of the five stages of medical device technology lifecycle i.e. concept, design, testing and trials and deployment stages. The extent of user involvement by stage shows that the highest user involvement was during the design stage followed by testing and trials stage, deployment stage and concept stage. The common finding between this review and studies by Kaulio (1998) and Gyula (2001) is the finding of higher user involvement during the early stages than in the latter stages of the medical device technology lifecycle, which is perhaps because the user involvement in the early stages saves time and costs including those associated with the later modifications (Tsai et al., 1997; Giuntini, 2000; McDonagh et al., 2002). In addition, the user involvement during the early stages of development lifecycle is regarded as important (Sato and Salvador, 1999; Truffer, 2003) as it helps in the incorporation of user needs (Saiedian and Dale, 2000). Therefore, user involvement at early stages have been suggested (Kyng, 1991; Ornetzeder, 2001) because it benefits to both users and producers (Sanford et al., 1998).

User involvement at the design stage was found highest because the involvement of users at design stage is considered vital (Sanford et al., 1998; Dorup et al., 2001). Highest user involvement at the design stage is to develop user centred designs that are regarded as successful product designs (Wai and Siu, 2003). The resultant designs are used to develop medical devices that have higher market usability (Gould and Lewis, 1985), improved equipment safety and efficiency (Lin, 1998) and may be successfully used and maintained (Fouladinejad and Roberts, 1996). Another reason for the higher user involvement at design stage is the requirement of formal design processes that should begin and finish with customer needs under regulation such as ISO 9001 (Powers and Greenberg, 1999). Nevertheless, each stage of the medical device technology lifecycle is important and user input during each stage of the medical device lifecycle would be definitely important and required.

The review has shown that numerous methods, both direct methods e.g. interviews, usability tests and questionnaire surveys and indirect methods e.g. observation and simulation (Noyes and Starr, 1995), are used for involving users in healthcare technologies development and assessment. All methods of enquiry have advantages and disadvantages, however, some methods are more appropriate than others and their selection and application depends on the purpose and context of the inquiry. For example, focus groups are useful for product concept evaluation (McQuarrie and McIntyre, 1986) and involving users in the interface design process (Nielsen, 1997). Similarly, user feedback method is regarded important for user involvement throughout the development process of medical devices such as blood parameter monitor (Bray, 2000).

The development of better products requires in depth understanding of all the actors and their activities (Staccini et al., 2001). However, involvement of different types of users, understanding of their needs and elicitation of their perspectives for developing medical devices require use of different methods (Biemans, 1991) and combination of both qualitative and quantitative methods (Edwards and Staniszewska, 2000; Tenopir, 2003). The combination of methods such as usability tests and contextual inquiry in early stages of the product lifecycle, according to Rockwell

(1999), leads to better targeted products, higher customer satisfaction and reduced developmental time. Combination of methods is also required to know the usability aspects of medical devices (Garmer et al., 2004). For example, the use of human factor approach and usability tests for the redesign of volumetric infusion device (Garmer et al., 2002b); usability tests, structured interviews and discussions for capturing user requirements in assistive technology (Buhler, 1996); questionnaire survey and usability tests (Lacey and Slevin, 2001) and task analysis, observation, simulation and questionnaire survey (Green et al., 2000) for developing user centred designs; activity theoretical perspective and usability tests for new medical technology (Hasu, 2000); focus groups and usability tests for ventilators development (Garmer et al., 2004) and interviews and usability tests for development and assessment of infusion devices (Obradovich and Woods, 1996).

The selection of method for capturing users' perspectives however depends on the type of medical device technology. Hyysalo (2003) is of the opinion that elicitation of the user needs for radically innovative technologies is yet to be proved by traditional methods such as market surveys and expert interviews. The emerging healthcare technologies require user involvement in trials and established healthcare technologies require discussions with the experienced and long term users (Buhler, 1996). Since the capturing of user perspectives at various stages of medical device lifecycle depends on the method applied therefore, selection of an appropriate method is of immense importance. In addition to the selection of appropriate method(s), the selection of users and mode and timing of their involvement is critical in medical device technology development and assessment.

Conclusion

User involvement is essential for developing and assessing medical device technologies from users' perspectives. Medical device technologies are developed and assessed by involving their users, which include clinicians, patients, carers and others. The users are involved mainly during design and testing and trial stages of the medical device technology lifecycle. The selection of appropriate method(s) is important for involving users and capturing users' perspectives. Future research may investigate benefits and barriers associated with user involvement in the development and assessment of medical device technologies.

Acknowledgement

This study arises from the Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) program, which is sponsored by the Engineering and Physical Sciences Research Council (EPSRC), United Kingdom. The views articulated in this study are entirely those of the authors. The authors greatly acknowledge the contributions of John Pappas and Joseph Adonu, PhD students, in reviewing some of the articles during their internship. The authors wish to thank colleagues in particular Professors Clive Seal and Terry Young for their valuable suggestions and comments on the manuscript.

References:

Amoore, J. and Ingram, P. (2002), "Learning from adverse incidents involving medical devices", *BMJ*, Vol. 325, No. 7358, pp. 272-75.

Baker, G. R., Norton, P. G., Flintoft, V., Blais, R., Brown, A., Cox, J., Etchells, E., Ghali, W. A., Hebert, P., Majumdar, S. R., O'Beirne, M., Palacios-Derflingher, L., Reid, R. J., Sheps, S. and Tamblyn, R. (2004), "The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada", *CMAJ*, Vol. 170, No. 11, pp. 1678-186.

Bennett, C. L., Nebeker, J. R., Lyons, E. A., Samore, M. H., Feldman, M. D., McKoy, J. M., Carson, K. R., Belknap, S. M., Trifilio, S. M., Schumock, G. T., Yarnold, P. R., Davidson, C. J., Evens, A. M., Kuzel, T. M., Parada, J. P., Cournoyer, D., West, D. P., Sartor, O., Tallman, M. S. and Raisch, D. W. (2005), "The research on adverse drug events and reports (RADAR) project", *JAMA*, Vol. 293, No. 17, pp. 2131-40.

Beverley, C. A., Bath, P. A. and Booth, A. (2004), "Health information needs of visually impaired people: a systematic review of the literature", *Health & Social Care in the Community*, Vol. 12, No. 1, pp. 1-24.

Biemans, W. G. (1991), "User and third-party involvement in developing medical equipment innovations", *Technovation*, Vol. 11, No. 3, pp. 163-82.

Bradley, C., Brewin, C. and Duncan, S. (1983), "Perceptions of labour: discrepancies between midwives' and patients' ratings", *British Journal of Obstetrics and Gynaecology*, Vol. 90, No. 12, pp. 1176-9.

Bray, D. D. (2000), "Creative collaboration: user-centered design in practice", *Medical Device & Diagnostic Industry*, No. March 2000, pp. 76-89.

Bridgelal Ram, M., Browne, N., Crowe, J., Grocott, P., J., M., Murphy, E., Norris, B., Shah, S. G. S., Robinson, I. and Weir, H. (2005), *A structured survey of published literature on methods to capture user perspectives in medical device development drawing on social sciences, health care, ergonomics and engineering*, Multidisciplinary Assessment of Technologies Centre for Healthcare (MATCH). Deliverable No. 6. Available: http://www.match.ac.uk/

Brockhoff, K. (2003), "Customers' perspectives of involvement in new product development", *International Journal of Technology Management*, Vol. 26, No. 5/6, pp. 464-81.

Bruce, J. and Mollison, J. (2004), "Reviewing the literature: adopting a systematic approach." *Journal of Family Planning and Reproductive Health Care*, Vol. 30, No. 1, pp. 13-16.

Buhler, C. (1996), "Approach to the analysis of user requirements in assistive technology", *International Journal of Industrial Ergonomics*, Vol. 17, No. 2, pp. 187-92.

Cahill, D. J., Thach, S. V. and Warshawsky, R. M. (1994), "The marketing concept and new high-tech products: is there a fit?" *Journal of Product Innovation Management*, Vol. 11, No. 4, pp. 336-43.

Chiu, C. C., Vicente, K. J., Buffo-Sequeira, I., Hamilton, R. M. and McCrindle, B. W. (2004), "Usability assessment of pacemaker programmers", *Pacing and Clinical Electrophysiology*, Vol. 27, No. 10, pp. 1388-98.

Cook, R. I. and Woods, D. D. (1996), "Adapting to new technology in the operating room", *Human factors*, Vol. 38, No. 4, pp. 593–613.

Cooper, R. G. and Kleinschmidt, E. J. (1986), "An investigation into the new product process: Steps, deficiencies, and impact", *Journal of Product Innovation Management*, Vol. 3, No. 2, pp. 71-85.

De, P. and Ferratt, T. W. (1998a), "An interorganizational information system in the health care arena: insights gained from a hierarchical analysis", In Agarwal, R. (Ed.), Proceedings of the 1998 ACM SIGCPR conference on Computer personnel research, March 26 - 28, 1998, Boston, Massachusetts, United States, pp. 214-23.

De, P. and Ferratt, T. W. (1998b), "An information system involving competing organizations", *Communications of the ACM*, Vol. 41, No. 12, pp. 90-98.

Dorup, J., Hansen, M. S. and Geneser, F. (2001), "User-centered design of medical learning software", In Daetwyler, C. (Ed.), Use of computers in medical education part II: Practical examples, StudienVerlag, Innsbruck.

Dutt, S. N., McDermott, A.-L., Jelbert, A., Reid, A. P. and Proops, D. W. (2002), "Day to day use and service-related issues with the bone-anchored hearing aid: the Entific Medical Systems questionnaire", *Journal of Laryngology & Otology*, Vol. 116, No. 6, Supplement 28, pp. 20-28.

EC (1993), "Council Directive 93/42/EEC of 14 June 1993 concerning medical devices", *Official Journal of the European Community*, No. L 169, pp. 1-51.

EC (2001), *Guidelines for the classification of medical devices.*, The European Commission, Brussels. Available: http://europa.eu.int/comm/enterprise/medical_devices/meddev/2_2_4-1part1_07-2001.pdf (29-09-2005).

Edwards, C. and Staniszewska, S. (2000), "Accessing the user's perspective", *Health and Social Care in the Community*, Vol. 8, No. 6, pp. 417-24.

FDA (1997), *Chapter V - Drugs and Devices. Federal Food, Drug, and Cosmetic Act 1997*, Department of Health and Human Services, U.S. Food and Drug Administration, Rockville, Maryland.

FDA (2003), *Why is human factors engineering important for medical devices?* U.S. Food and Drug Administration (FDA), Rockville, MD. Available: http://www.fda.gov/cdrh/humanfactors/index.html (08-06-2005).

Fouladinejad, F. and Roberts, J. R. (1996), "A computer aided learning package for training users and maintainers of medical equipment", In: Proceedings of the 18th Annual International Conference of the IEEE 'Bridging Disciplines for Biomedicine', 31 Oct.- 3 Nov. 1996, Amsterdam. Vol. 5, pp. 2211-12.

Garmer, K., Liljegren, E., Osvalder, A.-L. and Dahlman, S. (2002a), "Application of usability testing to the development of medical equipment. Usability testing of a frequently used infusion pump and a new user interface for an infusion pump developed with a human factors approach", *International Journal of Industrial Ergonomics*, Vol. 29, No. 3, pp. 145-59.

Garmer, K., Liljegren, E., Osvalder, A.-L. and Dahlman, S. (2002b), "Arguing for the need of triangulation and iteration when designing medical equipment", *Journal of Clinical Monitoring and Computing*, Vol. 17, No. 2, pp. 105-14.

Garmer, K., Ylven, J. and MariAnne Karlsson, I. C. (2004), "User participation in requirements elicitation comparing focus group interviews and usability tests for eliciting usability requirements for medical equipment: a case study", *International Journal of Industrial Ergonomics*, Vol. 33, No. 2, pp. 85-98.

Giuntini, R. E. (2000), "Developing safe, reliable medical devices." *Medical Device and Diagnostic Industry*, October 2000, pp. p.60.

Gotzsche, P. C., Liberati, A., Torri, V. and Rosetti, L. (1996), "Beware of surrogate outcome measures", *International Journal of Technology Assessment in Health Care,* Vol. 12, No. 2, pp. 238-46.

Gould, J. D. and Lewis, C. (1985), "Designing for usability: key principles and what designers think." *Communications of the ACM,* Vol. 28, No. 3, pp. 300-31.

Green, A., Huttenrauch, H., Norman, M., Oestreicher, L. and Eklundh, K. S. (2000), "User centered design for intelligent service robots", In: Proceedings of 9th IEEE International Workshop 'Robot and Human Interactive Communication', 27-29 Sept. 2000, pp. 161-66.

Gyula, S. (2001), "User involvement in product design in Hungary", In proceedings of International Summer Academy on Technology Studies, 'User Involvement in Technological Innovation', July 8-13, 2001.Deutschlandsberg, Austria, pp. 65-76.

Hasu, M. (2000), "Constructing clinical use: an activity-theoretical perspective to implementing new technology." *Technology Analysis & Strategic Management,* Vol. 12, No. 3, pp. 369-82.

Herbert, C. and Salmon, P. (1994), "The inaccuracy of nurses' perception of elderly patients' well-being", *Psychology and Health,* Vol. 9, 485-92.

Hyysalo, S. (2003), "Some problems in the traditional approaches to predicting the use of a technology-driven invention", *Innovation: The European Journal of Social Sciences,* Vol. 16, No. 2, pp. 117-37.

Kaufman, D. R., Patel, V. L., Hilliman, C., Morin, P. C., Pevzner, J., Weinstock, R. S., Goland, R., Shea, S. and Starren, J. (2003), "Usability in the real world: assessing medical information technologies in patients' homes", *Journal of Biomedical Informatics,* Vol. 36, No. 1-2, pp. 45-60.

Kaulio, M. A. (1998), "Customer, consumer and user involvement in product development: a framework and a review of selected methods", *Total Quality Management,* Vol. 9, No. 1, pp. 141-49.

Kaye, R. D. (2000), "Human factors (HF) in medical device use safety: how to meet the new challenges", (Ed.), Proceedings of the XIVth Triennial Congress of the International Ergonomics Association and 44th Annual Meeting of the Human Factors and Ergonomics Association, 'Ergonomics for the New Millennium', 29 Jul. - 4 Aug. 2000, San Diego, CA, United States, pp. 550-52.

Keiser, T. C. and Smith, D. A. (1994), "Customer driven strategies: moving from talk to action", *Managing Service Quality,* Vol. 4, No. 2, pp. 5-9.

Kittel, A., Marco, A. D. and Stewart, H. (2002), "Factors influencing the decision to abandon manual wheelchairs for three individuals with a spinal cord injury." *Disability and Rehabilitation,* Vol. 24, No. 1/2/3, pp. 106-14.

Kyng, M. (1991), "Designing for cooperation: cooperating in design", *Communications of the ACM,* Vol. 34, No. 12, pp. 65-73.

Lacey, G. and Slevin, F. (2001), "Putting the user at the centre of the design process." In abstracts of proceedings of International Conference on Technology and Aging, 12 - 14 Sept. 2001, Toronto, Ontario, Canada, pp. 65.

Liljegren, E. and Osvalder, A.-L. (2004), "Cognitive engineering methods as usability evaluation tools for medical equipment", *International Journal of Industrial Ergonomics,* Vol. 34, No. 1, pp. 49-62.

Lin, L. (1998), "Human error in patient-controlled analgesia: incident reports and experimental evaluation", in proceedings of the 42nd Annual Meeting 'Human Factors and Ergonomics Society', 5- 9 Oct.1998, Vol. 2, pp. 1043-47.

Lin, L., Vicente, K. J. and Doyle, D. J. (2001), "Patient safety, potential adverse drug events, and medical device design: a human factors engineering approach", *Journal of Biomedical Informatics*, Vol. 34, No. 4, pp. 274-84.

Marshall, R., Case, K., Oliver, R., Gyi, D. E. and Porter, J. M. (2002), "A task based 'design for all' support tool", *Robotics and Computer-Integrated Manufacturing*, Vol. 18, No. 3-4, pp. 297-303.

MATCH (2003), *Project 3 engagement with users (methods and metrics) project plan*, Multidisciplinary assessment of healthcare technology assessment centre (MATCH). Project Plan.

MATCH (2005), *MATCH: Multidisciplinary Assessment of Technology Centre for Healthcare*. Available: http://www.match.ac.uk/ (29-05-2005).

McDonagh, D., Bruseberg, A. and Haslam, C. (2002), "Visual product evaluation: exploring users' emotional relationships with products", *Applied Ergonomics*, Vol. 33, No. 3, pp. 231-40.

McGregor, M. and Brophy, J. M. (2005), "End-user involvement in health technology assessment (HTA) development: a way to increase impact", International Journal of Technology Assessment in Health Care, Vol. 21, No. 2, pp. 263–67.

McQuarrie, E. F. and McIntyre, S. H. (1986), "Focus groups and the development of new products by technologically driven companies: some guidelines", *Journal of Product Innovation Management*, Vol. 3, No. 1, pp. 40-47.

Moinpour, C. M., Lyons, B., Schmidt, S. P., Chansky, K. and Patchell, R. A. (2000), "Substituting proxy ratings for patient ratings in cancer clinical trials: an analysis based on a southwest oncology group trial in patients with brain metastases", *Quality of Life Research*, Vol. 9, No. 2, pp. 219-31.

Mulholland, S. J., Packer, T. L., Laschinger, S. J., Lysack, J. T., Wyss, U. P. and Balaram, S. (2000), "Evaluating a new mobility device: feedback from women with disabilities in India", *Disability & Rehabilitation*, Vol. 22, No. 3, pp. 111-22.

Nielsen, J. (1997), "The use and misuse of focus groups", *IEEE Software*, Vol. 14, No. 6, pp. 94-95.

Noyes, J. M. and Starr, A. F. (1995), "Working with users in system development: some methodological considerations", *IEE Colloquium on Integrating HCI in the Lifecycle*, 11 April 1995, pp. 7/1-7/3.

Obradovich, J. H. and Woods, D. D. (1996), "Users as designers: how people cope with poor HCI design in computer-based medical devices", *Human Factors*, Vol. 38, No. 4, pp. 574-92.

Ornetzeder, M. (2001), "Assessing technology from the users' perspective. possibilities and limitations of focus group discussions illustrated by ecological housing construction", in proceedings of International Summer Academy on Technological Studies, 'User Involvement in Technological Innovation', 8-13 July 2001, Deutschlandsberg, Austria, pp. 155-66.

Ostrander, L. E. (1984), "Attention to the medical equipment user in biomedical engineering", *Medical Instrumentation*, Vol. 20, No. 1, pp. 3-5.

Powers, D. M. and Greenberg, N. (1999), "Development and use of analytical quality specifications in the in vitro diagnostics medical device industry." *Scandinavian Journal of Clinical and Laboratory Investigation*, Vol. 59, No. 7, pp. 539-43.

Ritchie, J. and Spencer, L. (1994), "Qualitative data analysis for applied policy research", In Bryman, A. and Burgess, R. G. (Eds.), Analyzing Qualitative Data, Routeledge, London, pp. 175-94.

Rochford, L. and Rudelius, W. (1997), "New product development process: stages and successes in the medical products industry", *Industrial Marketing Management,* Vol. 26, No. 1, pp. 67-84.

Rockwell, C. (1999), "Customer connection creates a winning product: building success with contextual techniques." *interactions,* Vol. 6, No. 1, pp. 50-57.

Saiedian, H. and Dale, R. (2000), "Requirements engineering: making the connection between the software developer and customer." *Information and Software Technology,* Vol. 42, No. 6, pp. 419-28.

Samore, M. H., Evans, R. S., Lassen, A., Gould, P., Lloyd, J., Gardner, R. M., Abouzelof, R., Taylor, C., Woodbury, D. A., Willy, M. and Bright, R. A. (2004), "Surveillance of medical device-related hazards and adverse events in hospitalized patients", *JAMA,* Vol. 291, No. 3, pp. 325-34.

Sanford, J. A., Story, M. F. and Ringhold, D. (1998), "Consumer participation to inform universal design." *Technology and Disability,* Vol. 9, No. 3, pp. 149-62.

Sato, S. and Salvador, T. (1999), "Playacting and focus troupes: theater techniques for creating quick, intense, immersive, and engaging focus group sessions", *interactions,* Vol. 6, No. 5, pp. 35-41.

Shaw, B. (1998), "Innovation and new product development in the UK medical equipment industry", *International Journal of Technology Management,* Vol. 15, No. 3/4/5, pp. 433-45.

Staccini, P., Joubert, M., Quaranta, J.-F., Fieschi, D. and Fieschi, M. (2001), "Modelling health care processes for eliciting user requirements: a way to link a quality paradigm and clinical information system design", *International Journal of Medical Informatics,* Vol. 64, No. 2-3, pp. 129-42.

Stone, R. and McCloy, R. (2004), "Ergonomics in medicine and surgery", *BMJ,* Vol. 328, No. 7448, pp. 1115-18.

Tenopir, C. (2003), "Information metrics and user studies", *Aslib Proceedings: New Information Perspectives,* Vol. 55, No. 1-2, pp. 13-17.

Truffer, B. (2003), "User-led innovation processes. the development of professional car sharing by environmentally concerned citizens", *Innovation: The European Journal of Social Sciences,* Vol. 16, No. 2, pp. 139-54.

Tsai, W.-T., Mojdehbakhsh, R. and Rayadurgam, S. (1997), "Experience in capturing requirements for safety-critical medical devices in an industrial environment", in proceedings of 2nd IEEE High-Assurance Systems Engineering Workshop, 11-12 Aug 1997, Washington, DC, pp. 32-36.

Tsevat, J., Dawson, N. V., Wu, A. W., Lynn, J., Soukup, J. R., Cook, E. F., Vidaillet, H. and Phillips, R. S. (1998), "Health values of hospitalized patients 80 years or older", *JAMA,* Vol. 279, No. 5, pp. 371-75.

Wai, K. and Siu, M. (2003), "Users' creative responses and designers' roles", *Design Issues,* Vol. 19, No. 2, pp. 64-73.

WHO (2003), *Medical device regulations: global overview and guiding principles,* World Health Organization, Geneva.

Wilkins, R. D. and Holley, L. K. (1998), "Risk management in medical equipment management", in proceedings of 20th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Vol. 20, No 6, pp. 3343-45.

“take in Appendix A”.

This article has been published in the International Journal of Health Care Quality Assurance. Year: 2006, Volume: 19, Issue: 6 Page: 500 - 515

Appendix A. Data extraction template

ID	Reference	Year & Country of Study	Objective(s) / Question(s)	Device / Product	Method / Tool / Approach	Users / Participants	Product development stages at which users were involved					Findings &/or Conclusion	Researcher's Comments
							Concept	Design	Testing & Trials	Production	Deployment		
1	2	3	4	5	6	7	8a	8b	8c	8d	8e	9	10

Table I. Stages of the product lifecycle

Stage	Details
Concept	Starts with idea generation and includes technical, financial and commercial assessment
Design	Involves product development process from (re)design to prototype development
Testing and Trials	Starts with prototype testing in house and includes trails in the real field
Production	Includes production on large scale supported by business and commercial rationale
Deployment – marketing, launch and use	Includes product marketing, launch and use in the real field

Table II. Studies that reported user involvement in medical devices development and assessment

Ahasan, R., Campbell, D., Salmoni, A. and Lewko, J. (2001), "Ergonomics of living environment for the people with special needs", *Journal of Physiological Anthropology and Applied Human Science*, Vol. 20, No. 3, pp. 175-85.

Batavia, A. I. and Hammer, G. S. (1990), "Toward the development of consumer-based criteria for the evaluation of assistive devices", *Journal of Rehabilitation Research and Development*, Vol. 27, No. 4, pp. 425-36.

Bray, D. D. (2000), "Creative collaboration: User-centered design in practice", *Medical Device & Diagnostic Industry*, March 2000, pp. 76-89.

Buhler, C. (1996), "Approach to the analysis of user requirements in assistive technology", *International Journal of Industrial Ergonomics*, Vol. 17, No. 2, pp. 187-92.

Buhler, C., Hoelper, R., Hoyer, H. and Humann, W. (1995), "Autonomous robot technology for advanced wheelchair and robotic aids for people with disabilities", *Robotics and Autonomous Systems*, Vol. 14, No. 2-3, pp. 213-22.

De, P. and Ferratt, T. W. (1998a), "An interorganizational information system in the health care arena: insights gained from a hierarchical analysis", In Agarwal, R. (Ed.), Proceedings of the ACM SIGCPR conference on Computer personnel research, March 26 - 28, 1998, Boston, Massachusetts, United States, pp. 214-23.

De, P. and Ferratt, T. W. (1998b), "An information system involving competing organizations", *Communications of the ACM*, Vol. 41, No. 12, pp. 90-98.

Dorup, J., Hansen, M. S. and Geneser, F. (2001), "User-centered design of medical learning software", In Daetwyler, C. (Ed.), Use of Computers in Medical Education Part II: Practical Examples. StudienVerlag, Innsbruck.

Friedrich, G. (1999), "Sustainability and the design process." In proceedings of Summer Academy on Technology Studies, Austria.

Garmer, K., Liljegren, E., Osvalder, A.-L. and Dahlman, S. (2002b), "Arguing for the need of triangulation and iteration when designing medical equipment", *Journal of Clinical Monitoring and Computing*, Vol. 17, No. 2, pp. 105-14.

Green, A., Huttenrauch, H., Norman, M., Oestreicher, L. and Eklundh, K. S. (2000), "User centered design for intelligent service robots", in proceedings of 9th IEEE International Workshop on Robot and Human Interactive Communication, 27-29 Sept. 2000, pp. 161-66.

Handels, H., Rinast, E., Busch, C., Hahn, C., Kuhn, V., Miehe, J., Rossmanith, C., Seibert, F. and Will, A. (1997), "Image transfer and computer-supported cooperative diagnosis", *Journal of Telemedicine and Telecare*, Vol. 3, No. 2, pp. 103-7.

Hasu, M. (2000), "Constructing clinical use: an activity-theoretical perspective to implementing new technology", *Technology Analysis & Strategic Management*, Vol. 12, No. 3, pp. 369-82.

Hasu, M. and Engestrom, Y. (2000), "Measurement in action: an activity-theoretical perspective on producer-user interaction", *International Journal of Human-Computer Studies*, Vol. 53, No. 1, pp. 61-89.

Hummel, M., van Rossum, W., Omta, O., Verkerke, G. and Rakhorst, G. (2001), "Types and timing of inter-organizational communication in new product development", *Creativity and Innovation Management*, Vol. 10, No. 4, pp. 225-33.

Kittel, A., Marco, A. D. and Stewart, H. (2002), "Factors influencing the decision to abandon manual wheelchairs for three individuals with a spinal cord injury", *Disability and Rehabilitation,* Vol. 24, No. 1/2/3, pp. 106-14.

Lacey, G. and Slevin, F. (2001), "Putting the user at the centre of the design process", in abstracts of proceedings of International Conference on Technology and Aging, 12 – 14 Sept. 2001, Toronto, Ontario, Canada, pp. 65.

Lim, Y.-K. and Sato, K. (2001), "Development of design information framework for interactive systems design", in proceedings of 5th Asian International Symposium on Design Science, Seoul, Korea.

Miettinen, R. and Hasu, M. (2002), "Articulating user needs in collaborative design: towards an activity-theoretical approach", *Computer Supported Cooperative Work,* Vol. 11, No. 1-2, pp. 129-51.

Obradovich, J. H. and Woods, D. D. (1996), "Users as designers: how people cope with poor HCI design in computer-based medical devices", *Human Factors,* Vol. 38, No. 4, pp. 574-92.

Shaw, B. (1998), "Innovation and new product development in the UK medical equipment industry", *International Journal of Technology Management,* Vol. 15, No. 3/4/5, pp. 433-45.

Staccini, P., Joubert, M., Quaranta, J.-F., Fieschi, D. and Fieschi, M. (2001), "Modelling health care processes for eliciting user requirements: a way to link a quality paradigm and clinical information system design", *International Journal of Medical Informatics,* Vol. 64, No. 2-3, pp. 129-42.

Stickle, M. S., Ryan, S., Rigby, P. J. and Jutai, J. W. (2002), "Toward a comprehensive evaluation of the impact of electronic aids to daily living: evaluation of consumer satisfaction", *Disability and Rehabilitation,* Vol. 24, No. 1-3, pp. 115-25.

Woodside, A. G., Breaux, R. and E., B. (1998), "Testing care-giver acceptance of new syringe technologies", *International Journal of Technology Management,* Vol. 15, No. 3/4/5, pp. 446-57.

Table III. Methods used for capturing user perspectives by stages of the medical device lifecycle

Concept Stage	Design Stage	Tests and Trials Stages	Deployment Stage
Interviews	Interviews	Interviews	Interviews
Usability tests	Usability tests	Usability Tests	Usability tests
Questionnaire Surveys	Questionnaires surveys	Questionnaire surveys	Questionnaire surveys
User and producer seminars	User and producer seminars	User and producer seminars	User and producer seminars
Task analysis	Task analysis	Task analysis	Use experiment
Discussion	Discussion	Video recording	Video recording
Observations	Observations	Observations	Focus groups (Delphi method)
Simulations	Simulations	Simulations	
Users' feedback	Human factors approach	Human factors approach	
	Design sessions		

This article has been published in the International Journal of Health Care Quality Assurance. Year: 2006, Volume: 19, Issue: 6 Page: 500 - 515

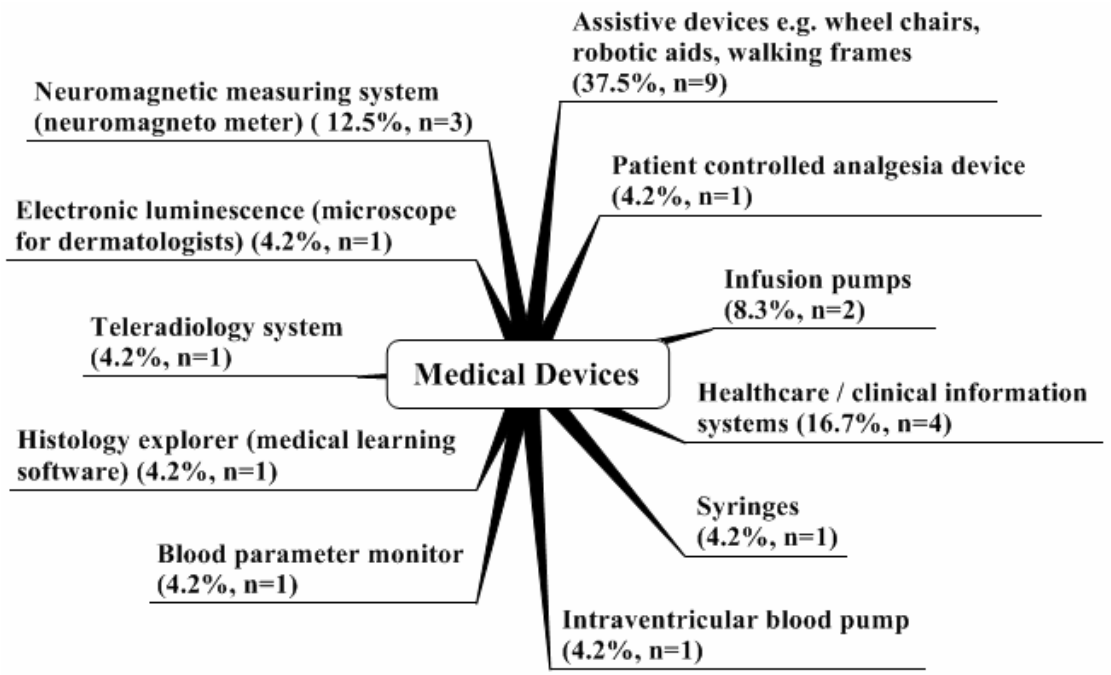

Figure 1. Types of medical devices developed and assessed by user involvement (% = frequency, n = number, total studies = 24)

This article has been published in the International Journal of Health Care Quality Assurance. Year: 2006, Volume: 19, Issue: 6 Page: 500 - 515

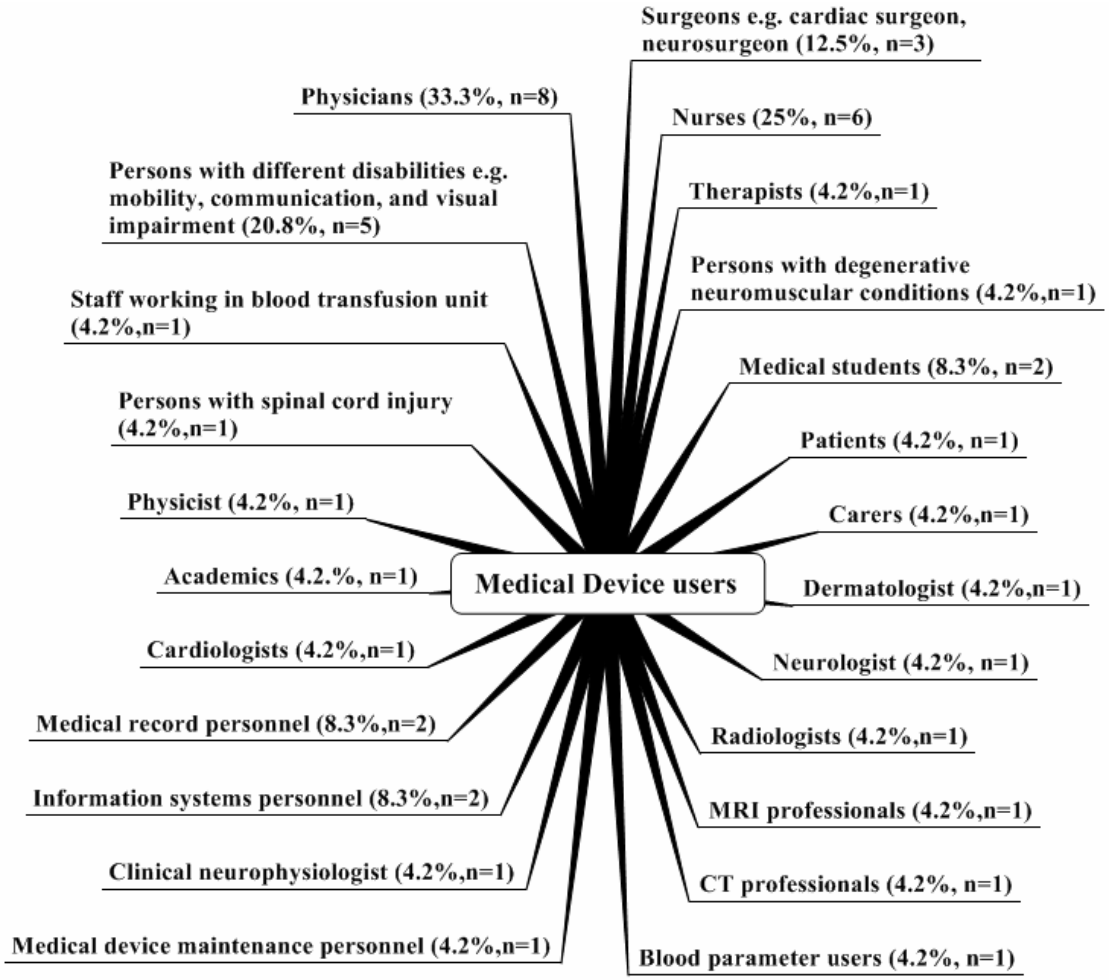

Figure 2. Types of medical device users involved in medical device development and assessment (% = frequency, n = number, total studies = 24)

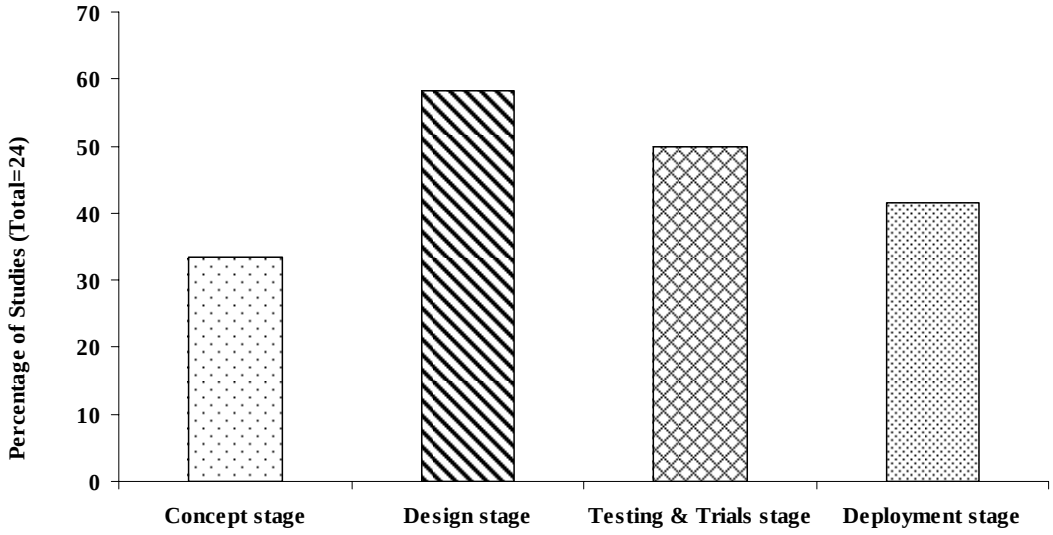

Figure 3. Extent of user involvement by stage of the medical device lifecycle