*This article has been published in the International Journal of Technology Assessment in Health Care. Year: 2007, Volume: 23, Issue: 1 Pages: 131- 137*

# Benefits of and barriers to involving users in medical device technology development and evaluation

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Short title:

## Benefits of and barriers to user involvement in MDTD&E

## ACKNOWLEDGMENTS

This work was carried out under the MATCH (Multidisciplinary Assessment of Technology Centre for Healthcare) programme, which is sponsored by the Engineering and Physical Sciences Research Council (EPSRC) Grant No. GR/S29874/01, although the views expressed are entirely those of the authors. The authors wish to thank MATCH colleagues especially Professor Terry Young, Brunel

University, for the invaluable comments on the manuscript. The authors are academic researchers and have no conflict of the interest in this work.

## ABSTRACT

**Objectives:** This study investigated the benefits of, and barriers to user involvement in medical device technology development and evaluation. **Methods:** A structured review of published literature in peer-reviewed journals. **Results:** This review revealed that the main benefits of user involvement were an increased access to user needs, experiences and ideas; improvements in medical device designs and user interfaces; and an increase in the functionality, usability and quality of the devices. On the other hand, resource issues, particularly those of time and money were found the key impediments to involving users in the development and evaluation of medical device technologies. This study has categorised both the benefits and barriers to user involvement also. **Conclusions:** The involvement of users in MDTD&E requires resources, which are limited; however, it is essential from both users and manufacturers perspectives.

**Keywords:** User, Medical devices, User involvement, Benefits and barriers, Development and evaluation, Assistive devices, Healthcare technology

## INTRODUCTION

Users of medical devices are involved in the development and evaluation of medical device technology due to their potentially vital role in the innovation, development, assessment, implementation and dissemination of the technology (1;3). Engagement with the users is also now required under medical device regulations (66). However,

such engagement is also associated with benefits and costs (20) that may encourage or discourage involvement of users in the development and evaluation of a particular technology. Therefore, this paper attempts to investigate the benefits of and barriers to the involvement of users in medical device technology development and evaluation (MDTD&E) and to identify the policy implications.

## METHODS

This paper is based on a review of carefully selected social science literature i.e. twenty-five studies that reported involvement of users in the development and evaluation of medical device technologies. The studies were identified through a rigorous and structured review of studies of user involvement in the medical device technology lifecycle published in peer-reviewed journals from 1980 to 2005, but in the English language.

The online bibliographic databases searched were Blackwell synergy, EBSCOhost, Emerald, International Bibliography of the Social Sciences, Inderscience, InfoTrac, Ingenta, JSTOR, Medical device link, ProQuest, Sage, ScienceDirect, Social Science Information Gateway (Sosig), SpringerLink and Taylor & Francis.

The studies were reviewed twice. During the first review, which took place from January 2004 to May 2005, information regarding types of methods, medical devices, the possible involvement of users, and the stages of the technology development cycle used, was extracted, which is reported elsewhere (71). The second review was conducted between September 2005 and February 2006 specifically to investigate the benefits of and barriers to the involvement of users in MDTD&E. The justification for re-reviewing the studies with this emphasis was that the earlier review

neither investigated nor reported the reasons for involvement or non-involvement of users in the medical device lifecycle.

The precise objectives of the second review were to find out answers to the following questions. Why were the users involved in MDTD&E? What were the factors that either encouraged or discouraged the involvement of users in MDTD&E? What are the policy implications of involving users in MDTD&E?

In this paper, medical device technologies are taken to include all medical devices and assistive technology devices as defined by the Global Harmonization Task Force (81) and the US legislation (27) respectively.

## RESULTS AND DISCUSSION

This literature review found that user involvement in MDD&E was reported in several studies (2;4;6;8;9;13;22-24;31-33;35;36;38;48-50;55;57;61;70;73;74;80). However, the number of the studies reporting involvement of users in MDTD&E, the main criterion for inclusion, was low. This may be because of confidentiality issues, especially in relation to commercially sensitive developments, or more probably because of the limited and non-standardised practice of the user involvement in MDTD&E over recent years.

Detailed analysis in this review reveals some of the key issues in relation to the benefits of and barriers to user involvement in MDTD&E presented in tables 1 and 2 respectively, and discussed in the following sections.

## Benefits of User Involvement

This literature review has shown that the major benefits of user involvement in MDTD&E include beneficial access to user ideas and perspectives, and improvement in the design, user interface, functionality, usability and quality of medical devices.

***Beneficial Access to User Perspectives.*** The development and evaluation of medical device technologies from users' perspectives, almost by definition, requires the involvement of users themselves (22) because users generate ideas for both new (11) and innovative (65;68;79) products; they indicate conceptual deficiencies and potential problems in current and future products; and suggest appropriate changes and solutions to the problems which those products are seen to pose (28;64;75). In addition, engagement with users helps in the elicitation of targeted user needs, opinions, expectations and experiences which may well be critical to both the short and long term deployment of the product (22;51). In particular the involvement of users is important at each stage of the product development cycle (8) to capitalise in a cumulative way on their contributions and thus to maximise their effect. However, it is more meaningful and crucial for the nature and direction of the product if users are involved in the early stages, such as concept and idea generation , as well as design (re)development , and prototype testing and trials stage, rather than only or mainly in the late stages of the product lifecycle (67).

***Lead-Users' Contributions.*** Amongst the user communities of any technology, the lead users, as defined by von Hippel (77), contribute significantly to the technology development and evaluation process (34;47;63;76;77). 'Lead users' provide information about major users' needs vis-à-vis new products as well as

recommending solutions to those needs at an early stage (76). In addition they can generate and make explicit key issues regarding the conceptualisation of new products, and product innovation (56) in less time and at less cost than the traditional ways in which this is usually accomplished (34). Of special value they also suggest improvements in user interfaces (22); propose solutions to product problems (17) and contribute to the early adoption (56) and early diffusion of products (76). There is also evidence that the identification of lead users' needs results in the development of 'breakthrough' new products, for example surgical drapes (78), surgical hygiene products (52), radically new X-ray systems and new biocompatible implants (45). Additionally, the literature shows that lead users' ideas are associated with highest value of intellectual property compared to the ideas generated by 'ordinary' – later - users (47).

**"Take in Table 1"**

***User and Producer Interaction.*** The development of technologies that fulfil user needs and expectations requires, in practice, in depth information about the users of technologies (7), which among other things requires engagement and communication with them. Although this may appear an extremely self-evident point, it has often been the case that such data has been extrapolated from general principles rather than researched, as it should be, empirically in each case. Communication and collaboration between users and manufacturers needs to be direct particularly in the case of improvement of existing devices and development or innovation of complex and specialised equipment (30;62), where general extrapolations to 'user needs' are of limited value. The evidence also shows that the direct and active interaction and cooperation between users and producers enhances quality (10;41), functionality,

usability, design (43), as well as effectiveness (44), and the adoption of medical device technologies (69). For example, improvements in key aspects of a ventilator (24) and the development of a innovative but complex medical device such as a neuromagnetometer (32;33;55) showed how the involvement of users was critical.

***Operational and Strategic Gains.*** This review has found that the involvement of users in the product development process helpfully reduces subsequent development costs (42;67;68) and just as important time over run (67); it determines product success and failure in many cases (25;26;29;46;72) and generally increases the value of new products (68). In addition, users play an important role in the implementation of new medical device technologies, and their integration in existing structures, such as the involvement of clinicians and medical laboratory staff in the implementation and integration of patient based record systems in relation to the wide range of tests carried out in microbiology and pathology laboratories (54).

***Regulatory Controls.*** Another advantage of involving users in MDTD&E is the fulfilment of regulatory requirements, which require user participation and user focused development of medical device technologies (14;66). This is not just in terms of a ritual fulfilment of basic statutory requirements, but in practice in ensuring a more effective set of ways in which those requirements can be innovatively met.

Thus, involvement of users in MDTD&E is rewarding (8). It helps in embedding user perspectives in medical device technologies to the benefit of users (51) as well as bringing benefits to the manufacturer through the development of successful products, thereby attract higher sales and profits (39;40;59). On the contrary, non-involvement of users in MDTD&E may lead to the development of user

interfaces that may have significant problems. For example usability problems may arise that may lead to safety issues such as occurrence of errors which would otherwise be corrected (22;24), but, without this mechanism of control, that can create unwanted and expensive consequences. In addition, there is a likelihood that such devices might be rejected by their users since they fail to meet their needs and skills, which in the worst case will lead to the financial lack of viability of the product (21).

## Barriers to User Involvement

This literature review has revealed that the key barriers to user involvement in MDTD&E are the demands thus generated for extra resources, mainly in terms of time and money involved and their relationship to the user characteristics, availability, cooperation, preparation and motivation, in the context of any given product.

***Resources.*** The most important requirement for involving users in MTD&E is the availability of resources i.e. time, money and labour, which are the most critical factors for manufacturers (5;10;24). There is of course no guarantee that the out-come of any user involvement will be positive (5;10;18). Findings from this literature review show that it is quite possible that user involvement in any product development cycle is cost effective (42); however, this involvement is also very time consuming (37;42) and the possibility of time over runs thus implied can not be afforded by every manufacturer on every occasion. Therefore, resources are one of the major constraints to user involvement in MDTD&E. However, it must be stressed that user involvement is, from this study, almost always of great value in creating a valuable and marketable product, and thus time over runs have to be set against the broader value of the process. It may also be the case that in more regularly

incorporating the direct assessment of user needs into the process of product development, a more economical and less problematic process will result.

***User Characteristics.*** This literature review has identified that users' availability (15;16;53), preparation, training and support (22), cooperation (41;60) and characteristics (8;16) are also critical factors in involving them effectively in the product development and evaluation process. For example, involvement of some types of users of medical device technologies such as the elderly and persons with certain types of disabilities (53) as well as some categories of clinicians could be difficult (15;16) because of their non-availability owing to their personal or professional circumstances. In such cases, it is worth considering, even as only a temporary expedient, the best possible, and available, surrogates of the particular medical device users, in the process of MDTD&E. For example it is possible to involve others as representatives (surrogates) instead of less available physicians working in emergency departments in the development and evaluation of patient healthcare information systems (15;16). Some of the users of medical device technologies such as persons with disabilities, the elderly, and other kinds of patients may require additional encouragement and assistance to take part in MDTD&E. Furthermore, the extent of user involvement in MDTD&E also depends on the type of the medical device technology concerned (8).

***Strategic Considerations.*** This review has found that it is not possible for some potential users to contribute adequately in development and evaluation of specific medical device technologies particularly the more complex technologies (57) because they might not possess sufficient technological knowledge and understanding

about products based on such technologies (46). This point should act as a warning to manufacturers that they should not expect solutions to complex technical problems from such users, concerning medical device technologies, particularly those of a novel nature. However, engagement with such users may be useful for the purpose of identification and clarification of user requirements and experiences, as well as in relation to vital features of the products (46). However , despite the general value of user involvement, it was found that such involvement does not provide any certainty that the products or technologies so developed will be always successful (5;10), or be perfect and function smoothly (18). This might be a deterrent for some of manufacturers to engage with users for the purpose of MDTD&E, although it must be noted that the certainty of success is not warranted by most other factors in the device development process.

**"Take in Table 2"**

***User-Producer Interaction.*** Overall the review has found unsurprisingly that cooperation between users and producers is essential for successful elicitation of user needs and knowledge (60). However, the interaction between users and producers in the manufacturing sector including medical device manufacturing processes may not be always as expected (12). Thus, the particular nature of the relationship between users and manufacturers can be an impediment on occasion to the type and effectiveness of user involvement in MDTD&E.

***Manufacturer's Attitudes.*** The involvement of users in the technology development and evaluation process depends not only on users themselves but also on the manufacturer's willingness to listen to them and integrate their input into the

technology development cycle. Therefore, the culture within the manufacturing organisation particularly the attitudes of product development personnel may affect the involvement of users in MDTD&E because they may regard the idea of user involvement overall as less valuable and unnecessary (37); thus, they may therefore oppose it (63). In this case, medical device technology manufacturers can be argued to need a cultural shift in attitudes (37) so that there is encouragement of user participation in the technology development and evaluation process (58). On the other hand, whilst it is possible that manufacturers are more than willing to employ user input into MDTD&E; however, the processes required for incorporating such user perspectives within in the technology development cycle are limited or ineffective (19). For example, methodologies that are reliable, robust, fast and cheap need to be identified developed and/or modified in order to facilitate the user involvement.

***Regulatory Controls.*** Other factors that can limit involvement of users in MDTD&E may include stringent regulatory controls and ethical approvals concerning the involvement of users. These may inhibit or prevent the easy incorporation of users in various stages of device development.

## LIMITATIONS AND FUTURE RESEARCH

### Limitations

The findings of this literature review are indicative rather than comprehensive since it is mainly based on social sciences literature. The inclusion of broader literature in the engineering and medical fields might have been useful, although the authors have found that there is generally limited published data in these fields on the issues they

have raised here. Another limitation of the literature, which echoes findings in other areas, is that that there is a general non-availability of the literature that reports about unsuccessful user involvement in MDTD&E.

### Future Research

Future research could with profit explore methodologies that reduce costs and time associated with user involvement in medical device technology development and evaluation.

## CONCLUSIONS

This literature review has revealed that the involvement of users in the development and assessment of medical device technologies is associated with significant benefits such as the generation of ideas by users, an improvement in device designs and user interfaces, much improvement in the functionality, usability and quality of medical devices, as well as access to and knowledge about user perspectives vis-à-vis medical device technologies. This review has also shown that the key barriers in involving users in MDTD&E are non-availability of key users, for various reasons, and the time and costs involved in the user involvement.

Involvement of users in MDTD&E therefore whilst requiring time, money and energy of both users and manufacturers, nevertheless brings benefits for both of these two major stakeholders of medical device technologies. Through involvement, users can get medical device technologies that fulfil their needs and expectations, which are likely to increase demand for such devices, whilst on the other hand manufacturers can receive financial gains owing to higher sales of the devices.

## POLICY IMPLICATIONS

In recent years, the role of users in the development of any product has been seen as of vital significance for the long-term viability of products and their subsequent development, it has been recognised that a key role is that of the consumer. However, the involvement of users in MDTD&E is either limited or underreported in the published literature. This underreporting could be due to either commercial confidentiality or a failure to get desired outcomes, or indeed a failure to recognise the importance of users as a whole. In addition, the limited practice of involving users could be due to financial and time constraints, which manufacturers face, as well as a tradition of discretionary involvement of users in the MDTD&E process. This in general could be due to the variable recognition and subsequently poor institutionalisation of user involvement. Therefore, user involvement needs proper integration in the development of medical device technology as the consumer role in many aspects of manufacturing and production has become decidedly more robust. It would be unwise to allow the more haphazard status of such involvement to continue in the form that it has been undertaken in the past. This may however need formalisation through the integration of user involvement in the health technology assessment (HTA) process requiring approval from both regulators and manufacturers.

## REFERENCES

1. Bairstow PJ, Mendelson R, Dhillon R, Valton F. Diagnostic imaging pathways: Development, dissemination, implementation, and evaluation. *Int J Qual Health Care*. 2006;18:51-57.

2. Batavia AI, Hammer GS. Toward the development of consumer-based criteria for the evaluation of assistive devices. *J Rehabil Res Dev*. 1990;27:425-436.

3. Bobrowski PE, Wilemon D. Restructuring to achieve integration in the medical technology development process. In: Proceedings of Managing in a Global Environment - IEEE International Engineering Management Conference. Eatontown, NJ, USA. Oct. 25-28,1992;67-70.

4. Bray DD. Creative collaboration: User-centered design in practice. *MD&DI*. 2000:76-89.

5. Brockhoff K. Customers' perspectives of involvement in new product development. *Int J Technol Manage*. 2003;26:464-481.

6. Brooks NA. User's responses to assistive devices for physical disability. *Soc Sci Med*. 1991;32:1417-1424.

7. Buckley KM, Tran BQ, Prandoni CM, Clark HM. Training future providers in home care and telehealth technologies: A collaborative effort between nursing and biomedical engineering. *Home Health Care Manag Pract*. 2002;14:362-371.

8. Buhler C. Approach to the analysis of user requirements in assistive technology. *Int J Ind Ergon*. 1996;17:187-192.

9. Buhler C, Hoelper R, Hoyer H, Humann W. Autonomous robot technology for advanced wheelchair and robotic aids for people with disabilities. *Robot Auton Syst*. 1995;14:213-222.

10. Campbell AJ, Cooper RG. Do customer partnerships improve new product success rates? *Ind Market Manag*. 1999;28:507-519.

11. Conway HA, McGuinness NW. Idea generation in technology-based firms. *J Prod Innov Manage*. 1986;3:276-291.

12. Conway S. *The role of users in the innovation process*. Doctoral Working Paper Series, No 10 (NS). Aston Business School, Birmingham, UK; 1993.

13. Craig J, Russell C, Patterson V, Wootton R. User satisfaction with realtime teleneurology. *J Telemed Telecare*. 1999;5:237-241.

14. Craven MP, Martin JL. How does the healthcare industry involve users in medical device development? - Pointers for UbiHealth. Paper presented at UbiHealth 2004: The 3rd International Workshop on Ubiquitous Computing for Pervasive Healthcare Applications. Nottingham, England. Sept. 6-7,2004.

15. De P, Ferratt TW. An information system involving competing organizations. *Commun ACM*. 1998;41:90-98.

16. De P, Ferratt TW. 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. Boston, MA, USA. March 26-28,1998;214-223.

17. Deslandres V, Pierreval H. Knowledge acquisition issues in the design of decision support systems in quality control. *Eur J Oper Res*. 1997;103:296-311.

18. Franz CR, Robey D. An investigation of user-led system design: Rational and political perspectives. *Commun ACM*. 1984;27:1202-1209.

19. Fundin AP, Bergman BLS. Exploring the customer feedback process. *Measur Bus Excell*. 2003;7:55-65.

20. Gales L, Mansour-Cole D. User involvement in innovation projects: Toward an information processing model. *J Eng Technol Manage*. 1995;12:77-109.

21. Gallivan MJ, Keil M. The user-developer communication process: A critical case study. *Inf Syst J*. 2003;13:37-68.

22. Garmer K, Liljegren E, Osvalder A-L, Dahlman S. 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. *Int J Ind Ergon*. 2002;29:145-159.

23. Garmer K, Liljegren E, Osvalder A-L, Dahlman S. Arguing for the need of triangulation and iteration when designing medical equipment. *J Clin Monitor Comp*. 2002;17:105-114.

24. Garmer K, Ylven J, MariAnne Karlsson IC. User participation in requirements elicitation comparing focus group interviews and usability tests for eliciting usability requirements for medical equipment: A case study. *Int J Ind Ergon*. 2004;33:85-98.

25. Gemunden HG, Ritter T, Heydebreck P. Network configuration and innovation success: An empirical analysis in German high-tech industries. *Int J Res Mark*. 1996;13:449-462.

26. Glen JMW, Lord M. New product development processes within the UK medical device industry. *Med Eng Phys*. 1996;18:670-676.

27. Government of USA. Assistive Technology Act of 1998. Public Law 105–394. Vol. 112 STAT.; Nov. 13, 1998;3627-3662.

28. Gronbaek K, Kyng M, Mogensen P. CSCW challenges: Cooperative design in engineering projects. *Commun ACM*. 1993;36:67-77.

29. Gruner KE, Homburg C. Does customer interaction enhance new product success? *J Bus Res*. 2000;49:1-14.

30. Habermeier KF. Product use and product improvement. *Res Policy*. 1990;19:271-283.

31. Handels H, Rinast E, Busch C, et al. Image transfer and computer-supported cooperative diagnosis. *J Telemed Telecare*. 1997;3:103-107.

32. Hasu M. Constructing clinical use: An activity-theoretical perspective to implementing new technology. *Technol Anal Strateg Manage*. 2000;12:369-382.

33. Hasu M, Engestrom Y. Measurement in action: An activity-theoretical perspective on producer-user interaction. *Int J Hum-Comput Stud*. 2000;53:61-89.

34. Herstatt C, von Hippel E. From experience: Developing new product concepts via the lead user method: A case study in a "low-tech" field. *J Prod Innov Manage*. 1992;9:213-221.

35. Hummel M, van Rossum W, Omta O, et al. Types and timing of inter-organizational communication in new product development. *Creativ Innovat Manag*. 2001;10:225-233.

36. Hummel MJM, Rossum Wv, Verkerke GJ, Rakhorst G. Product design planning with the analytic hierarchy process in inter-organizational networks. *R&D Manage*. 2002;32:451-458.

37. Kauppinen M, Kujala S, Aaltio T, Lehtola L. Introducing requirements engineering: How to make a cultural change happen in practice. In: Proceedings of the IEEE Joint International Conference on Requirements Engineering. Sept. 9-13,2002;43-51.

38. Kittel A, Marco AD, Stewart H. Factors influencing the decision to abandon manual wheelchairs for three individuals with a spinal cord injury. *Disabil Rehabil*. 2002;24:106-114.

39. Kristensson P, Gustafsson A, Archer T. Harnessing the creative potential among users. *J Prod Innov Manage*. 2004;21:4-14.

40. Kristensson P, Magnusson PR, Matthing J. Users as a hidden resource for creativity: Finding from an experimental study on user involvement. *Creativ Innovat Manag*. 2002;11:55-61.

41. Kyng M. Designing for cooperation: Cooperating in design. *Commun ACM*. 1991;34:65-73.

42. LaBahn DW, Ali A, Krapfel R. New product development cycle time: The influence of project and process factors in small manufacturing companies. *J Bus Res*. 1996;36:179-188.

43. Lacey G, Slevin F. Putting the user at the centre of the design process. In: Abstracts of the proceedings of International Conference on Technology and Aging. Toronto, ON., Canada. Sept. 12-14,2001;65.

44. Lasky FD, Boser RB. Designing in quality through design control: A manufacturer's perspective. *Clin Chem*. 1997;43:866-872.

45. Lettl C, Gemunden HG. The entrepreneurial role of innovative users. *J Bus Ind Market*. 2005;20:339-346.

46. Lichter H, Schneider-Hufschmidt M, Zullighoven H. Prototyping in industrial software projects-bridging the gap between theory and practice. *IEEE Trans Softw Eng*. 1994;20:825-832.

47. Lilien GL, Morrison PD, Searls K, et al. Performance assessment of the lead user idea-generation process for new product development. *Manage Sci*. 2002;48:1042-1059.

48. Liljegren E, Osvalder A-L. Cognitive engineering methods as usability evaluation tools for medical equipment. *Int J Ind Ergon*. 2004;34:49-62.

49. Lin L, Isla R, Doniz K, et al. Applying human factors to the design of medical equipment: Patient-controlled analgesia. *J Clin Monitor Comp*. 1998;14:253-263.

50. Lin L, Vicente KJ, Doyle DJ. Patient safety, potential adverse drug events, and medical device design: A human factors engineering approach. *J Biomed Inform*. 2001;34:274-284.

51. Luck R. Dialogue in participatory design. *Design Stud*. 2003;24:523-535.

52. Luthje C. Customers as co-inventors: An empirical analysis of the antecedents of customer-driven innovations in the field of medical equipment. Paper presented at 32nd European Marketing Academy Conference (EMAC). Glasgow, UK. May 20-23,2003.

53. Marshall R, Case K, Oliver R, et al. A task based 'design for all' support tool. *Robot Comput -Integr Manuf*. 2002;18:297-303.

54. McLaughlin J, Skinner D. Developing usability and utility: A comparative study of the user of new IT. *Technol Anal Strateg Manage*. 2000;12:413-423.

55. Miettinen R, Hasu M. Articulating user needs in collaborative design: Towards an activity-theoretical approach. *CSCW*. 2002;11:129-151.

56. Morrison PD, Roberts JH, Midgley DF. The nature of lead users and measurement of leading edge status. *Res Policy*. 2004;33:351-362.

57. Mulholland SJ, Packer TL, Laschinger SJ, et al. Evaluating a new mobility device: Feedback from women with disabilities in India. *Disabil Rehabil*. 2000;22:111-122.

58. Neale MR, Corkindale DR. Co-developing products: Involving customers earlier and more deeply. *Long Range Plann*. 1998;31:418-425.

59. Nijssen EJ, Biemans WG, de Kort JF. Involving purchasing in new product development. *R&D Manage*. 2002;32:281-289.

60. Noyes JM, Starr AF. Working with users in system development: Some methodological considerations. Integrating HCI in the Lifecycle, IEE Colloquium on. April 11,1995;7/1-7/3.

61. Obradovich JH, Woods DD. Users as designers: How people cope with poor HCI design in computer-based medical devices. *Hum Factors*. 1996;38:574-592.

62. Ogawa S. Does sticky information affect the locus of innovation? Evidence from the Japanese convenience-store industry. *Res Policy*. 1998;26:777-790.

63. Olson EL, Bakke G. Implementing the lead user method in a high technology firm: A longitudinal study of intentions versus actions. *J Prod Innov Manage*. 2001;18:388-395.

64. Ornetzeder M. Assessing technology from the users' perspective. Possibilities and limitations of focus group discussions illustrated by ecological housing construction. In: Proceedings of Technological Studies: User Involvement in Technological Innovation, International Summer Academy. Deutschlandsberg, Austria. July 8-13,2001;155-166.

65. Ornetzeder M, Rohracher H. User-led innovations and participation processes: Lessons from sustainable energy technologies. *Energ Policy*. 2006;34:138-150.

66. Powers DM, Greenberg N. Development and use of analytical quality specifications in the in vitro diagnostics medical device industry. *Scand J Clin Lab Invest*. 1999;59:539-543.

67. Rauterberg M, Strohm O, Kirsch C. Benefits of user-oriented software development based on an iterative cyclic process model for simultaneous engineering. *Int J Ind Ergon*. 1995;16:391-409.

68. Ritter T, Walter A. Relationship-specific antecedents of customer involvement in new product development. *Int J Technol Manage*. 2003;26:482-501.

69. Rohracher H. The role of users in the social shaping of environmental technologies. *Innovat Eur J Soc Sci Res*. 2003;16:177-192.

70. Samuelsson K, Larsson H, Thyberg M, Gerdle B. Wheelchair seating intervention. Results from client-centered approach. *Disabil Rehabil*. 2001;23:677-682.

71. Shah SGS, Robinson I. User involvement in healthcare technology development and assessment: Structured literature review. *Int J Health Care Qual Assur*. 2006;19:500-515.

72. Shaw B. The role of the interaction between the user and the manufacturer in medical equipment industry. *R&D Manage*. 1985;15:283-292.

73. Shaw B. Innovation and new product development in the UK medical equipment industry. *Int J Technol Manage*. 1998;15:433-445.

74. Stickle MS, Ryan S, Rigby PJ, Jutai JW. Toward a comprehensive evaluation of the impact of electronic aids to daily living: Evaluation of consumer satisfaction. *Disabil Rehabil*. 2002;24:115-125.

75. Tsai W-T, Mojdehbakhsh R, Rayadurgam S. Experience in capturing requirements for safety-critical medical devices in an industrial environment. In: Proceedings of 2nd IEEE High-Assurance Systems Engineering Workshop. Washington, DC. Aug.11-12,1997;32-36.

76. Urban GL, von Hippel E. Lead user analyses for the development of new industrial products. *Manage Sci*. 1988;34:569-582.

77. von Hippel E. Lead users: A source of novel product concepts. *Manage Sci*. 1986;32:791-805.

78. von Hippel E, Thomke S, Sonnack M. Creating breakthroughs at 3M8. *Harv Bus Rev*. 1999:47-57.

79. Voss CA. The role of users in the development of applications software. *J Prod Innov Manage*. 1985;2:113-121.

80. Woodside AG, Breaux R, Briguglio E. Testing care-giver acceptance of new syringe technologies. *Int J Technol Manage*. 1998;15:446-457.

81. World Health Organization (WHO). *Medical device regulations: Global overview and guiding principles*. Geneva: WHO; 2003.

**Table 1.** Benefits of user involvement in medical device technology development and evaluation

| Category | Benefits | References |
|---|---|---|
| Strategic | Source of idea generation for new products, product innovation and high intellectual property potential | (33;35) |
| Operational | Reduction in development costs e.g. costs incurred on redesigns | (8) |
| Product | Improvement of user interface | (22;49) |
| | Identification of conceptual deficiencies and potential problems and suggestion of appropriate changes | (4;8;48;61) |
| | Improvement in the functionality, effectiveness, usability and design | (9;22;23;36;49;50;57) |
| | Improvement in the quality and execution | (24) |
| User | Access to user perspectives e.g. user needs, knowledge, expectations, problems, experiences, perceptions, attitudes, satisfaction, rejection and acceptance vis-à-vis medical device technologies | (2;6;13;22;36;38;55;57;70;74;80) |

**Table 2.** Barriers to user involvement in medical device technology development and evaluation

| Category | Barriers | References |
|---|---|---|
| Operational | Resources particularly the time and money | (8;24) |
| User | Characteristics of users | (8) |
| | User support, preparation and training | (22) |