

Developing medical device technologies from users' perspectives: A theoretical framework for involving users in the development process

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ABSTRACT

Objectives: To suggest an acceptable and generic theoretical framework for involving various types of users in the medical device technology (MDT) development process (MDTDP).

Methods: The authors propose a theoretical framework suggesting different routes, methods and stages through which various types of medical device users can be involved in the MDTDP.

Results: The suggested framework comprises two streams of users' involvement in MDT development i.e. what might be called the end users' stream and the professional users' stream for involving these two groups respectively in the process of developing both simple and more complex and innovative medical devices from conceptualisation through to the market deployment. This framework implies various methods that can be used for users' involvement at different stages of the MDT lifecycle. To illustrate the application of the framework, a number of MDT development scenarios and device exemplars are presented.

Conclusions: Development of medical devices from users' perspectives requires not only the involvement of healthcare professionals but also that of the ultimate end users i.e. patients, people with disabilities and/or special needs, and their caregivers. The evidence shows that such end users quickly discard devices that do not fulfil their personal expectations, even though both manufacturers and healthcare professionals may consider those end users' requirements met. Developers and manufacturers need to recognise this potent potential discrepancy between the parties involved, and involve end users and professional healthcare staff directly in the MDTDP. The framework, the authors contend, is a step forward in helping medical device manufacturers plan and make decisions about users' involvement at different stages of the MDTDP.

Keywords: User involvement, Device development process, Medical device technology assessment, User perspective, Conceptual framework.

INTRODUCTION

Medical device technologies (MDTs) include medical devices and assistive devices (35), which have been defined elsewhere(14;38). There are a range of, often competing perspectives, concerning MDT such as regulators' perspectives, manufacturers' perspectives and users' perspectives. All these perspectives are important to assess and synthesize, but users' perspectives is particularly important for the success of a device. Users of MDTs are not homogeneous as they are often implicitly considered to be, but are constituted by different types and groups of people such as healthcare professionals, carers and end users e.g. patients, people with disabilities and/or special needs and elderly people, with different roles and interests (35). Involvement of the users is essential because they expect that the medical device that is supplied to them, or that they buy and use, fulfills their personal needs and requirements, which may indeed vary from one user to another, especially in the case of end users. The most effective way of developing MDTs from users' perspective therefore can be done by involving the healthcare professionals as well as the end users. For devices that are intended for the use by end users, views of and acceptance by end users is crucial to the device's role and longevity, no matter how well the device is manufactured, and how strongly it is recommended by healthcare professionals.

There is published evidence that end users' involvement in the MDT development process (MDTDP) is associated with several substantial advantages for manufacturers. For example, the generation of ideas for new products and product

innovation; access to users' actual requirements and expectations; a reduction in development costs; an improvement in device design, usability and safety; and the identification of potential problems at an early stage of the device development cycle, thus limiting costly device modifications and a reduction in device recalls (25;34).

Manufacturers therefore need to engage with the range of users of MDTs and involve them, as early as possible, in the development process (12).

Up to now evidence on users' involvement in the MDTDP is clearly focused on the views of healthcare professionals, particularly clinicians and nurses, while other types of MDT users, especially end users, such as patients, people with disabilities and/or special needs, elderly people and carers, particularly lay carers, are less likely to be involved in the process (4;11, p.173;25;33). The apparently minimal involvement of the end users (who we also call as non-healthcare professional users), can be for various reasons including their personal characteristics and a need for supporting, preparing and training them to enable their involvement in the MDTDP (34).

According to Andre et al (2), user involvement depends and/or is facilitated by the availability of an appropriate framework. In relation to MDT, a number of frameworks have been used. For example, the technology transfer model (36); the economic evaluation in health technology assessment (32); a framework for the development and evaluation of randomised controlled trials (8;26); a model of user engagement in medical device development (15), and the integration of a Bayesian framework in the medical device development cycle (37). However, no universal and formal framework for the involvement of users, especially end users, in the process of MDT manufacturing from concept development through to the market deployment has been reported in the literature (4;25;33). In the absence of an acceptable and proper framework, a meaningful users' involvement cannot occur systematically across the

medical device sector but it will take place haphazardly. This has had, and is likely to have, negative repercussions for both manufacturers and users of MDTs, for example the continuous abandonment of the devices by their users (3). There is therefore a need for an acceptable and generic framework for involving various types of users in the MDTDP. The authors therefore propose such a framework in this paper. However, before presenting our conceptual framework, we briefly describe some key concepts, i.e. stages of MDT development cycle, methods of involving users and types of MDT users, on which the framework is based.

Stages in MDT Lifecycle Relevant for Involving Users

The lifecycle of a medical device can be divided into several stages, over which there is some debate. Cooper and Kleinschmidt (9) described 13 stages in the lifecycle of a medical device, which were modified to 12 stages by Rochford and Rudelius (31). Elsewhere, seven stages of the medical device lifecycle have been mentioned (38). Shah and Robinson (33) reviewed the different stages of medical device lifecycle reported in a wide range of analyses and determined that the various stages of the medical device lifecycle can be placed into five key phases:

Stages of the Medical Device Lifecycle

- Concept stage (idea generation and concept development)
- Design stage (device (re-)design and prototype development)
- Testing and trials stage (prototype testing in-house and trials in the real field)
- Production stage (device production based on business and commercial rational)
- Deployment stage (product launch and use in the market and post-deployment user feedback)

Literature shows that users can be involved at four stages, i.e. concept, design, testing and trials, and deployment stages, of the above-mentioned five stages (33). We therefore suggest these four stages can best be used to develop our theoretical framework for involving users in MDTDP (Figure 1).

Methods for Involving Users

Recent published work suggests several methods that have been used for involving different types of users in the MDTDP (4;25;33). For example, interviews, focus groups, usability tests, customer feedback, cognitive walkthrough, cognitive task analysis, users and producers seminars and field observation methods used for involving the end users, such as patients, people with disabilities and/or special needs and lay carers, and the professional users, e.g., physicians, general practitioners, surgeons, nurses, cardiologists, radiologists, MRI professionals and physicists) in the development process of different types of MDTs. For instance, an inhaler (1), assistive devices such as robotic aids, wheel chairs, wheeled mobility devices (3;6;7;20;28), ventilators (13), teleradiology system (16), neuromagnetometer (17;27), intraventricular blood pump (18), telemedicine system (19), patient monitoring system (22), patient-controlled analgesia pump (23), and infusion pumps (12;29;39).

In our theoretical framework, we will be suggesting that many of the methods mentioned above can be successfully and directly deployed in relation to the involvement of the professional users and the end users at four different stages of the MDT lifecycle (Figure 1).

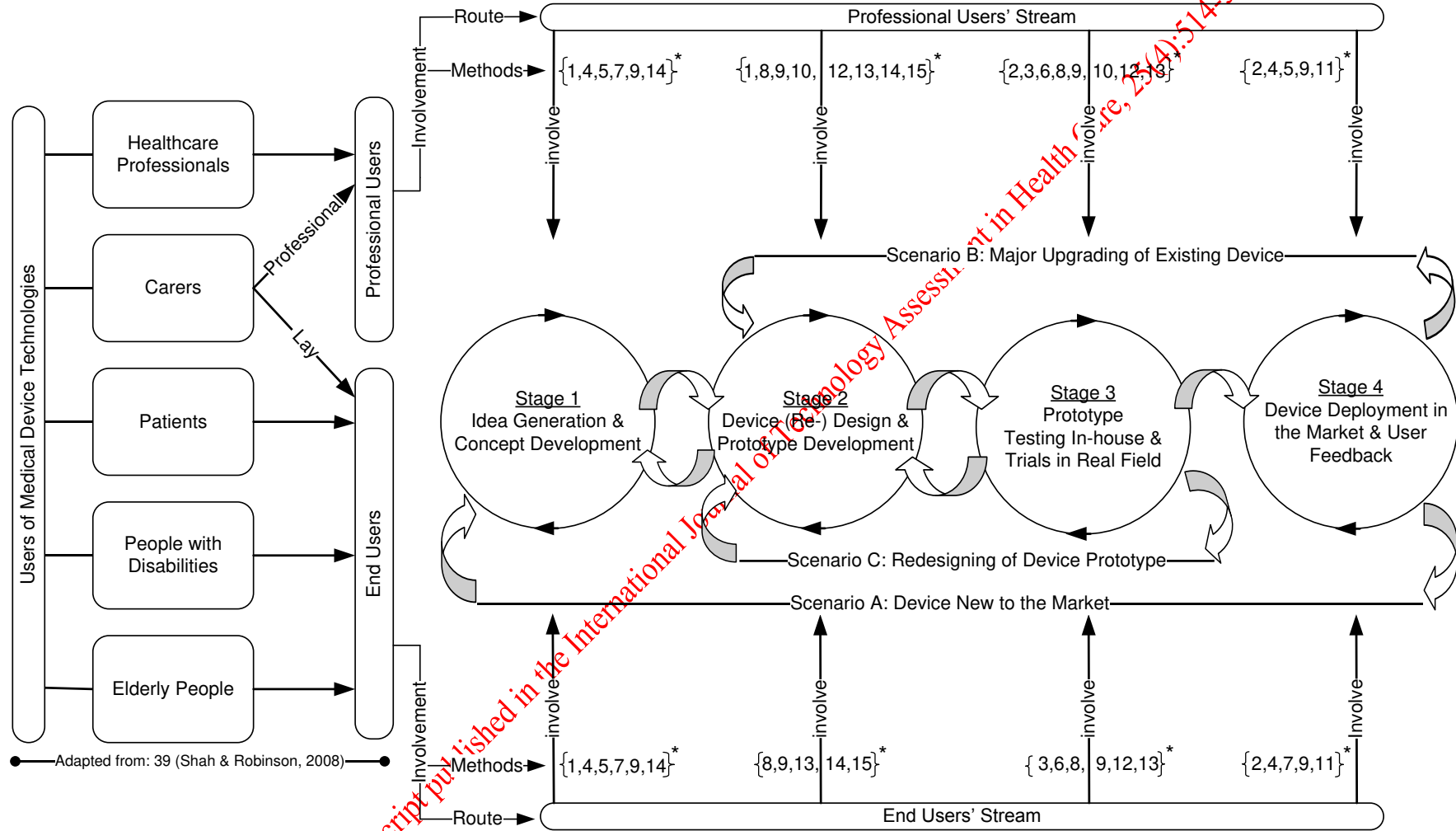


Figure 1. Theoretical framework for involving users in the medical device technology development process: streams, methods and stages

Users of Medical Device Technologies

Primary users of medical devices can be divided, based on their professional and personal traits, into different groups, such as healthcare professionals, patients, people with disabilities and/or special needs, elderly people and carers i.e. professional and lay carers (35). In addition, Shah and Robinson (35) are of the opinion that professional people use the devices for the benefit of patients, people with disabilities and/or special needs and elderly people – whom they describe collectively as ‘end users’.

In order to clarify further the term ‘user’ here, which often in practice has led to confusion in studies as to whom exactly is referred to by the term, we think medical device users can be classified into two major categories i.e. end users (non-professional users) and professional users. The former category may include patients, people with disabilities and/or special needs, elderly people and lay carers, essentially those non health care professionals directly using devices, whilst the professional users may include a wide range of healthcare professionals and professional carers. This further classification is based on a factual assumption that end users generally have no or less formal qualifications and training while the professional users are fully and properly qualified and skilled to use specific MDTs. In addition, they differ from each other in several other ways. In describing our framework, we will therefore use only two terms i.e. ‘end users’ and ‘professional users’ for those who employ MDTs (Figure 1).

CONCEPTUAL FRAMEWORK FOR USERS’ INVOLVEMENT

It is noteworthy that the MDTDP is an iterative process starting from idea generation and concept development through to device design and prototype development and testing, and device deployment in the market (5). We believe that the involvement of

users can be through an iterative process that can take place at different points in the MDT lifecycle (Figure 1). We also believe that in developing a MDT there can be three possibilities as under.

MDT Development Scenarios

Scenario A: Device New to the Market. In the case of development of a device new to the market, a lengthy and detailed iteration from the stage of concept development through to the stage of deployment / launching the device in the market will be required (Figure 2a). This type of device can be developed using either an existing technology or a new technology (10).

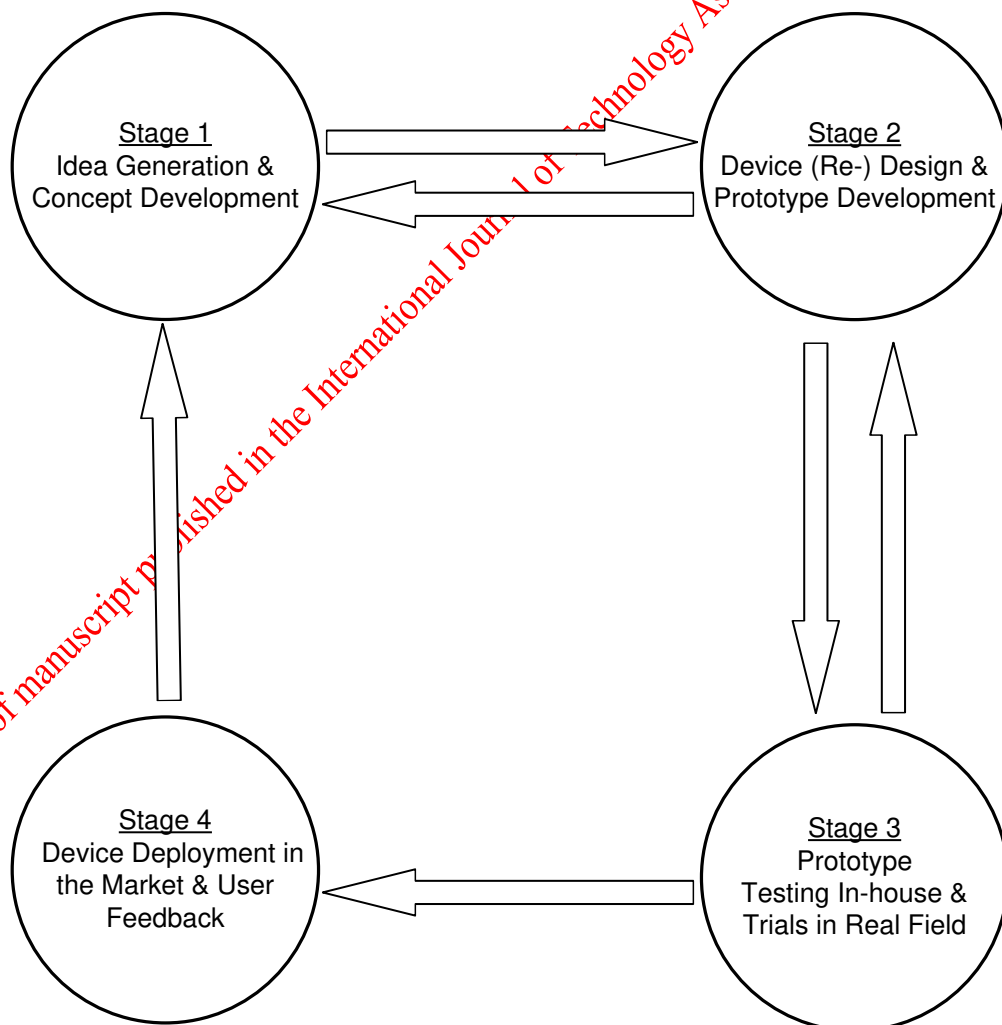


Figure 2a. MDT development scenario A: Device new to the market

Scenario B: Major Upgrade of an Existing Device. A major upgrade of an existing device will involve an iterative process between the design and prototype development stage, prototype testing and trials stage and deployment stage (Figure 2b).

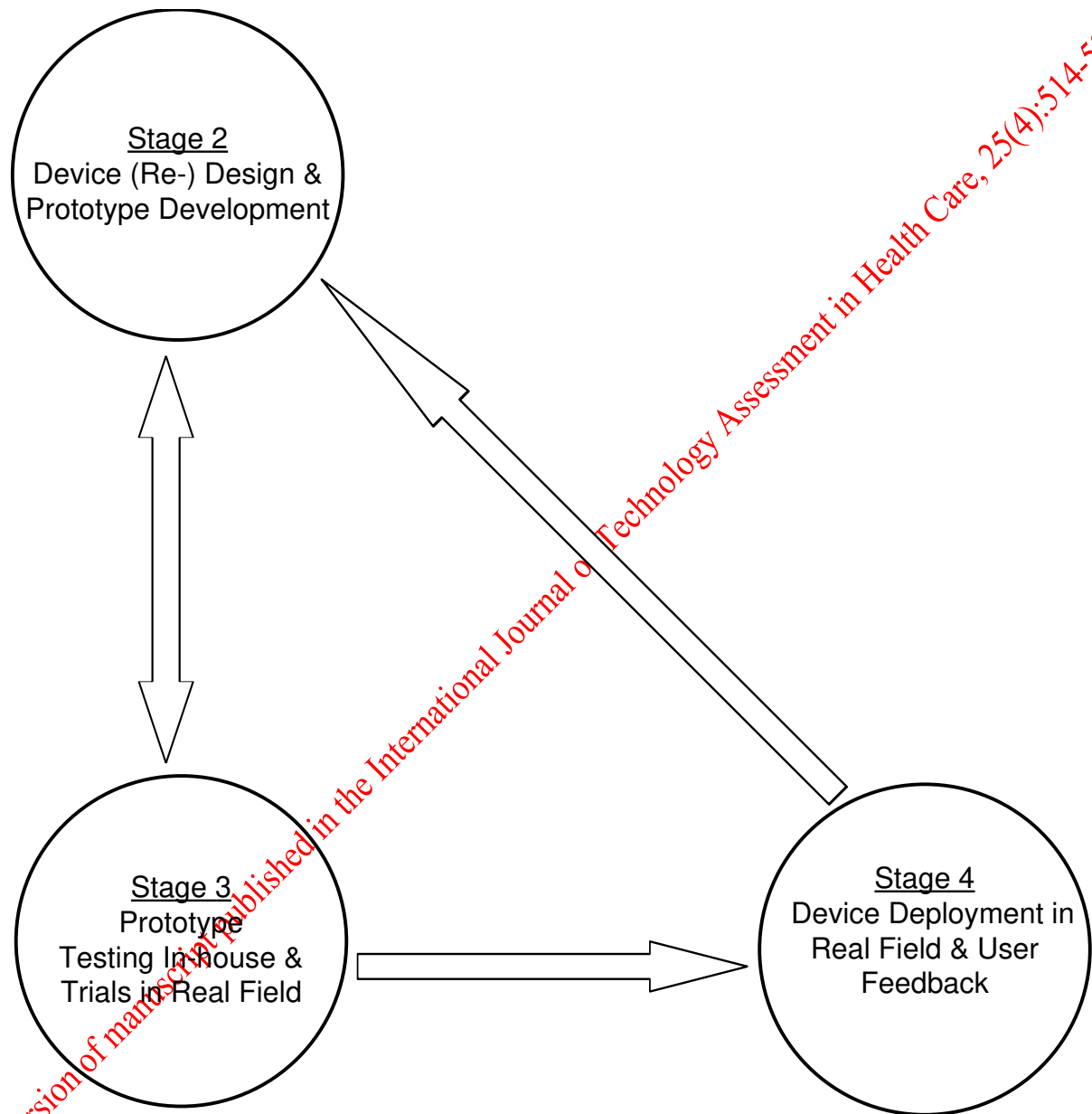


Figure 2b. MDT development scenario B: Major upgrading of existing device

Scenario C: Redesigning of a Device Prototype. The redesigning of a device prototype will involve an iterative process mainly between the design and prototype development stage and prototype testing and trials stage (Figure 2c). For prototype redesigning, users' ideas can be helpful that can be solicited through their involvement via the idea generation and concept development stage.

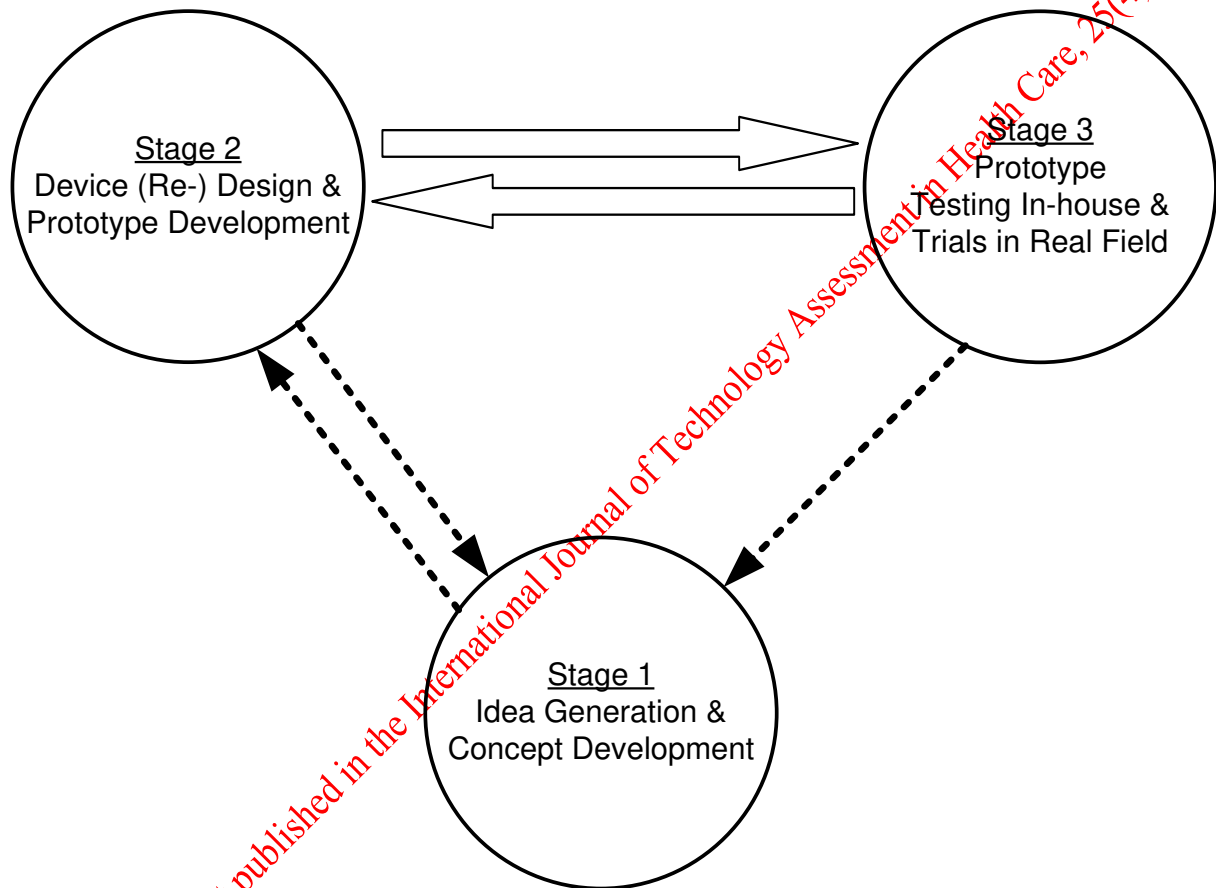


Figure 2c. MDT development scenario C: Redesigning of device prototype

Bearing in mind these possible scenarios and the iterative process of developing MDTs, we propose a conceptual framework (Figure 1), which suggests two routes by which involvement of particular types of users may be exercised and various methods can be applied for involving users in various ways at four different stages of the device lifecycle, as follows.

User Involvement Streams

In this framework (Figure 1), we suggest two routes i.e. end users' stream and a professional users' stream for involving users in the MDTDP. Each of the streams covers four stages starting from the idea generation and concept development, device design and prototype development, prototype testing and trialling through to the market deployment of the device. These four stages of users' involvement are proposed for the development of a device that is new to the market (Scenario A) (Figure 2a). However, as we have noted, major upgrading of an existing device (Scenario B) will generally involve three stages i.e. designing, testing and trialling and deploying of the device in the market (Figure 2b), on the other hand redesigning of a prototype (Scenario C) will require iterative user involvement primarily between two stages i.e. the design and prototype development stage and the testing and trials stage, however, soliciting users' opinions via the concept (idea generation) stage can be helpful (Figure 2c). The operation of the streams is described below.

End Users' Stream

We suggest that the 'end users' (EU) stream (Figure 1) is deployed for the involvement of end users i.e. patients, persons with disabilities and/or special needs and elderly people, in addition to lay carers. In general, this stream would be used by MDT developers for MDTs that will be used only by the end users themselves, and/or their carers as proxies for them, generally outside clinical settings and usually at their homes. We believe that devices used by the end users can be relatively simple and less complex as well as more complex and/or innovative. We therefore put forward two device exemplars for the application of this stream.

Exemplar 1. A medical device that will be used by the end user(s) and the device will not be very complex. For example, an inhaler device.

In the case of this type of MDT, the developers can use the EU stream, and involve end users in the iterative process between various stages of the device development cycle as

mentioned in and depending on the MDT development scenarios described above. In developing this type of devices, manufacturers can involve professional users, particularly healthcare professionals, such as clinicians, through professional users' (PU) stream for obtaining their opinions and suggestions regarding the device.

Exemplar 2. A medical device that will be used by the end user(s) and the device will be more complex and/or innovative. For example, assistive devices such as a robotic aid.

Developing this type of MDT, there can also be three scenarios mentioned earlier. In the case of developing this type of device new to the market, it is possible that the concept can come from the end user(s), the professional user(s) or the manufacturer. If the concept was developed by the end user(s) then they should be involved iteratively as described in the MDT development scenario A (Figure 2a) and using the EU stream (Figure 1). However, if the concept was developed by the professional user(s) or the manufacturer, then a model may be more appropriate as that in scenario 4, described under the PU stream.

In the case of major upgrade of this type of an existing device or redesigning of a prototype, end users can be involved as described in the MDT development scenario B (Figure 2b) or scenario C (Figure 2c) respectively and through the EU stream (Figure 1). In all the three cases, manufacturers can involve healthcare professionals particularly clinicians, through the PU stream (Figure 1), at later stages i.e. testing and trials stage and deployment stage for obtaining their opinion and suggestions regarding the device.

Professional Users' Stream

We suggest the professional users' (PU) stream for the involvement of professional users of MDTs (Figure 1). We propose that this stream should be used by MDT developers for creating medical devices that will be used only by the professional users i.e. healthcare professionals and/or professional carers for treating and/or caring for an end user or inserting/implanting the device in to the body of an end user by a healthcare professional.

In this stream, professional users can be involved iteratively between various stages of the device lifecycle depending on and as mentioned in the MDT development scenarios A, B and C described above. In addition, there will be a need to involve the end users, at the testing and trials stage and the deployment stage, to check the device performance. To make the application of the PU stream more plausible, we put forward two device exemplars.

Exemplar 3. A medical device will be used only by healthcare professional(s) for the treatment / diagnosis and/or care of the end user(s). For example, a neuromagnetometer.

To develop this type of device, there can be three scenarios i.e. A, B and C as mentioned earlier. For developing this type of device new to market (Scenario A), there can be two possibilities. First, if professional user(s) such as surgeon(s) developed the device concept, then we suggest that s/he/they should be involved from the concept development stage, through to device design and prototype development, testing and trials and the deployment stages of the device (Figure 1 & 2a). Second, if the manufacturer developed the concept, then the professional users may not be involved at the concept development stage but at the latter stages. We however suggest that they should be involved at this stage to avoid any unforeseen and potential limitations. For developing MDTs as mentioned in Scenario B or Scenario C, manufacturer can involve professional users at the stages and in the manner described in the respective scenarios (Figure 2b & 2c). Irrespective of the scenarios, there will however be a need for end users' involvement at the testing and trials and the deployment stages to evaluate the device performance (Figure 1).

Exemplar 4. A device will be used by the end user(s) but a healthcare professional will insert/place it in to the body of the end user. The device is more complex and/or innovative. For example, an implantable medical device.

There can be three scenarios i.e. A, B and C, as mentioned earlier, to develop this type of device. In scenario A, if the concept was developed by the healthcare professional(s) then

s/he/they can be involved at all four stages described in MDT development scenario A (Figures 1 & 2a). However, if the concept for developing this type of device came from the manufacturer, then the manufacturer may not involve healthcare professionals at the concept stage but at the device design and prototype development stage through to the testing and trials and deployment stages (Figures 1 & 2a). We however suggest that the manufacture involves healthcare professional at the concept stage to discuss the device concept to thrush out any potential limitations. In the case of developing MDT as mentioned in scenarios B and C, manufacturers should involve the professional users as described in the respective scenario (Figures 2b & c). Irrespective of the scenarios, there will however be a need to involve the end users at the testing and trials stage, and deployment stage to assess and assess the device performance.

User Involvement Methods

We suggest various methods (Figure 1) for involving both the end users and the professional users, using the EU stream and the PU stream respectively, in the MDTDP. The most common methods that we suggest for both types of the users and the streams include interviews, focus groups, brainstorming sessions and users-producers seminars at the concept stage; interviews, usability tests and users' feedback at the design stage; usability tests, interviews and discussion at testing and trials stage; ethnography, interviews and surveys for (post-) deployment stage of the device (Figure 1).

DISCUSSION

Practice has been very varied in involving users in the MDTDP and sometimes user involvement, particularly end user involvement, is very modest. Low or limited user involvement could be due to a number of factors such as a lack of funds and time available to manufacturers who are operating in a very competitive market (34). It may also occur through the personal limitations of users (through cognitive, physical, or informational problems) to meaningfully participate in the MDTDP (34). Despite above-mentioned constraints, there is

often a willingness among manufacturers to use feedback from users' in the development of MDTs. Nevertheless, there is then the poverty of effective frameworks to incorporate users' feedback in the MDTDP. It is the need for such a framework that we have addressed in this paper.

We have proposed a generic theoretical framework for directly involving both the end users (non-professional users) and the professional users in the MDTDP (Figure 1). We recognise that medical devices differ from each other depending on the nature and complexity of the technology involved, type of the intended user, the environment and context of the use and the type of medical condition for which the device(s) is used. The nature of medical devices and the type of the intended user are however the most critical issue in involving users in the MDTDP. In this framework, we have therefore suggested two routes i.e. EU stream and PU stream (Figure 1) through which needs of the intended users can be incorporated in the MDTDP.

In our framework, we have proposed that if the medical device being developed is a simple device that will be used by the end users then the EU stream will be the first choice to develop such device. This is because end users know their needs better than any body else. In addition, we assume, end users, and their lay carers, might already have used a similar device at some point in time; therefore, they may have experience and knowledge of the limitations of using such a device. End users therefore can be helpful in (re)designing and/or upgrading of existing devices as well as developing a new device that can be used for a similar purpose. It is also possible that healthcare professionals, and professional carers, can convey some of the needs and requirements of the end users, which they have come to know often through early contact with some of the end users. Manufacturers can therefore also involve professional users through the PU stream to get their perspectives about the device. An example is the development of an inhaler by Anderson et al (1), who involved both the end users i.e. asthma patients and their lay carers, and professional users i.e. physicians, general practitioners and asthma nurses from the concept and design development stages through to the testing and trials

stages and their perspectives were obtained by various methods, such as interviews, focus groups, usability tests and user feedback.

Our framework suggests that if the MDT being developed is both complex and/or innovative, which is to be used by either the end user or the professional user, and a healthcare professional, a professional carer, and/or a manufacturer suggested the concept, then the PU stream should be the first choice to develop such device. Nevertheless, the involvement of end users will be required at the later stages in particular during testing and trialing stage and at the stage of device deployment in the market to assess and evaluate the device performance. For example, involvement of both healthcare professionals and end users in the development process of a neuromagnetometer – a complex device that is used by healthcare professionals for the analysis of the human cortex (brain) activity in patients with certain medical conditions, such as epilepsy and brain tumours (17;27). There is a further example of such a deployment in relation to a complex and innovative device developed through users' involvement, which is the Gynecare TVT Secure System device for female stress urinary incontinence. This device was primarily developed by involving mainly professionals staff such as uro-gynaecologists and urologists, a primary route similar to the PU stream suggested in our framework, while end users (female patients with stress urinary incontinence) were used at the testing and trialing stage and deployment stage, a secondary route similar to that proposed in the EU stream mentioned in our framework (Personal email communication from Peter A. Meier, Principal Scientist, Research & Development, ETHICON GmbH, Germany). It is important to bear in mind that end users may not possess sufficient technical knowledge and understanding about such complex products to be able to fully give incisive assessments about them. Manufacturers therefore should not expect end users to solve major technical problems, therefore their involvement should be mainly for the purpose of identifying and clarifying their requirements and the vital features of the devices for them (21). Nevertheless, for innovative devices such as in relation to emerging medical technologies, end users can still be extensively involved at the testing stage of the device prototype (6).

We do not prescribe specific method(s) for involving the users at any point in the MDTDP because we believe that the selection of those particular method(s) depends upon the resources, both money and time, and expertise available to the MDT developer. Developers should therefore decide themselves whether to use any particular method, taking into account costs and resources available, together with the type of data required and the quality of information obtainable through the method. There is no doubt that the involvement of users in developing MDT is a protracted process; nevertheless, its impact on the device development is very great (6). “The manufacturers therefore need to build-in time and resource for such activities into the development plan and ensure end-user as well as professional-user value is captured in the product's value proposition” (Personal email communication by Michael Borroff, Director of Strategic Health Outcomes, DePuy International).

Limitations. The authors recognise limitations of this framework such as the need for its validation, which will be undertaken in collaboration with our industrial partners, and the generality in its description. The latter is however done purposely to provide a generic framework and for ensuring involvement of different types of MDT users and to present it as an easily understood approach for managers in the medical device manufacturing industry.

POLICY IMPLICATIONS

According to Marshall et al (24), a ‘designing for all’ approach is required in product development to meet the needs of users particularly the needs of specific groups of end users. The PU stream is the most widely used route of users’ involvement by the majority of device manufacturers. This practice has led medical research to be biased in favour of professional users, essentially only doctors / clinicians (30). We therefore would like to draw attention to a few important issues in this regard. Firstly, manufacturers must involve potential users, be they patients, healthcare professionals or carers who are actually going to use the device. Secondly, members of R&D staff within manufacturing companies must not be assumed to predict accurately actual users’ needs. Hence, it is unwise they should be involved as a total proxy on

behalf of the real users of the device. Nevertheless, there are exceptions, for example if a particular member of R&D who has ever used a device in his/her capacity either as a healthcare professional, caregiver or patient then he/she might be suitable to be involved in the development of such device and represent users' needs. Our framework (Figure 1) therefore ensures the involvement of different types of the medical device users to meet their specific and often hitherto unmet needs and requirements. Development of this conceptual work will support MDT manufacturers, particularly small and medium manufacturers (SMMs), who may have limited expertise with regard to engagement with users, especially end users, in developing decision-making protocols regarding users' involvement in the MDTDP.

CONCLUSION

The development and evaluation of medical devices from users' perspectives requires not only the involvement of healthcare professionals but also that of the ultimate end users i.e. patients, people with disabilities and/or special needs, and their lay caregivers. This is because the needs of various types of the users vary widely from each other. The evidence shows that such end users quickly discard devices that do not fulfil their personal expectations, even though both manufacturers and healthcare professionals may consider those end users' requirements met. MDT developers and manufacturers need to recognise this potent potential discrepancy between the parties involved, and involve end users as well as professional healthcare staff directly in the MDTDP. Nevertheless, the engagement of some types of medical device users, particularly end users may not always be possible for various reasons such as a lack of formally defined user involvement process, hence more formal approaches and a generic framework for involving end users needs to be developed and refined. The availability of a user involvement framework such as that proposed in this paper will help medical device manufacturers, particularly SMMs, in planning and developing strategies for involving end users and professional users in the MDTDP.

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