

Medical device technologies: Who is the user?

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Abstract

A myriad of medical devices deployed by many users play an essential role in healthcare, and they, and their users, need to be defined, classified and coded effectively. This study provides definitions of terms frequently employed to describe the users of medical device technologies (MDT) as well as a classification of such users. Devices are widely used, developed and assessed by many others than clinicians. Thus, users of medical devices need to be classified in various relevant ways, such as primary and secondary users; user groups such as healthcare professionals, patients, carers, persons with disabilities, those with special needs, as well as professionals allied with healthcare. Proper definition and classification of MDT users is particularly important for integrating the users' perspectives in the process of MDT development and assessment, as well as in relation to the regulatory, health and safety, and insurance perspectives concerning MDT.

Keywords: Medical devices, User, Classification; Healthcare; Technology; Taxonomy, User perspective.

1 Introduction

Despite protestations that healthcare has always been user-centred, which in a general and obvious sense is true, recently it has become far more explicit that directly involving many different types of users, and particularly end-users, at all stages of healthcare is crucial in the developmental and monitoring process. User involvement in healthcare services design and provision (Allsop and Taket, 2003), as well as in the medical device technology development and assessment (MDTD&A) process (Shah and Robinson, 2006), has become a touchstone of enlightened practice. As an important issue, it is said to be because users are the ultimate beneficiaries of such developments in everyday settings, and as a result there is no-one who can better judge the continuous operational performance of the device concerned, and recount any problems encountered in its use (World Health Organization, 2003).

In addition, users, who are now formally designated as customers (Rowley, 2000) or consumers (Mackay et al., 2000), have heightened expectations that not only services and products, including medical devices, that they buy will meet their particular needs, but that they should also have had a major role in their development (Poolton and Ismail, 2000). Therefore, a detailed engagement with users, and a formal assessment as well as fulfilment of their needs are important elements of modern product development (Brockhoff, 2003). This is even more true in the case of medical device technologies (MDT) because the position of users in relation to devices allows them to

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better judge the performance of the device concerned, than perhaps the performance of many pharmaceutical products, and thus isolate problems encountered in its use (World Health Organization, 2003). Increasing evidence shows that continuously interacting with medical device users and taking account of their needs from an early stage during the development and evaluation process results in the production of most successful and long lasting medical devices (Shaw, 1985; Brockhoff, 2003; Wai and Siu, 2003). However, conversely, ignoring user views may lead to the failure of MDT to meet user needs, and thus can result in under use or even rejection (Gallivan and Keil, 2003), having serious repercussions (Stone and McCloy, 2004), including a range of fundamental developmental errors (Kaye and Crowley, 2000; Food and Drug Administration, 2003; Ward and Clarkson, 2004). Such errors are not only important in terms of a device not being appropriately geared to users' perspectives (Samore et al., 2004), but are also, even more seriously, frequent causes of preventable injury and mortality (Nobel, 1996; Lin, 1998; Amore and Ingram, 2002; Baker et al., 2004; Bennett et al., 2005). Thus, emphasising user involvement and the incorporation of user perspectives, provides a clear rationale for risk avoidance and the associated necessary management strategies (World Health Organization, 2003; Small, 2004).

Thus tackling the relationship between the user and the device, amongst other things, requires the incorporation of users' perspectives directly in the MDTD&A process, which implies detailed information about users themselves, as well as their subsequent direct involvement (Thoren, 1996). Nevertheless, comprehensive and useful information about users of MDT can only be obtained, when they are properly defined, identified and classified. This no trivial problem, bearing in mind the variety of users, the variety of devices and the almost infinite range of settings in which devices may be deployed.

In addition, given the crucial role that the increasing numbers, types and complexity of medical devices play in the healthcare industry, MDT manufacturers across the globe are thus engaged in a continual search for the most appropriate ways in which user parameters can best be deployed in the design, development and assessment process. Given the enormous variety, categories and utilities of medical devices internationally, there have been a wide range of attempts to define and classify them in different countries and regions of the world (Health Canada, 1985; Australian Government, 1989; Therapeutic Goods Administration, 1989; European Community, 1990;1993;1994; HMSO, 1994;1995; Food and Drug Administration, 1997; European Community, 1998; Health Canada, 1998; HMSO, 2000; European Community, 2001; Industry Canada, 2001; Swissmedic, 2001a;2001b; Australian Government, 2002; HMSO, 2002; Department of Health, 2003; World Health Organization, 2003). In this process, there have been major attempts to construct useful taxonomies as medical devices have been categorised, coded and standardised (Food and Drug Administration, 2001; Global Medical Device Nomenclature, 2003; Food and Drug Administration, 2004; Newapproach, 2004).

Given the huge and widening portfolio of medical devices, a similarly widening range of their users has developed, which includes doctors, nurses, patients, family members and relatives of patients, and often a large number of professional caregivers and other professionals allied to healthcare (Kaye and Crowley, 2000; Swissmedic, 2001c; Department of Health, 2003; Therapeutic Goods Administration, 2003). However, despite this exponential increase in 'users', they have not been defined and classified in a formal way which would assist in the tailoring of products for particular user communities, as well avoiding increasing confusion as to who is the 'user' and how a device or product might best be developed for them.

The aims of this study then are to define, identify and classify users of MDT. However, rather than trying to develop a taxonomy for each device, the strategy of the analysis is to provide a more generic classification. The objectives of this paper then are to provide answers to the following questions:

- what does a user of a medical device mean?
- is there an accepted universal definition of the term medical device user?
- who are the users of MDT?
- what are the classes and types of MDT users?
- which types of MDT users are involved in MDTD&A?
- is there an accepted taxonomy of MDT users?
- what should be an acceptable conceptual taxonomy of MDT users?
- what are the implications of MDT user classification?

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In this paper, medical device technologies include medical devices and assistive technology devices and we therefore use the widely accepted definition of 'medical device' employed by the Global Harmonisation Task Force (World Health Organization, 2003) and the definition of 'assistive technology device' as given in relevant legislation (Government of USA, 1998).

2 Methodology

This study comprises a structured review of relevant published literature, and from this review, a novel conceptual framework is developed.

The Engineering and Physical Sciences Research Council (EPSRC) funded MATCH (Multidisciplinary Assessment of Technology Centre for Healthcare) (MATCH, 2006) which included a commissioned review of published literature on user involvement in MDTD&A in three academic disciplines that is healthcare, engineering and ergonomics, and social sciences. Bridgelal Ram et al (2005) and Martin et al (2006) reviewed the healthcare, and engineering and ergonomic literatures respectively.

Table 1 List of keywords used for literature searches

Assistive devices
Classification
Device users
Device developers
End-users
Focus groups
Innovation research
Innovative processes
Innovative product design
Healthcare technology
Medical device
Medical device design
Medical device technology
Medical device users
Needs assessment
Needs assessment tools
New medical technology
Participatory design
Questionnaire based survey
Requirement analysis
Taxonomy
Technological innovation
User centred product design
User criteria
User definition
User engagement methods
User input
User interests
User involvement
User needs
User needs assessment
User participation
User perceptions
User perspective
User requirements elicitation
User studies
User survey

We conducted an extensive structured review of social science literature between January 2004 and April 2005 to understand the particular ways in which users have been central to the process of MDTD&A.

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We extracted information in four defined categories:

- the types of users involved in MDTD&A
- the types of devices developed and assessed by user involvement
- the methods used for engagement with users for MDTD&A
- the stages of the medical device lifecycle in which users were involved.

We adapted the literature review process from the frameworks proposed by Beverley et al. (2004) and Bruce and Mollison (2004). Criteria for the inclusion of studies in the review were that they were published in English language peer reviewed journals and peer reviewed conference contributions from 1980 to 2005 describing user involvement in the development and assessment of new and redesigned medical devices; the contributions may relate to any country. Studies for the same period seeking to capture user needs and describing user involvement in the product development process were also reviewed. Studies were excluded if they did not involve any type of users in MDTD&A process (however broadly defined) or were theoretical rather than empirical in nature.

We prepared and used a list of 37 key words (Table 1) for searching different electronic bibliographic databases, which included Blackwell Synergy, EBSCOhost, Emerald, Inderscience, Ingenta, International Bibliography of the Social Sciences (IBSS), JSTOR, Kluwer, Medical Device Link, ProQuest, SAGE, ScienceDirect, Social Science Information Gateway (Sosig), SpringerLink, Taylor & Francis, and ZETOC.

We identified 556 articles by selecting their titles. Reading abstracts of the articles, we short-listed studies that fulfilled the inclusion criteria for full review. A research fellow and two social science PhD students reviewed 418 full articles independently and extracted information to a spreadsheet template developed in-house. Twenty-eight of the articles were reviewed by two different reviewers. The abstracted information was independently assessed and found to be remarkably consistent in its extraction, which confirmed the reliability of the literature review process and the criteria that were used to abstract the information.

3 Results

The findings of the literature review, particularly in relation to the methods used for engagement with users, the types of medical devices developed through user involvement and the stages of the medical device lifecycle during which users were involved, have been reported elsewhere (Shah and Robinson, 2006). Nonetheless, the unpublished and detailed information about types of MDT users involved in MDTD&A, and the novel conceptual work with associated classifications is presented in this paper.

The results show that twenty-nine studies reported the involvement of various types of MDT users in the process of MDTD&A (Table 2). We found that clinicians, as might be surmised, are not the only users of MDT; devices are also being widely used, developed and assessed by many others, ranging from patients and persons with disabilities, to carers, to many different types of professional staff allied to healthcare. This suggests that MDT users are not a homogenous group but have a great deal of heterogeneity, and use MDT from radically different perspectives. Furthermore, they are different from each other in several additional respects; hence, they could be defined differently in relation to their MDT usage by virtue of being in different classes, groups and types.

We found that none of the reviewed studies reported any operational definition or classification of MDT users in a formal and meaningful way. In many respects 'user' or 'users' were seen as self evident categories, in studies with totally different aims, objectives or structure, which appeared to require no further explanation. This state of affairs is very concerning for it appears that development or monitoring may be undertaken using different (but un-stated) baselines, and conclusions drawn about comparative value without the necessary formal criteria.

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Table 2 Types of MDT users involved in the MDTD&A process

Study/Author(s)	Year	Types of users involved	MDT developed / assessed
Batavia and Hammer	(1990)	Persons with different disabilities	Assistive device
Brooks	(1991)	Persons with disabilities	Assistive devices
Buhler et al.	(1995)	Persons with different disabilities	Wheel chairs
Buhler	(1996)	Persons with different disabilities	Robotic aids and wheel chairs
Obradovich and Woods	(1996)	Nurses	Infusion pump
Handels et al.	(1997)	Physicians, neurosurgeons, radiologists, CT* and MRI** professionals	Teleradiology system
Lin et al.	(1998)	Nurses	Patient controlled analgesia pump
Shaw	(1998)	Clinicians	Different medical equipments
Woodside et al.	(1998)	Carers	Syringes
Craig et al.	(1999)	Patients with neurological problems, neurologist, physician and other medical staff	Teleneurology
Friedrich	(1999)	Dermatologist	Electronic luminescence microscope
Bray	(2000)	Blood parameter monitor users	Blood parameter monitor
Hasu and Engestrom	(2000)	Doctor, nurse and clinical neurophysiologist	Neuromagnetometer
Hasu	(2000)	Doctor, nurse and patient	Neuromagnetometer
Mulholland et al.	(2000)	Persons with bilateral lower extremity disabilities	Wheeled mobility devices
Hummel et al.	(2001)	Cardiologist and cardio-surgeon	Intraventricular blood pump
Lacey and Selvin	(2001)	Persons with visual impairments	Robotic walking frame (walker)
Lin et al.	(2001)	Nurses	Patient controlled analgesia pump
Samuelsson et al.	(2001)	Persons with spinal cord injury, multiple sclerosis, stroke, cerebral palsy, spina bifida and mental disability	Wheel chairs
Staccini et al	(2001)	Staff working in blood transfusion unit	Clinical information system
Anderson	(2002)	Patients (asthmatic), general practitioners, nurses, carers and	Inhaler

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pharmacists			
Garmer et al.	(2002a)	Nurses	Infusion pump
Garmer et al.	(2002b)	Nurses	Infusion pump
Hummel et al.	(2002)	Physicians and person with laryngectomy	Voice-producing prosthesis
Kittel et al.	(2002)	Persons with spinal cord injury	Wheel chairs
Miettinen and Hasu	(2002)	Surgeons, clinical neurophysiologist, nurse and medical physicist	Neuromagnetometer
Stickle et al.	(2002)	Persons with degenerative neuromuscular conditions	Powered wheel chairs
Garmer et al.	(2004)	Nurses	Ventilator
Liljegren and Osvalder	(2004)	Doctors and nurses	Patient monitoring system

*CT = Computerised Tomography, **MRI = Magnetic Resonance Imaging (Ehrlich and Schroeder, 2004).

To investigate further, we consulted legislation on MDT such as that embodied in Australian (Australian Government, 2002), Canadian (Health Canada, 1998), the European Union (European Community, 1990;1993;1994;1998), the United Kingdom (HMSO, 1994;1995;2000;2002) and the United States (Food and Drug Administration, 1997) regulations but found no clear definition and classification of MDT users. However, "patients" and "users" were generally mentioned as separate entities in relation to medical devices, which suggest that patients are generally seen as in a different category from the device users, or perhaps they might even be seen as a subset of them. This lack of clarity implies that there is no accepted universal definition of the term 'MDT user', and certainly no classification used, and overall there appears to be, as we have noted before, no accepted taxonomy of MDT users. We therefore attempted to define and classify users of MDT as shown in Figure 1.

4 Definitions and Classification of MDT users

4.1 Definitions

We define a 'medical device user' as 'a person who uses a medical device for the treatment and/or care of him- /her-self or someone else'. The 'end-user' is defined as 'a person who is the ultimate beneficiary of the usage of a medical device and who can also be the user of medical device if using the medical device for him- /her-self'.

Thus, there can be more than one type of user involved in the use of a medical device and indeed, there can be both professionals and laypersons involved. For instance, in the case of a surgeon putting an implant into the body of a patient, the surgeon will be the 'user' and the patient will be the 'end-user'. In some cases, the 'user' and the 'end-user' may be the same person, as in the case of a patient with diabetes mellitus using a glucometer to check his/her sugar level or a person with a mobility disability using a wheel chair.

4.2 Classification

We suggest a helpful classification of medical device users could be as in Figure 1, in which we have divided medical device users into two classes, seven groups and several types and sub-types. We have classified MDT users in-to two classes i.e. primary and secondary, based on the purpose of the usage of medical devices. By 'primary users', we mean 'the users who deploy a device for the intended therapeutic use as envisaged by the manufacturer'. The intended use of a device is generally in the direct therapy of a person. We define the 'secondary users' as 'the users who use a device for a purpose other than the direct intended therapeutic use' such as testing, calibration, learning and research.

Based on the position of MDT user in a complex healthcare system, we have divided MDT users into seven groups i.e. healthcare professionals (fully qualified), patients, people with special needs (e.g. persons with disabilities or impairments), carers, non-clinical professionals working in healthcare organisations, students and trainees in the clinical / healthcare professions, and researchers.

We have categorised each group of MDT users into different types based on their common personal and professional traits, which can be further divided into sub-types as illustrated in Figure 1.

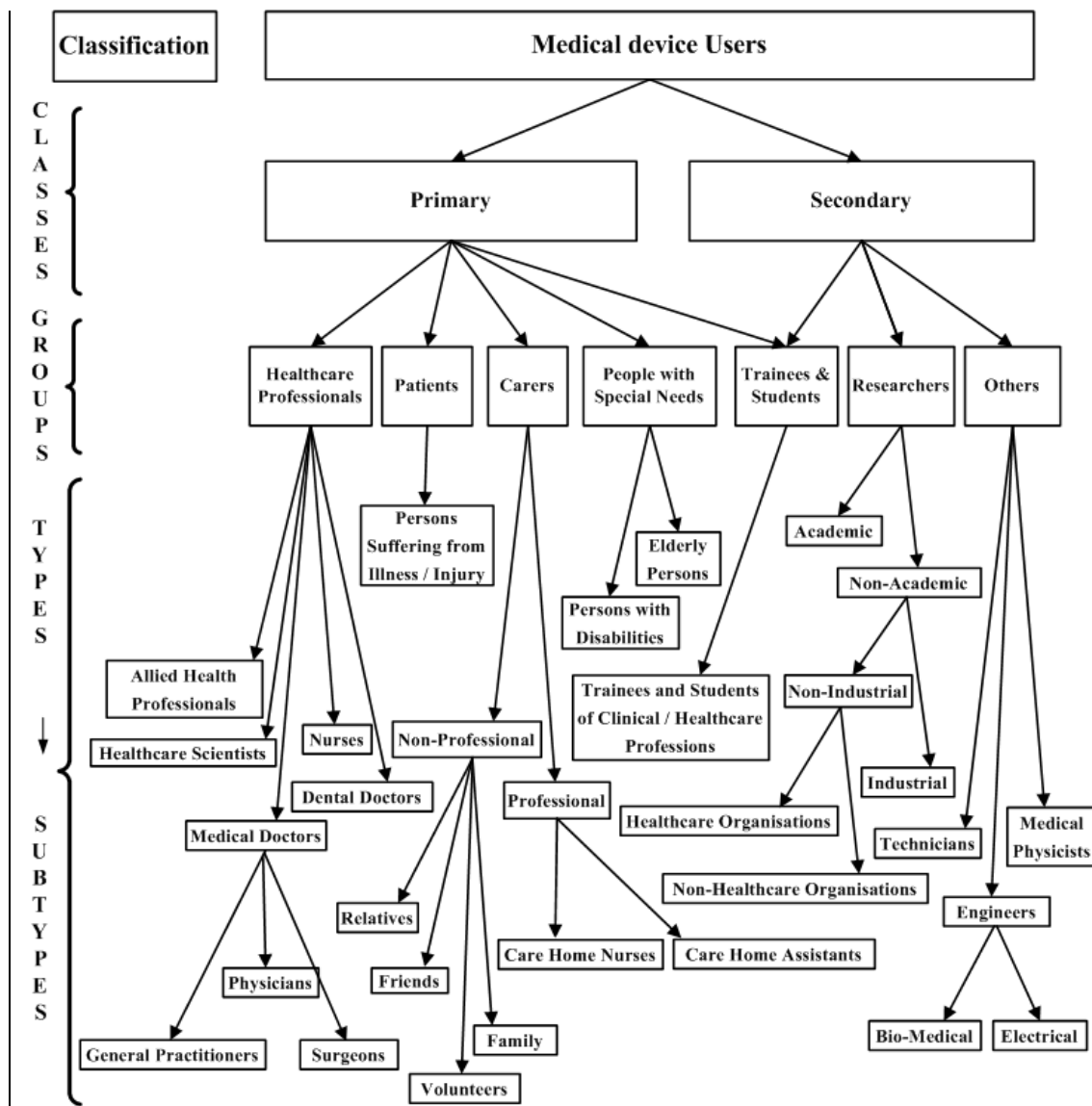


Figure 1 Classification of medical device technology users

5 Discussion

This paper shows that users of MDT, who have traditionally been regarded as just healthcare professionals and patients (World Health Organization, 2003), can be further helpfully subdivided depending upon the type of medical device being considered and the place in which the device is being used. For example, whilst many medical devices are of course used in healthcare facilities, increasingly they are used in care homes, private homes and elsewhere (Lehoux et al., 2004; Ward and Clarkson, 2004).

In the latter case, devices are often used by lay users themselves (World Health Organization, 2003), without direct continuous or immediate clinical supervision. Increasingly therefore, users of medical devices may comprise well trained, semi-trained and even untrained persons, both based on, and leading to sets of needs that vary in nature and degree from employing those devices which are installed, inserted or provided, and then closely and continuously monitored by clinical professionals (Potter-Brotman, 1994; Jones, 1996; Franke and von Hippel, 2002; Beverley et al., 2004). Users of medical device technologies may therefore be increasingly diverse, and include, amongst others, clinicians, patients, professional carers and family members or relatives of patients (Food and Drug Administration, 2003; Therapeutic Goods Administration, 2003) as well as persons having special needs.

Furthermore, the users of medical devices despite being diverse have a common desire in certain key parameters of such devices, i.e. they want safe, effective, reliable and useable medical devices (Kaye and Crowley, 2000). They, being both considered, and considering themselves customers, expect medical devices tailored to their individual and special needs in ways that were not considered as crucial when the sole arbiters of the device were other than the end-users (e.g. previously where a clinician or clinicians was/were the only key judge of effectiveness or quality) (Poolton and Ismail, 2000). Indeed since there are different types of the MDT users, therefore, the range of perspectives in relation to each device may be considerably greater, as well as each user's perspective being different (Teeravarunyou and Sato, 2001). Hence, detailed and timely information of their needs, requirements, preferences and experiences is essential for successful product development (Adams et al., 1998) and in meeting both users' and manufacturers' perspectives appositely (Margolin, 1997; Gerstheimer and Lupp, 2004). A successful product is thus not only the one which is commercially beneficial to the manufacturer (Glen and Lord, 1996) but the one, which is also beneficial to its users. That is it fulfils users' especially end-users' needs and requirements, which we have seen may be complex and possibly even probably different to the needs and requirements of either clinicians or manufacturers. Indeed fulfilling user requirements is crucial to obtaining commercial success. In addition, continuous user involvement is required to develop successful new products (Brockhoff, 2003), which require a high degree of continuing user satisfaction and acceptance (Griffin and Page, 1996) for their long term viability. Evidence shows indeed that dedicated interactions with users and capturing and integrating their knowledge into product development have been found to be generally associated with product success, value and profitability (Shaw, 1985; Biemans, 1991; Gruner and Homburg, 2000; Teeravarunyou and Sato, 2001; Ritter and Walter, 2003). Moreover, reduction of errors and improvement in the safety of end-users also requires that the users of MDT are taken into account during the MDTD&A process (Buckle et al., 2006).

There is evidence that users are involved in MDTD&A; however, they are mostly clinicians (Bridgelal Ram et al., 2005; Martin et al., 2006; Shah and Robinson, 2006) who will have only one of the many possible perspectives to bring to MDTD&A. As we have seen, there are other types of primary users of MDT such as patients, carers, laypersons and people with special needs. Consideration of different types of the primary users will be therefore required in the process of MDTD&A, for they may vary in their level of training, knowledge, experience and physical and mental abilities (Kaye and Crowley, 2000; Lewis, 2001) and to fulfil their needs, requirements and expectations. Of additional importance their environment, culture, social norms, perceptions and attitudes may also be different (United Nations, 1997). In this regard, an acknowledgement of the diversity of backgrounds, interests and skills of users is essential, as is a formal classification of MDT users such as that presented in this paper.

6 Implications of MDT user classification

The classification presented by this paper does not propose a hierarchy among the different groups and types of medical device users discussed here, nor do we intend to suggest watertight compartmentalisation between different groups of the users. Their needs, aims and objectives, may indeed overlap.

All types of users are, from our core argument, important in their own right. However, in the developmental process of a device some of them may be more important than others are in relation to particular stages. For example, primary users will be particularly important from device

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development, assessment and usage perspectives, whereas other types of user may be very important from usage, regulatory, insurance and health and safety perspectives.

Thus, overall we argue that the classification of MDT users presented in this paper is important for its application in development and assessment of MDT itself. It is also crucial from the regulatory, insurance and health and safety perspectives in healthcare.

6 Conclusion

It has been assumed by default if not by design that medical device users are in one of two ill-defined generic categories 'clinicians' and 'patients'. Such an approach has led to a narrow two-dimensional approach to users that has belied the richness and complexity of the ways in which, in practice, medical devices are employed in every day use.

As this study has shown, medical device users are heterogeneous and composed of different classes, groups and types. The users, being diverse, have varied needs and requirements. It is therefore imperative to recognise the diversity of medical device users if their perspectives are to be applied to, and integrated into, medical device technologies. Without acknowledging this issue, the development of medical devices will be both less effective and less relevant to the constituencies of users to which they are ostensibly addressed, and just as important will lead to the loss, or foreshortening of commercial opportunities for manufacturers.

In this regard, the definitions and classification of MDT users presented in this paper are particularly important in relation to the process of MDTD&A and its regulatory, health and safety, and insurance context.

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