World Health Organization

MEDICAL DEVICES: MANAGING THE MiSMatCh

An outcome of the Priority Medical Devices project

Context dependency of medical devices

Background Paper 5

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Contents

Preface

In 2007, at the request of the Government of the Netherlands, the World Health Organization launched the *Priority Medical Devices (PMD)* project to determine whether medical devices currently on the global market are meeting the needs of health-care providers and patients throughout the world and, if not, to propose remedial action based on sound research.

The project gathered the information required by conducting literature reviews and surveys, and by convening meetings of specialist consultants.

The project addressed various complementary issues:
- the global burdens of disease and disability;
- guidelines on clinical procedures for the management of diseases and disabilities;
- projections of future burdens of disease and disability in the context of demographic trends;
- cross-cutting issues, such as the training of medical device users, medical device design, contextual appropriateness of medical devices, and regulatory oversight;
- catalysts of, and barriers to medical device innovation and research.

The original objective of the *PMD* project was to identify gaps in the availability of medical devices. The findings of the project showed that gaps in the availability of medical devices is not the primary issue, but rather a number of shortcomings spanning several facets of the medical device sphere. This result prompted a change of direction in which the project shifted its focus onto the many shortcomings related to medical devices.

These problems, challenges, and failures amount to a mismatch, rather than a gap, that prevents medical devices from achieving their full public health potential.

The *PMD* project also produced a report *Medical Devices: Managing the Mismatch* aimed at achieving two objectives: the first, to inform national health policy-makers, international organizations, manufacturers and other stakeholders of the factors preventing the current medical device community from achieving its full public health potential; the second, to provide a basis on which all players in the medical device scene can together use the findings and recommendations of the *PMD* project to make public health the central focus of their activities.

This paper is part of a series of documents produced as background material for the *PMD* project report. The following papers are available as part of this series:
❶ A stepwise approach to identifying gaps in medical devices (Availability Matrix and survey methodology)
❷ Building bridges between diseases, disabilities and assistive devices: linking the GBD, ICF and ISO 9999
❸ Clinical evidence for medical devices: regulatory processes focussing on Europe and the United States of America
❹ Increasing complexity of medical devices and consequences for training and outcome of care
❺ Context dependency of medical devices
❻ Barriers to innovation in the field of medical devices
❼ Trends in medical technology and expected impact on public health
❽ Future public health needs: commonalities and differences between high- and low-resource settings

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Introduction and literature review

The objective of this paper is to provide a framework for the study of contextual factors relevant to the optimal use of medical devices in clinical practice, based on evidence from the literature. The context in which a (medical) device is used is of key importance for correctly using that device. In a study on the use of telemedicine video conferencing (TMVC), Al-Qirim (1) states, "it is important to address different contextual factors surrounding the adoption of TMVC and go beyond the mere technological ones. This should include, amongst others, individual characteristics, organizational, economical, political and social factors".

The current literature provides a variety of examples where the context in which a medical device was used was not sufficiently taken into account (what is referred to in this paper as 'context of use'). For example, WHO (2) notes 70% of the medical equipment in sub-Saharan Africa is lying idle due to, among other reasons, the absence of user-training and effective technical support. According to a review by Cheng (3), about 30% of the US$ 1.5 billion the World Bank invested in medical devices between 1997 and 2001 is not used. Of the

devices in use, 25 to 35% are not used due to downtime – equipment breaks and there is insufficient capacity to repair it. In a study of donations to Colombia between 1974 and 1979, Peña-Mohr (4) states that 96% of the foreign-donated equipment was not functioning properly within five years of donation. Such examples show the importance of improvements that should be made in order to enhance effective and efficient use of medical devices in a variety of settings.

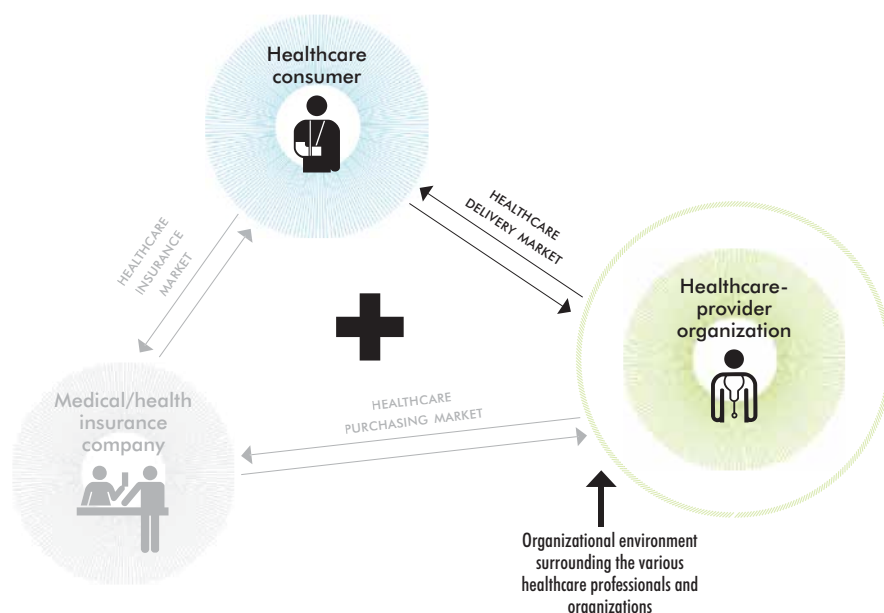## Identifying interoperable themes of this and other papers

This paper must be positioned in relation to some of the other topics discussed in the report *Medical Devices: Managing the Mismatch*. First, this paper does not concern itself with identifying which medical devices are appropriate in the context of the health-care needs of the population (i.e. allocation decisions based on disease burden). Second, this paper does not discuss how barriers to the diffusion of technology can be overcome; Petkova (5) discusses this, with a focus on analyzing barriers at the individual level. Finally,

certain terms used in this paper differ from those used in the literature. 'Acceptance' is used in this paper to indicate technology use, instead of 'adoption' or 'diffusion' because the latter terms do not necessarily indicate actual use. According to Masella and Zanaboni (6) and Kollmann (7), actual use can be compared with that in routine clinical practice.

Differences in technology acceptance between health-care settings and other sectors

Differences exist in the technology used in the health-care sector and other settings; because of this technology acceptance between sectors cannot be compared directly. Comparisons are problematic because health-care delivery often takes place in broader networks of care, which increases the interdependency of professionals (physicians, general practitioners, nurses, etc.) and organizations (hospitals, insurance companies, etc.). This makes diffusion and adoption of new technologies even more complicated than in other sectors (8). Figure 1 gives an overview of this.

According to Wu et al. (9), acceptance of information technology (IT) and information systems (IS) in health care and by health care professionals depend on compatibility, computer self-efficacy, availability of technical support and training, rather than in management support. Professionals' perceptions of management support are generally quite weak.

Sector professionals have greater influence on the organizational adoption of technology (10). Health-care professionals have a specific type of knowledge and a professional status based on special powers and prestige (11). Their greater influence is based on this. Because of this professional autonomy, the job performance of a health-care professional is assessed by a peer-review process, rather than a

Figure 1. Overview of the interdependency in health-care provision

supervisor conducting an evaluation of a manager. However, more and more studies on performance indicators are being conducted in order to make health-care quality and physician performance more transparent (based, for example, on the report by the Institute of Medicine *(12)*).

The second difference between health-care and other sectors is the former's aversion to trying unproven technologies or those lacking a strong evidence base *(13,14)*. In practice, however, many countries do not seem to realize that the management of medical devices is an important health-care priority *(5)*. This could be amplified in case of a lack of purchase information, lack information for maintenance and lack of information for use *(15)*.

A third difference is the diversity of the end-users of a product or service. Especially when the delivery of health care is seen as a service offered by the health-care professional to the patient; the patient is an end-user just as the doctor using the technology or medical devices to deliver that care is an end-user from the point of view of a device manufacturer. Roberts *(16)* acknowledges the importance of including both groups instead of focusing on only one of them.

Construction of the theoretical framework

Below is a theoretical framework for studying the context dependency of medical devices; it consists of three parts:

- *Contextual factors.* The contextual factors create the context of use, which focus on the needs of the device in order to ensure its proper operation (e.g. will the device be used in areas lacking infrastructure or having it).

- *The setting.* The setting describes the broader environment in which the device will be used (e.g. the disease, cultural factors and health beliefs), and is not directly needed to ensure the proper operation of the device.

- *Translation between settings.* Medical devices are initially developed for a specific context of use. When existing medical devices are transferred (translated) from their initial setting to a new one, challenges may arise.

Contextual factors

For the purpose of this discussion, context of use refers to an aggregate of factors that influence the use of a medical device in a day-to-day working environment. There are four layers of contextual factors: 1) characteristics of the health-care facility in which the device is used; 2) supplies and expertise required for the efficient operation of the device; 3) demands placed on the organizational structure of the health care delivery system by the device; and 4) expectations about the performance and possible results reached with the device.

Every layer is dependent on the underlying layer, as depicted in Figure 2. It is, for example, of minimal added value to focus on patients' expectations without addressing the adequate training of the local health care personnel operating the device. Conversely, a new and more effective surgical device is worth little when there is no basic infrastructure for sterilization.

Figure 2. Basic structure of the contextual assessment framework

Each of the four layers of contextual factors has an internal and external component. The internal component is considered to be under 'direct' control of the main actor who is deploying the medical device into active use (e.g. the health care provider). The external component is not under the direct control of the main actor. Examples of these components are described below.

Health-care facility characteristics

Compatibility with health care systems

Medical devices are rarely used on their own in health care facilities, and often function within a network of devices and services. Innovative devices should fit within the structure of existing devices and services (i.e. legacy systems) as much as possible without reducing the performance of the overall system. Integration can be challenging, however, specifically with respect to interconnectivity between devices and requires planning at all phases of development. Integration and compatibility provide an example of an internal component.

Location of the health facility

Placement of health-care facilities in relation to users (patients) is an example of an external component. This is of particular importance in countries with low population densities, and can become even more significant in low-income countries: the longer people have to travel to reach the health facility, the more expensive their treatment becomes *(17)*. For specific groups, such as day labourers, not only will the travel costs increase with the distance that has to be travelled, but they will also lose income due to loss of work while visiting the facility.

Supplies and expertise

Adequate training of those working with the medical device

A number of groups have to be considered within this example of an internal component. According to Raitoharju *(18)* earlier models studying technology acceptance in health care-related sectors focused mainly on physicians and nurses, largely neglecting patients' needs and desires when introducing innovative services. This is slowly changing, as are the roles played by health personnel. Painter *(19,20)* notes that the work of clinical engineers and biomedical equipment technicians is increasingly covering the role of technology manager (which involves risk management and managing larger staffs). Such evolving roles also incorporate the use of medical devices that are increasingly complex. Dankelman *(21)* suggests better training of medical professionals and monitoring and evaluation of their skills within the context of new device technologies and expanded responsibilities.

Producers and suppliers of parts for medical devices

An example of an external component, (spare) parts for medical devices are crucial to the efficient functioning of devices. As stated above, approximately 25 to 35% of medical devices are not used due to downtime *(3)*. Significant improvements can be made by improving technical support and maintenance to decrease

equipment downtime. Ensuring local infrastructure to produce, repair and/or provide mechanical support for devices is one such improvement, which has several advantages: parts can be made and shipped relatively quickly, reducing downtime of devices (a common constraint in low-income countries), mechanical problems can be addressed or repaired more easily, and the development of such infrastructure can also support the local economy.

Organizational structure

Demands devices place on the organizational structure of health delivery systems

Some devices require special forms of interdisciplinary collaboration between professionals within a hospital or clinic. It could be that departments that traditionally did not collaborate now have to do so, or have to collaborate in a different fashion. Such collaboration is an example of an internal component. Drinka and Clark *(22)* indicate increasing specialization as the main reason for the importance of (new forms of) interdisciplinary work and communication. An example is a tele-dermatologic setting in which the general practitioner can take a photo and send it directly to a hospital-located specialist for further assessment and feedback. In general, this interdisciplinary cooperation and knowledge sharing (i.e. organizational issues) is even more challenging to implement than merely connecting all the equipment (i.e. the technological part). This is in accordance with the research of Drinka and Clark *(22)*, who provide extensive methodology on the study of organizations and the implementation of interdisciplinary teams.

Collaborations between different parties in emerging health-care systems

The provision of health care generally takes place within a network of cooperating partners (see also Figure 1). Collaboration between different parties (e.g. physicians and civil servants) is an example of an external component. In general, the more complex the need for networks and cooperation are, the more difficult the introduction of new medical devices or services can be. Barriers to introduction can be political (e.g. the existing balance

of power between actors may be disturbed by a new device) but they can also be technological, that is based on, or needing to fit within legacy systems.

Furthermore, the introduction of a medical device into a health-care setting can bring a change in the doctor-patient relationship. This change can have consequences for the income or power of the incumbent health-care professionals, leading to resistance or objections against the new technology and its changes. Conversely, a lack of incumbent powers, stakes, or other investments can also offer opportunities. For example, when a country does not have an advanced technological infrastructure, it is easier to make a leap forward to a new health-care infrastructure based on new technologies (so-called leapfrogging[1] *(23)*). The rapid adoption of wireless phones in some developing areas without land-line connections is one example. A cellular phone can be used as an integrated part of a medical imaging system, which connects an independent medical imaging data acquisition device (DAD) at a remote patient site with a central facility for image reconstruction and control hardware and software systems *(24)*. The cell phone transmits raw data to the central facility and receives images, while simultaneously serving several remote patient sites. This may provide a solution to medical imaging in underserved areas by replacing the conventional stand-alone medical imaging device with a new medical imaging system made of two independent components connected through cellular phone technology. In addition, low-resource settings that need high-impact interventions because they have limited health care and public health options are usually very receptive to new technologies and typically have fewer status quo institutions and policies that might hinder the deployment of new technologies *(25)*.

Finally, relationships between device manufacturers and (health care) service providers can become problematic when integrating devices into health-care settings, as described by Sujan et al. *(26)*. In general, however, medical devices are more easily introduced into health-care settings than

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1 The concept of "leapfrogging" implies that developing countries can bypass older technologies and utilize the most up-to-date technologies available.

are drugs, possibly resulting from a less thorough assessment of safety and efficacy.

Expectations of medical devices

The final contextual factor deals with the expectations that patients and health-care professionals have about a particular device and its effect on quality of care.

Health-care professionals' expectations of performance and results

When it comes to implementing an innovative device and maximizing its usage by physicians, the device's efficacy is critically important. "Applications poorly adapted to the clinical setting will also have an impact – they confirm prejudices of sceptics, waste resources, and contribute to the diversion of research and industry interest towards other promising IT-sectors" *(27)*. Therefore, the needs of all users should be considered when designing and introducing a device. Kretschmer and Nerlich *(27)* cite telemedicine evaluations as an example; here it should be made clear that (ICT) (information and communication technologies) supported applications have the potential to generate benefit for patients and health professionals alike.

Results from Hu et al. *(28)* suggest that in the adoption process of new health technologies, perceived ease of use for a specific technology is not of major importance in hospitals and similar settings. In these locations, physicians generally have more administrative or professional support compared to home-care settings. As a result, physicians, in hospital settings may not consider ease of use as a very important factor, knowing that administrative or clerical support is probably available should an issue arise. On the contrary, home-care professionals working outside the physical boundaries of their own institution have to operate more independently and rely more on the degree to which innovative applications are user-friendly and easy to use in their patients' environments. Because this concerns health professionals, it is an example of an internal component of the system.

Patients' expectations of performance and results

An example of an external component, assessing and measuring the expectations

of patients can be difficult. When studying the average level of patient satisfaction, Owens and Batchelor *(29)* show that the expectation of patients, with regard to quality of care, may be low or non-existent. Even when the average level of satisfaction in a specific setting is high, patients still do not specifically raise their standards on what quality to expect (i.e. they perceive every offered help as welcome and almost always qualitatively appreciate health care as very good). Setting aside the fact that patients are often satisfied with the health care they received, initiatives are increasingly providing patients the possibility to rate the health care or health-care information they receive.

Some initiatives try to consolidate end-user value judgments into a formal structure. The Dutch research institution TNO[1] initially developed a standard for ensuring the quality of web-based health care information called Quality for Medical Information and Communication; more recently they transferred their knowledge into a new standard for assessment available to patients as well as health-care professionals. In the United States

of America, another standard has been developed – the Healthcare Information Technology Standards Panel (HITSP).[2] The idea behind HITSP is to encourage the public and private sectors to cooperate more closely and integrate standards for sharing information among organizations and systems, which will lead to better assessment of health professionals' and patients' expectations.

The elements constructing the setting

The impact and relevance of the contextual factors described above can be modified by the setting in which the device is used – and there are a variety of different settings. Two examples of such settings will be discussed, namely, the income level of the country or health system in which the device is used (low-, middle- or high-income) and the cultural beliefs that populations have around health.

Income level

Income level of a country or health system is an important element when factoring the context in which a medical device is

being used. A dearth of health facilities across a country often determines level of health-care access for residents. For example, people living a day's walk (or more) from a health facility will not seek care as often as those living an hour away. A decision to offer advanced medical treatments only in densely populated areas (i.e. larger cities) can inhibit local farmers or day labourers from visiting the facility to receive treatment *(15)*. One possible solution is portability; designing a device to be portable means it could be brought to patients in non-urban areas, increasing their access to it (*P. Kandachar, personal communication, 2008*). Simply transferring non-portable equipment from European countries would not be sufficient.

Cultural beliefs around health

The use of medical devices in health care is valued differently depending on cultural aspects of the setting. Lister *(30)* studied the differences between an industrialized and a more holistic (non-industrialized) approach towards health care. Industrialized or 'Western' approaches to health care make a clear distinction between mind and body, considering both as distinct entities *(30)*. In a holistic approach the mind and body are

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1 http://www.tno.nl/ (accessed on 13 October 2009).

2 http://www.hitsp.org/ (accessed on 13 October 2009).

Figure 3. Contextual assessment framework for use of translating medical devices into different settings
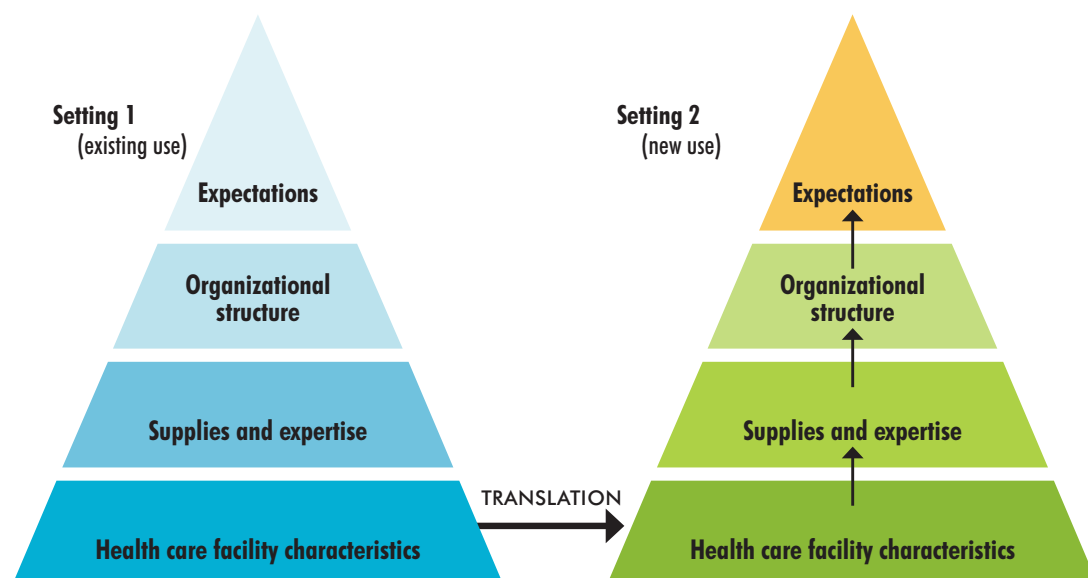
interrelated; there is a focus on traditional healing and spirituality (a disease is often seen as a psychological imbalance), and the traditional role of medical devices found in industrialized countries is often absent *(28)*. In some cultures, therefore, the significance of some medical devices is dismissed.

Furthermore, a culture's or community's acceptance of foreign technology can be perceived by peers or others as admitting a lower status *(31)*. Additional efforts may be needed in some settings to make the use of modern technologies socially acceptable.

The translation process between two settings

A medical device may function in its initial setting, but problems may occur if it is moved to another setting. Figure 3 shows an extension of Figure 2, by adding the translation component between two settings. As indicated in Figure 3, assessing the new settings should begin with the base layer and move upwards.

Donation of medical devices

A practical example of the impact of translating from one setting to another can be observed in the donation of medical devices. With regard to the donation of medical device technologies, Dyro *(32)* investigated the current state of medical equipment donation as well as possibilities for improving this process. According to Dyro *(32)*, one problem encountered frequently is that donors pay insufficient attention to the correct functioning of devices in the recipient setting. Furthermore, recipients also do not necessarily specify what they really need, nor do they invest time or resources in planning how to (organizationally or technically) support the new equipment.

In order to actively include both parties in the process of medical device technology transfer and create a common awareness, guidelines for medical equipment donation have been developed *(2)*, and have been mentioned in an engineer's handbook *(32)*. Such resources are intended to foster understanding through a standardized way of working to support effective communication between both donors and recipients. The broad use of such actions would be beneficial for the quality of the translation of medical devices between settings.

Practical examples illustrating the framework

This section illustrates the previously introduced framework. two different disease categories are described below, and an example from each will be used to highlight the framework: communicable diseases (e.g. malaria, tuberculosis, and HIV/AIDS); and noncommunicable diseases/accidents (e.g. road traffic accidents).

Diagnostics for tuberculosis

On a global scale, tuberculosis (TB) is currently one of nine diseases causing the highest number of deaths and disability-adjusted life years, DALYs *(15)*. According to dr Mark Perkins[1] "We are 100 years behind in TB diagnostics" *(33)*. The efforts to control TB would be more effective if the diagnostic tests were faster and simpler, which would increase access by patients in urban slums and/or isolated rural areas *(33)*. The main disadvantages of existing sputum smear microscopy (SSM)-based tests is that they are slow, cumbersome and expensive *(33, 34)*; existing test-sensitivity is limited; the test requires a laboratory examination causing a delay of several days; and many locations lack adequately trained microscopists and their equipment *(35–37)*.

1   Scientific director at FIND (Foundation for innovative new diagnostics)

The role of contextual factors

Keeler et al. *(38)* showed that improved diagnostic tests can have a significant impact on TB outcomes, and can reduce annual mortality by up to 36%. They recommend developing new TB tests that ideally require less infrastructure – no electricity, refrigeration, or clean water – and can be useable without training *(38)*. These points relate to the two bottom layers of the contextual framework as depicted in Figure 2. Finally, it is important that improved diagnostic tests for detecting TB have a higher sensitivity *(33, 38)*.

Road traffic accidents

In 2030, road traffic accidents will be among the largest cause of DALYs worldwide *(15)*. Especially when managing spinal injuries or those to extremities, X-ray equipment is of key importance *(39)*. Qi and Diakides *(40)* report survey data showing thermal infrared scanning (TIR devices) to be a cost-effective, safe, easy-to-use, and portable alternative to using standard X-ray scanning equipment. While thermal infrared scanning has not been widely recognized, due to the premature use of this technology and its disease-specific usability, recent achievements spurred renewed interest in the use of TIR *(40)*. But due to its smaller bandwidth, TIR devices are not usable as an alternative to X-ray for every diagnostic scan.

The role of contextual factors

The World Health Organization (WHO) issued a report in 2004 on the World Health Imaging System for Radiography (WHIS-RAD) *(41)*. WHIS-RAD is an X-ray-based medical imaging system that is relatively inexpensive and able to work in multiple settings. WHIS-RAD addresses issues that relate to the two lowest layers in the contextual framework (health-care facility characteristics, and supplies and expertise; see Figure 2). The device can be operated on batteries, capacitors and solar cells, making it relatively independent of the existing electricity infrastructure. It is easy to maintain due to its non-electrical moving parts and rugged design. Furthermore, the WHIS-RAD package includes a series of manuals, capable of training and educating anybody in the use of the system who is only generally familiar with diagnostic imaging *(41)*. The need for pre-existing expertise is therefore significantly decreased. This design is specifically tailored to the challenges of various contexts of use.

Concluding remarks

The acceptance of medical devices by end-users is a complex process, demanding active involvement of all actors to align all contextual factors. This paper proposes a framework for studying the role of these contextual factors and outlines the way in which they are interrelated. This framework takes into account both the contextual factors and setting-dependent elements, and is based on current literature.

The poor introduction or translation of medical devices from one context to another is often related to a lack of attention for adapting the medical device to its new setting of use. Special attention should be given to the challenges related to the translation of a device from one setting to another, and the fact that devices may encounter different problems related to contextual factors in different settings.

It must be stressed that this is a theoretical framework to guide further discussion, and make a contribution to unlocking the full potential of medical devices. Currently the literature provides relatively few studies on the acceptance of medical devices (e.g. when compared to drugs or to the extent of use of medical devices), and more such studies are needed.

References

1.   Al-Qirim N. Championing telemedicine adoption and utilization in healthcare organizations in New Zealand. *International Journal of Medical Informatics*, 2007, 76(1):42–54.

2.   *Guidelines for health care equipment donations*. Geneva, World Health Organization, 2000 (WHO/ARA/97.3).

3.   Cheng M. *An overview of medical device policy and regulation*. World Bank, HNP brief No. 8, February 2007 (http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2007/03/02/000310607_20070302113845/Rendered/PDF/388190HNPBrief801PUBLIC1.pdf)

4.   Peña-Mohr J. Distributing and transferring medical technology. A view from Latin America and the Caribbean. *International Journal of Technology Assessment in Health Care*, 1987, 3(2):281–291.

5.   Petkova H. *Barriers to innovation in the field of medical devices.* [Background paper 6 of the Priority Medical Devices project]. Geneva, World Health Organization (http://whqlibdoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.6_eng.pdf).

6.   Masella C, Zanaboni P. Assessment models for telemedicine services in national health systems. *International Journal of Healthcare Technology Management*, 2008, 9(5/6):446–472.

7.   Kollmann T. Attitude, adoption or acceptance? Measuring the market success of telecommunication and multimedia technology. *International Journal of Business Performance Management,* 2004, 6(2):133–152.

8.   Andriessen JHE. *Working with groupware: understanding and evaluating collaboration.* London, Springer, 2003.

9.   Wu JH, Wang SC, Lin LM. What drives mobile healthcare? An empirical evaluation of technology acceptance. In: *Proceedings of the 38th Hawaii International Conference on System Sciences.* Hawaii, Hawaii International Conference on System Sciences , 2005, 6:150a.

10.   Hu P, Chau PYK, Sheng, ORL. Adoption of telemedicine technology by health care organizations: an exploratory study. *Journal of Organizational Computing and Electronic Commerce*, 2002, 12(3):197–221.

11.   Succi MJ, Walter ZD. Theory of User Acceptance of Information Technologies: An Examination of Health Care Professionals. In: *Proceedings of the 32nd Hawaii International Conference on System Sciences. Hawaii,* Hawaii International Conference on System Sciences, 1999, 4:4013.

12.   Institute of Medicine. *Crossing the quality chasm: a new health system for the 21st century.* Washington, National Academies Press, 2001.

13.   Hofstede G. *Culture's consequences: international differences in work-related values.* Beverley Hills, Sage, 1984.

14.   Barlow J, Bayer S, Curry R. Implementing complex innovations in fluid multi-stakeholder environments: experiences of 'telecare'. *Technovation*, 2006:26(3):396–406.

15.   Hansen J et al. *A stepwise approach to identify identify gaps in medical devices (Availability Matrix and survey methodology)* [Background Paper 1 of the Priority Medical Devices project]. Geneva, World Health Organization (http://whqlibdoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.1_eng.pdf).

16.   Roberts EB, ed. *Generating technological innovation*. Oxford, Oxford University Press,1987.

17.   Hardon A et al. *From access to adherence: the challenges of antiretroviral treatment: studies from Botswana, Tanzania and Uganda.* Geneva, World Health Organization,2006.

18.   Raitoharju R. When acceptance is not enough – Taking TAM-Model into healthcare. In: *Proceedings of the 38th Hawaii International Conference on System Sciences*. Hawaii, Hawaii International Conference on System Sciences , 2005, 6:150c.

19.   Painter FR. Clinical engineering certification. In: *Proceedings of the Twelfth Annual International Conference of the IEEE Engineering in Medicine and Biology Society.* 1990, 1–4 Nov: 1978–1979.

20.   Painter FR. ACCE works to restore certification of clinical engineers. *Journal of Clinical Engineering*. 2002, 27(2):85.

21.   Dankelman J et al. *Increasing complexity of medical technology and consequences for training and outcome of care* [Background Paper 4 of the Priority Medical Devices project]. Geneva, World Health Organization (http://whqlibdoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.4_eng.pdf).

22.   Drinka TJK, Clark PG. *Health care teamwork: interdisciplinary practice and teaching.* Westport CT, Greenwood Publishing Group, 2000.

23.   Moran V. Health technology assessment in Europe: The challenges of communicating and applying lessons learned from high income countries to middle-income countries. Presented at the *European Health Management Association Annual Conference 2009,* Innsbruck, June 25th 2009 (http://www.ehma.org/files/Valerie%20Moran.pdf, accessed 4 November 2009).

24.   Granot Y, Ivorra A, Rubinsky B. A new concept for medical imaging centered on cellular phone technology. *Plos One*, 2008, 3(4):e2075.

25.   Thomas R.Population health technologies – emerging innovations for the health of the public. *American Journal of Preventive Medicine*, 2004, 26(3):237–242.

26.   Sujan MA, Koornneef F, Voges U. Goal-based safety cases for medical devices: opportunities and challenges. In: Saglietti F and Oster N, eds. *Computer safety, reliability, and security.* Heidelberg Berlin, Springer, 2009, 4680:14–27.

27.   Kretschmer R, Nerlich M. Assessing the impact of telemedicine on health care management. *Studies in Health Technology and Informatics*, 1999, 64:46–51.

28.   Hu P et al. Examining the technology acceptance model using physician acceptance of telemedicine technology. *Journal of Management Information Systems*, 1999, 16(2):91–112.

29.   Owens DJ, Batchelor C. Patient satisfaction and the elderly. *Social Science & Medicine*, 1996, 42(11):1483–1491.

30.   Lister M. Transfer of medical technology to developing countries. *Indian Journal for the Practising Doctor,* 2004, 1(2):69–74.

31.   Malkin RA. Design of health care technologies for the developing world. *Annual Review of Biomedical Engineering,* 2007, 9:567–587.

32.   Dyro JF. Donation of medical device technologies. In: Dyro JF, ed. *Clinical engineering handbook*. Burlington, Academic Press, 2004:155–162.

33.   *$ 30 Million research effort to develop new tests for deadly infectious diseases*. UNDP, World Bank, WHO, Bill and Melinda Gates Foundation. Geneva, World Health Organization, Tropical Diseases Research (TDR), 22 May 2003.

34.   Dye C et al. Prospects for worldwide tuberculosis control under the WHO DOTS strategy. Directly observed short-course therapy. *Lancet*, 1998:352(9144):1886–1891.

35.   Salaniponi FML et al. Care seeking behaviour and diagnostic processes in patients with smear-positive pulmonary tuberculosis in Malawi. *The International Journal of Tuberculosis and Lung Disease,* 2000, 4(4):327–332.

36.   Hawken MP et al. Under-diagnosis of smear-positive pulmonary tuberculosis in Nairobi, Kenya. *The International Journal of Tuberculosis and Lung Disease*, 2001, 5(4):360–363.

37.   Martinez A et al. Evaluation of new external quality assessment guidelines involving random blinded rechecking of acid-fast bacilli smears in a pilot project setting in Mexico. *The International Journal of Tuberculosis and Lung Disease*, 2005, 9(3):301–305.

38.   Keeler E et al. Reducing the global burden of tuberculosis: the contribution of improved diagnostics. *Nature,* 2006, 444 (Suppl 1):49–57.

39.   Mock C et al. *Guidelines for essential trauma care*. Geneva, World Health Organization, 2004.

40.   Qi H, Diakides NA. Thermal infrared imaging in early breast cancer detection. In: Hammoud RI, ed. *Augmented vision perception in infrared: algorithms and applied systems*. London, Springer, 2009:139–152.

41.   Holm T. *Consumer guide for the purchase of X-ray equipment*. Geneva, World Health Organization, 2000 (WHO/DIL/00.1Rev1).