



Engaging stakeholders in the home medical device market

Delivering personalized and integrated care

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Introduction

The home medical device market is growing. Although forecasts for the growth of this global market vary from extremely optimistic^{1,2} to more cautious,³ there is consensus about the major factors driving this growth: the increase in chronic medical conditions, advances in technologies, the rising cost of healthcare and user expectations.

Patients' roles in their own care is now increasingly important. Medical devices are already widely used in the home although the general public does not readily recognize the fact. Simple devices, such as adhesive plasters for minor cuts, bandages, support stockings, walking sticks etc. through to more sophisticated devices such as home blood pressure monitors are found in nearly every household. In vitro diagnostic medical devices are also widely used in the home, for example pregnancy test kits and blood glucose strips and monitors.

Table 1 – Diversity of medical device use, environments and intended users

Traditional hospital use	Home use	Lifestyle devices	New technology
<i>Professional user</i>	<i>Over the counter</i> <i>Lay user</i>	<i>Lay user</i>	<i>Professional user</i> <i>Lay user</i>
Oxygen therapy	Plasters	Pulse monitors for sport	Computer and mobile apps
Infusion pumps	Bandages	Fitness bands	
Humidifiers	Walking sticks	Body composition monitors	
Monitors	Blood pressure monitors		
Pulse oximeters	Pregnancy test kit		
Dialysis machines	Blood glucose strip		

The cost of healthcare, pressure on hospital in-patient services, and potentially improved quality of life factors are driving a move towards treating patients at home. As a result, more devices that we traditionally associate with hospital use are making their way into the community.

This paper considers the implications for manufacturers of medical devices when a professionally used device moves to the community, or for those manufacturers designing devices specifically for that market. It also considers factors that healthcare providers need to consider in supporting the use of sophisticated devices at home. Lifestyle devices such as those used in sports are beyond the scope of this paper although, the proposed medical devices regulations may well include more devices currently in this category. Implications for software and apps are also briefly considered.

Identifying and engaging stakeholders

To be successful in the home medical device market, it is important for manufacturers to have an understanding of the end-users and other stakeholders in the market, such as telecommunication firms and network providers, and how to engage them in a way that delivers personalized and integrated care to the patient. Each party has their own strengths, needs and barriers to adoption of potentially beneficial technology. Engaging these different users requires differing strategies from home medical device manufacturers.

The intended use of the device

For the manufacturer of home medical devices, the key question is who will be the user – a professional visiting the home or a lay user. This is evident by defining the intended use of the device. The intended use states what a device is, what it is for, what type of patients and what type of user. Inherently, it also defines the regulatory scheme for approval of the device and conformity assessment route. The intended use prompts the manufacturer to consider needs for user support, such as technical advice, clinical advice, provision for spare parts and what to do in the event of product malfunction or failure. Identifying and knowing the intended user will frame the context in which these concerns are addressed.

The intended user

As medical devices move out of the clinical environment into the home, medical device designers must make numerous assumptions about the environment and the skills, abilities and the physical and mental state of the expected users. Medical devices used in the home are likely to take more of a beating than those in the clinical environment – they could be dropped, have food or drink spilt on them, or be accessible to young prying hands or household pets. They can pose a danger to users for whom they were not intended. Infants and children, for example, could be strangled by cables from the device. BS EN 60601-1-11:2010, *Medical electrical equipment – Part 1.11: General requirements for basic safety and essential performance – Collateral standard – Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*, specifically addresses these issues, provides requirements and tests for ‘how rugged is enough?’ guidance. Usability engineering and testing for home use become vital requirements for ensuring the adequacy of the design. A forthcoming BSI white paper, *The growing role of usability and human factors engineering for medical devices: What is required in the new regulatory landscape?*, covering this topic will be published in the autumn.

Medical devices should be designed so that they perform as intended over the expected lifetime of the device. There are various design features that could be incorporated into devices intended to be used in the home to mitigate against such risks, such as password protection, panels hiding critical device controls, and the use of colour-coded or unique connectors. Patients may feel self-conscious about their medical condition and/or using their medical devices in public, so the aesthetics are especially important.

Patients and caregivers must be able to use the devices as intended by the manufacturer safely and properly without any ambiguities. The needs, abilities and education level of intended users also have to be taken into account when creating user labelling and training materials. For example, if the device is fitted by a medical practitioner, are the instructions written for them, or for the patient who is taking the device home? What happens if it fails? Learning styles and capabilities vary, so multimedia training materials might be more effective for some than extensive and complicated written manuals. It is important to consider the education level of the potentially least-educated user when designing home-use device labelling. Terminology, in particular medical references, should be restricted to common lay-terms. Where clinical nomenclature must be used, definitions should be provided.

Protection of the patient’s safety is critical. With the differing capabilities in patient cognition, dexterity, mobility, vision, hearing or acceptance of technology, it is important for devices to be matched with users for whom they are appropriate and for whom they have been designed and tested. Creating a usable interface that is easily understood is important for engaging patients and their families or other informal caregivers. Using the existing technologies which a patient is already likely to have at home, and which the patient already knows, maximizes the familiarity they will have with an interface, and reduces the number of different technologies which the patient needs to master.⁴ As medical devices proliferate in a patient’s home, there is a risk that dissimilarity and lack of integration between the devices can create a complexity that discourages patients and caregivers from using the devices,⁴ particularly if there is a learning curve for mastering the devices. The current generation of patients is more tech-savvy and more likely to be online than any previous generation. Taking advantage of technology that is already accepted by patients, such as mobile apps, common telecommunications devices, and web-based interfaces on pre-owned devices, can contribute to the acceptance of new devices. Creation of a standard interface for home devices would make training transferable among devices and contribute to the usability of the devices.⁴ Of course at a time when technology is rapidly

changing, this is not an easy solution. An easy-to-use, strategically-connected and interoperable solution should be the end-goal.

The interconnected nature of home devices becomes apparent when we also consider what sort of environment the device needs to operate, such as its power supply, water supply, operating temperatures or gas supply. Some devices may need to be registered with the local authority or fire department, and home insurers may wish to be consulted. For cloud-based services, such as sharing devices used for reporting monitored activities or physiological parameters, cyber security is a pertinent consideration, especially given that a wireless implantable device has already demonstrated the ability to be hacked.

What makes the situation even more complex is that patients don't necessarily make a distinction between their medical devices and other technological aids. In addition to their health, wellness, and medication management devices, they use devices to monitor or assist in activities of daily living, devices for communication, education and socializing, devices for home security and for safety.⁴

It is important that verification and validation of the usability of the device by the manufacturer involve tests with users in actual or simulated conditions. The manufacturer should not forget to conduct studies on the proposed labelling and training to assess readability of the user documentation and suitability of the warnings. Validation testing should be carried out using production units and include both objective and subjective data. Regulators will be heavily focused on how well the user was defined and on the usability validation protocols and results as a primary gate for approval.



Using an automatic blood pressure cuff to monitor health in the home

Healthcare and healthcare providers

Engaging healthcare providers is critical to the effectiveness of home medical devices. The data from the devices are useful, but only when there is someone receiving them. Patients can help themselves, but often they rely on caregivers to notice aberrations or trends in the data, and it is this early intervention that has the most value for the patient. Manufacturers should consider the need for collecting the patient's symptomatic data in addition to any physiological data collected by the device, in order to give the healthcare provider a usable picture of a patient's state of health. Unfortunately, a typical long-term care or medical provider may be reluctant to engage with technology.² The learning curve for introducing new technology and mastering new routines can be daunting, especially to staff who may be overwhelmed or overworked. Moreover, healthcare professionals are human-focused, and adept at hands-on care, and may not fully embrace or trust straight-up technology.

The benefits to these users need to be demonstrable, such as helping comply with regimens, helping to proactively address health issues, and improving patient outcomes. When devices are used in areas in which professional judgement is not a requirement, they free up scarce staff for more important matters, where judgement or the human touch is needed.

In addition, new types of care, such as monitored care, can be a cost-effective intermediate step between independent living and assisted care. While not a substitute for hands-on human care, the technology can lengthen the reach of specialty for traditional caregiving staff. In situations in which accessing medical care is difficult or costly for patients, they may find it a barrier to seek medical attention. If the patient has transportation problems that make it difficult to see the doctor, as with patients experiencing mobility problems, or patients without ready access to transportation, doctors may accept home medical devices as a good choice for part of the patient's care, and the device may be a cost-beneficial solution to the patient, even if they must pay for it. These medical devices can empower specialty staff to engage rural, non-accessible patients more quickly, efficiently, and at far less cost to the provider. It is also a way to provide healthcare in remote areas where access is limited by a shortage of healthcare professionals.⁵

The role of the doctor

Doctors may find that their acceptance of home medical devices for their patients is predicated in part on the institutional incentives of the organizations in which they practice. Where incentives favour reimbursement of on-going services, more typical in the US, home medical devices that reduce the need for medical care may not be as readily prescribed or endorsed by doctors. Those situations in which reimbursement is outcomes-based, or that emphasize value for money, are more likely to result in doctors adopting home medical devices for patients than those in which a doctor operates against the structure of the employing organization.

Doctors are more readily engaged by devices that provide a filter between the data from the devices and the practitioner. Those filters may be in the form of human aides who receive and view daily data, and are able to make judgements, or devices that provide some sort of analysis or can tailor the data to suit the doctor's needs. For example, devices may be designed to send the data only when vital signs are outside of acceptable ranges. As an alternative, the data may be presented in a summarized and aggregated form. A doctor who has prescribed blood pressure medication, for example, may prefer to see readings aggregated over a 30- to 60-day period to determine whether the medication and dosage is appropriate, rather than to receive daily readings. Such preferences should be considered when designing a home medical device. Manufacturers should seek out doctor feedback during the design of the device to clearly understand the preferences and needs of these stakeholders.

Payors

Payment mechanisms for home medical devices and for healthcare services vary widely by country, and even within countries. Canada, for example, has a national health policy but the principal payors are health insurance plans for each province or territory.⁶ In Europe, where the approval of home health devices is harmonized, pricing and reimbursement still varies by country, and like Canada, by region of country in some cases.⁷ The US, which is the largest market for medical devices, is fragmented with numerous private health insurance plans as well as national plans. The policies themselves may change, adding to the complexity. In the US, for example, Medicare, the federal

health insurance program for US citizens over the age of 65, has moved to a more outcomes-based model, curtailing reimbursement for hospital readmissions within 30 days,⁸ and creating incentives for the coordination of care.

The dollars at stake are large enough that payors have begun to take an interest in home monitoring devices for patients. Evidence is showing the effectiveness of devices at reducing the demand for healthcare. A large-scale study of the use of home telehealth devices by the US Veterans Health Administration, which included 30,000 participants over four years, demonstrated positive results from home monitoring of patients, in the form of reduced emergency room visits, reduced hospital readmissions, reduced length of hospital stays, and reduced mortality.⁹ The cost of the devices themselves are minimal compared to the cost of preventable hospital readmissions, so that payors are potentially willing to bear the cost of the devices for the patients in the interest of long-term cost savings. This is most true when the payors have some control over the dispensation of medical care, for example in the case of national health programs, or in situations in which they operate the clinics or hospitals in which care is administered.

Payors are also cautious. They are interested in working with market leaders, and looking for proven outcomes, which is difficult in a young market dominated by small entrepreneurs. A strategy that facilitates prevention and early intervention may be helpful with this part of the market. Longitudinal, scientifically sound studies can play a role with payors. Re-usable devices, or lower cost, disposable devices may be attractive to payors, particularly those motivated to meet a particular regulatory milestone, or to meet a particular time threshold. Pilot projects that can be used to demonstrate cost savings from a particular product may be useful, as well as partnerships with care professionals who can provide a medical response to significant data.

Telecommunications firms

Telecommunications firms have the advantages of market penetration, in some cases a very large customer base, and brand recognition. In addition, many such firms support technological products, and have a proven infrastructure. Organizations of this type are accustomed to providing the 'roads' for technology, but may find providing the 'automobiles' a lucrative new strategy, given the projected growth in this market.

One of the difficulties for telecommunications firms is that while they have their products in the customers' homes, they don't have any expertise in the family and caregiving lifestyle and healthcare needs. Their technicians would benefit from a background in health and wellness support, which they do not typically have. Another difficulty is that, as larger firms in regulated industries, telecom firms understand the importance of compliance, and recognize that they are large targets for potential enforcement. Medical privacy laws are a particular concern for these firms, because it's an area in which they have not previously needed to be compliant.

These companies may choose to be distributors of existing devices rather than becoming manufacturers themselves. Pilot projects are a useful way to engage telecom firms, allowing them to test the market and identify the roadblocks they need to address. In particular, a pilot project that prevents their staff from having access to protected data until they are compliant may be of interest to such firms. They may be looking for regulatory consulting services in addition to the home medical products, or to data management services that insulate them from the need for expensive privacy compliance. These firms may be interested in partnering, at least initially, as they get started in this market.

Computer and electronics manufacturers have similar strengths, interests and concerns. The growth in this market provides additional outlets for their products. Apple, for example, recently announced its entry into this market.¹⁰ Firms of this type may be interested in partnering with device companies to provide the necessary components, or to provide the platform for a medical device. But the cost to them is in the regulatory compliance and the adherence to quality standards that is required for medical device manufacturers.

Mobile apps

Mobile medical apps are software programs that run on mobile communication devices and perform the same functions as traditional medical devices. These device types have the advantages of a relatively low cost for



Smartphone synchronizing health information app from smart watch

development, short development time and widespread market acceptance. At present, it is a wide-open market with many manufacturers. One projection shows the global mobile health app market growing to \$26 billion by 2017.¹¹ Mobile apps have advantages to the patient, in terms of cost and familiarity, by using technology already known and used by many patients, and even more caregivers.

The downside is that many newcomers to health apps are unprepared for the complexity and the cost, in terms of money and time, that regulatory compliance requires in order to legally participate in the market. Mobile app developers need to plan for regulatory compliance or risk being banned from national markets. Mobile app developers can benefit from associations with existing medical device manufacturers to develop in a compliant environment, and to ensure their effectiveness and safety for patients. Existing medical device manufacturers can benefit from entering the mobile app market because of the tremendous reach of this market segment into the patient population that could benefit. There are also benefits to these developers from coupling with products that are more easily monetized.

In considering mobile app platforms, due attention should be paid to security. Software which facilitates control of devices such as infusion pumps and pacemakers should be mindful of vulnerabilities which could have an adverse effect on the patient. Devices which store and maintain confidential patient information must be protected using up-to-date safeguard measures. In an age of software viruses and hackers, developers should ensure their software is robust and able to maintain current security measures as software vulnerabilities emerge. It is prudent and necessary to consider the malicious 'unintended user' as a part of the risk management process.

Not all mobile health apps would necessarily be considered medical devices and regulated as such. In Europe and the US, the definition of a medical device essentially centres around diagnostic and/or therapeutic purposes. The regulatory concerns depend on the intended use statement and claims made by the manufacturer, as the same device may be considered a medical device in one case, but not in another. For example, a device measuring heart rate purely to assess fitness would not be considered a medical device, while the same device measuring heart rate as a diagnostic test would be. It is also important to determine whether its use benefits an individual patient. Devices that are intended for use specifically to monitor patients in drug trials, for example, or those intended to provide data on epidemiology, would not be medical devices, as currently defined. If the device is a medical device, the manufacturer has no choice but to comply with the applicable regulations.

Safety and essential performance

It is the manufacturer's responsibility to determine applicability of standards to their device and demonstrate compliance. While there is no mandatory requirement to use standards, there is a presumption of conformity when consensus or harmonized standards are used. Otherwise, the onus is on the manufacturer to demonstrate how their method of achieving compliance is equivalent to or better than the relevant consensus or harmonized standards.

There are a number of standards and guidance documents for the manufacturer covering human factors and usability engineering. These include:

- IEC 62366, *Medical devices – Application of usability engineering to medical devices*;
- AAMI/ANSI HE75: 2009, *Human factors engineering – Design of medical devices*;
- *Draft guidance for industry and food and drug administration staff – Applying human factors and usability engineering to optimize medical device design*.

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* is the de facto international safety and essential performance standard for medical electrical devices. The IEC 60601 family of standards include both collateral and general standards. The collateral standards specify general requirements applicable to subgroups of medical devices or a specific characteristic not fully addressed in the general standard. Examples include:

- IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests, which covers electromagnetic compatibility*;
- IEC 60601-1-6: 2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*;
- IEC 60601-1-8, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems, which covers alarms*;
- IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment, which covers devices used in the home*.

Particular standards are specific to a particular device type. Examples of Part 2 standards that might be encountered within the home monitoring scenario include:

- IEC 60601-2-30, *Medical electrical equipment – Part 2-30: Particular requirements for safety, including essential performance of automatic cycling non-invasive blood pressure monitoring equipment*; or
- IEC 60601-2-47, *Medical electrical equipment – Part 2-47: Particular requirements for safety, including essential performance of ambulatory electrocardiographic systems*.

They modify the IEC 60601-1 general and collateral standards to create a device-specific set of requirements rather than general broad brush requirements.

IEC 60601-1 also refers to the risk management standard ISO 14971, *Medical devices – Application of risk management to medical devices for specific technical issues*, such as providing pass/fail criteria for a specific test or justifying an alternate solution. IEC 62304, *Medical device software – Software life-cycle processes*, which specifies life-cycle requirements for the development of medical standalone or embedded software, is also referenced by Amendment 1 of IEC 60601-1 3rd edition.

Devices used in a home healthcare environment can frequently be used in locations with unreliable electrical sources and poor electrical grounding. IEC 60601-1-11 specifies environmental conditions for use, transport and storage between uses. This standard also addresses the potential lack of training of lay users and their level of education in the development of the accompanying documents and in the labelling of the device. The standard specifies additional drop tests and specifies more stringent electromagnetic compatibility limits for emissions.

Essential performance is the performance of a clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk. The definition has been clarified in the latest version of IEC 60601-1 to explain that the intent is to focus on the performance of clinical functions. This distinction is important because not all performance functions will be considered as essential performance. Unacceptable risk occurs when a product's failure may cause harm to a patient, operator or the environment. For example, if a battery-operated thermometer failed to display the patient's temperature, this could be considered an acceptable risk since it will not cause harm to the patient. While it would be frustrating for the doctor, this malfunction does not physically hurt anyone; however, if the thermometer displayed the incorrect temperature, the doctor may be unaware of a serious condition and would be unlikely to treat it.

The opportunity and requirements of transformation

There is a growing market for home medical devices, driven by demographics and healthcare costs. Studies are now demonstrating the effectiveness of these devices for helping patients avoid costly emergency room and hospital visits and to remain living in their homes. As patients become more accepting of technology, the use of home medical devices becomes easier. Even in emerging markets, simple technology has the potential to have a big impact on a patient's wellbeing.

The FDA recently led the regulatory bodies in releasing several guidance documents related to consideration of home use devices. Examples include:

- *Mobile medical applications, Guidance for industry and food and drug administration staff*, September 25, 2013;
- *Design considerations for devices intended for home use, Draft guidance for industry and food and drug administration staff*, December 12, 2012;
- *Radio frequency wireless technology in medical devices, Guidance for industry and food and drug administration staff*, August 13, 2013;
- *Medical device home use initiative*, White Paper, April 2010.

All parties will need to actively collaborate and contribute to the development of strategically connected healthcare systems in order to overcome barriers to use. With the merger of clinical and technical support functions, an infrastructure change will likely be needed. All of this translates to a remarkable opportunity for manufacturers of home medical devices who can find their niche, if they know how to reach users and to provide value to them, safely and effectively.

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Published white papers

The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices – An Overview of the Likely Outcomes and the Consequences for the Market, Gert Bos and Erik Vollebregt

Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance, Hassan Achakri, Peter Fennema and Ito Udofia

Effective Post-market surveillance - Understanding and conducting vigilance and post-market clinical follow-up, Ibim Tariah and Rebecca Pine

What You Need to Know About the FDA's UDI System Final Rule, Jay Crowley and Amy Fowler

Forthcoming papers

The growing role of usability and human factors engineering for medical devices: What is required in the new regulatory landscape?, Robert North (October, 2014)

Innovation (working title), Mike Schmidt and Jon Sherman (November, 2014)

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BSI is keen to hear your views on this paper, or for further information please contact us here

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