MEDICAL DEVICES: MANAGING THE Mismatch
An outcome of the Priority Medical Devices project

Trends in medical technology and expected impact on public health
Background Paper 7
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Contents

Preface 2
Introduction 3
Convergence of medical devices and information technology 4
Decentralization of care delivery 6
1. Remote clinical monitoring of patients 6
2. Portable technology 6
3. Telemedicine 6
Computer-aided surgery and robotics 8
1. Computer-aided surgery 8
2. Robotics 8
   a. Clinical uses 8
   b. Nonclinical uses of robotics 9
Radiofrequency identification 10
1. Patient safety 10
2. Workflow management 10
Barriers to the diffusion of medical technology 11
Targeting unmet needs in future technology research 12
1. Needle-free drug delivery devices 12
2. New diagnostic technologies for pathology testing 12
3. Simplified supply-chain requirements 12
4. Increased automation 12
References 13
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:
1. A stepwise approach to identifying gaps in medical devices (Availability Matrix and survey methodology)
2. Building bridges between diseases, disabilities and assistive devices: linking the GBD, ICF and ISO 9999
3. Clinical evidence for medical devices: regulatory processes focussing on Europe and the United States of America
4. Increasing complexity of medical devices and consequences for training and outcome of care
5. Context dependency of medical devices
6. Barriers to innovation in the field of medical devices
7. Trends in medical technology and expected impact on public health
8. Future public health needs: commonalities and differences between high- and low-resource settings

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This publication was produced under the direction of Josée Hansen.

The named authors alone are responsible for the views expressed in this publication.
Introduction

In its 2004 Human Development Report, the United Nations estimated that of earth's 6.1 billion people, 4.9 billion live in low-resource developing nations, while the remaining 1.2 billion live in high-resource developed nations. This means that the potential market for medical technologies in developing nations is about five times larger than that in developed nations. However, the majority of medical device developers and manufacturers are located in, and primarily serve, developed countries and they are largely unaware of how to overcome the many barriers, from financial to technical, to making these devices available in developing nations. According to WHO, for a variety of reasons, 70% of the medical devices originating in developed nations cannot be used in most developing nations. The unavailability and dysfunctional quality of medical devices in poor countries is a significant public health problem. Although globally, public health officials have become increasingly experienced and effective in responding to the disease burden in developing nations, engineers have yet to roll out medical devices that are designed specifically for use in these nations.

Recognizing how different trends in medical technology can affect health outcomes requires an awareness of the differences in health-care needs and health-care delivery capacity between developed and developing countries. Based on more than 40 years of collective experience advising hospitals and healthcare providers on health technology issues, it is anticipated that over the next 10 to 15 years, several trends in medical technology will significantly influence patients' access to health care and the way that health care is delivered. In particular, the convergence of medical devices and information technology (IT) is likely to result in the development of a number of technological health-care innovations in the future. A striking example that is already emerging is the area of electronic medical records (EMRs), which, through the integration of medical devices and IT, will be able to store and transmit data gathered electronically from clinical notes, diagnostic equipment, patient monitoring systems, alarms and other sources via computer networks.

It is significant to note that the content of this paper was initially developed from a United States perspective, and may or may not be directly applicable to different contexts. However, the diffusion of new health technologies and the trends described in this paper may be more relevant for informational purposes, to gauge some recent developments.
Convergence of medical devices and information technology

A major trend affecting health care will be the intensification of technology convergence, especially that which involves the sharing of medical information between medical devices and IT applications/networks. Commonly, this includes the exchange of patient and medical information, such as vital signs, patient alarms, radiographic images, cardiac waveforms or clinical laboratory results, planned and/or implemented treatments and prescribed drugs, patient histories, etc. The objective of such systems is to permit all of the health professionals involved in a patient’s care to have instant access to current information about the patient. The systems can also be adapted for use by hospital and government administrators and billing departments, as well as by researchers focusing on health-care costs and by those assessing the clinical effectiveness of specific treatments.

Many medical technologies can be folded into this convergence, including anesthesia machines, wireless infusion pumps, electrocardiogram machines and cardiology information systems, endoscopy units with stored video images and radiofrequency identification (RFID) systems. These devices and systems usually depend on different forms of information transfer (e.g. waveforms, numeric data, or video images) and require information movement to and from different elements, such as hospital information systems, clinical information systems, or electronic medical records (EMRs). These systems usually have different data communication and interface protocols. The seamless exchange of patient and medical data is a complex task requiring sophisticated solutions to insure that converging technologies yield the desired benefits (9).

In the medical field, the potential benefits of successful technology convergence include workflow streamlining, seamless recording and exchange of information, as well as an overall improvement of patient care. So far, only limited data are available demonstrating that these benefits are real. The intuitive theory is that rapid access to comprehensive, uniformly presented patient data will result in improved clinical decision-making and the identification of potential clinical problems while they are still readily manageable. Although these and other rewards of convergence are likely to be wide-ranging, there are substantial, difficult and costly challenges to be met if all of these rewards are to be realized. Moreover, expectations in this area, from access to patient information anytime and anywhere, to the simplification of the administrative aspects of health care, are very high and thus difficult to meet.

For example, effective medical technology convergence could consist of integrating patient monitoring, and staff communication mechanisms, to improve the response time of nurses to patients in need of help (10).

From a technical perspective, there are numerous hurdles to achieving reliable, effective technology convergence. Although the makers of radiology equipment have addressed the need for open communication through the adoption of Digital Imaging and Communications in Medicine (DICOM) standards, for producers of others kinds of medical devices, there is much work to be done in this area which, in many respects, is still in its infancy. Even when open communication standards have been adopted, the affected medical devices rarely provide true plug-and-play connectivity. To be sure, achieving connectivity between multiple systems produced by different manufacturers is complicated. One of the most important factors for achieving successful technology convergence is standardization, which is currently being addressed on several levels.

One initiative called Integrating the Healthcare Enterprise (11) is working on standardized device interoperability protocols (such as DICOM and Health Level Seven) to allow multiple devices from different types of vendors to relatively easily communicate with one another.

Of course, as systems integration grows within a health-care facility, security and software-related risks increase as well. However, once systems are integrated and working within a single network, the facility should have better, more secure control over the exchange of information and be able to create a more seamless knowledge environment for clinicians. Nevertheless, the security of contacts between the networks of different care facilities will probably continue to be a problem for some time to come.

Responding to, and enabling the convergence of technologies is a challenge for all health-care facilities. Overall, with carefully planned systems and vigilant administration, the benefits of converging technologies to patients, and health-care delivery in general, are likely to be manifest. But if convergence systems are poorly planned, poorly implemented or poorly managed, they can adversely affect clinical care and patient safety, and lead to inefficiencies, unintended consequences, significant interruptions in operations, and/ or significantly increased and unnecessary costs (9).

Technology convergence holds the promise of markedly improving patient care and safety. At the same time, however, integrating a large number of medical devices and IT networks can increase risk to patients if any of the elements in the interconnected chain of care delivery technology fail. Thus, effective fail-safe mechanisms, as well as the capacity to easily manually override the system, are essential. In addition, successful integration of medical devices...
and IT systems requires a reliable source of electrical power as well as reliable telecommunications networks (12,13). In many developing countries, medical technology convergence will almost certainly be slowed by the following factors: an irregular supply of electric power, which is a widespread problem; a lack of experience designing, operating and maintaining reliable information networks; and a lack of experienced staff coupled with the inability of public hospitals to attract and afford highly trained IT professionals. Some developing countries may be able to circumvent these and related problems and adopt new medical and information technologies at a faster than normal pace (16). For example, it may be possible to directly implement some of the newest telemedicine applications using “smart” phones without having to rely on IT infrastructures that employ traditional wired landline telecommunications networks (15,16). In some developing countries support for advanced technologies is being provided by more advanced developing countries, which has technical expertise that rivals that of high-resource nations but is generally available at a much lower cost (17,18).

In their efforts to achieve successful medical technology convergence, virtually all countries are hobbled by the fact that most IT professionals lack experience working with medical devices, and training is needed in this specific area.

In the immediate future, most technology convergence activities will focus on the continued development and deployment of EMR systems that can collect patient data from multiple sources and integrate the relevant information into a coherent and usable format for clinicians (19). These systems will permit physicians to remotely detect changes in patient health by observing patterns and trends in collected physiologic measurements (20). EMR systems will likely evolve to integrate patient data from more clinical areas, such as imaging, physiologic monitoring and laboratory tests.

However, designing, manufacturing and applying EMR systems is costly. And, although widespread adoption of EMRs might appear to present a financial challenge primarily to low-resource countries, economic obstacles to EMR implementation also exist in some high-resource nations.

Although medical technology convergence has the potential to improve public health, it is a relatively new field for which little research on its impact is yet available. The treatment of heart disease will probably be among the first clinical areas for which the patient care benefit of technology convergence will be realized. For example, through basic steps such as home automated monitoring of blood pressure, patient weight, respiration, etc. (all securely transmitted to physicians and hospitals), physicians will have early warnings about problems related to the management of chronic congestive heart failure. With real-time access to such patient data, physicians can instantly modify treatment, especially drug dosing, to prevent a worsening of the disease and potentially avoid hospitalization and even the death of the patient.

Table 1. Convergence of medical devices and information technology: Implications for medical devices and potential implications for public health

<table>
<thead>
<tr>
<th>Implications for medical devices</th>
<th>Implications for public health</th>
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<tr>
<td>Multi-disciplinary teams (engineers, dieticians, computer scientists, technical maintenance, and medical ethicists in terms of confidentiality issues [e.g., electronic medical records system]).</td>
<td>More efficient way to collect and share information and data, resulting in valuable data analysis.</td>
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<tr>
<td>Can be labor intensive.</td>
<td>Reduced errors during data entry.</td>
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<tr>
<td>Could be difficult to apply in deprived areas, rural settings, and low-resource countries.</td>
<td>May assist clinicians in working more efficiently through faster flow of information and more patients seen.</td>
</tr>
<tr>
<td>Can have negative implications for user access (medical professionals and patients).</td>
<td>Has the potential to improve patient outcomes and patient safety by giving clinicians real-time access to all patient data through electronic medical records system.</td>
</tr>
<tr>
<td>Builds up expectations in patients and can lead to pressure on healthcare systems to deliver high-quality service to financially more able sections of the population.</td>
<td></td>
</tr>
<tr>
<td>Risk of technical faults, patient safety, and security of personal information if systems are not well-planned and managed.</td>
<td></td>
</tr>
<tr>
<td>Is infrastructure-dependent. This puts medical devices of this type at risk of not being operational in under-funded countries (lack of electricity).</td>
<td></td>
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<tr>
<td>Has the potential to provide better exchange of information in clinical environment, and save time and cost if good connectivity is provided.</td>
<td></td>
</tr>
<tr>
<td>Has the potential to make more efficient use of limited expertise – one surgeon or laboratory specialist can diagnose remotely several cases without physically traveling to each clinic (site). Potential for developing countries to be affected by shortage of staff.</td>
<td></td>
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<tr>
<td>Need for more research in systems integration, preventing faults, network enforcement, and training in use for several kinds of professions.</td>
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Decentralization of care delivery

In all countries, regardless of their resource levels, increasing shortages of trained clinical personnel and growing numbers of patients with chronic diseases will require that more care be delivered outside of hospitals if patients are to receive timely, appropriate diagnosis and treatment (21,22). Technology that can facilitate the delivery of complex, sophisticated care in the home and other nontraditional settings includes the following:

1. Remote clinical monitoring of patients heading

Remote-monitoring devices allow many patients with chronic diseases to receive improved follow-up and disease management from home or secondary care facilities without needing to visit a hospital or physician’s office. In rural settings, such remote clinical monitoring can spare patients long, difficult, often health-threatening journeys (23). In urban settings, remote monitoring can be especially beneficial for disabled or elderly patients (particularly nursing home patients) who may not be ambulatory (24). With remote monitoring, patients receiving home-care often experience improved outcomes because they receive earlier clinical attention and treatment. Patients may also have an improved quality of life simply by avoiding frequent clinic or hospital visits.

Depending on the capabilities of the device(s) used, home-care monitoring systems can automatically (or on demand) collect one or several physiologic measurements, such as blood pressure, heart rate, etc. from the patient and transmit the data by telephone or Internet to a nurse or physician in a different, sometimes far distant location, for review.

Working in consultation with a physician, a nurse can communicate with the patient through the monitoring system regarding symptoms, patient concerns, changes in medication, diet and lifestyle habits. In the future, remote monitoring systems may be linked to the patient’s electronic medical records so that clinicians can detect changes in patient health by following trends in accumulated physiologic data. To be most effective, EMR systems may need to be designed to permit efficient transfer of patient data between various health-care professionals and facilities where a patient has received care, as well as between the point of care, such as emergency care personnel at an accident site and a remote health-care facility (24–28).

2. Portable technology

Various kinds of self-contained, portable technology will permit more patient care to be delivered outside the traditional hospital setting. One current example of this growing trend is the portable ultrasound unit. Clinicians can use this technology to examine patients in the field and then take the collected data back to a regional clinic or central hospital for detailed analysis. In the United States, for example, the military is a strong advocate for research into making smaller and more portable versions of currently available health-care technologies, such as mechanical ventilators and imaging systems that will allow delivery of some advanced level of care in the field (29–40).

3. Telemedicine

The use of telemedicine, defined as “the use of medical information exchanged from one site to another via electronic communications for the health and education of the patient or health-care provider and for the purpose of improving patient care, treatment, and services” (41) has grown in recent years, especially in developing countries (42). It will continue to expand as the chronic disease burden grows in both industrialized and developing nations. However, this will occur only if there are sufficient numbers of appropriately trained clinicians (which there are not at present) to use the technology as adjuncts to and facilitators of patient care (43,44). Telemedicine electronically provides medical information and services at a distance, especially for patients who would otherwise not have access to care (45–47). The introduction of new technologies that permit decentralized delivery of medical care at increasingly advanced levels can also result in expanded use of telemedicine (48). Telemedicine can be used to connect homebound patients directly with care providers or to permit local clinicians to consult with specialists at other locations (42,49). Telemedicine can be expected to be rapidly integrated with new developments in medical technology, such as remote portable devices and patient monitoring equipment, as well as with nonmedical services.

Table 2. Decentralization of care delivery: Implications for medical devices and potential implications for public health

<table>
<thead>
<tr>
<th>Implications for medical devices</th>
<th>Implications for public health</th>
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<tbody>
<tr>
<td>Greater reliance on portable devices.</td>
<td>More patient care can be delivered outside the traditional hospital setting.</td>
</tr>
<tr>
<td>Increased reliance on developments in nonmedical technology (e.g. communication networks for telemedicine, long-life batteries, and alternate power sources).</td>
<td>Quality of care can be improved. It may allow clinicians to monitor patients more closely and deliver more timely care, potentially improving outcomes.</td>
</tr>
<tr>
<td>Remote-use technology could accommodate needs of end-users (e.g. patients, family caregivers, and other non-clinicians) with safeguards to protect against inadequate user training.</td>
<td>Increase ability of rural health-care professionals to perform highly specialized procedures through remote supervision.</td>
</tr>
<tr>
<td>Remote devices may vary in complexity depending on which patient data are required.</td>
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</tr>
<tr>
<td>Portable devices are likely to require greater durability than stationary (i.e. hospital-based) devices.</td>
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technology, such as “smart phones”, handheld computers, and high-speed Internet services to accommodate heavy data transfer (50). A potential benefit of this technology is that it would allow healthcare personnel in the field to adjust a patient’s medication or modify treatment in real-time after consultation with a remotely located specialist, and after review of the latest patient information (51). Telemedicine will also allow rural and other medically underserved areas in all countries, rich and poor, to benefit from electronic consultation with trained physicians and specialists (52–54). It is anticipated that this will result in far more health care being delivered by non-physician health-care providers working at a distance in consultation with, and often under the direction of, physicians (55–57).

Some health-care experts have expressed fear that telemedicine may cause a decrease in the availability of specialists in the developing world. For example, some radiologists are compensated at a far higher rate for Internet consultations for Western colleagues than they are for local consultations. As a result, radiologists may deny services to local patients and dedicate the majority of their time to providing foreign consultations. As the use of the Internet expands and the need increases for such consultations in the developed world, this type of consultation may extend to other fields such as neurology (especially for the evaluation of stroke patients in the emergency department), pathology, and psychiatry. Although still largely in the research phase, telemedicine holds the potential to allow surgeons to perform surgery remotely through the use of robotic assistance and advanced communication systems (58–60).
Computer-aided surgery and robotics

Although still largely in the research phase, telemmedicine employing advanced computer and communications systems holds the potential to allow surgeons to perform surgery through the use of robotic and specialized imaging devices. As increasing numbers of surgical procedures continue to become less invasive, more surgical interventions will be performed using remote imaging guidance as well as robotic assistance.

1 Computer-aided surgery

Computer-aided surgery (CAS), also referred to as image-guided surgery or surgical navigation, is already well-established in neurosurgery, and is becoming more common in spinal, otolaryngologic and orthopaedic surgery (61,62). CAS technologies are under development in other surgical areas, including trauma, cardiac, and gynecologic procedures. Image-guided surgical systems usually consist of an imaging component and a surgical tracking component, which together create three-dimensional images of the relevant anatomy. CAS allows some procedures to be performed that, because of unusual anatomic features or obscured visibility, would not be possible with conventional surgery. CAS also enables surgeons to frequently check their progress and positioning (for example, the location of instruments relative to a tumor) during surgery. Some CAS systems incorporate intra-operative imaging technology that allows live images to be taken and recorded during surgery. Although beneficial, intraoperative imaging is not widely used, due to the added expense of acquiring and using an intraoperative imaging system, as well as the increased procedure time for taking and registering the images. CAS appears to lead to improved surgical outcomes, reduced complications, shorter recovery times, and lower mortality. However, for most procedures, improvement in clinical outcomes has not yet been well-established in the published literature. Proper training in CAS system use is essential. Improper use can cause navigation inaccuracies and may lead to injury, system malfunction, or surgery delays (63).

2. Robotics

Expanded use of robotics will affect both the clinical and the nonclinical aspects of medicine and the delivery of health care.

a. Clinical uses

In clinical laboratories, advanced robotics and related automated devices will permit large numbers of sophisticated diagnostic tests to be performed with fewer personnel. However, most laboratory automation systems will continue to require complex support and servicing by skilled technicians, which may limit their diffusion in low-resource countries.

In operating rooms, use of robot-assisted surgical systems is certain to increase, in large part because of the growing number of surgeries that can now be performed using minimally invasive techniques. Some of these procedures will employ new techniques that are not available in conventional surgery. It is likely that robot-assisted surgical systems will continue to be found primarily in high-resource countries for some time because of the high acquisition and maintenance cost of these systems. Currently available robot-assisted surgical systems can cost between US$ 1.5 million and US$ 2 million to purchase, while annual maintenance runs to about US$ 150 000. The proprietary surgical instruments designed for use exclusively with the robotic surgery system (i.e., scissors, forceps/pick-ups, needle drivers, electrosurgery) can be used in up to 10 surgical procedures before they must be replaced. The average per-procedure cost for the proprietary robotic surgical instruments is approximately US$ 2 000. Robotic surgical systems have an estimated useful life of about five years.

Robot-assisted rehabilitation devices can range from comparatively simple (adjustable motor-driven treadmills) to quite sophisticated (computer modulated biofeedback systems). In rehabilitative medicine, robotic-assisted physical therapy may allow therapists to serve more patients while providing better, more intensive care to each. As populations across the globe live longer, the number of people with age-related disabilities (stroke, orthopaedic problems, cardiac disease, traumatic brain injuries, amputations, etc.) requiring physical rehabilitation treatment...
will grow very substantially and could overwhelm the capacity of physical and occupational therapists to meet patient needs.

Robot-assisted rehabilitation devices can be expected to have a significant positive impact on health care in both high- and low-resource countries in the future. However, research in robot-assisted rehabilitation is still in its early phases (64).

b. Nonclinical uses of robotics
Robots will also be used in nonclinical applications in health-care delivery – most commonly as labor-saving devices. Various types of computer-controlled robots currently available can, for example, be used to deliver supplies to different departments throughout a hospital, or, in pharmacies, to help ensure that the correct medications are dispensed. In general, these kinds of robots are intended to allow health-care personnel to engage in more skilled work. In the operating room, robots, which are suited to performing menial, repetitive tasks, can, for instance, hold a laparoscope in place for several hours during a laparoscopic procedure, freeing surgical residents, scrub nurses and others to engage in activities that employ their clinical skills. In another example, delivery robots can free nurses from transporting patient blood samples to the clinical laboratory for analysis, thus allowing them to spend more time with patients (65).
Radiofrequency identification

The increased use of radiofrequency identification (RFID) tracking technology in health-care delivery will have important implications for patient safety and as a labour-saving tool in workflow management.

1. Patient safety
Embedding tiny RFID tags into all medical devices will provide surgical teams with a reliable, virtually fail-safe method of scanning patients for instruments and sponges that may have been left inside them before incisions are closed and immediately post-operatively. RFID technology can also be used to verify patient identity and reduce the risk that surgery will be performed on the wrong body part or the wrong patient.

2. Workflow management
RFID has tremendous potential as a labour-saving technology in hospitals. RFID tags/badges can be used to precisely track the location of medical equipment, patients, clinical staff, and occupied beds throughout a hospital without requiring hospital staff to make telephone inquiries or conduct physical searches for the people or equipment. RFID can help staff quickly assess the current workflow and bed management status in different clinical departments by simply referring to a computer monitor where this information is displayed and constantly updated.

<table>
<thead>
<tr>
<th>Implications for medical devices</th>
<th>Implications for public health</th>
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<tr>
<td>Widespread use in nonmedical applications lowers average cost and makes RFID technology cost-effective in many medical devices.</td>
<td>May improve care by reducing the following risks to surgical patients: (1) patient misidentification; (2) wrong body part; and (3) leaving surgical tools inside patients.</td>
</tr>
<tr>
<td>Relatively simple to integrate into most medical devices, including most implanted devices.</td>
<td>Inventory and workflow are better managed.</td>
</tr>
<tr>
<td>Addition of RFID unlikely to require changes in device use or affect normal operation.</td>
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</table>

Table 4. Radiofrequency identification: Implications for medical devices and potential implications for public health
Barriers to the diffusion of medical technology

Some technologies, such as telemedicine, are already being widely used to improve public health in both developed and, especially, developing nations, and their use is expected to grow (42). However, in developing countries, many barriers have impeded, and continue to impede, the diffusion of medical devices and IT, thereby slowing improvements in public health. These barriers cover a wide range, including lack of reliable water and power; lack of replacement parts; cost and other financial issues; lack of experienced, trained technical and clinical staff; lack of consumables such as syringes and catheters; lack of appropriate public infrastructure; political instability; regulatory constraints and corruption (7,66– 76).

Thus, in many developing countries, addressing fundamental problems such as failing or absent infrastructure may be a priority for improving public health before considering the adoption of various new medical technologies (77). However, some IT technologies, such as remote patient monitoring and telemedicine, can actually circumvent some infrastructure problems – poor roads, for example, and widely scattered health-care facilities.

Nevertheless, regardless of what medical technology is or is not available, certain infrastructure components are essential for good public health. For example, access to plentiful supplies of clean water is essential in helping prevent (and thus avoid the need to treat) many infectious and parasitic diseases, as well as making it possible for health-care facilities to function. Reliable electrical networks, lacking in many poor countries, and access to alternative power sources (such as petrol and gas-powered generators, local solar or wind power, etc.) would permit many developing nations to employ medical technologies that are currently commonplace in most industrialized nations (78). Improvements in basic infrastructure could also reduce logistical difficulties in obtaining spare parts and replenishing supplies of consumable medical items. Reducing infrastructure-related obstacles to technology diffusion might also encourage skilled clinicians to serve low-resource areas and enable circulating physicians to reach distant care facilities more easily. Difficult working conditions caused by poor infrastructure, low wages and other factors may prompt experienced physicians and nurses in low-resource countries to relocate to high-resource countries where working conditions are much easier, where they are well paid and have the use of advanced medical equipment.

Other barriers to greater use of medical devices in developing nations appear to arise from certain assumptions by device manufacturers and potential device users. According to the Engineering World Health study, most manufacturers hold the erroneous belief that medical devices must be simple and cheap to be marketed in developing nations (7,79). From the user perspective, however, developing nations tend to perceive these simple and cheap medical products as being of inferior quality (7). The solution is not simply to reject sequester certain kinds of medical technology on the grounds that it is inappropriate for use in poor countries, but instead to modify the design of the equipment to accommodate the special needs of these countries.

To increase the use of medical devices in developing nations, social marketing may be needed to make engineers aware of the barriers to greater device use. Then, engineers could be more easily able to design medical devices that are innovative and adaptable to suit developing nations. Suitable devices are likely to generally require minimal training and little or no electricity, or use battery power, while being locally affordable and sustainable (7,80–87). Because local device production could increase the availability and appropriateness of medical devices, developing nations could explore new ways to build capacity that may include a nation’s human, technical, governmental, and resource potentials (47). Through capacity building, developing nations can form partnerships with medical device manufacturers (73).
Targeting unmet needs in future technology research

While the trends discussed so far in this paper will undoubtedly play a very significant role in improving health-care around the world, other major health care needs will remain. Research to develop new or improved medical technologies will help meet some of these needs and have a substantial public health impact in the following areas:

1. Needle-free drug delivery devices
Eliminating the need for needles and both disposable and reusable syringes for the administration of vaccines and other medications would have a significant health impact in all countries. Needle-free technologies would eliminate the burden of safe disposal of used needles, thus lowering the risk of needle-stick injuries among health-care personnel. It would also eliminate the dangerous practice of re-using unclean disposable (single-use) needles, thereby preventing infections caused by dirty needles and syringes (88). In addition, needle-free technologies might result in cost-savings and environmental benefits by eliminating the need for specialized procedures for safe handling and disposal of used needles and related medical waste. If, as is probable, needle-free technologies are developed, high initial cost is apt to be the principal barrier to their widespread adoption.

2. New diagnostic technologies for pathology testing
Development of diagnostic technologies that minimize or eliminate the need for large analyzers and the associated materials needed for their operation could allow a clinical laboratory to diagnose disease sooner, potentially allowing healthcare providers to expedite appropriate treatment and improve patient care (89). Improved laboratory technologies could also reduce or eliminate a significant portion of the skilled equipment maintenance required with conventional (i.e., reagent-based) pathology testing technology. In addition to reducing costs, this could help reduce shortages of biomedical engineers and properly trained maintenance personnel which, in many regions, are acute. The development of portable, battery-operated, solid-state testing equipment would allow health-care providers to perform critical pathology testing in nontraditional settings outside of clinical laboratories.

The development of alternate laboratory testing technologies such as lateral flow and microfluidics, and the integration of portable analytic equipment into telemedicine systems would help developing countries leverage limited medical resources and specialists. Despite other infrastructure deficiencies, most developing countries do have access to cellular telephone service. Using “smart” phones and hand-held personal digital assistants, health-care personnel could perform pathology testing in the field and transmit the resulting data to specialists in other locations. In turn, specialists could communicate with and, in real-time, guide field personnel who would administer timely, appropriate care and closely monitor patients.

3. Simplified supply-chain requirements
In many developing countries, patient access to vaccines and some other pharmaceuticals is often severely limited because many vaccines and several classes of injectable drugs need special shipping and storage, notably, continuous refrigeration, which requires a reliable electrical supply. The development of powdered and inhaled vaccines and injectables that do not require cold storage would undoubtedly make many agents more widely available in developing countries.

Problems with proper medication storage may arise even when special requirements such as continuous refrigeration are in place. If the refrigeration is not sufficiently cold, or if it begins to fail, RFID technology combined with temperature monitors installed in the cold storage units could help prevent spoilage of the contents. When the temperature rises above a preset level, an RFID tag in the refrigerator transmits a warning signal through a central server so that the temperature problem can be corrected before entire lots of medical supplies are ruined (91).

4. Increased automation
Automated health-care technologies can improve patient care and safety while reducing personnel requirements and possibly costs as well. In high-resource countries, expanded and new automated laboratory testing systems could increase the volume of diagnostic lab tests performed while using fewer highly-trained (and expensive) technicians. In low-resource countries where the need for reprocessed, single-use devices, from syringes to endoscopes, is great, but where there is a scarcity of personnel trained in safe reprocessing techniques, the availability of automated medical device reprocessing technology that relies on standardized procedures could be invaluable.
References


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