

B10 | THE POLITICS AND LANDSCAPE OF MEDICAL DEVICES IN A GLOBAL MARKET

The size of the medical device sector as a commercial enterprise is frequently underestimated, as is its importance to the contemporary practice of medicine. The innovation of medical device technologies in the healthcare system, as with pharmaceuticals, is a process in which a variety of social, economic and medical interests and visions meet. Government officials and healthcare policy-makers espouse a policy of modernization that promotes continual innovation in medical technology and practice. However, the pursuit of medical device innovation is often controversial, and modes of evaluation of the benefits and costs associated with new medical technologies are far more difficult than the standard approaches for testing and conducting clinical trials for pharmaceuticals.

Contemporary healthcare is characterized by the use of a multitude of medical devices, ranging from the bandage to the endoscope, from the thermometer to magnetic resonance imaging (MRI), from the portable blood pressure monitor to the condom, from the cancer screening test to the heart pacemaker, from the human cell and tissue therapies now termed ‘regenerative’ medicine to the diagnostic technologies of the much-heralded genomic medicine. These technologies are hugely different from each other as artefacts in their clinical modes of use, in their clinical significance, and in their impact on society.

Medical devices encompass therapeutic, diagnostic, screening, inert and powered technologies. The contemporary trends affecting the development of device technologies include the incorporation of information and telecommunications technologies (ITCs) – the increasing embedding of software into devices, and the increasing use of electronic communication between devices in use and ‘servers’ and their host organizations; miniaturization in general, especially that which enables ‘point of care’ tests and ‘near patient’ medicine and therapeutic intervention; and many developments associated with the advance of biomaterials and biotechnology. The latter include the development of ‘combination products’ in which elements of devices are combined with pharmaceutical or biological technologies, resulting in technological convergences called combination products (for example, ‘companion diagnostics’, in which a genetics-based diagnostic test is combined with a particular drug therapy, or a drug-delivery system using software-programmable infusion pumps).

The global market for medical devices includes a massive range of products. The fastest-growing sub-sectors include in-vitro diagnostics, orthopaedics and



Image B10.1 The size of the medical device sector is frequently underestimated (Jose Leon Uzcátegui)

wound management, where there is a vast proliferation of different kinds of devices. Estimates of 10,000 device families and 400,000 different devices are not uncommon. The value of the global market was estimated at US\$105 billion in 2001, but it has also been reported to be close to US\$200 billion, about half the size of the global pharmaceutical market, and growing steadily (DTI 2005). The USA accounts for about 43 per cent of the total market, Europe for over 20 per cent, and the Asia-Pacific region for over 15 per cent. China's market is in the region of US\$20 billion for medical devices, and India's in 2011 was estimated as worth US\$3 billion.

The leading companies in the sector include enterprises such as Johnson & Johnson (specializes in the multi-product health sector), the 3M Group, Baxter International (specializes in devices related to the blood and circulatory system), Tyco International, GE Healthcare, Medtronic, Alcon, and specialists in other sectors such as the electronics company Siemens. The largest companies are highly specialized in their areas of focus. Medtronic is sometimes referred to as the world's leading medical-technology company. However, many companies in the sector are small and medium-sized enterprises (SMEs). For example, the UK sector has over two thousand companies, of which around 85 per cent are small firms. Roughly 75 per cent of medical device activity in the UK is in the supply of medical and surgical equipment, with diagnostics product suppliers accounting for most of the rest. China's main medical devices industry association reports some three thousand company organization members.

Medical device innovation, safety and regulation

Innovation The structure of the medical technology industry contrasts with that of the pharmaceuticals industry in that the majority of technological innovation occurs in SME companies. Major device companies frequently acquire early-stage companies once a business model for their technologies has been stabilized. They improve the efficiency of producing the technology and use distribution networks for trading. Typically also, the large companies have a strategic aim of undertaking the iterative improvement of a given product through several product generations, thereby promoting a long-term contractual commitment from purchasers. Technological innovation is endemic, ranging from slight variants or modifications to existing devices to some breakthrough technologies. Some single-device types, heart pacemakers, for example, may have hundreds of different models available to the end-user.

Regulation The regulation of medical devices depends to some extent on the claims that manufacturers make about a device regarding its functionality and in particular its ‘mode of action’, which in some combination products is not always clear even from a scientific point of view. Compared to pharmaceutical regulation, medical device regulation is generally considered to be less onerous for manufacturers. Safety concerns are often less pronounced in device assessment at the point of application for entry to the market, because many devices have less extensive physiological effects than pharmaceuticals, and those that do (for example, implants) tend to have long-term physiological effects which cannot be assessed in short-term trials. This means that ‘post-marketing surveillance’ in the form of clinical studies, registers and incident-reporting systems (‘vigilance’) is incredibly important for devices. For medical devices and related technologies, the extent and nature of technical standardization achieved through specific regulatory regimes are crucial to understanding both the industrial economy of production and the system of public health protection for ensuring the safety, quality and efficacy of devices entering the healthcare system.

Across the globe, medical device regulation is patchy. The more developed regulatory regimes, expectedly, are in the USA and the EU. These are constituted in quite different ways, the US system being more centralized in its regulatory agency and highly prescriptive about the material composition and production of device technologies, and the EU system, established in the 1990s, relying on adherence by producers to ‘essential requirements’ defined by technical (ISO and other) standards, and policed by mandated commercial and technical organizations known as ‘notified bodies’. The latter have been one of the main targets of the recent ‘recast’ of the European medical device laws (directives) that have been debated in the European Commission and Parliament during 2012/13, fuelled partly, although not initially, by the PIP breast implant scandal (BBC 2013; European Commission 2012). At the

international level, a Global Harmonization Task Force (GHTF) bringing together the dominant regulators was recently replaced by the International Medical Device Regulatory Forum (IMDRF) in 2011 with similar goals, although excluding trade associations from representation.

Regulatory regimes are still at a relatively less advanced stage in LMICs. The China Food and Drug Administration (CFDA) has been developing regulations for some time, and in 2013 released a proposed regulatory framework for public comments. Conversely, while India has been debating the adoption of a formal regulatory framework for several years, it has so far only introduced a special category under the jurisdiction of the Drug Controller General. Brazil's system combines elements of the US and EU systems. Most established formal regulatory systems distinguish different classes of devices on a 'proportionate' system according to the health risk deemed to be associated with their use (HIV test equipment, for example, being in the highest class).

In line with World Health Assembly resolution WHA60.29, the WHO aims to ensure improved access, quality and use of safe and appropriate medical devices (WHO 2013). As part of this initiative, WHO is producing an expanding set of information based on the monitoring of levels of diffusion of devices across low- and middle-income countries (LMICs).

Safety and regulatory enforcement As with pharmaceuticals, the poor quality of devices is a commonly reported problem, along with alleged and sometimes proven corruption. As is the case in the medicines market, the problem of quality in the medical devices sector is far too often conflated with alleged counterfeiting. In 2010, the WHO reported that 8 per cent of the medical devices in circulation globally were potentially counterfeit (News Medical 2010). Regulatory authorities such as the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) and the USA's Food and Drug Administration (FDA) are now actively engaging with this issue and global initiatives have begun to appear. The Australian Therapeutic Goods Administration reported in 2011 that contact lenses, condoms, blood glucose test strips and surgical mesh were subject to counterfeiting. The MHRA has acted in the matter of the selling of devices through eBay or other internet portals, and has identified, and confiscated, fake or non-safety-certificated devices such as dental equipment, including unsafe X-ray technology, and fake digital thermometers. The fact remains, however, that there is a paucity of reliable data on the quality of devices, particularly in LMICs, and conflation and confusion over the use of the terms spurious/falsely labelled/falsified/counterfeit (SFFC) that are preferred by WHO.

Another notable safety issue is that of the improper reuse of single-use devices. Historically, a majority of devices were intended for reuse because of the cleanable materials used (glass, ceramic, etc.), but as awareness of the infectiousness of diseases such as HIV and hepatitis increased, the policy has

changed. The Western regulatory agencies now issue warning notices against this practice, and the EU's Medical Device Directives, for example, make a clear distinction between those intended and those not intended for reuse. The regulatory position varies nationally: in France, the practice is illegal; Germany and the UK have guidelines of different types in place. While there are supported regimes for reprocessing certain devices for reuse (cleaning, sterilizing, etc.), the unregulated use of this practice appears widespread. Surgical technologies are among those devices that are deemed single-use only, but these, too, are frequently reused in different parts of the world. For example, a survey in Brazil has reported that angiographic, diagnostic and therapeutic cardiac catheters were widely reused with limited protocol guidance in many Brazilian hospitals (Amarante et al. 2008).

The quality of medical devices in the global marketplace may also be regulated by agreements on mutual inspection regimes. Exporters of medical devices may be registered with the regulatory agency of the importing country, which may then inspect the producer's premises and processes. The extent to which this inspection is actually carried out is low; the FDA, for example, inspects around 5 per cent of registered device exporters to the United States in a year (GAO 2008).

Nexus between the device industry and healthcare systems As with the pharmaceutical industry, there is a conspicuous interdependence of healthcare delivery systems and medical device industries and their respective market strategies, captured by notions of 'corporate health' and of a 'medical-industrial complex'. Many devices are developed with the direct collaboration, if not the initial conception, of practising physicians. In the advanced industrial health systems, this situation has attracted criticism, including from within the medical professions themselves – for example, in the case of artificial hips, which are mostly produced by a global US-dominated orthopaedic industry consisting of fewer than ten multinational companies. Commentators in the orthopaedic profession have criticized the apparent dependency of the profession upon industry (Sarmiento 2003).

Access and organization

The introduction of new or novel medical devices into a healthcare system inevitably requires the reorganization of infrastructure, the redesign of 'patient pathways', the frequent retraining of staff, and the reassignment of organizational roles, quite apart from the initial handling of resource issues.

Tuberculosis is an example of a lethal disease that is widespread in LMICs and which has become even more of a problem because of the development of multi-drug resistant (MDR) strains. TB detection and diagnosis have been upgraded in the higher-income national health systems. However, India, the country with the highest number of TB and MDR-TB cases, for example,

is unable to cope with the scale of the problem given its existing laboratory facilities. It is clear that upgrading and the adoption of a new test regime, as recommended by WHO, will not occur without funding external to the public healthcare system. Innovation of diagnostics in this field has been shown to be inextricably bound with a need for product standardization at levels acceptable to governments: ‘the way a diagnostic test is standardized as a product in a box can lead to challenges in the field if the test requires different laboratory control practices than are locally available’ (Engel 2012). Thus, the ‘roll-out’ of even accepted technologies confronts a wide range of issues of expertise, working practices, physical facilities, organization, modes of standardization, patient acceptability, competing technologies and practices, all of which require adaptations before they can be incorporated into routine healthcare systems. Such considerations enter into the use of many other types of technology in LMICs, such as advanced molecular diagnostics that can be applied for the treatment of many infectious diseases.

Health system oversight The other side of the coin of social access and system adaptation to needed technologies relates to issues of safety, efficacy and cost-effectiveness. In high-income countries (HICs), the major government-endorsed mechanism that has been developed for this function is known as Health Technology Assessment (HTA) (Faulkner 2009; Lehoux 2006). This is a set of highly technical methodologies for assessing and comparing the potential benefits and risks of technological interventions. The assessment of risks pertaining to the technical performance, safety and efficacy of medical devices is a key part of the evolving regimes of evidence-related governance. Healthcare system procurement organizations may be less concerned about the cost-effectiveness of medical devices, since new devices often have less impact on healthcare budgets than new pharmaceuticals. Nevertheless, there are movements in the advanced healthcare systems to tie scientific evidence and procurement processes closer together in ‘evidence-based purchasing’ and similar schemes.

Unlike for medicines, there is not really a ‘rational use’ movement in the case of medical devices, although support for this might gather force among policy-makers if they were to bracket medicines and technologies together as ‘medical products’ (e.g. WHO 2011). What constitutes the ‘user base’ of devices is difficult to define, let alone monitor. Local and clinical factors are far more influential in determining or influencing patterns of uptake of devices, and, unlike with medicines, high-level global or national health policy cannot easily ascertain or draw up a shortlist of ‘essential devices’ to parallel ‘essential medicines’. Thus, evaluations and interventions to improve the rational deployment of devices in a healthcare system are more piecemeal in the case of devices, and this applies to advanced healthcare economies as well as LMIC healthcare economies, although clearly not to the same extent.

Equally, the academic study of device adoption and diffusion is significantly less extensive than the study of the uptake of and compliance with medicines regimes. There have been movements in HICs, in the last decade or so, that are beginning to tackle this. However, with some exceptions (Yamey 2011), there are as yet only a few examples of this.

The politics of medical technology and global health

As the importance and potential benefits of the range of existing and developing medical devices is increasingly recognized, as the number of scandals in the field receive wide global publicity, and as regulatory regimes are tightened up, it is becoming clear that there is a growing need and a timely opportunity for further advocacy and activism to promote public health goals worldwide related to the use of medical devices. Technological innovation creates pressure for innovation in clinical use, but the way this manifests itself varies across different health systems. Seductive visions of technological progress are used to influence healthcare policy-makers. This creates pressure on healthcare policy-makers and creates demand among patients and citizens through media exposure and the publicizing of innovative technologies. At the same time, medical device policy must address emerging technologies, which hold many uncertainties (e.g. nanotechnology).

Many medical devices have attracted controversy, although relatively few of these have emerged into the public sphere. Expertise in the evaluation of the performance of medical devices is often disputed. This has been the case for many years – for example, the controversy over the materials used in breast implants (Kent 2003), promoted by an industry which is largely shaped by commercial enterprise in plastic surgery (except in the case of breast reconstruction following surgery for cancer or congenital malformations). In the United States and Europe, consumer and support groups for women have emerged and are mounting legal class action cases against certain manufacturers. Aside from safety issues, there have been some cases where the intended users or recipients have actively resisted the innovation in question. This has been the case in Europe, for example, with cochlear implants, capable of restoring some sound signals to people who are profoundly deaf. There have been public disputes between deaf communities and parents of deaf children, on the one hand, and device developers, clinicians and public health professionals, on the other. Refusal to accept the device has been engendered by resistance from deaf language-signing communities, who fear disruption of family communication styles (Blume 2010).

In most LMICs, the penetration of devices used routinely in HICs is very low. Thus, for example, access to computer tomography (CT) is one per 64,900 people in high-income countries and one per 3.5 million people in low-income countries (WHO 2010). The first MRI scanner in a public hospital in Botswana was not introduced until 2011. In 2012, Ghana became the first

West African country to introduce advanced MRI scanning technology in public hospitals. The challenge in LMICs is to judiciously promote access to devices, while keeping in mind local medical, economic and cultural conditions. Unfortunately there is scarce research to guide the use of (often) expensive medical technologies in resource-poor settings. There are concerns in India, for example, that unrestricted access to imaging technologies has prompted doctors with inadequate training in radiology to set up imaging centres, leading to wrong diagnosis (Chakravarthi 2013).

Medical device multinational companies (MNCs) are now developing business strategies geared to the capacities and to the medical needs of the populations of emerging economies. For example, GE Healthcare, which holds the largest share of China's medical equipment market, has announced that it will develop middle- and low-end products targeting China's rural market. MNCs are adopting a similar strategy in India, to overcome constraints to expansion of their markets – currently restricted to major cities (Deloitte and Confederation of Indian Industry 2010).

We are witnessing new forms of inter-industry collaboration in the areas of mobile and electronic health (mHealth and eHealth). While these have been used for some time for the simple dissemination of public health messages in LMICs, future technological developments are of public health significance in both the developed countries and the LMICs, especially given the massive penetration of mobile communication and smartphone devices among rural populations. Remote medical monitoring is one area in which partnerships between medical device companies and telecommunications companies are being forged – for example, to produce systems for remote monitoring for patients implanted with cardiac rhythm management devices.

Portable devices clearly represent an attractive opportunity for companies seeking markets in LMICs. An example is the development of a handheld ultrasound device, launched by a major multinational with a global marketing strategy encompassing both high-tech hospitals in the developed healthcare systems and rural healthcare providers in the LMICs – although recent research indicates that the role for such a device is by no means straightforward, as it requires clear definition of use, revision of clinical pathways for acceptance, and involves issues of ultrasound image-reading expertise (Faulkner et al. 2013). Another example of miniaturization is an ultra-portable electrocardiogram (ECG) machine produced and priced for the Indian market by GE.

Medical tourism is one of the indirect forces shaping demand for medical technologies in some LMICs. Medical tourism is a growing industry in developing economies such as India and China, where entire 'medicities' are being set up, with consequent demands on technologies and techniques acceptable to patients, many (although by no means all) of whom travel from abroad for treatment.

Conclusion

The global health community is beginning to start engaging with issues related to access to medical devices. Public health issues concerning medical devices are beginning to attract attention. Many difficult issues at the international political level still need to be addressed, not least of which are those related to intellectual property and global trade regimes (WTO–WIPO–WHO 2012).

An area for future scrutiny relates to the public health role and value of medical technologies, especially where challenges clearly outstrip resources. While the medical device industry, for obvious reasons, makes claims about how new devices (and technologies) can ‘revolutionize’ healthcare, there are too few independent studies that examine such claims. Technology can also drive the way health systems are organized – for example, the installation of expensive equipment requires scales that promote setting up of more tertiary-care facilities. Clearly those making choices need to bear in mind economic, social and political considerations. Regulatory regimens need much better evidence as regards the cost-effectiveness of a range of medical technologies, so as to prioritize adoption of such technologies in national health systems.

Another area for further work relates to the dominance of MNCs in LMIC markets for a range of medical devices. Challenges for self-reliant production of medical devices straddle issues of technology development and transfer, research, IP (intellectual property)-related barriers, etc. Public health practitioners need to start engaging with the complexities that are linked to the development of medical devices, their use in health systems and their regulation.

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