



MEDICAL DEVICES: MANAGING THE Mismatch

An outcome of the Priority Medical Devices project

Barriers to innovation in the field of medical devices

Background Paper 6

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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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Introduction

This paper forms a background contribution to *Medical devices: Managing the Mismatch*. Its objective is to locate the factors that explain the absence of priority medical devices from certain markets, their inappropriate use where they are present, and the lack of invention and subsequent diffusion into clinical practice in cases where the need exceeds availability. Questions the paper aims to address include the following:

- What defines innovation in medical devices? What are the stages of the innovation process?
- What are the trends in the development of medical devices? What are the barriers reported in the literature?
- Why are medical devices available on the market not being used in health care? What are the barriers to diffusion?
- Would innovation close the gap in the availability, appropriateness and acceptability of medical devices in the management of high burden diseases?

- What are the barriers to innovation?
- Who are the stakeholders in innovation?

Consideration is given also to the similarities and differences between innovation processes in high-resource settings on the one hand, and in low- and medium-resource countries on the other. The purpose is to understand what prevents innovation from occurring domestically within low-resource countries, and what hinders the optimal use in poorer countries of devices manufactured by technically advanced countries.

These goals are pursued in several ways: firstly through a search of the literature including the terms ‘medical devices’, ‘biomedical innovation’ and ‘diffusion’. The purpose of this is to explain the nature of innovation in medical devices, to identify the stages of the innovation cycle, and to report trends in their development that are

likely to impact on the innovation process. This paper offers examples from several empirical studies in order to substantiate theoretical claims from the literature about how innovation occurs in the biomedical sector. The focus is then narrowed to the concrete conditions that inhibit or accelerate innovation in medical devices. Following this is a more detailed account of the barriers to use in medical devices and a review is offered of models by which innovation takes place. This supplies the analytical framework of the current study. The paper concludes with a comparative model of innovation in priority medical devices for high-, medium- and low-resource settings, which views innovation as a process comprised of separate stages and which captures the disparities between different economies in terms of the way in which innovation occurs. The model reflects the empirical findings from the *Priority Medical Devices Project* survey (1).



Literature review of innovation diffusion: nature, stages, trends

Knowing is not enough;
we must apply. Willing is
not enough; we must do.

GOETHE

The WHO Commission on Intellectual Property Rights, Innovation and Public Health views innovation as a “process cycle of three major phases that feed into each other: discovery, development and delivery” (2). Within the innovation cycle, a public health need creates a demand for products of a particular kind, suited for the particular medical, practical or social context of a group, and feeds into efforts to develop new or improved products (2).

Diffusion of innovation in health care

The ‘innovation diffusion’ literature spans a number of academic disciplines – from sociology, to medicine, psychology, communication studies, economics, political science, information and communications technology – with each realm conceptualizing the topic differently, and articulating it in a different language, such as ‘dissemination’, ‘implementation’, ‘adoption’, ‘adaptation’, ‘use’, ‘reach’, ‘uptake’, ‘spread’, ‘translation’, or ‘transfer’ of new ideas and knowledge. Each of these areas also uses different criteria to judge the ‘success’ and ‘quality’ of diffusion, or the extent to which a technology has ‘diffused’ into practice.

The mechanisms by which innovations spread are sometimes differentiated between diffusion (passive adoption by individuals and organizations), and dissemination (active attempt to influence the rate and success of adoption) (3).

There is a specific body of literature on innovation diffusion in health care (4–10), which builds upon various models. Health care is a particularly interesting domain

within which to explore the development of technology for several reasons. They can be grouped under three broad assertions.

1. Medical innovation frequently occurs in ways different from other fields due to the emotional factors attached to the concept of health and illness and the political commitment to offer citizens the latest advances in medicine (11).
2. Novel biomedical technologies have two aspects – on the one hand, they stand for promises for better health and improved quality of life, and on the other, they are associated with higher cost of services. In the context of scarce resources and attempts to reduce expenditure, health policy- and decision-makers have to prioritize. As a result, some technologies diffuse whereas others do not.
3. A perceived gap exists between ‘best evidence’ and ‘evidence-based practice’. Technologies with reported clinical validity often fail to integrate into medical use, and thus prevent patients from benefiting from scientific progress (12). This raises the question of why clinical evidence alone is insufficient to ‘push’ forward innovation, and what other factors may exist, that hinder the diffusion process.

Fitzgerald and colleagues (7) assert that health care is an interesting and complex domain, populated by a diverse set of groups, of which the medical profession have retained primacy, particularly in the decisions to adopt an innovation at the local level. This is achieved mainly via inter-professional alliances and networks for change, which may facilitate or inhibit diffusion.

A health-economics study exploring the impact of technological change on rising health-care spending shows that the rate of innovation is sensitive to changes in

the financing and delivery of health care, including the level of reimbursement that new interventions will be able to obtain (6). For example, percutaneous transluminal coronary angioplasty (PTCA),¹ first assigned to a surgical Diagnosis Related Group (DRG),² provided a much higher compensation than the procedure itself cost. This stimulated rapid adoption of the method, and a high level of incremental innovation in PTCA catheters. On the other hand, cochlear implants³ were placed in a DRG that covered only a fraction of the cost of the device. This led to under-diffusion but also to reduced subsequent research and development. Therefore, by limiting payment for sophisticated technologies, some of which are based on the latest advances in science, cost-reducing mechanisms such as DRGs can disincentivize innovation.

Cost is not the only contextual factor that impacts innovation. Social forces and contingencies (accidents) also shape new technology. This includes cases where robust evidence may confirm (or reject) the need for an innovative approach, however it is not sufficient for diffusion without the context of innovation. An example is the use of trastuzumab- a drug for the aggressive Her2 form of breast cancer – in the UK and Northern Ireland. This particular type of cancer affects about 20– 30% of breast cancer patients (14). The case attracted numerous media headlines due to a series of legal contestations and appeals over the restricted availability of the drug through the National Health Service (NHS). At first, the medication was licensed for the treatment of advanced breast cancer that had spread in the breast or to another

¹ A surgical investigation based on inserting a small catheter in the femoral artery with the help of a camera, with the specific aim to clear up and bypass acute pathological obstructions affecting the arteries.

² Diagnosis-related groups (DRG) have been introduced in the hospital sector of many health-care systems over the past 10 years, as a cost-containment measure based on the expected costs of inpatient treatment as a fixed flat-rate tariff for hospital services, as opposed to previous per diem charges. By limiting expenditure in a certain ‘group’ of conditions to a pre-calculated lump sum, covering standard basic procedures, DRGs encourage less diagnostic testing, shorter lengths of hospital stay, and outpatient care (7,13).

³ Surgical implantation, into the mastoid cavity of the ear, of an electrical transducer that transmits sound to the brain

organ. Based on clinical evidence of the drug's efficacy, the British National Institute for Clinical Excellence (NICE) issued guidance stating that health trusts had to provide trastuzumab only for advanced-stage patients. As a result, many patients in the early stages of this type of breast cancer were refused the medication, even in circumstances where their cancer specialist had recommended it. Cancer charities criticized this restrictive policy, and the postcode lottery provision of the drug, which was given to 90% of early-stage Her2 breast cancer individuals in some areas of England and only to 10% in others. Under sustained pressure from clinical professionals, patients patient groups, politicians and the public, NICE issued its final guidance on trastuzumab in 2006, approving the drug not only for advanced-stage patients, but also for use in early-stage breast cancer.

This example reinforces the view that medical innovation can be a highly contested area of decision-making, where clinical evidence, technical attributes of the technology and data on cost-effectiveness only partially influence implementation. Diffusion is affected also by its broader context, such as stakeholders' interests, the political climate, and public expectations. Only some technological innovations accomplish their intended use, as originally meant by the designer and others "drift"¹ into alternative applications. (14)

Other empirical studies identify multiple cases where validated evidence fails to achieve widespread implementation. Lang, Wyer and Haynes (12) report the case of the Ottawa Ankle Rules, first derived in the early 1990s, as a highly sensitive bedside diagnostic method for appropriate referral for X-ray. Despite systematically reported diagnostic accuracy of the Ottawa Ankle Rules, i.e. 98% sensitivity, 32% specificity, and high acceptance by patients and health care staff, the clinical uptake of the method is inconsistent, and its use in clinical practice remains relatively low (11). This suggests that evidence-base alone is

often insufficient to achieve widespread translation.

Fitzgerald and colleagues (7) explored the process of diffusion of eight different innovations in the United Kingdom, which were considered within two major sectors of health care – acute and primary admissions – and upon which the strength of the scientific evidence varied. The aim was to see whether scientific proof would guarantee diffusion and if so, to what extent. The study found that there was little correlation between strong scientific evidence and opportunities for widespread translation of medical innovation. For example, even though there is much evidence concerning Heparin use following orthopaedic surgery, this has resulted in continuous controversy. Its diffusion has remained at what Fitzgerald and colleagues (7) call the "debated" stage.

Another instance of an innovation that failed to diffuse widely based on the strength of evidence alone is the use of the computer support systems for treatment of diabetes in primary care (7). The St. Vincent Declaration of 1989 set out a guideline delineating a standard of care for diabetes, a directive supported with evidence, but many general practitioner's were not convinced that the evidence was relevant to their patients in primary care, and felt that the standards were appropriate mainly for acute cases of diabetes. As a result, the innovation did not find wide acceptance. It illustrates that new knowledge can be ambiguous and interpreted according to particular contexts, which can affect the degree of translation into daily use.

If robust scientific evidence is not enough to guarantee that a novel medical technique will disseminate into widespread use, this raises the question of which other factors come into play to determine the future of an innovation. In the next section, several perspectives are presented that reveal the factors affecting the dynamics of the innovation process.

Unpacking the concept of innovation diffusion

A popular way of thinking about medical innovation is one in which a group of scientists has a new idea (original basic

research), which then moves in a linear progression from the laboratory to animal models and applied research, to select populations (targeted development), to manufacturing and marketing, and finally to adoption and use at the patient's bedside, as depicted and critiqued by Gelijns and Rosenberg (6).

While some technologies may follow this linear trajectory, this is not a predominant model of diffusion in medicine. There is a substantial body of literature that supports the contrary – the idea that innovative biomedical technology is assimilated in a complex, non-linear, dynamic pattern, often contingent upon a mix of factors. These factors can originate from the attributes of the technology itself, from the context within which the new procedure is meant to operate, or from the interaction between the specific technology and the context (9) in which the device operates (5,6,8,9).

Everett Rogers's work since the 1960s and notably his 1995 publication *Diffusion of Innovations* is a recurrent reference point for diffusion studies at large (7,9,16,17). Rogers offers a framework for considering innovations as new ideas or practices adopted over time by members in a social system. The author defines diffusion as a process by which an innovation is communicated through certain channels over time among the members of a social system, following a five-step process (18):

- Knowledge
- Persuasion
- Decision
- Implementation
- Confirmation

The 'successful' spread of an innovation follows an S-shaped curve (Figure 1). According to Rogers, people are influenced by many factors in their decision about whether to adopt an innovation or not. Determinants include the utility of the innovation, any disruptions that it may cause to existing habits, personal or social values, social status of opinion leaders, and the cultural propensity of individuals to innovate (tolerance or resistance towards change culture) (17,18).

Within a defined population, there are several sub-populations with different ability and willingness to adopt. Individuals

¹ "Drift" is a concept originating in the field of evolutionary biology (particularly in the sense of genetic drift), which has been adapted to other fields such as health services research, (e.g. the use of a leprosy drug to treat dementia). The concept is employed to denote a situation in which a technology is used differently from the designer's intent, implied in the original prescription, so that the innovation might develop in unanticipated ways.

Figure 1. The S-curve, cumulative distribution of adopters over time

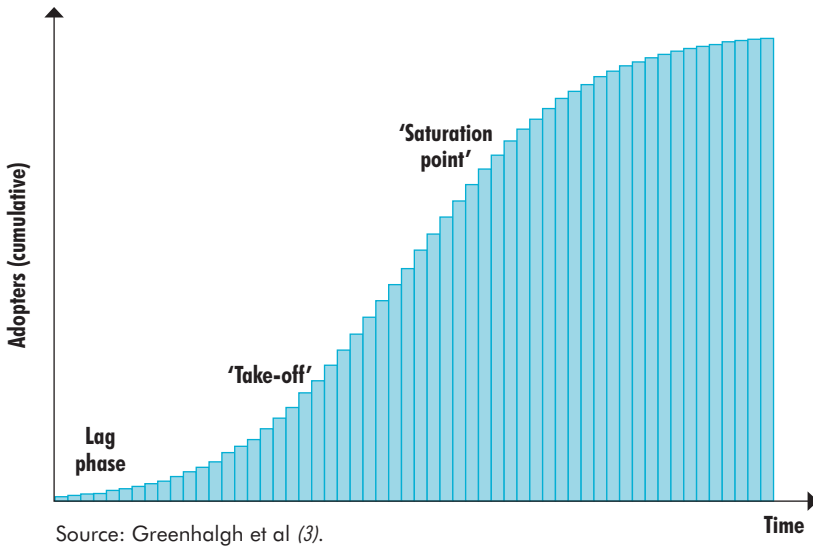


Figure 2. Distribution of new adopters of an innovation against time

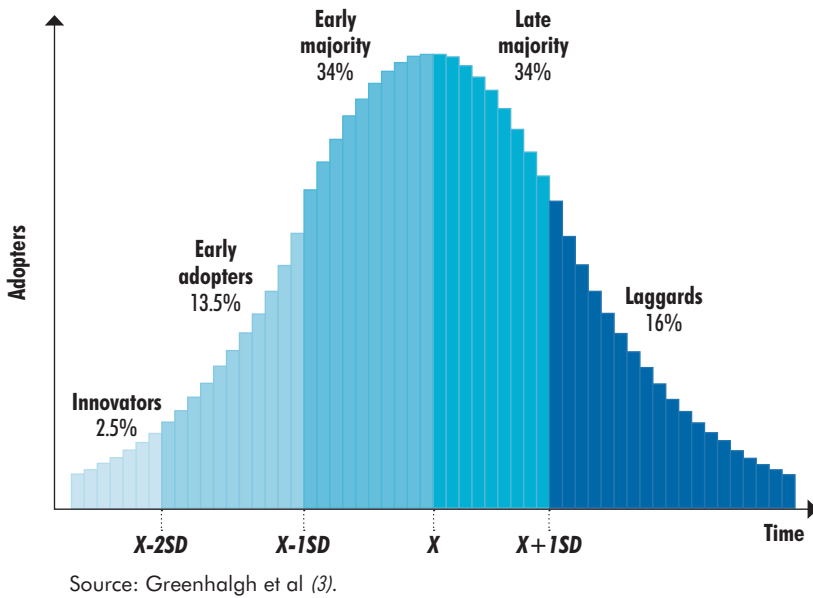
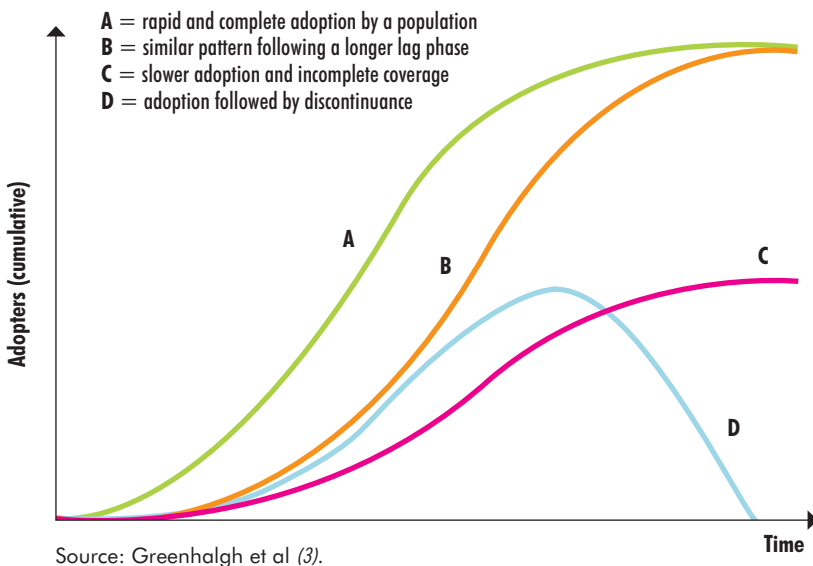


Figure 3. S-curves for different innovations and populations



who are more than two standard deviations earlier than the mean in adopting an innovation ('innovators' comprising 2.5% of the population); those between two and one standard deviation earlier ('early adopters' comprising 13.5% of the population); those with one standard deviation on either side of the mean ('early majority' and 'late majority', respectively 34% each); and those beyond one standard deviation from the mean ('laggards' making up 16%) (3, 18) (Figure 2).

Three points are worth noting. Firstly, that categories, such as "innovators" or "early adopters" are not a reflection of personality features of individuals, but are mathematically defined cut-offs for the adopters of any particular innovation by a population (3). Secondly, the classical S-shaped curve, which shows the pattern of innovation adoption, is the combined curve of the subpopulations of adopters (i.e. 'early adopters', 'late majority', etc.). If separated, the sub-groups of adopters would each have a respective S-shaped diffusion curve with a longer or shorter lag phase and a greater or lesser part of the population that ultimately adopts (3). Thirdly, different innovations introduced into different populations produce a cumulative adoption curve of the same basic shape (S-curve) but with different slopes (rates of adoption) and intercepts (proportion of people adopting) as demonstrated in Figure 3. According to Greenhalgh and colleagues (3), curve D (discontinuation) is the most common diffusion curve of all types, and the challenge is to explain the different adoption curves – (A) rapid and complete adoption, (B) longer lag phase, (C) slower adoption and incomplete coverage, and (D) adoption followed by discontinuance (3).

The purpose of the diffusion model is to describe the step-wise increases in the number of adopters and predict the development of a diffusion process. In the product innovation context, for example, the model provides forecast of first-purchase sales of innovations, where the number of adopters defines the unit sales of the product and its growth (19).

Leadership from those whose opinions are

trusted – “opinion leaders” or “change agents” – is important in innovation adoption as a mechanism to influence others through conformity, so that the spread of ideas among individuals occurs by imitation (16).

Given the importance of “opinion leaders” in this model, particularly at the early adoption stage, any attempt to influence diffusion would need to address the attitudes of opinion leaders first. This could be achieved through mass media and persuasion, or what emerges as a more effective approach, through strong interpersonal ties, such as exchanges about the innovation with peers. These are regarded as more trusted ‘channels’ to deal with resistance or apathy towards a novel idea, and to influence strongly held attitudes (18).

The assimilation of innovation is complex, iterative, and frequently beset by shocks, setbacks and surprises (3).

Critique of the linear model of innovation diffusion

The linear model of innovation diffusion has been critiqued on several grounds. Fitzgerald and colleagues (7) express concern that the simple, stage-like design offered by Rogers presents the innovation-decision process as essentially one of choice between accept and reject, which does not explain why or how the knowledge or evidence is accepted. The authors query a common premise in health policy – that for many conditions there is one optimal solution, based on science; a position conveyed also through agencies such as NICE in the United Kingdom, which is supposed to disseminate evidence and guidance in a top-down pattern to clinical staff (assuming that there is a single unified body of facts).

An objection to this vertical model of knowledge translation can be forged on the grounds that there is rarely agreement among professionals on one optimal solution. As a consequence, a single solution is unlikely to be implemented; and further, interpretations and priorities among those who adopt an innovation (so-called ‘adopters’) affect their willingness to subscribe to innovation diffusion. This

means adopters have an active role in the dissemination process, rather than the “passive” function (as mere receptors of ideas from opinion leaders) ascribed to them earlier by Rogers. Therefore a linear model that takes little account of contextual influences in technology implementation, such as the presence of multiple professions in the health-care arena, with different value systems applied to the credibility of evidence, seems flawed. Fitzgerald and colleagues (7) maintain strongly that knowledge is ambiguous, and a contested phenomenon. Acceptance of such knowledge has to occur prior to changes in practice, and only after a process of debate in local contexts.

Consoli and colleagues (5) also largely reject the linearity of innovation diffusion and deem the model “laboratory bench” to “patient bedside” an under-representation of a much more complex process. Diffusion is a dynamic process through problem sequences (5). This places knowledge translation on a trajectory of change, which involves identifying clinical problems and finding answers by generating innovative ideas. Paradoxically, these ideas can pose problems to existing modes of practice and can therefore have a destabilizing, even disruptive effect on established order, e.g. pre-existing clinical practice, or financing and organization of services (8). The problem–solution rationale for initiating innovative strategies ties in with Hughes’ concept of innovation as a pattern of “reverse salients”, which affect technological developments by driving effort towards corrections of technical problems in an incremental way (20).

The innovation of the intraocular lens for cataracts articulates this logic well (5). The technology has diffused into practice becoming one of the most frequently performed routine operations in the industrial world today. However, it has gone through a trajectory of problem–solution sequences, with an initial lack of acceptance of cataract replacement, with preference being given only to removal. Two events shifted the diffusion process: a community of practitioners enthusiastic about intraocular lenses, who developed shared norms concerning their use, and the adoption of a new technique which

dramatically reduced the incision size for the lens and necessitated the development of smaller, folding lenses.

Over the next 30–40 years the technology evolved in a step-wise pattern, structured around a co-evolution between the invention of devices, medical practice and industrial participation in a mutually constitutive way. This was a systematic, distributed process where problems were solved by the engagement of multiple actors, such as specialist consultants, university departments, firms and state regulators, at the interface of what Blume (4) calls the “inter-organizational structure”. What this, and other examples (e.g. the incremental improvement of the oral contraceptive pill to reduce estrogenic risk, and the refinement of endoscopes through fibre-optics) show is that it is a misconception to make a clear distinction between research and development, and the adoption of medical innovation as implied by the linear model. The development of an innovative technique often continues well after its introduction in medical use. Clearly, adoption is the beginning of a prolonged process of redesign, feedback and adaptation to users’ demands (6).

It may also be the case that the technological innovation itself does not originate within the medical sphere. Gelijns and Rosenberg (6) assert that a high percentage of medical devices have emerged not from clinical research, but through importing of technologies developed elsewhere (e.g. lasers, ultrasound, magnetic resonance spectroscopy and notably, the computer), which are then modified to suit the needs of the medical sector, thus strengthening the capacity to perform ‘upstream’ biomedical research. Magnetic resonance imaging (MRI) for instance, a technology that originated from basic research on the structure of the atom was later transformed into a major diagnostic tool, which has in turn improved the ability to research various internal organs, highlighting the non-linear nature of the innovation process (6).

Despite the shortcomings of the linear model, two concepts are particularly valuable. One is the delineation of phases in the innovation process, upon which subsequent research has built, including the

criticism that the neat stages misrepresent a much more complex reality. The other is the idea of interpersonal influence through social networks, opinion leaders and change agents, as the dominant mechanism for diffusion (18). According to Greenhalgh and colleagues (16), adoption decisions occur via patterns of friendship, advice, communication and support existing among members of a social structure, where different groups have different types of social networks. Doctors, for example, often operate in informal, horizontal networks, effective in spreading peer influence. Nurses, however, are observed to have more formal, vertical networks, better placed for “cascading” information and passing on authoritative decisions (16).

With these provisions in mind, translation of knowledge into practice can be understood as a long-term learning process – characterized by a constant exchange of feedback between the developers of medical technology (e.g. research and development laboratories or clinical practices), and its

users (e.g. physicians, regulators, payers, insurers) – which gradually reduces the uncertainty associated with new treatment options.

The role of expert users is traditionally associated with physicians, acting on behalf of their patients, not only as sources of information but also as specialists in the field with the skills and tacit knowledge necessary to turn new ideas into applicable solutions. While the medical profession, and particularly specialists, are indeed a key driving force behind innovation, the reciprocal relationship – innovation driving forward specialization – is also worth considering. In fact, Blume (4) suggests precisely that new technologies foster specialization (division of labour) in medicine, an example of which is the invention of the thermometer, pioneered by Hermann Boerhaave in the 1700s, which permitted delegation of the practical part of diagnosis to assistants, leaving the physician to apply diagnostic skills to the interpretation of the data obtained. A

secondary effect of the division of tasks, based on the use of advanced techniques, is an ascended status of doctors over non-clinicians, such as the nursing profession, and the establishment of certain hierarchies in the medical profession.

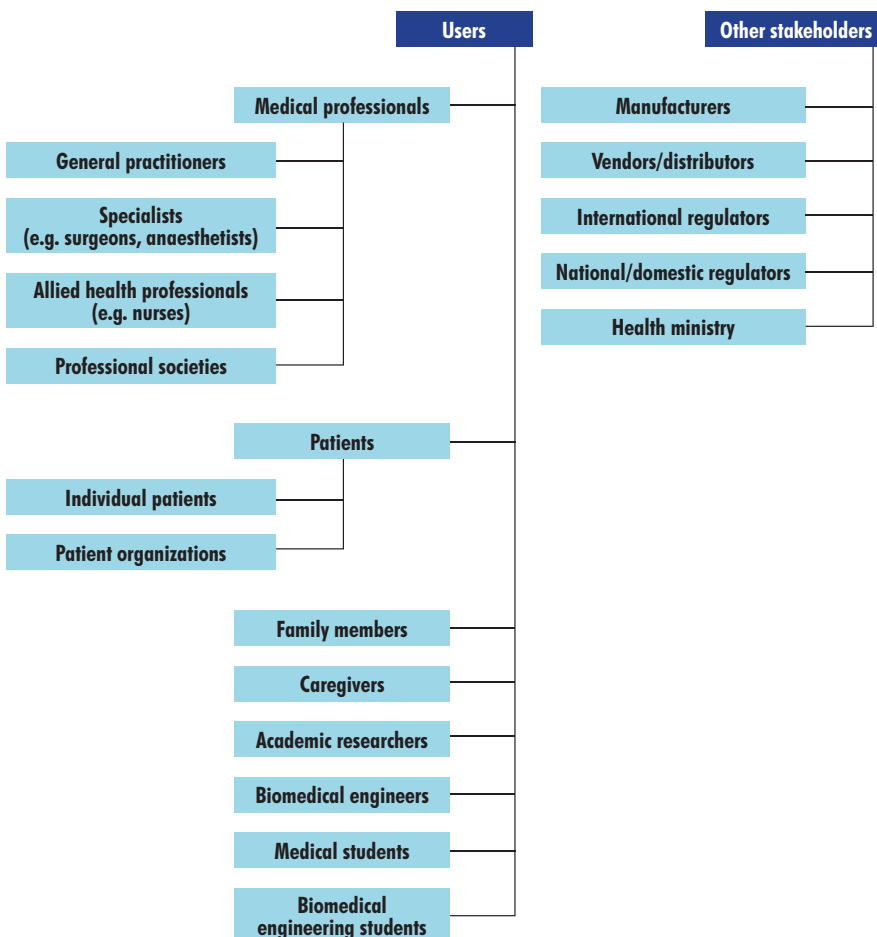
The changing composition of the users of new medical devices

While medical professionals still hold an essential position as users of innovative clinical methods, other participants in the diffusion process are important. These include patients, health economists, government officials, managers, insurers and regulators, all of whom are increasingly important in identifying demands for new technologies, as well as which services will be integrated into mainstream care, and how they will be used, distributed, paid for, evaluated and monitored. This has shifted the balance of determinants of innovation from factors such as clinical evidence and decisions made principally by doctors and scientists, to cost-efficiency and sociopolitical considerations, such as equity of access, and involving non-clinicians in the decision-making process of adoption. What once could be called “an extreme information asymmetry between physician and patient” (6), which gave clinical professionals unlimited power to determine the demand for novel techniques, is now mostly outmoded, with patients now active participants in decisions about health and access to state-of-the-art services.

In spite of the increasing role of social and economic factors in the innovation adoption process, medical practitioners retain their “medical mode of control” (4) and still have powers to facilitate or block innovation.

For many physicians, innovation is seen as a symbol of higher quality of care, but also as a source of prestige, status and distinction. It attracts research grants to hospitals, particularly in public care systems such as the British NHS, but also in private in-patient sectors where in order to attract a greater market share, managers aim to offer potential ‘customers’ a wider range of state-of-the-art technologies. In addition, new technologies give a certain status to specialists in terms of availing clinicians of powerful instruments to control, through which they can revalidate

Figure 4. Stakeholders involved in the innovative process



their profession: “by inventing technologies which need highly specialized medical expertise to operate, physicians are securing a role for themselves” (4). This ‘protectionist’ policy by clinical specialists through “inventing” methods whose use relies on certain expertise becomes even more evident against the backdrop of prospects for replacement of surgical work with robots (21).

Finally, an important determinant of the innovation process is the payment mechanism for medical services in different health care systems. In countries such as Germany, where insurance companies act as third-party payers of services, patients and medical practitioners can be seen in

isolation from the financial implications of their decisions. This has been changing over the past 10 years, with increasing costs, shared by patients in the form of co-payments, and a reduction of the number of reimbursable services as part of compulsory care. Figure 4 captures the main stakeholders involved in the innovation process as potential beneficiaries of the current report.

In summary, this section has considered the literature on the translation process from a critical stance. It has been shown that although the linear model (18) has some merits, for example, in its conceptualization of opinion formation within peer groups, its linearity does not do justice to the complex

and contextualized feedback mechanisms that operate to influence technological development in medicine. Furthermore it was argued that scientific evidence is not sufficient to ‘push’ through assimilation on its own; rather, there is an interplay between the technological and social systems so that diffusion engages multiple actors at an interface of “inter-organizational structure” (4). Finally, diffusion can result from relatively stable organizations and processes (‘regularities’) but can also be influenced by unpredictable events (‘contingencies’) that make it neither an entirely random, nor a predictable process. The next section will start to unpack the implications of these conclusions in more detail.



Trends in medical device development and barriers to innovation

The purpose of this section is to identify barriers to innovation in medical devices for the developing world as part of the WHO publication *Medical devices: Managing the Mismatch*. It examines perspectives from the existing literature on obstacles to the effective adoption of medical devices. Problems meeting the needs of low-income countries by technologies designed elsewhere are also considered. In this respect, the paper identifies a considerable gap in current innovation work. Much attention is focused on factors that hinder the adoption of devices in low-resource settings (acquired through import or donation) that have already been designed outside their domestic context (typically in developed countries). Little is said, however, about why there is limited domestic innovation in low-income countries in the first place, and how to tackle its absence. What are the barriers to local development of medical devices?

A mismatch in design for different contexts is not limited to separate countries. There are examples within high-resource settings where innovative solutions designed for one context (e.g. a hospital) do not address the need in another (e.g. home-care).

The verified answers to these questions may only be possible with input from empirical work. However, the purpose at present remains to offer insights into trends and barriers to innovation identified in the literature from a critical stance, but also to try and anticipate possible reasons why priority medical devices are not generated or appropriately used in certain environments.

Medical devices cover a wide range of instruments, from weighing scales to sophisticated implants, imaging systems and laboratory equipment, that are used at all levels of health services as inputs to patient care and as tools in medicine for the prevention of disease, disability and death (22). According to the World Health Organization (WHO), medical devices are

at the core of public health interventions for the prevention of death or disability, and for managing the diseases of poverty (23).

These traits are recognized by the WHO publication *Medical devices: Managing the Mismatch*, which uses the term “priority” to denote gaps in the availability of appropriate medical devices for the prevention, diagnosis and treatment of high-burden diseases in selected low- and middle-income countries.

Populations in industrialized countries often take for granted modern medical technology and expect to be treated with state-of-the-art equipment, whereas people in financially-disadvantaged countries frequently experience shortages of essential supplies, such as syringes or oxygen masks. The stark contrast between these realities is not difficult to explain, but extremely hard to tolerate from humanistic, medical and ethical points of view. Indeed developing countries, which are often exposed to the pressing circumstances of food crises, civil wars, or severe infringement of human rights, can hardly make their health care systems a first priority. They can neither consistently spend to bridge gaps in health-care provision, nor match the high level of material and human resources that advanced economies deploy, which is needed to develop and introduce missing medical devices or maintain those already provided from donor countries.

There is an obvious need to seek ways of closing the gap between what is needed and what is available in terms of medical devices in financially-disadvantaged societies.

In response to this challenge, governments, industry and charities have shown a willingness to invest in or donate medical devices to developing countries, as part of an overarching aim to achieve “Health for All by 2000” as set out in a WHO project from 1979 (24). One of the reasons some

people thought this goal was within reach was because the technologies needed to perform key interventions (such as oral rehydration solutions, food supplements, antibiotics, vector control agents, water pumps and latrines) were inexpensive, well-known and effective (25). The logic ran that if these technologies were successful in targeting causes of disease in developed countries, they must be equally effective in helping the developing world. Although some early success was registered, the campaign was largely a failure (26). One example of a failed attempt to ‘transplant’ technology from advanced to less-developed countries is the case of malaria, which was eliminated in the developed world by the application of engineering techniques (draining swamps, salt flats, and contained sewer systems) and pesticides. Substantial investments by WHO and others to apply these same technologies in the developing world have been generally unsuccessful, and malaria remains one of the largest killers of children and pregnant women in sub-Saharan Africa (25).

Explanations for the failure amounted largely to mistrust in the government by local communities, expensive installation and maintenance of engineering solutions, and high levels of emigration of health professionals, all of which disincentivize large public projects (25). Clearly a number of factors in the local context of developing countries influence technology diffusion in unanticipated ways, and expectations that familiarity with the equipment, its affordability, and effective application alone would be sufficient to guarantee their successful use did not live up to reality.

Within the narrower domain of medical devices, such factors apply as well, which reinforces the argument that ‘transplanted’ equipment from high-income countries to middle- and low-income ones rarely translates appropriately. While devices brought in from abroad might officially be

'available' in developing countries, they are not always exploited to their full capacity, for which there are certain barriers to blame. These are presented in more detail in the following section.

Imported versus locally produced medical devices

Medical technology in developing countries is often imported.

Import, with reference to medical device movement, is used as a broad term in the literature to denote acquisition of equipment by developing nations from outside their own domestic setting. This includes devices that are sold (often at discounted prices but nevertheless to make a profit) by the exporting developed countries. The term also refers to donated items through aid intervention. In this respect, several trends emerge:

- Developing countries represent new market opportunities for the medical device industry.
- There is a strong degree of reliance by low-resource settings on imports of medical equipment from developed countries.
- A large number of medical devices acquired by developing countries remain idle, suboptimally or inappropriately used.
- Research attention focuses on barriers to diffusion of imported medical devices, and on how industry in developed countries can (re)design instruments for the developing world in view of local deficiencies.
- There is sparse literature on barriers to invention of medical devices locally within developing countries.

The developing world – a growing potential market for the medical device industry

It is estimated that developing countries altogether represent an immense potential market for medical devices in view of the sheer size of their total population (4.9 billion), generating an aggregate gross domestic product (GDP) comparable to that of the developed nations (27). This creates a strong incentive for high-income economies, notably the United States, Europe and Japan to produce equipment for export to the developing world. In

addition, many multinational companies have already established manufacturing facilities in new destinations, such as China, as a way of accessing the local market directly but also exploiting opportunities for lower production cost. Some companies relocate their business off-shore altogether and produce medical devices for re-export to the home country.

China is a rapidly growing market, with a share of 34.4% of the Asia-Pacific market's value, and an estimated annual medical device market growth rate of 14.9% in the period 2002–2006 (28). In nominal terms, the Chinese medical device market is worth around US\$ 14 billion with a projected value in 2011 of US\$ 23.2 billion, which represents an increase of 69% since 2006. A factor that contributes to the attractiveness of this market for foreign entrants is the limited number and small-scale of local production and development of medical equipment, which gives large multinational corporations considerable market advantage.

The reality is that scarcely any large scale local production of medical devices takes place in the developing world, or where it does, it is under the control of multinational companies for export purposes (25).

Exports of medical devices by developed economies for profit purposes constitute one possible channel of acquisition for low-income countries. Other ways in which health-care equipment reaches the developing world include aid interventions, joint partnerships, and provisions of supportive systems, often the result of diplomatic initiatives funded by high-income economies.

In spite of changes in the global economic landscape by steep market growth in some countries (e.g. China and India), overall there is still a large degree of dependence on donor assistance in the area of health care. Reliance on aid for medical devices is caused mainly by persisting financial problems in low-income nations, lack of resources in public health care systems, and a growing burden of disease. Donations usually include physical equipment and spare parts, and in some countries, nearly 80% of health-care equipment is

funded by international donors or foreign governments (29). Assistance can take different forms, such as corporations acting directly or through private voluntary organizations, or governments providing aid to other governments, while the intended beneficiaries can range from individual health-care facilities to entire health systems (29).

Despite considerable investments, a majority of developing countries do not seem to recognize the management of medical devices as a public health priority, or lack the capacity to do so. This often means that equipment is procured in ways that do not correspond to standards of efficacy, quality and safety (23). In sub-Saharan Africa, for example, almost 70% of equipment is found to lie idle due to mismanagement of the acquisition process, absence of user training and lack of effective technical support (29). Another study reported that over 50% of the medical equipment in developing countries is not functioning, not used correctly or not maintained, with some being entirely unnecessary or inappropriate to fulfil its intended purpose (23). In addition, about 30% of the medical equipment that the World Bank spent US\$ 1.5 billion on between 1997 and 2001 was found to remain unused (22). Of the devices in use, 25 to 35% was not used due to downtime (e.g. equipment breaks), often with an insufficient capacity to repair the technology.

What other reasons are there that might account for the failure of most medical devices once they reach developing countries? Why does equipment known to be effective in advanced economies not work in low-resource settings? The following text provides some answers.

Barriers to medical devices

As illustrated earlier, technology diffusion in medicine is a complex, non-linear and dynamic process. There are obstacles to the introduction of any innovative method, procedure or piece of equipment, regardless of whether it takes place in a developing or developed country. Common barriers to innovation do exist for both high- and low-resource settings, such as limited staff training on how to use the new device,

hostility on the part of established medical practice and reluctance to admit the need for skill upgrade (as seen in the intraocular lens example in the United Kingdom). However, differences are observed in the ways that countries are able to respond to these challenges.

An example of this can be seen in the case of invasive interventions such as cardiac pacing or blood pressure monitoring through electrodes, and catheters entering the heart or great vessels. Used at first in the 1950s, these devices caused concern in the 1960s and 1970s due to the risk of micro shock – a small electrical current not perceptible by normal human contact that could be channelled via the invasive devices to cause cardiac fibrillations (22). This issue was addressed in developed countries through intense research by scientists who improved the design of the devices. Users were also educated accordingly. Such response to a ‘technical’ barrier of this type requires knowledge, skills and resources in operation, which are not readily available in low- or even medium-resource settings. As medical devices gradually evolved, the issue of maintenance emerged, which again, industrialized countries were able to solve by appointing technical experts in hospitals. This did not occur in many poorer health-care systems, due to lack of financial resources, but also other factors, such as a dearth of educational opportunities and emigration of trained professionals from developing to developed countries. This example shows how priorities and opportunities diverge between high- and low-income societies but also that most medical devices are designed for the industrialized countries, which has implications for their appropriate use in financially-disadvantaged settings. While responses to identical challenges in medical technology can differ between developed and developing nations, there are certain barriers to innovation that are unique to the developing world. These are addressed as follows.

Cost

The cost involved in purchasing medical devices can present a major obstacle to their use in developing countries. For

example, a single MRI scanner can cost more than a million US\$ to purchase, and together with operating costs can take up a significant proportion of a developing country’s health-care budget.

The cost of capital, however, is only the tip of the proverbial iceberg, with many recurrent costs hidden underneath, such as service contracts, spare parts, depreciation, consumables (e.g. accessories such as needles), training, etc. Such costs are presented in Figure 5.

Spare parts

The lack of spare parts for the repair of medical equipment can present a serious barrier to continuous use. Most devices put into operation generally function effectively at first, but some components will inevitably need replacement after a certain period of use. Data from an Engineering World Health (EWH) study of medical equipment in developing world hospitals point to four main reasons for this shortage of spare parts (25).

- The spare parts are no longer produced.
- Purchasing the part requires a credit card (few people in the developing world

have a credit card).

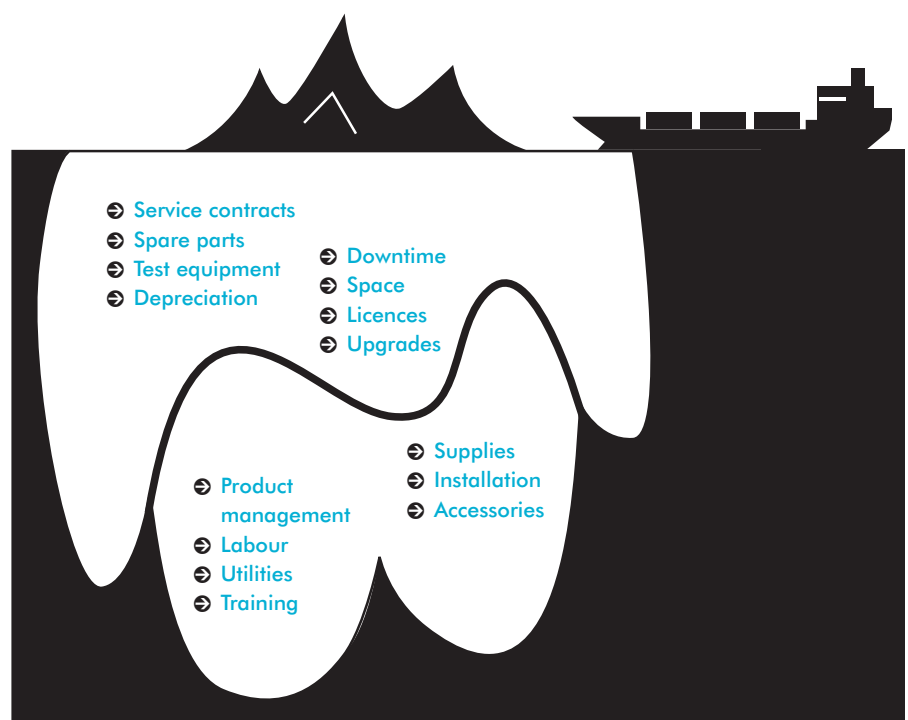
- Health staff members believe that purchase of spare parts is a poor use of resources (e.g. requesting a new device altogether from a sponsor in a developed country can be seen as a better option than meeting the cost of a spare part).
- Technical staff members do not act due to frustration, lack of tools and manuals, and/or corruption.

However, the EWH study also found that the lack of spare parts may not actually be a predominant barrier. Only 12.3% (120 out of 975) of the broken equipment actually required a spare component that could not be found or was not produced in low-resource countries (26).

Consumables

For their appropriate use, some medical devices require accessories (i.e. consumables). An intravenous (IV) infusion pump, for example, needs compatible IV sets that must be replaced for each patient (22). While the pump itself might be provided for free by a medical device donor, its subsequent use requires a

Figure 5. The hidden costs of medical devices



Source: Adapted from (22).

continuous supply of IV sets and therefore a recurrent budget, the absence of which in most developing countries presents an impediment that can lead to poor-quality services, but also to devices being left idle, or even to pressure on governments to provide for the running costs (22).

This example assumes that there is access to consumables on the market and that the problem lies in inability to provide a continuous stream of money for their purchase. In most cases, however, the consumable is simply not available in the country or has highly specialized features, which inhibits its replacement with substitutes (25). In fact the inability to find alternative consumables is cited as one of the most common barriers to the purchase of medical equipment by hospitals in the developing world, and by donating organizations (25).

Expertise and training

The importance of up-to-date medical knowledge and technical skill to operate increasingly complex equipment cannot be overstated. Dankelman (21) illustrates the long learning curve involved in mastering device-dependent procedures such as colonoscopy, minimally invasive surgery, robotic surgery and endovascular procedures. While there are certain benefits to for patients from treatments based on advanced instruments (e.g. laparoscopic surgical tools can be inserted in the abdominal area through small incisions, allowing an improved healing process), the risks of incidents and complications remain high due to various factors, like working in only two dimensions and hand–eye coordination problems. Technical skills on how to operate equipment form an essential element of its effective use. In this respect, the lack of a training curriculum for surgeons that is adapted to rapid changes in technology (or clear guidelines and standards), renders the skill of surgeons inadequate in many cases and presents a barrier to technology diffusion.

Although Dankelman’s study (21) deals with the technology-driven need for training in developed European countries, the same issues concern developing countries that are at the receiving end of medical devices. In fact, the need to train doctors

and technicians on how to use imported medical devices in low-resource settings is even greater due to the fact that health professionals have less exposure during their education to advanced equipment than their colleagues in relatively wealthy nations.

Training in the appropriate use of devices is so important that the lack of trained personnel in developing countries constitutes a considerable barrier to diffusion. Complicating matters is emigration of qualified health practitioners to high-income countries where better career opportunities await (“brain drain”). “Brain leak” can also occur, that is where workers educated to perform a specific task in a hospital then emigrate elsewhere (25), to another district hospital for example. This phenomenon acts as a disincentive for some hospitals to invest in their employees’ education, as they might lose personnel to another hospital (e.g. a private one) or to emigration abroad.

The safety and treatment outcome of medical devices is directly linked to the operators’ skills and to how the equipment is managed, not only on a single-case basis but consistently. The traditional one-time training by the manufacturer as a condition of purchase is insufficient, particularly in view of the high turnover of personnel in developing countries and the need to train new staff frequently (22). This mandates a systematic approach to education and training, including the publication of instruction manuals in local languages and ensuring that minimum standards are maintained. Cheng (22) proposes a framework based on “Good Management Practices” in technology management, which considers that a single health-care facility might not be able to afford an in-house management system, and recommends that a group of regional facilities pool resources for a shared service in such a scenario.

Infrastructure

The lack of reliable electricity and water supplies in many developing countries acts as a barrier to medical devices, particularly in view of the fact that most equipment comes from economically advanced nations with well-developed infrastructure and is designed to function in an environment

provided with basic conditions (e.g. power, water, road network, etc.). Material infrastructure as basic as this is not readily available in low-resource countries. Rural settings in particular are exposed to recurrent shortages of water and electricity. For instance, the poor quality of roads can make a trip to a large town to obtain water difficult. Basic provisions, such as oxygen supplies, can be scarce. For example, an informal study in the United Republic of Tanzania in 1991 showed that three quarters of district hospitals have cylinder oxygen supplies for less than a quarter of the year (30). Dobson reports (31) that largely due to the lack of infrastructure and failure in the ‘oxygen chain’ (finance, vehicle and fuel, ordering and delivery, road system, storage, stock control, etc.), in many developing countries up to 75% of the district hospitals are without a regular oxygen supply.¹

Barriers to local development of medical devices: international and local regulation

The value of regulation for medical equipment is indisputable in terms of providing assurance for safety and quality of care. This view underpins standards developed by major international organizations such as The Global Harmonization Task Force, the World Trade Organization and the International Organization for Standardization (32).

Such standards can be helpful in providing useful directions for the governments of many countries, especially those that lack medical device-specific regulation.

While the promotion of standards and control of medical devices is undoubtedly essential, excessive regulation – particularly one that is insensitive to domestic context – can also act as a barrier to local innovation. It can potentially hinder domestic innovation by subjecting new technologies to lengthy and expensive licensing processes, thus increasing the cost and the time that local manufacturers have to invest in addition to production costs. As a consequence, technologies with relatively low development costs, such as immune-diagnostics, may

¹ Oxygen for clinical use can be provided either from a cylinder of compressed gas or from an electrically powered oxygen concentrator. Cylinders have been more widely used in the past, but for logistic and cost reasons they are not always available in sufficient quantity – or even at all – at district hospital level in developing countries (31).

become unaffordable. Some products that are of significant value to low-income countries may be removed from the market due to perceived risks associated with their use, based on high standards in advanced industrialized countries (where guidelines usually originate) (33). For example, as the EWH study found, original replacement batteries for a defibrillator can cost between US\$ 200 and 300. It might be possible for a local manufacturer in a developing country to produce a cheaper alternative option, but which is very unlikely to meet international standards (such as operating at 0° C) (25).

In sum, by imposing robust standards, the international community in medical device regulation seems to deter rather than stimulate local innovation, which “kicks out the ladder” from under producers of equipment in developing countries (34), and compromises the ability of these local producers to thrive,

Cultural and social context

Medical devices do not exist in a vacuum, but are part of a broader context. From the very inception of a new piece of equipment, treatment or procedure to complete adoption in clinical practice or decline thereafter, innovation is influenced by multiple interests of the involved stakeholders.

While some key aspects of the medical device context were already discussed, such as material infrastructure and economic resources, there are other important issues which affect the creation and diffusion of equipment, such as traditional cultural practices for example.

Medical practitioners who apply bio-scientific principles in treating patients tend to view the mind and the body as two separate entities. This often differs from holistic care based on traditional healing, which emphasizes spirituality and has less use of technology (35). Many traditional communities in developing societies are proud of their culture, often dismissing western values and sometimes also reject medical devices, even if they are supplied at lower cost (1,25).

Barriers to innovation in high-resource countries

So far the paper has concentrated on barriers to innovation in low- and medium-resource settings. It is generally thought that high-resource countries experience fewer obstacles due to better provision of funding and infrastructure, and relatively stable health care systems. Furthermore, innovation in medical devices occurs primarily in high-resource countries where traditionally there is more experience and expertise in technology development. Nevertheless, difficulties exist in these settings as well, and can hinder innovation.

One such challenge is reimbursement. This particularly concerns European Union (EU) countries with insurance-based health-care systems. Negotiating compensation for a new medical technology as part of statutory mainstream health care can be a problem, particularly with regard to innovations not yet included in the reimbursable catalogue of benefits. This applies especially in cases of uncertainty about whether the new device should be included or excluded from the mainstream package of care. Cost-containment measures can also affect reimbursement. For example, Diagnosis-related groups (DRGs) have been introduced for inpatients in many settings.

They limit reimbursement to services nationally agreed to be necessary for a diagnosis or therapy/treatment. This means that if there is a new device which has not yet been integrated in the DRG, it will not be reimbursed under this system.

Further, many EU countries experience administrative, regulatory and sometimes bureaucratic barriers to innovation, particularly in medical devices and generally in biomedical technologies. One such example is the lengthy assessment procedure of innovation through the German Joint Federal Committee (G-BA) or the evaluation of new technologies for provision by the British NHS through NICE. While these institutional steps are necessary to ensure high quality and cost-effectiveness of innovation, they can slow down the process of delivery to patients and discourage innovation.

To summarize, there is limited, if any, innovation of medical devices locally in developing countries. Considering their sizeable populations, the increasing burden of disease, and their low financial capacity to deal with pressing health-care needs, low-income countries have relied heavily on

Table 1. Barriers to innovation in medical devices

- **Supplier-driven**
- **Linguistic barriers, i.e. literature not translated into national languages**
- **Maintenance contracts are missing**
- **Insufficient staff**
- **Limited access to technical information or it is unavailable**
- **Poor maintenance and repair facilities**
- **Lack of a “training culture”, i.e. poor use of a daily protocol and instructions.**
- **Manuals dense and not easily understandable**
- **Cost**
- **No spare parts**
- **Problems with service maintenance of defective medical devices**
- **Unrecognized standards for quality control & maintenance**
- **Inadequate guidelines**
- **Lack of coordination**
- **Not enough copies of user manuals for all users**
- **Procurement issues with mediating ministries (due to acquisition at the central level)**
- **Direct link broken between producer/vendor & end user**
- **Shortage of technical expertise**
- **Lack of funding and trained staff for support**
- **Weak management culture**
- **Lack of quality assurance**
- **Technical information sometimes withheld by industry**

Source: Hansen et al. (1)

Table 2. Stages of medical devices life-cycle

Concept stage: starts with idea generation and includes technical, financial and commercial viability.

Design stage: involves actual product development processes from design to prototype development.

Testing & Trials stage: starts from prototype testing 'in-house' and includes trials in field, going to market, selling and production.

Production stage: includes production on a large scale supported by a business & commercial rationale.

Marketing & use stage: includes product launch in the market and post-launch use.

Source: Adapted from Shah and Robinson (34).

at truly addressing the needs of low-income countries.

Solutions to this last issue can be found in three possible avenues: (i) that technologies originating in high-resource countries be re-designed in a way which compensates for limited resources or infrastructure in low-resource countries; (ii) that barriers to the adoption of devices be addressed; and (iii) that underlying barriers to development of medical devices in low-resource nations be addressed.

Most effort so far seems to have focused on the first point: finding ways on the part of industrialized importing/donating countries to re-design medical devices for low-resource settings. The literature on barriers to innovation reflects this trend. Current work seems to concentrate on barriers to designing medical devices for developing countries by high-income economies, so that ideas are generated outside low-resource settings rather than within them. Table 1 lists several barriers to innovation. In Table 2, the stages of a medical device are outlined.

obtaining medical devices from abroad. The response by the developed world has been to provide various types of equipment, most of which remains under-used at best, not utilized, or misused at worst. Several reasons have been identified for this gap between procured and operating equipment, most notably the lack of material and human resources to maintain medical devices, the absence of spare parts and consumables, lack of technical expertise and inefficient management. This prevents developing countries from making appropriate use of imported medical devices and suggests that one way to address the difficulties in assimilation is for industrialized economies to re-design technology so that it takes into account local deficiencies (e.g. lack of infrastructure).

Another observed trend is that low-resource countries represent a large emerging market for the medical device industry of developed economies, and as such offer ample opportunities for direct exports, re-imports, and off-shore business, with the advantage of low-cost manufacturing and cheap labour. This acts as an incentive for industrialized nations to penetrate new markets by developing equipment which caters to local needs. This places the onus for device production on manufacturers in advanced donor countries and shifts the attention away from local innovation in low-resource societies. This creates a problem in which the market is driven by industry or supply rather than by public health needs, resulting in many efforts that are ineffective

Model for the analysis of barriers to innovation in priority medical devices

Several perspectives from the literature

To dispute linearity in technology assimilation does not mean that innovation should be taken as a chaotic phenomenon (37). Although empirical research largely rejects diffusion models based on a neat order of phases following each other in a predictable sequence (16,37), it is possible to identify a structure built around different categories of diffusion. This allows the identification of states of routinization and also serves as an axis for comparative studies between different technologies, or between diffusion pathways of the same technology in different national contexts.

This paper set itself the aim to gather evidence from the ‘innovation’ and ‘medical device’ literature on trends in diffusion of medical technology and on models according to which innovation takes place. The main objective is to find out why medical devices available on the market are not being used in the health care of selected low- and medium-resource countries. The purpose is to identify the reasons for suboptimal or inappropriate use, which are termed ‘barriers to diffusion’. A related issue also addressed by the paper concerns the absence of certain medical devices from the market altogether, which can be due to the lack of imports from developed economies or to the absence of local innovation. Together these factors can constitute barriers to invention and subsequent diffusion. This inevitably leads to the question of whether innovation (the whole sequence of invention plus diffusion) is able to close the gap in the availability, appropriateness and acceptability of medical devices in the management of high-burden diseases. An important distinction needs to be made at this point between ‘invention’, ‘innovation’ and ‘diffusion’ of medical technology. These terms are often used interchangeably, which is why it is important to distinguish between them. Several perspectives from the literature help to delineate the boundaries of the innovation stages.

According to Roberts (38), innovation is a broad term that can be used to describe both the invention of dramatic new capabilities and of incremental improvements to products and processes that have previously existed and are modified to fit new conditions. In addition to medical device or product innovation, innovations can apply to the manufacturing process, the mode of practice and organizations. Innovation also includes adoption, taking something that someone else had previously done and applying it in a different environment, such as the adaptation of medical devices designed in the developed world to conditions in financially-disadvantaged countries.

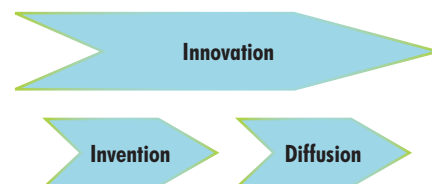
With respect to the actors involved in the innovation process, Roberts (38) disputes the model that says the manufacturer is a main innovator based on successfully identified market needs. The author asserts that the users (e.g. the physician, the academic medical community, or the patient) play a much more substantial role than merely being sources of helpful information regarding their needs to a manufacturer who then innovates. Instead, the user is seen as the principal driving force behind most medical device innovations; the user not only identifies the need but also develops the initial solution to that need, implements it by placing the solution into first trial use, and often makes copies or detailed specifications of the innovation available to other practitioners. At the very least, the user acts as a linchpin to the innovating company (38). Only later does a manufacturer enter the picture by taking on the users’ innovation and engaging in the commercial development (i.e. engineering for manufacturing, reliable field use and service, and volume scale-up).

Roberts (38) sees the medical device innovation process as one dominated not by firms, but primarily by individuals, who are usually in academic and/or clinical settings, involved in the development and use of new technology in their respective

medical fields. While these innovators are seen to hold a primary function in the innovation process, the role of the device manufacturing companies tends to be supportive and secondary with respect to most innovative products. However, data from Roberts’ 1987 study notes also that a large part of potentially valuable user perspectives and insights are dormant in academia, due mainly to the traditionally restricted role of academics with respect to commercial technology transfer and exploitation.

Pouvourville (39) draws a clear distinction between invention and innovation, where innovation is characterized by its diffusion, namely an invention with no market is not an innovation. A visual representation of this distinction is found in Figure 6.

Figure 6. Innovation comprises of invention and diffusion



Source: Based on Pouvourville (39).

Put simply, invention can be perceived as the creation of a new piece of medical equipment or the modification of an old one, following an innovative idea, while diffusion is the process of its translation into use. Diffusion involves the activities associated with developing the new idea into a product, bringing it to the market and succeeding or failing (38). Innovation encompasses the entire sequence of activities from the identification of the need for a new medical device, to the generation of a solution, and its onward evolution into a product used in practice. Therefore, innovation necessarily incorporates diffusion.

Roberts (38) distinguishes the innovation of medical devices from that of

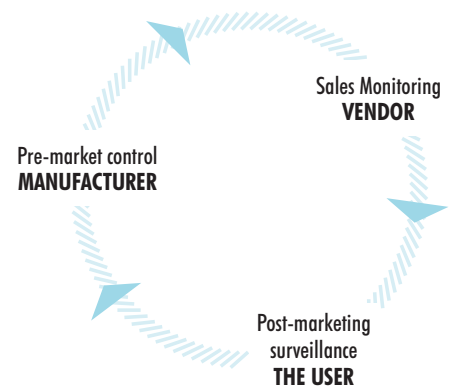
pharmaceuticals by arguing that the former process is usually incremental rather than relying on fundamentally novel knowledge or long periods of basic research typical of drug innovation. Furthermore, medical device innovation is based primarily on gradual engineering problem-solving by individuals (users) or small firms, who often apply existing knowledge or techniques to newly defined problems (38). Figure 7 presents the different phases in the lifespan of a medical device, as a linear sequence of actions, from conception and development by the manufacturer, to advertising the product by the vendor, to use and disposal by the end-user.

This model of neat linear steps, however, is largely outmoded. Instead, a cyclical, dynamic model of constant exchange of information between multiple stakeholders is a more accurate way to describe innovation (Figure 8). Frequently it is the final user of medical equipment (e.g. doctors, biomedical engineers or patients) who are best positioned to innovate and who identify the need for a novel device or for the improvement of an existing technology. Users often invent, more so than the manufacturers themselves and therefore can move from the end stage in the scheme to its beginning. This is captured in Figure 9.

Hotchkiss’ personal experience as a designer of wheelchairs for Nicaragua provides an interesting insight into the

problems of obtaining and maintaining affordable wheelchairs by disabled Nicaraguans (41). The vast majority of people in the country use second- or third-hand hospital-type chairs imported from the US and other developed countries. These chairs often have hard tyres and non-removable armrests and footrests, giving the users little flexibility or mobility, in addition to frequent reported breakdowns and inappropriate functionality for outdoor conditions (41). Certain features in the infrastructure of Nicaragua, such as narrow doorways, high pavements and lack of access to buildings for wheelchair users, impede the use of many medical devices, particularly those designed to function in “barrier-free” industrialized environments. In an attempt to adjust this type of medical device to local conditions, Hotchkiss came up initially with a wooden folding seat that was thought to be an appropriate prototype; it allowed for a simpler and stronger folding mechanism than the average imported US wheelchair (41). However, the use of a wooden chair requires a cushion to prevent the formation of ulcers on people with spinal cord injuries. Although cushions were provided during the first year of use of the wheelchairs, most Nicaraguans could not afford a replacement once the cushions wore out. Therefore the lack of financial means to replace a consumable as simple as a cushion was one of the major reasons for change in the design for local users (41).

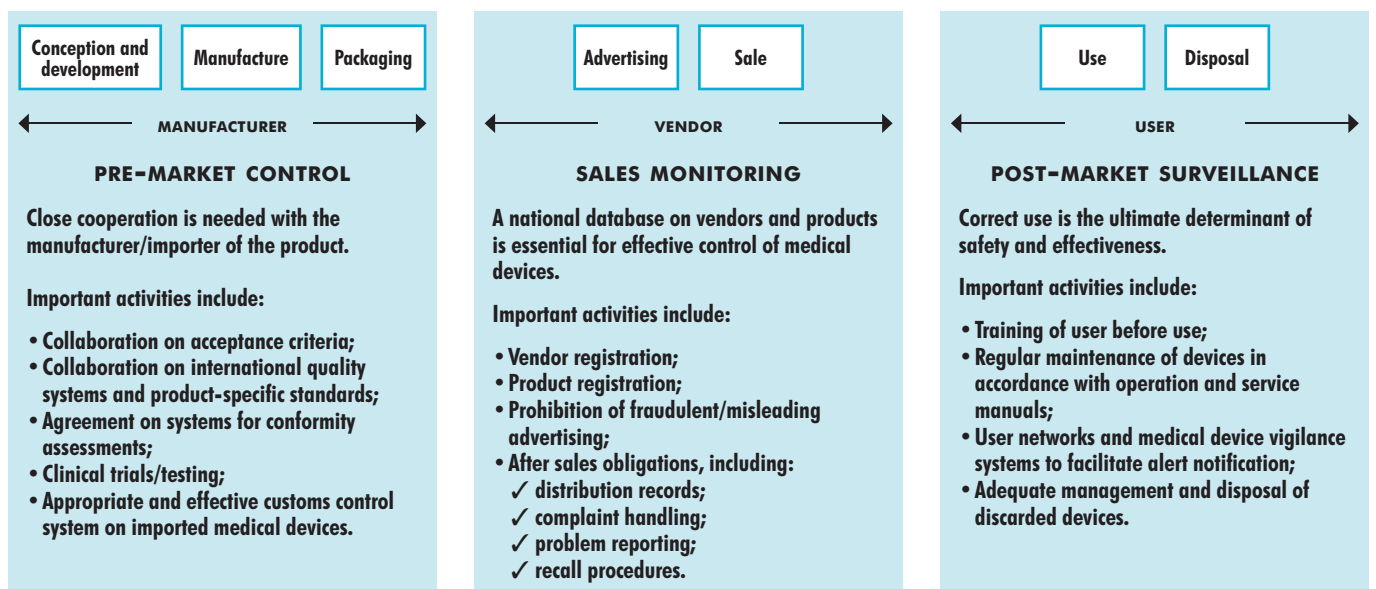
Figure 8. A cyclical model of diffusion



This example highlights two important points. Firstly, innovation in medical devices is not limited to the creation of an entirely new piece of equipment but can instead involve the alteration of existing devices in order to adjust them to specific local conditions. Adaptation of a medical device for use in a context different from the original infrastructure constitutes a valid form of invention and consequent diffusion, which altogether make up the innovation process. The second observation in this instance concerns the essential role of users as innovators, as previously noted.

Greenhalgh and colleagues (16) discuss the differences between *diffusion* (which the authors also call “pure diffusion” or “passive spread”, denoting an unplanned, informal, decentralized and largely horizontal process, often mediated by peers), *dissemination*

Figure 7. The phases in the lifespan of a medical device



Source: WHO (40).

(active, planned, formal, often centralized efforts to persuade target groups to adopt an innovation, more likely to occur via vertical hierarchies), *implementation* (active efforts to mainstream an innovation within an organization) and *sustainability* (making an innovation routine until it reaches obsolescence).

This process can also be considered as 'knowledge translation'. Lang, Wyer and Haynes (12) use this term to describe any activity or process that facilitates the transfer of high-quality evidence into effective changes in health policy, clinical practice or products.

Fitzgerald and colleagues (7) identify six levels of dissemination: widespread, variable spread, debated, limited pockets, pilot and no spread at all. This model considers dissemination in relation to the influence of scientific evidence on the comprehensiveness and rate of diffusion. This is a suitable method to compare "states" of achieved adoption rather than "processes" or patterns of diffusion. However, this approach considers innovation in terms of the relative determining power of only one factor – clinical evidence. By way of concentrating on a single factor – which, as was concluded in the last section does not necessarily have much explanatory power – the model restricts the intensity of the search for other factors, which might have a similar (limited) effect or conversely, might bear more significant consequences for the assimilation process.

Blume (4) established a structure for comparative analysis of technologies based on three concepts: inter-organizational structure, career and problematization based on an analysis of new diagnostic imaging techniques. This will be discussed below.

Inter-organizational structure designates the interaction between clinical and market aspects of a new technology. It shows the information flow between the hospital department and industry.

The concept of career is central to Blume's sociological analysis of technology diffusion. It comprises several phases – exploration, development, integration (diffusion, evaluation and assessment), and feedback:

- **Exploration** – describes the history of attempts to realize a certain vision. For an imaging technology this is the period leading up to the first working prototype and the first publications reporting its successful use.
- **Development** – the industrial involvement in the emerging technology. In the case of imaging innovation, it began with the publication of the first human in vivo images using the first prototype of the technology. This phase ends with commercial manufacture and the new device being brought to market.
- **Integration** – diffusion, evaluation and assessment. For imaging technology, it began with the first specification of its clinical use and ended when the innovation became routine practice. This does not imply 100% diffusion (i.e. all hospitals using the instrument), but a widespread consensus that it is good practice and that professionals need to accommodate the innovation.
- **Feedback** – development of improved models and the search for new applications if the innovation is judged to be successful.

Blume's (4) third concept refers to *Problematization*, that is what is problematic about the technology, when, for whom and with what result. *Problematization* can take many forms, for example, the establishment of new regulatory requirements in regard to a device, or regulations governing the circumstances under which it can be used or its use reimbursed.

In this model, scientists have a key role in the innovation process as technical problem solvers and actors who bring incremental improvements in devices (e.g. better speed and sensitivity). Blume (4) argues that the successful introduction of a new medical device cannot be accomplished without the cooperation of the medical profession as the source of clinical reports attesting to the utility of the innovation. However, routine use of a new device depends also on budgets allocated by hospital managers, by government institutions in state-funded health-care systems, (e.g. the United Kingdom), or on negotiated financial streams between sickness funds and service providers in insurance-based systems (e.g. Germany).

A health professional's position in the 'status hierarchy' depends on his/her performance. For example, a radiologist's status in the hierarchy depends on how well he/she masters the X-ray equipment, which is provided, maintained and updated by the industrial sector. This exemplifies the view held by Blume (4) that technologies evolve through acceptance by "relevant social groups" of actors via negotiation as maintained in the social construction of technology literature (42–44).

Brown, Rappert and Webster (45) propose a model for considering innovation in terms of country-specific "configurations". The authors distinguish between "close knit" and "loose knit" configurational types in different European nations, in terms of the nations' integrative and coordinating capacities to respond to technological change. For instance, a "close knit" arrangement, which is determined by a stable, complex network of organizations, high levels of regulation, and high resource-dependency is expected to resist innovation due to overspecialization and reluctance to change. At the opposite end of the spectrum lie "loose knit" configurations comprised of 'de-centred' relations, weak institutional integration, underdeveloped regulation and low resource-dependency. While structures of this type are expected to provide a more flexible approach to innovation, there is a concern that they may be unable to build innovative momentum.

Meyer and Goes (9) see innovation diffusion as a dynamic, multilevel process of choice with nine identified steps under three broad stages: knowledge-awareness, evaluation-choice and adoption-implementation. The stages and steps are presented in Figure 9.

The authors conducted a study tracking 300 decision-making processes concerning the adoption of 12 medical innovations across 25 hospitals. The research design used built on a proposed model that captures three classes of determinants of innovation diffusion, namely:

1. *Attributes of the innovation*: These include technical features such as clinical utility, validity, and diagnostic sensitivity; degree of manual skill or specialized medical training needed to use the new technique. Innovations

are more likely to be adopted by organizations if, compared to other innovations, they require less skill to use, expose patients and doctors to fewer risks and are more observable.

2. *Contextual attributes* include: include characteristics of market environments, organizational size and structural complexity, and leaders’ ‘power’ in terms of resource allocation. Innovations are more likely to be assimilated into organizations in environments that are urban, affluent and in which few patients rely on state health insurance. Technologies are more likely to be adopted in organizations that are large, complex and eager to penetrate new markets. There are better prospects to diffuse in organizations where chief executives have long tenures and high levels of education, and where physicians have been recently trained.
3. *Factors arising from the interaction*

between the innovation and its context: These include an innovation’s compatibility with the tasks and experiences of potential users, such as the presence of medical practitioners able to apply the new technique, and the extent to which a manager, or chief executive officer (CEO) supports or opposes adoption. Innovations are more likely to translate into practice in organizations where the new technologies are compatible with medical specialization and where CEOs are influential proponents.

The three determinants of innovation adoption are presented Figure 10.

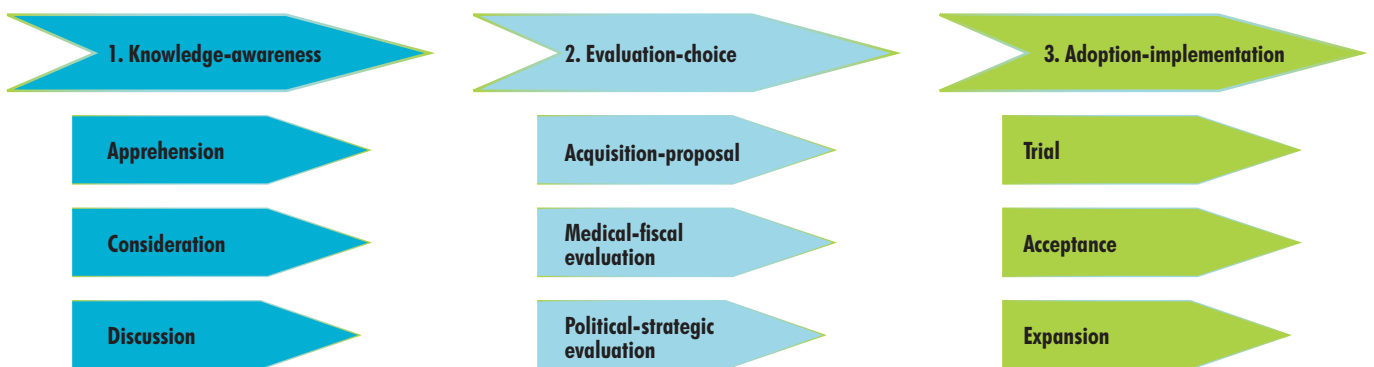
In this model the uptake of an innovation is the dependent variable, and its three determinants – innovation attributes, context and “innovation-decision” attributes – are the independent variables.

The study demonstrates that the three factors strongly influence the diffusion of medical innovation. Innate characteristics of the technology significantly affect adoptability (this factor accounted for 40% of variance in technology diffusion between the 25 studied hospitals). The combined effect of innovation and context accounted for 12% of the variance in adoption. Lastly, contextual factors had the least predictive power in regards to technology diffusion (11%).

Outcomes of the literature review

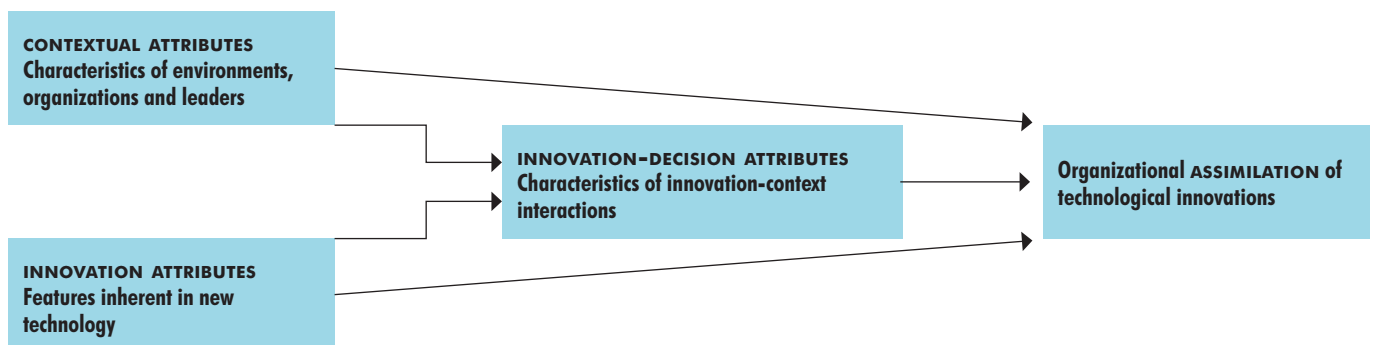
In sum, several key points are worth noting based on the literature review of trends in medical technology, the identified barriers to innovation in the developing world, and the models according to which new or adapted equipment is seen to translate into use, namely:

Figure 9. Innovation diffusion as a multilevel process of choice



Source: Based on Meyer and Goes (9).

Figure 10. A model of innovation assimilation



Source: Adapted from Meyer and Goes (9).

- Innovation comprises invention and diffusion (translation into use).
- Innovation can include adaptation, i.e. applying already existing devices in a different environment.
- Innovation in biomedical technology takes place in a complex, non-linear, dynamic pattern.
- Innovation does not happen solely as a direct and logical consequence of established scientific evidence, but instead is affected by a combination of socioeconomic, historical, institutional and political influences.
- Innovation in medical devices is a gradual process, often based on incremental improvements to existing products.
- In essence, innovation in low- and medium-resource countries predominantly consists in the modification of medical devices obtained through procurement from industrialized economies and their adaptation to fit local conditions.
- Users play a key role in the process of medical device innovation, which frequently occurs in an upstream direction.
- Innovation takes place under the influence of three main factors: attributes of the medical device, the context where it operates and the interaction between the context and medical device.

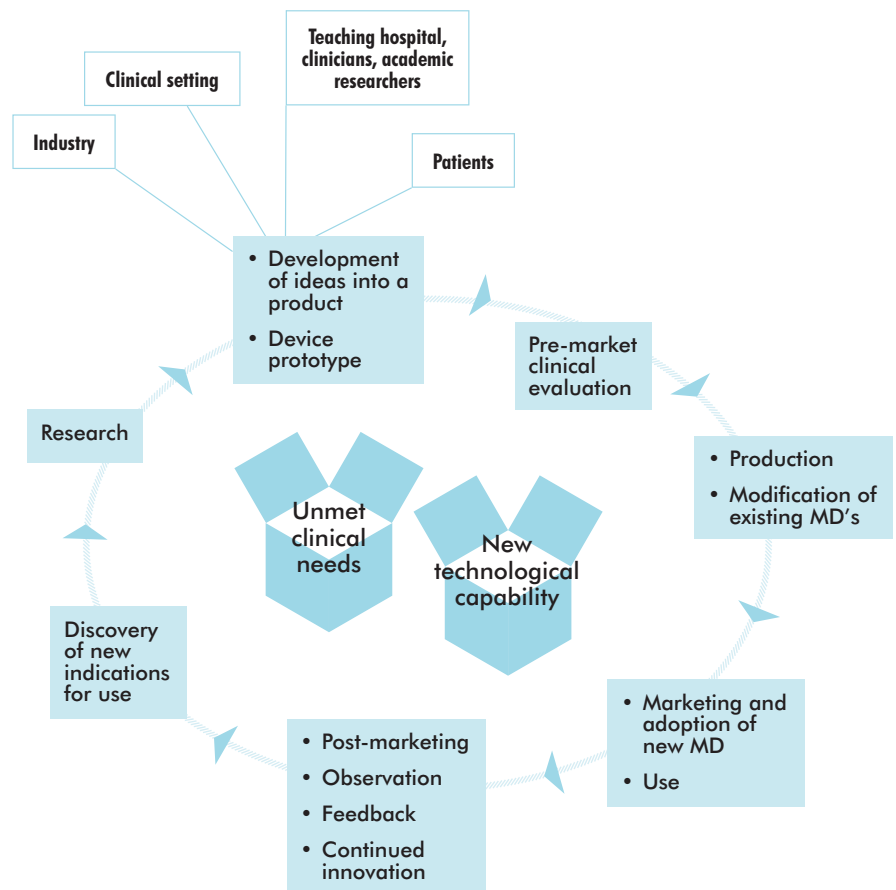
Towards a new model of medical device innovation

Figure 11 captures the main stages of innovation diffusion, and what is necessary for a new device to reach market. As the literature review illustrated, and the survey (1) confirmed, many of the elements necessary for diffusion of new technologies are missing in low-resource countries. Following the phases in the figure below (clockwise from research) shortcomings and barriers include:

- Lack of sufficient local research and research tradition
- Inability to develop new ideas into prototypes using only local resources due to lack of established know-how mechanisms to capture domestic projects and ideas
- Low domestic investment (capital and workforce) in innovation
- The majority of medical devices being imported, which leads to:
 - Little incentive to build experience in pre-market clinical evaluation and other stages before procurement
- Multiple barriers to adopting imported devices designed in different contexts (high-resource countries) to local contexts (low-resource countries)
 - Cost
 - Need for spare parts and consumables
 - Lack of expertise and training
 - Limited infrastructure
 - Cultural and social incompatibilities
- Insufficient (if any) post-marketing observation and feedback mechanisms
 - Lack of systematic reporting of faults during use
 - Absence of systems to record where, when and how ideas are generated and followed through
- Lack of a direct link between clinical needs (locally) and design of devices (abroad).

This model presents the key elements necessary for innovation to occur (this includes the invention of a new device and its diffusion for wider use). The model can be applied to high- as well as to medium-

Figure 11. Dynamics of medical device innovation



and low-resource settings. In high-resource settings there is relatively good connectivity between the components of the model. For instance, established technical capability, expertise and innovation systems are able to pick up where clinical needs lie. Stronger industry stakeholders in high-income countries are well-placed in terms of finances to facilitate inventions. There are also established links between academia, manufacturers, sales, marketing and post-marketing. Despite this, problems still exist in wealthier countries. One issue is the lack of clear-cut mechanisms to reimburse innovative technologies as part of mainstream health care. However there are many more missing blocks in low- and medium-resource countries. The lack of

innovation infrastructures to take up new ideas, for example, can prevent innovators from moving forward. Small enterprises rarely have the financial means to develop a product on their own. Where medical devices are imported in low-resource settings from elsewhere, their adequate local use is made all the more difficult by high maintenance cost, inconsistent training, brain drain, lack of consumables and spare parts, poor road networks and physical infrastructure, absence of procurement culture, insufficient management, inadequate user manuals and additional barriers. Significant steps need to be made to address the barriers to innovation.

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