International Journal of Gynecology and Obstetrics 85 Suppl. 1 (2004) S3–S13

International Journal of GYNECOLOGY & OBSTETRICS

www.elsevier.com/locate/ijgo

Achieving appropriate design and widespread use of health care technologies in the developing world. Overcoming obstacles that impede the adaptation and diffusion of priority technologies for primary health care

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Abstract

Objectives: To identify and describe constraints facing the development and dissemination of technologies appropriate for public health care challenges and solutions in the developing world. *Methods:* Review of lessons learned in development and introduction of numerous health technologies as experienced by a non-profit organization working on technologies for 25 years. *Results:* Many obstacles prevent appropriate technologies from reaching widespread use and acceptance. These include low profit margins in developing world markets, regulatory constraints, and the need for systems changes. Strong public/private-sector partnerships and realistic approaches to working in these environments make a difference. *Conclusions:* There is a growing awareness of the need for new technologies and experience with strategies that can make them happen. Some technologies with documented value for maternal care in developing world settings appear to be stuck short of widespread acceptance and use. Understanding the factors impeding their progress can enable the public sector and its collaborators to organize and facilitate their progress more effectively.

Keywords: Technologies; Developing countries; Appropriate design; Private-sector partners; Introduction; Mainstreaming

1. Introduction

1.1. What are 'health technologies for the developing world'?

Technology can be defined in a variety of ways. In this paper, 'technology' refers to products that are bought and sold (not procedures). The paper discusses the means by which suitable technologies are developed, made, distributed, and adopted, and become standard in the delivery of health care to resource-poor developing world populations. Almost all such technologies get stuck somewhere in this pipeline. The objective of the paper is to identify common blockages and suggest ways for overcoming them.

1.2. Failure of markets

The private commercial sector is adept at generating suitable and affordable technologies and getting them to the people who need them. Users of these technologies, however, must be able and

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0020-7292/04/$30.00
doi:10.1016/j.ijgo.2004.01.009

willing to pay a price that provides a reasonable rate of return on the investment needed to create, make, and market the products. Public health institutions and the populations they serve in low-income countries have many needs, but they lack resources and therefore do not offer attractive markets for investment. Without money, need does not translate into demand.

It follows that the simplest approach to making suitable technologies available would be for the public sector to define the need and guarantee the market. With such guarantees, all needs could and would be met by the commercial sector. The public sector rarely takes such risks, however; a global crisis that threatens the health, peace, or prosperity of the wealthy industrial nations is often required to prompt action.

To overcome market failures in the absence of market guarantees, the public and donor community must partner with commercial entities to share the costs and risks of designing, validating, marketing, and distributing suitable technologies.

The following section describes the product pipeline, and pays special attention to the major blockage points where even well-targeted technologies can languish.

2. Achieving appropriate design

2.1. Essential role of the public sector

In developing world health care—particularly in primary health care—the technologies used in the industrial world are often inappropriate [1]. They usually require well-functioning infrastructure—power, clean water, support systems, waste collection—as well as high levels of training and supervision, and high patient mobility and compliance. These conditions of use are often unavailable in low-income countries. Additionally, the health care priorities and spectrum of diseases in low-income countries differs from those in industrial countries, and requires unique diagnostic, treatment, and prevention tools.

Some needs can be met by adapting existing technologies. Others require new design. In either case, the health products industry has little incentive to send its market researchers into the periphery of developing country health programs to assess needs and define products. The public sector must do it. This is the first sticking point.

Needs assessment and performance criteria. Universities, non-governmental organizations (NGOs), and development agencies are profound sources of knowledge about health needs in low-income countries. Some researchers go beyond an exploration of need to define a solution—an intervention that may include a technology. The performance characteristics of this technology may not be adequately elucidated, however, and the approach may suffer from a lack of international consensus.

Arguably, defining the performance characteristics for a needed technology is the most important task for the non-commercial sector. The ideal output is a clear description of minimum performance that a technology will require to solve a problem (for example, effectiveness, conditions of use, cost, and durability) [2]. That description should be validated in diverse settings and broadly endorsed by the international public health community. This information can prompt donors to support product development and enable developers in the commercial and non-profit sectors to move forward with design.

Achieving consensus on solutions can be a complex and expensive exercise requiring many international meetings, publications, prioritization exercises, and endorsements by key agencies. Resistance to change and fear of innovation are often evident during this process. In addition, the ultimate users of the product may have very different priorities for a device than providers or purchasers of the product do. In some cases, consensus on solutions can only be achieved or enabled by the pilot introduction of prototypes. Such prototypes are only feasible for technologies that can be produced on a limited scale without high capital investment.

Consensus is achieved more easily if the need is within the scope of a high-profile global or regional program (such as immunization, AIDS, tuberculosis, or family planning). Outside these concentrations of resources and central coordination, building consensus can be more difficult. One long-term strategy for safe motherhood and other

such orphan areas of health care that have not received such high levels of attention is to raise them to a higher level of priority in the global community.

Economic sustainability—an essential criterion. Appropriate design is essential to but not sufficient for the success of a technology. The technology must also be available for the long term, affordable, and of adequate and consistent quality. Except in rare circumstances, this requires that the technology be undertaken by the commercial sector at some point. The most critical factor in achieving transfer to a commercial partner is reasonable assurance of a market (see below). At the design stage, there are also some important considerations, collectively known as design control, that include excellent record keeping, attention to manufacturability, raw material availability, and intellectual property. The progress of a technology is often impeded by these issues.

2.2. Design control

Wherever original design takes place, it must be as rigorous as in the commercial health industry setting. Almost all health products require some level of regulatory clearance or pre-qualification. Recent design control regulations, the increasingly stringent standards of internal review boards (human subjects ethical review), and future licensees or collaborating manufacturers demand a prescribed and disciplined approach to record-keeping and process. Consequently, it is more difficult for a lone developer to advance in the process of design and development. However, there are possibilities for early collaboration, particularly by technology-oriented NGOs, collaborating commercial companies, or contracted service groups. Also, some health care service providers are willing to test concepts, join focus groups, and conduct design-stage clinical trials.

2.3. User as co-designer

The only sure way to fully meet user needs is to involve the user in the design process. Design concepts must be challenged in a variety of settings, cultures, and programs. Cycles of testing and refinement are often needed, particularly for technologies involving critical human factors (e.g. devices and diagnostics). Drugs and vaccines may also perform differently in various cultures or with different levels of nutrition, co-infection, or external conditions. The participation of target populations in these trials is indispensable.

2.4. Donor as venture capitalist

In the past, donors generally have not been keen on underwriting design and development of new health technologies. Their interest has increased in recent years, but the levels of funding are still not sufficient by commercial standards, which leads to long development periods, premature expectations, and donor fatigue. Donor interest may be stimulated by demonstrating:

- A clear and well-supported understanding of the need.
- Well-developed technology performance characteristics to meet the need.
- A network of qualified partners willing to commit if resources are made available.
- A realistic view of the hurdles involved.
- A credible projection of the value in terms of benefit that could be attributed to the technology once in widespread use.

The significant investment in new technologies made by some donor or development agencies is often not recognized or supported by other agencies, or even by implementing divisions of the same agency. Bridging these institutional policy gaps between innovation and implementation can help overcome impediments to the diffusion of new technologies for developing world health programs.

2.5. Public–private partnerships for design

Early involvement of a competent and committed private commercial firm can help overcome the impediments noted above [3]. Industrial world health firms of all sizes may become involved in advancing products for developing world health if:

1. The need is clearly defined.

2. A reasonable consensus exists among the international public health community.
3. A meaningful collaboration is offered to raise funding, design, field test, align policies, and promote the product.

Many local health product firms in emerging countries (e.g. India, China, Indonesia, and Brazil) have met international quality standards in production and are willing to add new products for local and international markets, although their research and development capacity may be limited.

A private partner at the design stage may not be the right partner for later stages of the product pipeline (such as marketing), however. Therefore, all parties should recognize the need for multiple partners and envision various scenarios of collaboration to clarify the roles of each partner.

Adapting existing products. A firm may be more willing to enter partnerships for developing world applications if they already have an adaptable product or platform. Start-up companies are less disposed than established companies to such collaboration because their survival depends upon achieving early returns on investment; they are focused on more immediate and lucrative markets. However, start-ups often possess innovative technologies that could solve intractable problems in developing world health. While it is possible to induce these innovators to collaborate, the public sector investment is higher. These small firms are at risk when access to financial resources is limited [4], suggesting the need for donor-supported venture capital and financing programs.

3. Progressing from design to product

3.1. Managing intellectual property (IP)

Independent assessment and management of intellectual property is absolutely critical in public-private partnerships for technology. Commercial companies must ascertain their 'freedom to practice' according to issued and pending patents in industrial and target low income countries. Donor investments can be lost if commercial collaborators lose their property rights to other claimants through litigation.

Also, firms sometimes change ownership, leadership, and business plans; today's great collaborator can be tomorrow's most problematic partner. Carefully worded agreements therefore must be executed up front in all these partnerships. These agreements must ensure public health access to the technology, independent of what happens to the commercial partner. They also address critical issues such as affordability, diligence, and quality, as well as spelling out the roles of the partners. For some firms, just negotiating the agreement can be a deterrent to collaboration, since the firm may not have experience with international donor requirements or legal language.

The parties representing the needs of low-income countries are in a stronger position if they can offer intellectual property to the commercial partner, even more so if the inventions also have value for industrial country markets. In this case, the parties can negotiate strong terms in favor of the developing world markets and persuade the firm to absorb more development costs in exchange for rights to industrial country markets. Technologies in the public domain offer no protection to commercial firms and are consequently harder to 'sell' to potential commercial partners.

However, technologies that are exclusively controlled by one commercial party can create a monopoly on supply. International and bulk procurement agencies dislike monopolies because there are no competitive forces to control price and because United Nations agencies (in particular) shy away from endorsing a single brand. This creates a paradox because single parties will often control inventions of value to developing world health. Furthermore, inventions developed by the non-profit or public sector may have to be offered exclusively to a commercial partner if the amount of capital required to scale up, manufacture, and market is very high and/or the scale of demand does not justify multiple producers.

To reduce the risk of escalating prices from a monopoly, the parties can devise a plan to stimulate competition in the longer term. This is a risky strategy and must be implemented with care; it may discourage innovation directed at developing world health care needs or render a product economically unsustainable. If the market is stimulat-

ed by the innovation, other suppliers will sometimes come forward with alternative designs without any prompting.

3.2. The role of 'bridging' organizations

A few organizations manage public/private partnerships to advance technologies on behalf of the public health sector. As donor investments in technology increase, and design control, licensing, IP, and access issues grow more complex, more such organizations will appear. These organizations function similarly to commercial product development organizations, except that they are supported by donors and seek to achieve social rather than financial returns on investment. Bridging organizations are more flexible and can manage uncertainties, change direction, make trade-offs, and respond to opportunities more effectively than bureaucracies. They will not always be successful but they can significantly reduce the risks associated with making appropriate technologies available to low income countries.

3.3. Validation and revalidation: building the evidence base

There is no certainty in predicting when a technology designed for developing world use will be perceived as sufficiently validated to warrant general acceptance. However, the process can be made more efficient by careful staging of field trials and selection of collaborators, well-designed operations research (e.g. for cost-effectiveness or local approval), targeted publication and communication of results, and early initiation of policy dialogue with key gatekeepers. Model programs can sometimes be effective at gaining widespread attention and, in the best cases, can scale up to national adoption. Technologies with benefits that are easier to demonstrate and observe will generally spread faster. Ultimately, innovative technologies require a critical mass of champions to overcome the endemic resistance to change in public health programs.

Creating and supporting product champions. Owners make great promoters. If influential people believe in the benefits of a technology and feel that they have a stake in its success, they will use their networks to spread the word. Fostering champions requires good evidence, good management, transparency of process, and willingness to share the ownership of the project. In practice, this unlimited level of openness has to be balanced against the confidentiality that is often necessary for commercial collaboration and intellectual property management. However, closely 'branded' technologies will generally have a harder time achieving widespread acceptance in the international public health community.

3.4. Regulatory barriers

The Global Harmonization Task Force, founded by Japan, the European Union, United States, Canada, and Australia, has developed a 'gold standard' for health products all over the world. Many National Regulatory Authorities (NRAs) also depend on these standards. Donors investing in technologies for developing world health programs can be concerned that bypassing these authorities may lead to concern about double standards. Yet there are advantages and disadvantages to the strict requirements of these major regulatory bodies.

When is industrial world licensing appropriate? While regulations offer unmatchable assurance of safety and quality of design, development costs and time can double or triple if technologies are subjected to the process required for licensure by industrial world bodies. Technologies with relatively low development costs (like immuno-diagnostics) may become unaffordable as a result. Additionally, products with very little application in industrial countries may gain little value from this level of regulatory clearance, particularly if they are to be manufactured in low income countries (where the NRAs will control manufacturing quality). Some products of enormous value to low income countries have been taken off the market because of a level of risk that is unacceptable to the industrial world, even though the benefit-to-risk ratio was quite different and overwhelmingly life-saving in low income countries (e.g. rotavirus vaccine).

The complexity of the technology and the extent of innovation involved often define the regulatory strategy. The regulatory strategy for a developing world technology must be considered on a case-by-case basis to achieve the optimum balance among safety, affordability, availability, and accessibility.

Altering standards of practice. The new technology or intervention often requires a change in the standard of practice at the broadest level of developing world health care service delivery systems. The costs and level of effort associated with changing behavior in every primary and first referral level facility is formidable—arguably much higher than the cost of developing a new technology. This burden can be eased considerably if: (1) The technology requires no change in practice (e.g. the substitution of one vaccine by a better one). (2) The technology controls behavior (e.g. auto-disable syringes). (3) The technology requires only a minor adaptive change that is compatible with or simplifies current practice (e.g. oxytocin in the Uniject™ device). (4) The technology is to be used frequently so that new skills are quickly reinforced (in contrast to emergency technologies that may be used only rarely in peripheral practice).

4. Finding a manufacturing partner

As mentioned previously, the global health community must work with commercial companies to ensure sustainable supply of high-quality products. Sooner or later, the appropriate technology must be converted to a manufacturable product, scaled up, produced efficiently, and distributed to the programs and people in need. The engines of private enterprise—profit and an expeditious return on investment that equals or exceeds that of another product or market—drive these commercial organizations. Persuading a competent firm to take on a product aimed exclusively at developing world health programs is a challenge. These companies are generally most concerned about the market: whether it exists, how big it is, and who actually selects and buys the products.

4.1. Measuring the market

The people who use, the people who choose, and the people who pay the dues. In the international and developing world public health sector, entities selecting suitable technologies (through endorsement, recommendations, and guidelines) are often separate from those that actually buy the products. Still other people use the products. The communication among these three entities is generally limited. Each might view the value of the product quite differently: one in terms of global public health impact, another in terms of procurement costs, and another in terms of local acceptability and advantage over alternative interventions. Often, the whole-systems cost-effectiveness equation does not come into full perspective during these transactions. Instead, several factors play a dominant role in the acquisition of technologies: direct donations of technology or aid tied to products from the donor country (which buys the product), the manner in which the product life-cycle costs are distributed across sectors or levels of the health care system, and the influence that sales representatives can have on the process. Procurement decisions based upon comparative technology assessment are not common at the local level. All of these factors complicate the process of assessing markets and greatly extend the ramp-up from early adopters to wide-scale use. Nevertheless, some measure of the market is needed to convince manufacturing partners to get involved.

Demand versus need. The developing world's need for almost all technologies is extremely high, but the funds and ability to absorb the technologies are severely limited. Manufacturers are primarily interested in demand—that is, consumers' willingness and ability to buy. Latent demand is only important if it can be converted to real demand at reasonable cost. Technology assessment and procurement groups are generally the parties that assess demand, but unless the technologies benefit an internationally coordinated program or campaign, the selection and procurement decisions are usually made at the national or even sub-national level. These local markets can be extremely diffuse and costly to reach, influence, and aggregate into an economically sustainable enterprise. Unless the

public sector is willing to take on the marketing and distribution of the product, the complexity and uncertainties associated with these tasks relative to the value of the market are formidable obstacles to many international firms.

Local manufacturers and distributors may be better positioned to market technologies that depend on local networks and influence for successful introduction and uptake [5].

Central and local procurement. Health care products are purchased by international agencies [e.g. the United Nations Population Fund (UNFPA) and United Nations Children's Fund (UNICEF) Supply Division], bilateral agencies [e.g. the United States Agency for International Development (USAID)], and a variety of international organizations and programs specializing in a particular health care area such as immunization, blood banking, family planning, tuberculosis, and malaria. These entities rely on technology assessments carried out by the World Health Organization (WHO) and/or their own technical divisions. The international procurement agencies generally respond to requests from client countries for specific technologies, although those products generally must be approved by WHO and by the procurement agency. (Although these agencies may endorse a certain generic category of technologies and may decline to supply others, they do not actively promote the use of specific products.) Many well-validated technologies get stuck because they lack substantial assessment data or advisory or promotional messages coming from these agencies or from other sources. Consequently, awareness of and confidence in the technology at the country level remain low and no stream of requests is forthcoming.

The power of special global programs. New technologies usually diffuse much faster in vertical, centrally coordinated programs. International consortia can mobilize funding and coordinated action around a particular disease or strategy. National authorities then agree at the beginning to design and build their programs according to a set of standardized protocols and products selected through a consensus process of technology assessment, training, communications, and central procurement. The manufacturers' tasks of submitting products for assessment and estimating demand are made easier by this 'one-stop' marketing arrangement, although the extent to which the product meets the need and is cost-effective relative to alternative interventions becomes very critical because of its potential global impact. Also, technologies can become 'locked in' to these programs, which limits innovation, particularly if the new technology requires a change in standard practice at the service delivery level.

Commercial appeal. A technology may have special appeal for a manufacturer if:

- It has an application in wealthy countries as well as low-income countries.
- It fits in well with their current product line.
- It offers access to new markets for its other product lines.
- The market is potentially very large, notwithstanding the uncertainties.
- It serves a pressing public relations need.

4.2. Due diligence in partner selection

Some carefully designed and validated technologies have been sidelined because they have been placed in the hands of a manufacturing partner who is unable to achieve availability, quality, or affordability. Manufacturing businesses change ownership or leadership with surprising frequency. Some fail altogether, some do not perform to the terms of their agreement, and some experience insurmountable obstacles. To manage these risks, the group representing public sector interests must perform due diligence when selecting partners, carefully developing agreement terms that provide for the above contingencies, establishing agreed-upon milestones, and performing audits. Most importantly, the public sector partner must ensure close communication and collaboration during the introduction and mainstreaming of the product.

4.3. Sharing the risk

The manufacturing partner will expect the public health sector or its representative organizations to take a share in the investment and risks of the project. Negotiations with prospective manufacturing partners will ultimately depend on the designs,

data, resources, and commitment that the public health representative brings to the table. Although the manufacturer may recognize a public relations value of a public/private partnership, they cannot tolerate a losing proposition or an impossible mission.

5. Introducing technologies

Introduction should begin quite early in the design and development process. Collaborators involved in the design or validation stage can identify with the technology and its potential impact, become early adopters, and act as powerful advocates for widespread use. Data gathered for design control, validation, and licensing purposes can build the evidence base and help persuade donors, gatekeepers, and decision-makers of the value proposition.

5.1. Developing the value proposition

Why should health care program managers and international agencies subscribe to the new technology? Why is the technology better than existing or alternative interventions? What major problems does it solve? Because change is expensive and complicated to implement at the periphery of the developing world health care system, the impact of the innovation must be substantial and the costs must be absorbable. This value proposition must be clear and well communicated for the technology to be successfully adopted.

Benefit. Some benefits are obvious; others are less apparent. The public health community may not recognize benefits that seem obvious from the technology developer's point of view. Many extensive, systemic, and soluble problems that are commonly observed and anecdotally reported may require considerable time and effort to become officially recognized. Furthermore, the data-collection effort required to put the problem on the public health agenda may be beyond the scope of the technology developer or champion. Unsafe injection serves as one example: Visitors to health care facilities observed the risks of unsafe injection for a decade until the volume of concern finally prompted a broad analysis of the problem and gave credibility to the safety syringe (e.g. auto-disable) technologies that offer quick and effective solutions.

Some technologies offer system benefits, which are less tangible and harder to measure. For example, the benefit of pre-filled, single-dose injection systems (like the Uniject™ device) for delivering uterotonics or vaccines includes simplicity of use, which allows less trained village health workers to administer the medicament safely and effectively in low-infrastructure settings. Program managers may not concede that the complexity of current regimens is a problem, and they may not be willing to pay the extra cost of changing from multi-dose to single-dose formats, or changing from standard to non-reusable injection devices. Overcoming this resistance may require local trials, model programs, and documented results from routine use in other countries.

Low frequency of use and consequent low repetition of practice can erode the value of some technologies. This may be particularly true of life-saving technologies used in obstetric or neonatal emergencies. At the level of the village midwife, the needs for these technologies may be so rare that training is not reinforced by practice. As a result, the technology falls into disuse as service providers forget the training and lose confidence in their ability to manage the technology. Reinforcing exercises or training must be planned to raise the confidence of program and financial managers.

Clearly, it is the perceived—rather than real—benefits that matter for technology introduction. The value proposition for a technology needs to be continually updated as new data become available, so that perceived and real benefits merge as early as possible in the introduction process.

5.2. Economic analysis

The potential benefits may be convincing, but the costs also must be ascertained.

Whole system costs. The life-cycle cost of a technology may not be obvious to a decision-maker. Depending on the technology, the cost may include procurement, delivery, training, fuel, maintenance, repair, depreciation or replacement, and

disposal. Introduction of the new technology or intervention generally requires a ripple of other changes including supporting technologies (e.g. regulated-dose injection technologies to support the introduction of magnesium sulfate) and services, as well as changes in protocols and procedures, budget allocations, and personnel. An analysis of these changes and associated costs in a variety of typical settings is essential to an understanding of value.

If the introduction of a technology can reduce the whole-system costs, or if it can save significantly more lives or gain disability-adjusted life years (DALYs) at the same or modestly greater system costs, the technology is justified. However, these results may not be persuasive to purchasers, program managers, or service-facility supervisors, if their share of the overall costs increases as a result.

Sector costs. Efforts to introduce point-of-care diagnostics for infectious disease offer a lesson in the importance of determining which groups pay for what. Point-of-care tests can have great benefits because the results are available while the patient is still in the health center, allowing providers to offer immediate treatment and conserve drugs. Although primary health care service providers appreciate the diagnostics, many countries allocate budgets for clinical testing only to laboratories. As a result, health centers must decide whether to buy rapid tests out of their own budgets or continue to send samples to the laboratory and forgo the advantage of point-of-care testing. They often choose the latter. The laboratory has an incentive not to endorse or encourage the use of point-of-care tests. All these vested interests influence national health budget allocations.

Clearly, introducing some technologies requires substantial system reform. International agencies are best positioned to provide the necessary influence. Early endorsement of the technology by—and strategic collaboration with—relevant WHO divisions becomes particularly important with discontinuous ('paradigm-shifting') innovations. The capability and resources of different WHO divisions vary greatly, so technologies that fit into coordinated central programs with a global emphasis are more likely to benefit than those for health care problems that are not on the 'center stage.'

5.3. Working with early adopters

Early adopters of a technology—e.g. groups or programs that were previously involved in design-stage trials or validation of the technology—are invaluable and deserve attention. As collaborators, early adopters can help refine and operationalize the technology, develop training protocols and materials, generate cost-benefit and impact data, and act as advocates and showcases for the value proposition.

Model programs. Large demonstration projects with district, state, or even national scope can be built around the good offices of pioneer and early adopters. These model programs can test and demonstrate the scalability of the technology and the associated system changes. Successful model programs can be compelling in shifting policy, adjusting budgets, and bringing about a widespread change in standard practice.

Spreading the word. Advocates must disseminate information about a new technology's usefulness and impact. Decision-makers at all levels must be aware of the technology and its value proposition. Mainstream adopters must hear about it from multiple and credible sources. They must have opportunities to observe it in action without taking risks. They must become aware that it is a 'best practice.' This type of 'critical mass' of communication about a technology's demonstrated benefits is essential to moving beyond the early-adoption stage.

5.4. Working with the gatekeepers

A few international organizations play an essential, normative role in developing world health care practices. They establish best practices and develop guidelines for interventions, training, essential drugs, equipment, and supplies. Sometimes they carry out technology assessments and make recommendations for specific technologies. In a few cases (e.g. vaccines), these organizations audit and qualify manufacturers. WHO is the most notable of these groups and has the broadest scope,

as it spans all health topics (although not with equal intensity). WHO review and endorsement of revised guidelines for a new technology are essential to ensuring broad applicability, raising confidence of national program managers, and enabling central procurement agencies like the UNICEF Supply Division to purchase and distribute the products.

In the last decade, WHO has become more adept at advancing technologies, although they are still constrained by policy when dealing with individual commercial entities and products. They are also spread very thin, so that one staff member may cover a wide range of specific health problems. Finding and establishing working relationships with relevant divisions and key staff members early in the design and development process is very valuable and encourages a continuing dialogue. As a result, the technology and its potential impact can be discussed at international workshops and consultations, leading to a wide scrutiny and understanding of the value proposition among the relevant experts in the international consulting and advisory community.

These interactions are critical in validating the technology; raising donor interest; identifying testing sites, collaborators, and early adopters; and ultimately justifying the technology and changing standard practice and guidelines to accommodate it.

6. Mainstreaming

''In health care, invention is hard but dissemination is even harder'' [6].

Dissemination of innovation occurs quite reliably according to the S-curve model. The technologies are initially taken up by innovators, who consist of a very small portion (approx. 3%) of the population who are attracted to new technologies and are willing to take risks, but are not usually influential. The innovators are observed by another segment (approx. 12% of the population) termed 'early adopters.' Early adopters are often opinion leaders who are willing to try out new ideas and who can convince others to adopt them. They influence the 'early majority' (approx. 35%), which is more cautious and relies more on personal networks than scientific data to assess the risks in taking on a new technology. The 'late majority' (35%) will only take up an innovation when it appears to have become standard practice and has been taken up by local early-majority practitioners. The remainder of the population (15%) is likely to resist unless forced to change by regulation.

With regard to health care programs for low-income countries, this model is complicated by the decision-making processes of the gatekeepers who influence the choice of technology, the donors and purchasers who buy the technology, and the users. Each group has its own early- and later-stage adopters who have to be dealt with in the context of their own institutional and policy environments. The actions or inaction of these three stakeholder groups can profoundly affect the process of mainstreaming technologies for developing world health care, so each must be taken into account in the planning and process.

For mainstreaming, we are concerned with moving the technologies from early adopters to early- and late-majority users.

6.1. Creating demand and reducing uncertainty at the national and program levels

Establishing policy and guidelines at the level of WHO or other normative organizations is essential but will not guarantee that the technology will be taken up across the developing world.

Field demonstrations. National decision-makers often need convincing through observation and practice that is closer to home. Programs should make every effort to facilitate local trials and exchanges of experience between national health care program leaders. Training materials and job aids, free products for trial, trial protocols, and technical assistance can all be useful in promoting local testing.

Programs must tolerate—and, in many cases, encourage—local adaptation of the materials, protocols, or support systems (and sometimes the technologies themselves) within limits that do not jeopardize safety and effectiveness. Local adaptation encourages ownership of the new intervention and is more likely to lead to adoption.

Policy dialogue. Local policies, practices, budgets, and guidelines need to be adjusted to the new technology. Often, these changes can be facilitated through central guidelines and consultations supported by local champions.

Need for adequate and consistent supply. The mainstreaming process can be severely disrupted if the supply of the technology cannot meet the early demand. Since market forces are often contorted in developing world public health markets, it is not always possible to keep up with demand. An entity acting on behalf of the public sector interests must pay attention to the supply and demand so that interventions to redress the balance can be made in a timely way.

7. Conclusion

Many hurdles impede the development, introduction, and dissemination of technologies that are appropriate for developing world public health care programs. The international public sector, however, is not yet fully prepared to support or facilitate these processes. Nevertheless, there is a growing awareness of the need for such technologies and a growing experience with the strategies that can make them happen.

Some of the technologies with documented value for maternal care in developing world settings appear to be stuck short of widespread acceptance and use. This paper may give some understanding of the factors that may be impeding their progress as we discuss ways to move them forward.

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