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Diffusion of Novel Healthcare Technologies to Resource Poor Settings

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Abstract—A new product has completed clinical trials in a distant, resource poor hospital using a few dozen prototypes. The data looks great. The novel medical device solves a widely felt problem. The next goal is to integrate the device into the country's healthcare system and spread the device to other countries. But how? In order to be widely used, the device must be manufactured and distributed. One option is to license the intellectual property (IP) to an interested third party, if one can be found. However, it is possible to manage the manufacturing and distribution without licensing. There are at least two common means for manufacturing a novel medical device targeted to resource poor settings: (a) formal (contract) manufacturing and (b) informal (local) manufacturing. There are three primary routes to diffusion of novel medical devices in the developing world: (1) local distributors (2) direct international sales and (3) international donations. Perhaps surprisingly, the least effective mechanism is direct importation through donation. The most successful mechanism, the method used by nearly all working medical devices in resource-poor settings, is the use of contract manufacturing and a local distributor. This article is written for the biomedical innovator and entrepreneur who wishes to make a novel healthcare technology or product available and accessible to healthcare providers and patients in the developing world. There are very few documented cases and little formal research in this area. To this end, this article describes and explores the manufacturing and distribution options in order to provide insights into when and how each can be applied to scale up a novel technology to make a difference in a resource poor setting.

Keywords—Global health, Resource-poor settings, World health, Bottom of the pyramid.

INTRODUCTION

The first round of clinical trials on a new device looks great! At least one NGO says they would incorporate the device into their programs if it were available in the countries where they work. The Ministry of Health in one of the preferred target countries is already interested in the device, probably the country where the research protocol was completed. There also seems to be interest from some private sector hospitals and health care providers. In other words, the device is ready to be manufactured and diffused throughout a resource-poor healthcare system. But how?

This is a common problem. Many universities, nonprofits, NGOs, companies and individual entrepreneurs are developing, technologies and products that may have application in the developing world.[9] There are multiple funding sources for the research and development of global health technologies, e.g., Saving Lives at Birth, Ashoka Changemakers, NIH Framework. There are also design competitions and conferences, e.g., EWH, Rice360, BMEIdea.

Yet, despite all of this design activity, very few novel medical device designs move forward, i.e., become used on a large scale in the developing world.[9] There are technical reasons for this. In some cases the designs are simply not ready. In others, they do not truly solve the problem. In others, they are too costly, too complicated or introduce a problem more difficult than the one they solve. But, in some cases, the prototyped design is accepted and solves a problem. Yet, it still fails to move forward.

Often the problem is the failure to use a standard diffusion channel. The most common diffusion channel for nearly any product is commercial sale for profit. Some people do not select this route believing that there is no way to make profit on medical devices in the developing world. While developing countries certainly are challenging markets, this perception is both incorrect and unfortunate. It also leads to the belief that devices must be donated to reach markets in a resource poor setting. In fact, donation of medical devices is both an ineffective and inefficient means of

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reaching developing world markets with a novel medical device.[13] For inventors considering licensing as their diffusion option they are often unable to find a licensee due to the limited markets of the developing world.

Figure 1 summarizes the most common, successful approaches to manufacturing and distributing a medical device in the developing world. Whether a device is licensed to a third party or not, there are at least two common means for manufacturing a novel device (a) formal (contract) manufacturing and (b) informal (local) manufacturing. There are three primary routes for distributing medical devices to hospitals or clinics (1) through local distributors (2) through direct international sales and (3) through international donations. In what follows, we describe each option and their advantages and disadvantages.

BACKGROUND

Before beginning the discussion of product diffusion, it should be noted that bringing a new medical device to any market is complex and risky. In fact, though it may seem counter intuitive, bringing a device to market in the developing world is often more complex, expensive, time consuming and risky than bringing the same device to market in a resource-rich setting. In light of this caveat, some background information can be offered.

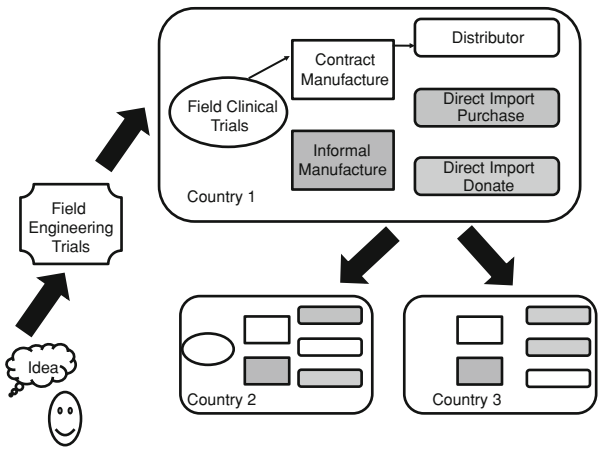

FIGURE 1. A brilliant idea for a novel healthcare technology for a resource poor setting will first pass bench, then field engineering trials to confirm critical aspects of the client's operation and acceptance of the device. After this point, each country must be approached differently. The inventor can, and in some countries must, now initiate clinical trials to serve both as validation and marketing tools. Manufacturing can be accomplished using a combination of informal, local manufacture or contract manufacturing, which can be local or foreign. It is possible to select a single manufacturing option with country-by-country diffusion strategies. Diffusion can proceed in each country through distributors, the most common approach, or through direct import for sale or donation.

The US Food and Drug Administration divides the products found in a hospital into pharmaceuticals and medical devices. The latter category can further be divided into durable goods and consumables. Pharmaceuticals and consumables are manufactured and distributed through channels that are somewhat different from the more durable medical devices. Therefore, this article is restricted to the consideration of durable medical devices and more specifically novel, durable medical devices that are ready for market.

By "novel" we mean both existing products that are new to the developing world, and new products developed specifically for developing world applications and use. A healthcare technology is not ready to "go to market" until it is proven to have been safe and effective in some fashion, usually a clinical trial. Although most developing world countries do not have strong medical equipment regulations (World Health Organization[22], p. 18) most healthcare institutions will not approve a product for purchase or use in their facility—and clinicians may not use it—until there is evidence that it will work. So, for the purposes of this paper, we will assume that the device has already been built, at least a few dozen prototypes, and tested on humans under a research protocol in at least one resource poor country. We also assume there is interest in scaling to most of the healthcare system in the initial country, and spreading to new countries.

For the purposes of this article we will be limiting our target countries to low income countries (LIC), as defined by the World Bank's World Development Indicators. However, the device might be manufactured in a middle income country (MIC) or even a high income country (HIC). The project must be funded. Unfortunately, the amount of money—mostly in salaries and travel—required to move a product forward, even in the developing world, is considerable. Even a simple project, for which the initial clinical trials and manufacturing drawings are complete, will need a full-time staff of at least one or two devoted to the diffusion of the product. Once the project reaches this stage, it is almost certainly not possible to continue to work on the device part time or with volunteers. Often, specialized expertise may be required both in the areas of manufacturing and distribution. Importantly, whether the product will ultimately be donated or sold has little impact on the financing that will be required. Obtaining financing is a major challenge. Banks and venture capital investors will rarely fund developing world projects. Many projects rely on angel investors, grants, or personal resources, at least in the early stages.

The healthcare system in the developing world is more complex than might be expected. There are

typically three sectors in health care service delivery: (1) the public (government) sector, (2) the private sector and (3) the NGO sector, including faith-based organizations.[16]

The public sector consists of all government owned and run facilities. The public sector purchases through a structured and formalized process of issuing tenders, and receiving bids from vendors. Very rarely may a public facility go directly to a vendor and execute a purchase. Equipment funded by, or donated by, external agencies like the World Bank, Global Fund or PEPFAR in most cases use the target country's tender mechanism, while applying the procurement policies and procedures of the donor.

However, the tender mechanism is rarely open to novel medical devices. This is because novel technologies must usually first be evaluated, incorporated into service delivery protocols, such as testing algorithms for diagnostic equipment, and included in an approved product list before a product is eligible to bid on a tender. Because of the long planning cycles for some international organizations, it can take 1 or 2 years before a novel, available technology can be incorporated into the tender system.

The private sector, on the other hand, is unencumbered by much of the bureaucracy and processes of the public sector. Often, many of the most prominent and innovative clinicians are in the private sector (often in addition to holding positions in the public sector[10]). While the market for equipment is likely to be smaller in the private sector than in the public sector, it is often much easier to introduce new products in the private sector. The private sector also, often, has the resources to make the purchase. The private sector includes a wide range of providers, from a few large private hospitals, to clinics, numerous individual practices and private pharmacies. It is often said that the private sector serves only the top echelons of society. However, this is not the case. In fact, often the poorer the country the higher the proportion of health care services found in the private sector.[12,21]

The popularity of the private healthcare system in very poor countries can be understood when one considers that in resource-poor settings, patients—even at the public hospitals—must often pay the healthcare provider, purchase their own medical supplies outside the public hospital and buy medicine at a local, private pharmacy. They also must endure to long travel times and long waiting times when using the public facilities. Faced with these obstacles, many people find that the private sector fees are acceptable in exchange for their convenience, especially for minor issues.

Finally, the NGO sector often provides a significant proportion of health services.[21] For example, in the democratic republic of Congo, the Catholic Church provides an estimated 40% of the health services, and in Zambia there are some 100 mission hospitals and clinics.[15] Other NGOs may provide general healthcare or services focused on a particular region or disease.[15]

For a novel healthcare technology, NGO (often faith-based) hospitals and clinics represent an organization with strong public sector credibility but with the operational flexibility of a private sector institution. For these reason, they can be an attractive early partner.

MANUFACTURING

Once a device has been prototyped, a mechanism to manufacture the device must be found. There are only two common options, (a) local, informal manufacturing or (b) formal, contract manufacturing. Informal manufacturing typically involves local artisans with limited or no formal licensing. Contract manufacturing involves companies, called original equipment manufacturers (OEM's) with expertise in manufacturing but limited or no sales and marketing capabilities.

One of the largest manufacturing sectors in any resource-poor setting is the local, informal manufacturing sector.[6] It is therefore tempting to consider the local manufacture of novel healthcare products. Indeed there are a few examples of such success, e.g., Jaipur Foot, Whirlwind Chairs, TATCOT Tanzania. But these are rare, constituting less than 5% of all medical equipment found in resource poor hospitals.[17] In fact, quality control issues, the difficulty of scaling informal manufacturing and the increased costs associated with local, informal manufacturing, usually make the more traditional contract manufacturing approach more appealing for novel medical devices, even in resource poor settings.[6]

Contract manufacturing dominates the medical device industry.[14] In fact, contract manufacturing dominates most industries. Think about the Apple iPhone. It is assembled by FoxConn (the OEM) under a contract. FoxConn, in turn, accepts components from other subcontractors. Not only does FoxConn make the iPhone and iPad (sold by Apple) but they also make the Kindle (sold by Amazon), the PlayStation (sold by Sony) and the Xbox (sold by Microsoft). They have a great depth of knowledge of electronics manufacturing but without an ability to sell or market products. FoxConn is a typical, sophisticated contract manufacturer.

By using a contract manufacturer, the maker of a novel medical device enjoys a tremendous reduction in the amount of capital required to scale the manufacturing. The contract manufacturer will already own the machines required to complete the manufacturing steps, be they injection molding, circuit board soldering

or welding. By using a contract manufacturer, the novel device maker avoids having to learn the local (to the manufacturing plant) labor laws, customs or sources of materials. There is also a tremendous advantage in speed to market. It is not unusual for a new company to take 3 years to obtain permission to manufacture a product in the developing world. A contract manufacturer could be able to start manufacturing the same device within weeks or months.

The vast majority of contract manufacturing is now occurring in India and China.[5] Even when the cost of shipping is considered, in most cases, the cheapest location to manufacture components is in China. Chinese contract manufacturers operate with profit margins as thin as 1%.[23] However, India has a tight network of university and industry cooperation that can be ideal for small scale manufacturing typical of medical devices.[1]

Despite the dominance of China and India, there are many established medical device contract manufacturers in the developing world. These range from workshops attached to hospitals or clinics to full-scale tubular welding companies making chairs and tables.[17]

A novel company's' success often depends on finding the appropriate contract manufacturer. Sophisticated contract manufacturers in the US and Europe can take the product from sketches and prototypes to computer-aided-design drawings, molds and contracts with subassembly providers. However, they are often expensive and may not share an interest in the developing world or have experience in that market.

If a contract manufacturer in a developing nation is selected, one must assume that they will have less sophistication and less breadth of capabilities. They are more often smaller and more specialized in the developing world.[8] So, a single product may need to engage several, perhaps one for welding, one for circuit boards and a third for injection molding.

One of the best sources for information concerning local contract manufacturing is the distributors. The distributors often know who has local manufacturing capabilities and the distributors themselves may be only one step short of being able to manufacture, at least for final assembly.

In fact, the model of local, final assembly is even becoming popular in the US,[18] where foreign shoe companies will ship components of shoes to the US for final assembly. Levi Straus now cuts parts for their pants in the US but the local tailor does the final sewing and delivery. This model is probably easily extrapolated to slings, baby warming devices, bili-blankets and other similar devices.

One of the most commonly cited problems working with contract manufacturers in China, or any developing nation, is intellectual property (IP).[5] Inventors are often concerned that their IP will be stolen.[19] Indeed, protecting the IP can be challenging, or even impossible, in some countries. It is possible to reduce the risks. The most obvious strategy is to be clear when working with the manufacturer. They will almost certainly create some of the intellectual and physical property, for example the drawings for the mold creation and the molds themselves. While it might be tempting to consider delivering final drawings to the manufacturer and using copyright protection to control them, this is rarely effective as the drawings are unlikely to be an exact match to the needs of the manufacturer, their brand of manufacturing equipment, *etc*.

Ultimately, probably the best protection against losing control of the IP is an exclusive license with the contract manufacturer. If they know that a competitor will undercut their profits with counterfeit product, the contract manufacturer will defend the IP vigorously and this in their own country where they know the laws and politics far better than the inventor.

Another benefit of an exclusive contract with the contract manufacturer is that they may provide some initial capital, to create the molds, for example. They also have tremendous design experience in their area. They will be much more willing to share that expertise when they know they have exclusive rights to manufacture the result.

By far the most difficult part of working with a local contract manufacturer is communication. This is only partially related to language. There are large differences in the culture of contracts and agreements around the world. Even the use and acceptance of contracts can vary. There can also be ethnic and race-related tensions when a contract manufacturer is engaged to manufacture something that violates their values. This is somewhat common as many novel technologies, especially health technologies regarding women, cross value systems.

If a formal contract manufacturer is selected locally, a common problem is the perception—or reality—that the quality of the device will be inferior. This should be considered at the design stage. If the device is designed for local manufacture and construction, it should have designed in appropriate, rigorous testing protocols for each stage. The product will require frequent, unannounced visits to the manufacturing partner and random testing of extracted parts. In addition, an effective distributor who is well respected in the country can counteract the perception problems.

DIFFUSION

There are three primary routes to diffusion of novel healthcare technologies in the developing world (1)

through local distributors (2) through direct international sales and (3) through international donations. Even if the innovator elects to license the product to a third party company, one of these primary routes will be engaged.

Distributors

Nearly all hospitals and clinics, including those in the developing world, obtain most of their supplies, equipment and consumables through distributors. This is true of the public, private and NGO sectors.

Most parties prefer dealing with local distributors, because they are nearby, speak the local language, understand the culture and practices, and are more likely to stand behind their product because they have a vested interest in an ongoing relationship. If a hospital were to attempt to stock their shelves without a distributor, they would have to contact each manufacturer overseas directly, overcome the language barriers, organize the transfer of payments—often in foreign currencies, organize transport, insure the shipment, clear the shipment through customs, pay any duties, and more. And this assumes that the manufacturer is even willing to sell their product directly to a hospital (many will not). Because few hospitals have expertise in all of these areas, it rarely makes sense for an individual institution or health care provider to bypass distributors.

Given clinics and hospitals' dependence on distributors, finding and engaging a suitable local distributor is critical for the diffusion of a novel medical device. The appropriate distributor must be identified, screened, contracted and monitored. And, all of these steps require an on-the-ground presence.

Correct engagement of a local distributor can accelerate the diffusion of a technology considerably. An example of the successful use of traditional distributors for the diffusion of medical devices is the rapid HIV diagnostic.[2] However, failure to engage an effective distribution strategy can lead a device to languish. An example of a clinically proven medical device that has failed, at least in part due to distribution failures, is Project Impact, a hearing aid for resource-poor settings that has been unable to find an effective distribution approach.[3]

Medical device distributors exist in every country in the world, including every developing world nation. For example, Zambia and Mozambique each have more than a dozen distributors of medical products. Malawi has at least ten and larger countries like Ethiopia, Uganda, Tanzania and Nigeria have more than that. Yet, identifying them—and especially the ideal one for the new product—can be a challenge.

Many inventors of novel products try to use the internet to attempt to identify distributors. While some distributors have websites, this is still relatively rare in the developing world.

A good source is the U.S. Commercial Service.[20] The U.S. Commercial Service is the trade promotion arm of the U.S. Department of Commerce's International Trade Administration. Their offices in more than 75 countries assist US companies in expanding their business. They often develop market research reports on the medical sector. They are helpful in facilitating contacts and in some countries they offer a distributor search service called the Gold Key Matching Service, for a modest fee.

Identification of potential distributors can also be as simple as looking in the local yellow pages under "Medical Importers/Distributors." Another straight forward approach is to ask health care providers from whom they purchase their equipment and supplies. Finally, using the contacts that have been established through the field trials is an easy and effective way of finding reputable distributors.

It is important to note that in the developing world, no matter what strategy is used, it will be necessary to be in the country to find and establish a relationship with the distributor. Distributors will often ignore e-mails and may discount phone call introductions as well.

In general, developing world distributors specialize in the areas of medical supplies and consumables, instruments, pharmaceuticals or medical equipment. It is quite rare that a medical device distributor will also work with non-medical devices. A few will operate in more than one country. However, each in-country subsidiary may have very different capacities than the main office, and may be little more than a warehouse or logistics coordinator. A novel medical device inventor should assume that they will need to find a distributor (or even a new diffusion strategy) in nearly every country in which they intend to sell their device (see Fig. 1).

The smallest distributor in the developing world will be a single person who deals with only one manufacturer or one line of equipment from that manufacturer or even one medical item such as safety cabinets. However, some distributors in the developing world are sophisticated companies with dozens of employees, including some that have engineers, marketing staff, sales staff, warehousing and delivery vans.

One thing which is not a barrier is that distributors are constantly looking for new products and getting into new lines of business. So, they will always be willing to talk with an inventor even to the point of overstating their capacities and experience.

Each potential distributor candidate must be screened to ensure they can meet the needs and interest of the inventor and represent the product. It is best to develop a screening tool that lists all the capabilities the selected distributor must have for the product. Among the considerations would be their experience in the selected health area, their portfolio of products in the health area, their sales and support capabilities, their warehouse and logistics capabilities and their ability to market products to the most likely users of the product.

Once the preferred candidate distributor has been selected, a contract must be consummated between the key partners. One important term will be exclusivity. It is usually necessary to grant exclusivity for the product to one distributor in each country. Distributors are reluctant to invest time and resources into marketing a novel medical device if users may ultimately buy the product from someone else.

In general, a novel device manufacturer should not attempt to write or consummate a distributor agreement without experienced, local, legal counsel. The key terms of the typical contract will cover the length of the contract, the structure of compensation to the distributor and escape clauses, usually tied to performance goals.

Once the contract is consummated, the real work of medical device diffusion begins. This includes registering, importing, marketing and supporting the product. The provider of a novel medical device technology should expect to help create marketing materials for the local market, to participate in workshops and events, to train the distributor and their staff, to visit potential clients, and to meet with stakeholders like the Ministry of Health or local universities, all in partnership with the distributor. Terms for these activities, like payment and frequency, should be clearly spelled out in the contract or in verbal agreements. Keep in mind that in many developing nations, personal interaction, rather than email, phone or other electronic means, is critical to building a constructive relationship. The inventor should expect to have a representative on the ground for much of the first year of working with a distributor.

The distributor will help with obtaining registration for the medical device. Registration, also called licensing or market authorization, is the approval by the local national regulatory authority for the import and distribution medical products. All medical products must be registered, or obtain a waiver for each shipment, in nearly all nations.

Ideally registration should be a well-defined process with clear requirements, steps and forms. However, in many developing countries this is not the case. In practice, this lack of transparency means that one will need a local person or company who understands local regulations, and has the experience and contacts to navigate the bureaucracy and processes. That is an important role for the distributor, and a key selection criterion.

It should be noted that the price of the product does not affect the need for registration. Even products that are donated, or distributed free of charge, must be registered. Importing products in luggage is usually illegal and not very practical for diffusion on a larger scale.

The distributor is typically also the importer. They will handle all the logistics of importation—paying the required taxes upon importation, paying any required customs or duties and storing the devices until their sale and delivery. In some case, this may be all the distributor does. They may not be directly involved in the sale or donation of the device.

A primary reason for engaging a distributor in each country of interest is their ability to help market the device through their network of contacts. An established and successful distributor will have established contacts at most of the nation's hospitals, public and private, and at the Ministry of Health.

The inventor should anticipate having to provide initial training to the distributor, initial marketing materials, and perhaps having to conduct a research project to validate or evaluate the product with a selected doctor or institution. The distributor may be able to help set up the trial, but the inventor should expect to pay for it and execute it.

Because most of the early marketing will require one of the inventor's staff to be on the ground with the distributor, it may be prudent to second an employee to the distributor. In this way, someone who is answerable to the inventor is embedded in the distributors' organization and focused on the product including training, support and marketing.

Any sophisticated medical device is going to need service and repair. It may also require a supply of consumables. An established well-trained distributor may be able to provide consumables, maintenance and repair services. If the distributor is not able to provide these services they will need ongoing technical support and oversight, usually from the inventor's organization.

If the product is to be sold, one should expect that distributors will add no less than a 25% mark-up. This mark-up is added on top of any costs such as of transport, import duties, taxes and warehousing. However, if they are providing sales, service, technical support, training (user or patient), and marketing such as workshops for doctors and nurses, then they will add higher margins. If the product is to be given away in the country, the fees will not be calculated based on

a percentage of the product price, but rather based on the cost or value of the services the distributor provides, perhaps a fixed fee per unit distributed.

All the required screening, selecting, contracting and cooperating with the distributor is time consuming. But the range of time required to reach market can vary tremendously. Introduction of a consumable that replaces an already existing product but is cheaper or easier to use can be just a matter of a few weeks. This also applies to equipment that performs a function in a way that most clinicians will recognize. However, if user training is required, the time will certainly stretch into months. If the device is a piece of laboratory equipment, it is more likely to require governmental approval, including validation and evaluation and this can take many months. If the product is truly novel, research, sometimes within that country (some will ignore research carried out in other countries), will be required, stretching the time out to years between the first step in a country and the first sale in that country.

Direct International Sale

In some cases, the MOH, or the donors supporting a particular program, require that products be procured through a government issued international tender. This process bypasses the distributor, allowing the Ministry of Health to directly import the medical product. This is thought to lower overall costs by encouraging open competition. This is not done by the individual hospitals in the public health system.

However, the tender can be a barrier for the novel device. In many cases, the bidding is limited to certain companies, for example those that possess certain certifications or approvals, or are already known in the country. Or, the technical specifications for the medical equipment may be so narrow as to exclude the novel device, often because it is not known to the providers or the procurement specialists. Without local representation that is known to those in the Ministry of Health or others writing the technical specifications, it may be impossible to get them written in a way to make a novel device acceptable or eligible.

Despite the difficulty of bypassing the distributor, this can be the only approach for some technologies, for example large pieces of equipment, such as imaging equipment or unique treatment devices for which the market is very small or highly customized to local needs.

Direct Import Donation

Finally, many inventors initially favor directly importing the product, bypassing the distributor, for donation to one or more hospitals or health care providers. Medical institutions in the developing world receive large amounts of donations of medicines, equipment and consumables every year. At first it may seem that this must be the mechanism that brings the most benefit to the people who need it the most. However, this is rarely the case.

Offices, store rooms and spare operating rooms at health care facilities around the developing world are full of products, equipment and medicines that were donated and rarely, if ever, used. According to the director general of the World Health Organization, 70% of donated complex devices do not work and 70–90% of all donations never function as intended.[13] Overall, according to Perry and Malkin,[17] 40% of medical equipment in resource-poor settings is out of service. In fact, Compton[4] reported that 60% of medical device donors admit to donating broken equipment. A recent study that we conducted of donated new equipment suggested that new equipment donations perform no better, and in some cases even worse, than used equipment donations because they are more difficult to support.

If broken equipment was the only problem with donations, there would be an easy solution. But, the reasons for failed donations are often more subtle than the equipment simply being of inferior quality or breaking while shipping. Often donated equipment is not incorporated into the Ministry of Health protocols. So, no support for training, supplies or consumables is provided. This is particularly true of novel medical devices. The procedure which uses the equipment may not have been approved by the Ministry of Health for reimbursement (again, particularly for novel devices). Donated equipment may not respond to a need recognized by the hospital administration (even if that need is clear to the hospital staff) leading to even further reduced support.

A lack of support can doom a donated medical device. There may be no manuals or training in the local language (often the training is more expensive than the equipment). About 25% of all donated equipment is sidelined because of poor user training.[11]

Very simple faults in the equipment, such as a broken fuse or dead batteries account for 15% of all donated equipment failures.[11] Without local support, medical staff cannot be expected to be able to determine that a fuse is broken, obtain a replacement (if one is available in the country) and replace it.

When the first round of donated consumables is depleted, without support resupply may be difficult or impossible to obtain from within the country, especially for donated novel devices which may not be compatible with existing supplies. Even when proper clinical training is provided, it is extraordinarily rare to provide technical training to the technical staff (if there

are any). Yet, only the simplest of medical equipment does not require preventative maintenance and occasional repair.

Perhaps the most fundamental problem with medical equipment donations is that they do not significantly reduce the total financial burden on the recipient hospital. The initial cost of a medical device is the smallest fraction of the total cost to own and operate the device (World Health Organization[22], p. 47). Any larger scale donation of equipment requires registration, importation, duties, customs, taxes and warehousing, as already discussed. In addition, medical equipment accumulate costs related to supplies, spare parts, depreciation, management, utilities, training, accessories, installation, and more (World Health Organization[22], p. 47).

Despite the risks, some novel devices may be sufficiently independent of service and supply chains that a donation is appropriate. Most inventors will still be unable or unwilling to manage the registration, importation, shipping and other related expenses. A practical alternative is an MSRO (medical surplus recovery organization). MSRO's are non-governmental, typically non-profit organizations that specialize in the donation of medical devices (typically used) to resource-poor settings. An MSRO can handle the shipping, import, customs, and in some cases, distribution of a medical device. Very few MSRO's will also be able to handle the training of personnel.

MSRO's do not deal with marketing the device or its registration or regulatory approval. Some will refuse to deal with the device if it is not registered. Others may ship both registered and unregistered devices. There are few, if any, MSRO's that handle the maintenance and service or resupply of donated medical equipment.

Selecting an MSRO is relatively easy. There are more than 100 organizations in the US alone that donate a few or many medical devices to the developing world each year. Both The Technical Exchange for Christian Healthcare (www.techmd.org) and The MedSurplus Network (medsurplusnetwork.org) maintain a list of MSRO's ranging from single individuals to sophisticated organizations with warehouses and computerized inventories.

Licensing

In the developed world, many inventors do not take their devices to market themselves. Rather, they often license the IP to a, typically larger, better-funded organization with expertise in medical device manufacturing and distribution. However, in global health, licensing is not common because few companies specialize in marketing medical devices in the developing world and the potential financial return on investment is often not attractive.

Licensing is a contractual process by which the holder of IP authorizes another party to use that IP. For our purposes, it means giving a company or organization permission to commercialize and distribute the novel medical device. This arrangement is intended to take advantage of the talents and expertise of both parties.

Licensing is not an alternative to the three routes presented above for getting a product to market and into use. One of those routes still has to be chosen. Also, the inventor will almost certainly still remain intimately involved in the project as research protocols are conducted, ministries are convinced to adopt the product and distributors are trained. However, the inventor does not have to raise the capital that is needed to take the product to market. Since the expense related to bringing a medical device to market in the developing world often far exceeds the market for that device in the short to medium term, the holder of the IP should not expect to receive a significant licensing fee.

TABLE 1. A comparison of the principle advantages and disadvantages of each of the manufacturing and diffusion approaches.

	Principle advantages	Principle disadvantages
Manufacturing		
Contract manufacture	Most common approach Least expensive	Difficult to find in target country
Informal manufacture	Common in other fields Low barrier to entry	Rare in medical devices Uniform quality challenging
Diffusion		
Distributor	Most common approach Might handle taxes, training, marketing, service	Difficult to find excellent partner May expect high fees
Direct import purchase	May be able to avoid expense of distributor Private sector provides simplified route to acceptance	Difficult to get novel devices tendered Still may require distributor to provide local registration, support and training
Direct import donation	Ideal for small scale distribution	Rarely successful Rarely sustainable for large scale

An example of a successful product that was traditionally licensed for developing world distribution is Uniject, a single-use, prefilled syringe for vaccines.[7]

Because there is often little or no profit to be quickly made with a novel medical device for the developing world, organizations, usually non-profit, have emerged to facilitate alternative licensing. Among these organizations are ICON (IPPF), WomanCare Global, BroadReach HealthCare, Concept Foundation, Maternova, Sustainable Heath Enterprises, Bill and Melinda Gates Foundation, Venture Strategies Innovations, ColaLife, Population Services International, DKT, Bio Ventures for Global Health (BVGH), the Corporate Council on Africa (CCA). Some of these organizations will license and market products, some provide financial support, others help match inventors to funders and others only help facilitate some aspects of technology transfer and scale-up. However, it is important to note that these organizations face all of the same marketing challenges as for-profit entities, and to be truly sustainable, the product must still be profitable in the long term.

Licensing a novel medical device to a non-profit is a new but growing alternative for the inventor. As with any maturing industry, the results vary from organization to organization, from product to product and from country to country.

CONCLUSIONS

It is exciting to see the first data set showing that a novel medical device solves a long-standing problem in a developing world hospital or clinic. It may seem obvious that everyone will want to purchase the technology and little more than a web site or a few brochures will be required to create a stampede of orders.

In fact, evidence in one country that a device works is just the beginning of a very long process of scaling up a novel medical technology to reach throughout the country and into other countries. There is no easy path. The options described here all have their challenges and advantages (Table 1).

Donation may be the quickest and easiest way to get product into a country in the short term, but it has limited scope for scaling up, does not often lead to acceptance by the healthcare system at large and is rarely sustainable.

Direct importation without a local distributor will probably work for expensive equipment with limited markets.

However, by far, the use of in-country distributors is the most common and most successful approach to diffusion of a novel medical device in a resource-poor setting. Because this route requires capital and time, the inventor may decide to license the technology to a business or an NGO, if one with the necessary expertise and resources can be found. Each country must be considered individually (Fig. 1) and focusing on a single country, at least at first, is another strategy to reduce the risks and costs for the inventors.

It is impossible for a new medical device company with a novel, promising technology to execute that process alone. There will be distributors, manufacturers, importers and a need for time and money. Great clinical data is the start. The adventure is about to begin.

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