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**APPROPRIATE DESIGN OF MEDICAL TECHNOLOGIES FOR EMERGING
REGIONS: THE CASE OF AUROLAB**

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ABSTRACT

Healthcare delivery in emerging regions presents a unique set of challenges and is characterized largely by poor infrastructure. Though there is significant variation from country to country – and even within countries – in emerging regions, common themes emerge, such as overreliance on direct payment schemes, unreliable supply chains, and intermittent power in rural settings. These themes in turn impose particular design requirements on manufacturers of medical devices and pharmaceuticals; this paper focuses on these design requirements. We illustrate the importance of designing specifically for the developing context, using the example of Aurolab, a non-profit medical manufacturer located in Tamil Nadu, India. Started in 1992, Aurolab began operations with the manufacture of intraocular lenses (IOL), implantable polymer lenses for cataract surgery, becoming the first to produce this technology in India. Today Aurolab produces a variety of medical devices and ophthalmic pharmaceuticals, and deliver their products to 120 countries worldwide. Aurolab's products illustrate many of the key design requirements for healthcare delivery in India and in other emerging contexts.

INTRODUCTION

Healthcare delivery in the developing world is constrained by a host of issues related to infrastructure. While this paper focuses on the design of medical devices and pharmaceuticals for the developing world, over 1 billion people still lack access to clean water and over 2 billion lack access to clean sanitation [12]; together these contribute significantly to the global burden of disease (GBD) [4]. Healthcare infrastructure for these people is virtually nonexistent.

The paper specifically uses the case of a non-profit medical manufacturer, Aurolab, to discuss the need for appropriate design, where the appropriate design focuses both on the users of the technology and the infrastructure in which it is to be used. This case is initially framed within a specific disease context: cataracts.

To understand the role of the technology, it is first necessary to understand the basic principles of cataract surgery. The lens of the eye is responsible for focusing light on the retina (inner surface of the eye) to create an image. Cataract development clouds this normally transparent lens, impairing vision. Cataract surgery involves removal of the clouded lens; this lens is typically replaced with an artificial product known as an intraocular lens, or IOL. Untreated cataracts contribute significantly to the blind population of the world.

Blindness costs an estimated US\$25 billion [16] to the world economy; this economic hardship is not isolated to the blind, but affects their families and communities as well. Up to 80% of blindness is preventable or curable with access to quality eye care and appropriate technologies [17].

It is worth noting that there is a lack of literature on appropriate design of health technologies for developing regions ([6] is a notable exception). There are two reasons for this. The first is that almost all medical technologies are developed in industrialized world (US, Europe, and Japan) and 80% of these technologies are consumed by these regions [10]. This distribution is indicative of the *10/90 Gap* – only 10% of health research expenditures are spent on 90% of the global disease burden. Secondly, those few that have pursued appropriate design are largely practitioners from NGO's and

private companies that do not have significant incentives for, or access to, publishing.

BACKGROUND: AUROLAB

Aurolab is one of the only non-profit organizations in the world that produces medical devices or pharmaceuticals. This socially-driven organization produces ophthalmic technologies more cost effectively than any other comparable manufacturer, delivering their products to over 120 countries and owning 7% of the global market for intraocular lenses (IOLs). Moreover, their success has made affordable to those who could not previously afford it, a superior surgical procedure for cataracts. Their success is a factor of: a value-driven and forward-looking organizational culture; prudent financial planning and strategic decisions; and a strong emphasis on engineering over pure production.

Located in Tamil Nadu, India and started in 1992, Aurolab began operations with the manufacture of IOLs. Their primary motivation was to enable delivery of a surgical technique (ECCE, extracapsular cataract extraction) with better health outcomes to patients who could not afford it. At a time when ECCE was practically unheard of in developing countries due to the high cost of consumables and the lack of training and facilities necessary to conduct microsurgery, Aurolab brought down the price of IOLs from more than US\$300 to less than US\$10, enabling widespread adoption of the newer ECCE procedure.

Much of the success to this point has been due to the close relationship between Aurolab and local organizations, such as the Aravind Eye Care System (AECS) and the Affordable Hearing Aid Project (AHAP), but also because much of the work has been done by local engineers who have an understanding of the context. Though in some cases it is possible to directly transfer technologies from the industrialized to the developing world, in many cases this is not feasible.

Aurolab has pursued different strategies to obtain the capacity to produce their different products, but the organization prefers to identify partners with expertise to provide the necessary training and equipment, rather than their own research and development. This has changed in recent years as the organization has been faced with new challenges to their existing technology transfer process, but we will not discuss those changes at present.

Aurolab's first attempt to transfer a technology was the three-piece PMMA (polymethylmethacrylate) IOL. It took two years to locate a potential technology transfer partner willing to provide the necessary training and equipment to produce the three-piece PMMA lenses. IOL International, a U.S. company that did not have sufficient manufacturing capacity to meet their needs, was searching for production partners to support their goals. Aurolab filled this need, and had the resources as part of its affiliation with AECS to quickly develop the production capacity. Through financing from AECS, Sight Savers International, and Seva Foundation, Aurolab paid IOL International in cash and in-kind (IOLs) for the transfer of technology necessary to produce the three-piece PMMA lenses.

Additionally, AECS provided space for the new production facility, and conducted renovations and upgrades costing US\$80,000 to prepare for the production of lenses. Aurolab repaid these costs to AECS through in-kind transfer of lenses. Equipment and training were included in the technology transfer package. Some specific product designs were provided during the initial transfer; Aurolab added other designs to satisfy the specific market requirements. Aurolab did not acquire the patent or licensing rights since there was no need for such an arrangement. There were no royalty or licensing fees involved.

The Aurolab model of technology transfer has been largely tied to the relationships that Aurolab has with organizations such as Project Impact (Berkeley, California, USA; IOL, hearing aids) and Moorfield's Eye Hospital (London, UK; pharmaceuticals). Many of these relationships have been made possible because of Aurolab's affiliation with AECS.

COST

Cost, or pricing in many cases, can serve as a major barrier to accessing health technologies. In the United States, the United Kingdom, and other industrialized nations, 3rd party payer systems are prevalent (e.g. private insurance schemes, government-subsidized care); in contrast, most people across the developing world directly bear the cost of services. While design has the potential to impact cost, low cost alone is insufficient to generate an appropriate solution. In particular, there is a need to adapt design to the existing healthcare infrastructure. Because of the partnership, AECS has remained Aurolab's most important customer. The reason that AECS has been successful in deploying services that use Aurolab technology is that they have provided the necessary infrastructure (see Fig. 1).

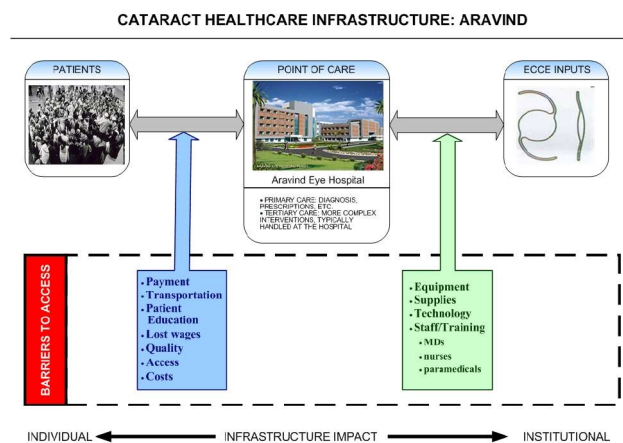


Figure 1: Cataract healthcare infrastructure at Aravind Eyecare System. Though it plays a critical role, technology is only one piece of a complex infrastructure needed to provide cataract services.

Reducing the cost of eye care consumables has been critical for increased access to high-quality ophthalmic care, not only in India, but across the developing world. Aurolab has played a leading role in this arena, particularly with respect to cataract-related products. The IOL (see Fig. 2) has been the flagship product – or more precisely family of products – for Aurolab, as it represented their initial manufacturing venture,

and continues to be one of the most important divisions of the organization. How was Aurolab able to reduce the cost of eye care consumables so drastically? The answers to that question are presented here in the context of the IOL, though they are more generally applicable to Aurolab's entire product line.

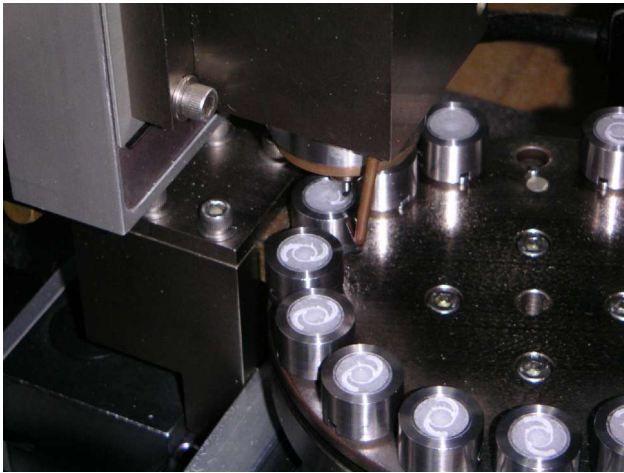


Figure 2: The IOL is a synthetic, polymeric lens inserted into the eye as a part of cataract surgery. This photograph shows the die cutting procedure.

An objective and detailed comparison of production cost between Aurolab and a Western manufacturer such as Alcon or AMO (Advanced Medical Optics, formerly a part of Allergan) is not possible because of the proprietary nature of information that would be needed from the latter. Still, an analysis of the costs to Aurolab reveals some key insights. Dr. Balakrishnan, managing director of Aurolab, indicates that the cost structure for Aurolab is not that different from their competitors. He also says, "In some areas Aurolab costs are higher than their competitors."

Most notable among areas in which Aurolab costs are higher is raw material acquisition, since materials primarily come from Western suppliers. Shipping and lower volume purchasing both contribute to increased raw goods costs. Still, the raw material cost is a small fraction of the selling price of multinational manufacturers. One Indian manufacturer indicates that "the real cost of PMMA (branded original Perspex® UV CQ¹) to the manufacturer is not even US\$0.40 per IOL, even after absorbing the cost of raw material of the rejects (40%) during the various stages of the manufacturing process of IOLs. Even if [an Indian] competitor uses an inferior PMMA, the company is not going to save more than 40 cents per IOL" [9].

Equipment also comes from Western sources, though Aurolab does not necessarily need or use the most modern machining equipment. That is not to say that Aurolab uses outdated equipment, but that they only use the technology that is necessary for meeting their production specifications. In this regard, it is difficult to gauge the difference in equipment costs. That same Indian manufacturer mentioned earlier states, "Other than labour, almost everything, including consumables, used in the manufacture of IOLs in India is imported" [9]. That brings

¹ An ultraviolet light-absorbing material that is an industry standard for production of PMMA lens implants.

us to the areas in which Aurolab enjoys cost savings over Western manufacturers; these include: personnel at all levels including labor, administrative staff, engineering, and management; R&D (though unlike most Western manufacturers they have costs associated with technology transfer), marketing, and operating expenses.

Moran provides one of the few estimates of the manufacturing costs of IOLs; he claims that no manufacturer spends more than US\$15 for the marginal cost of IOL production [13]. The motivation for this work was the secrecy surrounding the cost structure of IOL manufacturers. The authors' review of the most recent public financial records of the largest IOL manufacturers (Alcon, AMO, and Bausch & Lomb) did not yield any useful information about the actual costs of IOL production.

In any case, the Aurolab cost of IOL production is likely within an order of magnitude of its Western competitors, so product pricing is critical, as indicated by Dr. Balakrishnan: "Pricing decisions may account for biggest savings over other manufacturers." Aurolab's pricing decisions are a result of the organization's mission to make eye care affordable. When Aurolab was founded in 1992, PMMA IOLs sold for nearly US\$100 in India. Today, Aurolab sells equivalent lenses for less than US\$10. Even with their mission in mind, Aurolab cannot lower the price too close to the production cost because of the effects on consumer perception of quality. As Mr. Krishnakumar, Aurolab Manager for Regulatory Affairs, indicates, they must also account for the market price of lenses: "If Aurolab reduces [the] price further, doctors will be afraid of purchasing [the] product." Aurolab's pricing decision maintains a fine balance between portraying poor quality on the one hand, and operating against their mission on the other. Aurolab's management believes that it operates in a corrupt market where big businesses lure customers with favoritism and kickbacks. In spite of this, Mr. Sivanand, Marketing Manager, states that "since Aurolab has a positive mission and a good image with [surgeons], some will buy our lenses based on that."

Aurolab has likely had little impact on IOL pricing by multinational manufacturers; the drop in U.S. prices in the mid-1990s was a result of Medicare reducing its reimbursement for IOLs [8]. However, Aurolab has definitely created a market environment for development of low-cost ophthalmic goods. Since 1992, there has been a proliferation of generic manufacturers in India², most of these being for-profit entities. One notable exception is the Fred Hollows Foundation, which sells in India (they produce lenses in Nepal and Eritrea) and started distributing IOLs shortly after Aurolab [5]. Competition among these many companies has driven the cost of IOLs to large-scale cataract programs – including the World Bank Tender – to less than US\$5 [3]. Quality among these players varies widely and without a central regulatory body for medical devices in India, there is no objective standard by which to compare manufacturers.

² At the time of publication, one industry directory listed 27 Indian IOL manufacturers from 6 states, plus New Delhi.

QUALITY

Quality is a product of design-for-manufacturing. There are clinical needs for quality, but there are also non-critical quality issues related to branding. Aurolab's commitment to quality has earned it business in the face of competition that has been able to produce and sell lenses for even lower prices.

Some IOL complications can be serious enough to require removal or exchange of the lens [2]. These complications may induce reduced vision or chronic pain. Most of these complications are related to surgical procedure, postoperative care, or IOL design, but it is apparent that undetected manufacturing defects (or poor tolerancing) may induce unwanted effects, such as those associated with power labeling³. Other defects may lead to broken haptics⁴ or cracked optics in the case of foldable IOLs [14].

One study evaluated single-piece PMMA IOLs from eight generic manufacturers (including Aurolab) marketing their products in India [3]. The intent of this study was to assess "quality ... with respect to compliance with international standards for the manufacture of IOLs, specifically those parameters most likely to affect patient postoperative visual acuity and the long-term biocompatibility of the implanted lens."

The findings of this study indicated that: (1) only two manufacturers (Fred Hollows and Indo-American Optics) fully complied with the international optical and mechanical standards, according to their statistical generalizations; (2) only three manufacturers (Fred Hollows, Indo-American Optics, and Omni lens) were without critical manufacturing defects in the tested lenses; (3) only two manufacturers (Fred Hollows and Intra Ocular Care) met the surface quality and bulk homogeneity (Aurolab had 1 out of 10 samples that failed these tests); (4) two manufacturers (International Medical Devices and Intra Ocular Care) had levels exceeding specifications of MMA (methylmethacrylate monomer) in their samples; and (5) only one manufacturer (Fred Hollows) met all the authors' specifications.

Aurolab's performance on these metrics follows. Its lenses passed 3 out of 4 ISO 11979 (mechanical and optical) tests; the samples failed the clear optic diameter test by approximately 0.3%. Nine out of ten samples passed ISO 11979-3(4.11) (surface and bulk homogeneity) testing; the lone failure had a mark on the clear optic surface; other than Fred Hollows, Intra Ocular Care, and Aurolab, no manufacturer had more than 6 out of 10 samples passing this test. Finally, Aurolab's lenses had a low level (0.5%) of MMA, suggesting the use of clinical grade (as opposed to industrial grade) PMMA in IOL production.

This was a highly controversial study, in part because of the authors' affiliation with the Fred Hollows Foundation, the "winner" of the evaluation [1,7,9,11]. Only a selected set of manufacturing criteria were used to judge the IOLs; for

example, the study did not examine lens power or sterilization. Moreover, the study did not attempt to make distinctions among manufacturers with gross failures and those whose results fell marginally out of specification. This was even more glaring given the small sample size (10 lenses per manufacturer); these samples were used to determine statistical estimates of the general process, but this can be highly misleading.

The value of the study is in identifying that manufacturers with widely varying standards of quality and process control sell IOLs to the Indian market. Because of the potential harm that defective lenses may cause patients – and because of the general inability of a surgeon to determine the efficacy of a particular lens during surgery – it is critical to use high-quality lenses. The difficulty lies in identifying quality lenses, since foreign regulatory approval (FDA, CE) is cost-prohibitive to many low-cost manufacturers. Though there is no regulatory body for medical devices in India, there is one for pharmaceuticals. Further, the formation of a regulatory body for devices under the same Drug Controller of India is underway at present.

Aurolab obtained FDA approval for a non-IOL product (suture needles) through the 510(k) process⁵ [15]. Still, though the direct 510(k) costs begin at \$2,802 in 2005, the associated costs can be quite high. For example, a company filing a 510 (k) is required to have a United States agent with an employee to serve both as a correspondent to the FDA and liaison with the foreign manufacturer. Aurolab also pursued certification through other avenues. Aurolab was the first company in India to receive ISO 9000 certification and the CE mark for many of their critical ophthalmic surgical products. Interestingly, though such certification was not mandatory, Aurolab's action prompted other manufacturers to pursue such certification.

PACKAGING AND PRODUCT SUPPLY CHANNELS

Besides their emphasis on low-cost, high-quality products, Aurolab has faced many other context-specific design challenges. To address a poor healthcare supply chain infrastructure in India and across the developing world, they created a bundled surgery kit with all the necessary supplies to perform 5 cataract surgeries. By sourcing some supplies from other manufacturers and leveraging their diverse line of products (some manufacturers only produce IOLs while Aurolab also produces microsurgical sutures and ophthalmic pharmaceuticals), Aurolab was able to provide a simple innovation that has had significant impact. Without all the necessary supplies, the supplies on-hand are useless; the bundle allows surgeons to source their cataract-related products from a single supplier, thereby eliminating much of the uncertainty of the supply chain. This has in part been successful because of the prevalence of the disease. Cataract surgeries are performed in batches, rarely in isolation; in contrast, this is, relatively speaking, a low-volume surgery in industrialized regions.

³ Power labeling here refers to the optical power of the lens. Some manufacturing defects may result in improper product classification, leading directly to substandard patient outcomes.

⁴ The typical looping extension to the IOL that anchors the lens.

⁵ A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA).

Another Aurolab product with a strong impact is viscoelastic (brand name *Aurovisc*TM) – a high molecular weight solution of hydroxypropyl methylcellulose – which is injected into the eye during cataract surgery. When Aurolab started production, there were only 2-3 manufacturers of viscoelastic worldwide and it was not sold in pre-filled vials, presenting both a logistical inconvenience to surgeons in the field and a cost burden for those performing smaller volumes of surgery. Although pharmaceutical companies source the main ingredient from the same set of biotech companies (Aurolab sources from Germany), Aurolab was able to bring the price down significantly. After their work with IOLs, Aurolab successfully eliminated the second biggest barrier for cataract surgery in terms of cost of supplies.

Reuse of single use devices and drugs is common in emerging nations to further cut costs. Understanding this market reality, Aurolab designed products such that reuse would not lower the performance, safety or efficacy of the product. For example, Aurolab made sure through rigorous testing that reuse of suture needles for few more cases would not cause any performance degradation of the product under normal use. Another example is that the packaging of some of the single use drugs is designed such that a small quantity of the drug may be extracted more than once through a rubber enclosure using sterile syringe needles without compromising sterility.

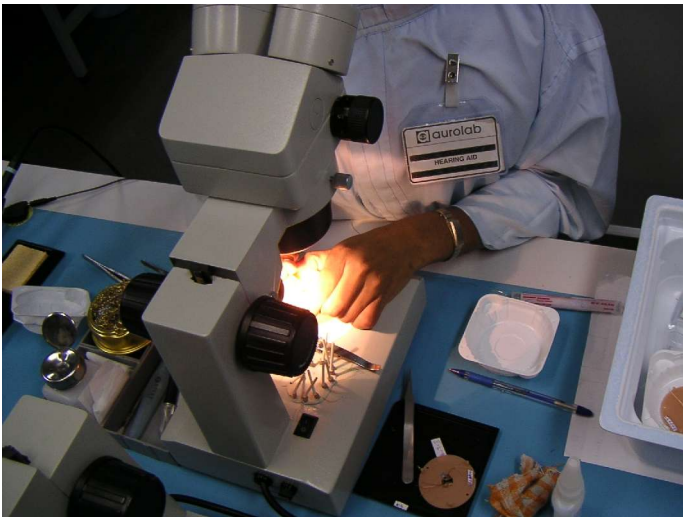


Figure 3: Aurolab produces and services low-cost, digitally programmable, analog hearing aids. This photograph shows an assembly procedure.

Aurolab exhibited the same ingenuity throughout its product range. To address intermittent access to power, they developed a solar battery recharger for their low-cost hearing aid. Additionally, this is less detrimental to the environment, provides a better service to people from rural communities, who may not have ready access to battery vendors, and is more cost-effective for low-income groups. To address lack of refrigeration, Aurolab developed a new formulation for an antifungal medication that has an increased shelf life. Other approaches to this problem – in different contexts – include production of a different medication, or in some cases development of more reliable refrigeration. They have even addressed the need for support and maintenance with their

modular design of the hearing aids (see Fig. 3). Not only is there local capacity to build these electronic devices, but there is also the ability to diagnose and repair them.

CONCLUSIONS

Aurolab in conjunction with AECS has managed to overcome challenging barriers to accessing eye care technologies in a developing context. This mission-driven organization has holistically tackled the problem on various fronts. The focus of this work has been on design issues, but their success is clearly due to more than good design. Notably, Aurolab's successful technology transfer process, successful partnering for delivery of this technology, organizational development and culture, leadership, and human resources capacity all played critical roles in the success. Still, the history of this organization provides a meaningful case for examining appropriate design in the context of medical devices and pharmaceuticals for emerging regions.

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