This is paper was originally written for the Science and Technology Policy course at University of Colorado at Boulder in Spring 2007.

When referencing this paper, please cite the *Technology in Society* publication

Williams, Logan D. A. 2008. "Medical technology transfer for sustainable development: A case study of intraocular lens replacement to correct cataracts." *Technol Soc* 30(2): 170-183, doi:10.1016/j.techsoc.2007.12.012

Logan D.A. Williams Email: <u>ldawilliams@gmail.com</u>

Intraocular Lens Replacement to Correct Cataracts: A Case Study of Medical Technology Transfer for Sustainable Development

Logan D.A. Williams^{ab1}

^aMechanical Engineering, University of Colorado UCB 427, Boulder CO 80309-0427 Phone: 303-492-4184 Fax: 303-492-3498 Email: Logan.Williams@colorado.edu

^bCenter for Science and Technology Policy Research, University of Colorado 1333 Grandview Ave, Campus Box 488 Boulder, Colorado 80309-0488

Short Title IOL Replacement for Sustainable Dev.

Vitae

Logan Williams is a Master's student in the department of Mechanical Engineering at University of Colorado at Boulder. She has previously performed research on a novel ultrasound system with potential application as a cardiovascular disease diagnostic device. This work is co-authored in Applied Physics Letters. She is interested in national and international policies for: emerging medical and agricultural biotechnologies, technology transfer and global engineering education.

Abstract

Cataracts account for almost 50% of blindness in the world (17 million people). The magnitude of this problem is stunning, and affects the sustainable economic progress of developing nations where 90% of the blind are located (and likewise 90% of the \$19 billion dollars in lost global productivity each year). The Vision 2020 program has called for eliminating cataract as a cause of avoidable blindness through Intraocular Lens Replacement surgery (IOL surgery), a relatively cheap solution with good outcomes. This paper will (1) give background on the scope and problems surrounding international technology transfer of IOL surgery (2) develop the international medical technology transfer framework adapted from work by Lall and Wei (3) compare programs in the countries of Nepal and Nigeria, (4) evaluate the success of their technology transfer of intraocular lens replacement and (5) provide recommendations for sustainable international transfer of IOL surgery.

¹ <u>Present Address (starting August 1, 2007)</u> Science and Technology Studies, Rensselaer Polytechnic Institute 110 8th St., Sage Building 5th Floor, Troy NY 12180-3590 Phone: (518) 276-6574 Fax: (518) 276-2659 Email: Idawilliams@gmail.com

1. Introduction

1.1. Cataract Disease

Cataracts, or occlusion of the lens(es), are the leading cause of blindness in the world. Bi-lateral cataracts alone account for 47.8% (17.7 million people) out of the 37 million blind in 2002 [1], [2]. With an aging population, the number of blind men and women is expected to increase annually, resulting in 76 million blind by the year 2020 [3]. This is especially a cause for concern in developing nations where 90% of the world's blind are located [4].

The causes of cataract are not well known. Clinicians have seen a high correlation to exposure to ultraviolet light, and vitamin A deficiency, and a very high association with smoking. A recent study performed in the United States shows a very high correlation to lead accumulation in older men [5]. Low weight before 1 year of age, a common condition in developing nations, may also be correlated to children having a higher risk for cataract development later in life [6]. There is no consistent correlation between size at birth and later age-related cataract [7]. This may indicate that the above mentioned environmental conditions which impact personal eye health after birth are more important in cataract development than pre-birth conditions. However, the genetic effect of heritability has been reported as having significant correlation to nuclear and cortical cataract [8].

Cataracts are one of the most easily corrected causes of blindness. Several techniques are available including: lens removal and aphasic corrective glasses, lens removal and replacement, lens capsule draining and refill with a polymer substitute for the crystalline lens [9], [10], [11], [12], [13], [14], [15]. Extracapsular Cataract Extraction and Posterior Chamber Intraocular Lens Implantation (ECCE & PC-IOL, referred to in this paper as IOL surgery) is fast, and relatively cheap with good long-term outcomes for visual acuity [15].

The blindness epidemic negatively impacts the ability of developing nations to sustain development. Unfortunately, without the infrastructure and support systems common in industrialized nations, the blind are unable to live fully productive lives. In fact, the care they require from a sighted family member may contribute to a reduction in the economic livelihood of their families [16]. Visually impaired people are less well socially integrated, and at higher risk for suicidal behavior [17], [18], [19]. The relatively simple outpatient surgeries described can dramatically improve the quality of life of the visually impaired [8], [20].

1.2. Vision 2020

In 1997, the World Health Organization (WHO) Program for the Prevention of Blindness and Deafness published a document called "The Global Initiative to Eliminate Avoidable Blindness" in which they outlined the global priorities to fight blindness by targeting: cataract, trachoma, onchocerciasis, childhood blindness, refraction, and lowvision services [4]. In 1999, the WHO joined together with the International Agency for the Prevention of Blindness (IAPD) (Hyderabad, India), to create the "Vision 2020 – the right to sight" program with the goal of eliminating avoidable blindness by the year 2020. Operating on approximately \$200 million USD each year, the objectives of Vision 2020 are to: (1) Create awareness of the magnitude of global blindness and visual impairment, and, the fact that 75% can be cured or prevented with existing technologies and knowledge (2) Organize for more efficient mobilization and use of resources in developing eye care services (3) Implement sustainable and equitable eye care services at the regional level (4) Prioritize locally and nationally available resources to control avoidable causes of blindness and visual impairment [1].

Vision 2020 organizes annual workshops for each country to develop individual Vision 2020 plans and national eye care service programs. The IAPB keeps track of Vision 2020 affiliated training programs under the following categories: Ophthalmology, Low Vision/Rehabilitation, Community Eye Health, Mid Level Ophthalmic Personnel, Eye Care Management Personnel,

The Vision 2020 Link Program run by the International Center for Eye Health (London, England) started exploring institutional links between ophthalmic departments in the UK and Africa in 2005 [W1], [W2]. The goal is to provide "in-service training in which skills shared can be clinical, technical, community-based, organizational or managerial [W3]." This training is tailored to the specific needs of the developing nation's institution as defined by a "Needs Assessment".

The WHO has found that the Vision 2020 program has been successful in increasing cataract surgeries in Morocco, India, Nepal, Sri Lanka and Thailand. Other countries, particularly in the continent of Africa, have seen less success.

This paper will compare the programs in the countries of Nepal and Nigeria, and evaluate the success of technology transfer of intraocular lens replacement with the international medical technology transfer framework which was developed based on work by Lall and Wei [21], [22].

1.3. Economic Burden of Blindness

In 2000, the global productivity loss due to blindness was \$19 billion (2000 USD) per year [3]. Due to an increasingly larger and older population, this loss has been projected to grow to an astounding \$50 billion (2000 USD) per year by the year 2020 without intervention. A second analysis which includes both the costs of an able bodied family member providing care for a blind family member, and, the reduced productivity of persons older than 64, estimates that the annual projected loss will be \$77 billion (2000 USD) by the year 2020 without intervention. However, because of the Vision 2020's efforts to reduce blindness, the year 2020 estimated annual global productivity loss will only be \$26 billion (2000 USD) (or \$41 billion in the secondary analysis).

Ninety percent of this economic burden of blindness resides with least developed countries who are already at an economic disadvantage, having a per capita income of less than \$635 (1993 USD) compared to a per capita income greater than \$7911 (1993 USD) in industrialized countries [23].

It has been argued that a stand alone program, such as Vision 2020, which does not simultaneously encourage economic development, will be ineffective in permanently reducing the prevalence of blindness [23]. However, this paper shows that under certain conditions, Vision 2020 can be an impetus for medical technology transfer and the creation of supporting infrastructure and human capital for sustainable development.

1.4. Cultural Barriers to Transfer of Intraocular Lens Replacement Technology

Cataracts are the leading cause of both blindness (visual acuity less than 3/60) and low vision (visual acuity of less than 6/18 and greater than 3/60) worldwide [2]. Eightytwo percent of the world's blind (or 30.3 million) are over the age of 50. Women are twice more likely to be visually impaired than men. *This suggests that the demographic requiring IOL surgery in developing nations can be described as mostly women older than 50 with incomes below the poverty level*. Any address of cultural barriers to intraocular lens replacement must carefully consider this demographic.

One might assume that costs feature most prevalently as a barrier to intraocular lens replacement surgery. Among impoverished people costs are very important, however, the situation is a little more complex (as will be shown in the discussion of IOL surgeries in Nepal and Nigeria) and opportunity costs are closely linked to family support. Costs for human capital and infrastructure are static (not dependent on surgical volume), and costs for medical supplies are continually decreasing with successful imitation and innovation in developing countries [24]. However, even when surgeries and transportation are made available free of charge, there is still a poor response from potential patients. *This suggests that the two most important barriers to IOL surgery are poor awareness and poor family support*. Please see Table 1 for a list of cultural barriers to intraocular lens replacement surgery.

1.4.1. Poor Awareness

Poor awareness can be further broken down into: lack of knowledge about what IOL surgery is, some knowledge of surgery but not the specifics of who, when or where, and, knowledge of surgery but little understanding of how it might be beneficial among those who still have some degree of physical independence [24], [25]. This is complicated by illiteracy, as many studies have shown that literate populations are more likely to undergo the surgery than illiterate [25], [26].

Some success has been found in increasing awareness by advertising through radio, but, arguably the best results come from asking former patients with successful outcomes from IOL surgery to act as representatives to their communities. It might be worth the effort to study why targeted potential patients with some degree of physical independence reject surgery as having the ability to provide increased benefits /quality of life. Perhaps former patients acting as community liaisons are more successful in "selling" the idea of IOL surgery because potential patients: (1) accept them as a trusted charismatic disseminators of scientific knowledge, (2) receive said knowledge in a "safe" environment [27].

1.4.2. Surgical and Follow-up Costs

In addition to the fixed costs of infrastructure (building and equipment depreciation and maintenance) there are fixed costs for hiring, training and paying staff [24]. The remaining surgical costs are for disposable medical supplies including: dilating eye-drops, ciprofloxacin eye-drops, anesthesia (licodaine), Betadine, silk suture thread, buffered saline solution, rubbing alcohol, etc. used in surgery. Follow-up costs may include ciprofloxacin and dexamethasone eye-drops, pyrimon eye-drops and steroid ointment and if necessary the cost of further corrective surgery [28], [13]. In total

(without additional corrective surgery) the minimum cost for IOL surgery on one eye is \$20-37.

1.4.3. Poor Family Support

Poor family support can be further broken down into: travel costs, opportunity costs and incentives.

Developing nations often have a very low ratio of physicians and surgeons per capita [29]. Medical personnel are concentrated in cities whereas the poor in need of IOL surgery are more often found in rural areas with poor access to health care. Patients often must travel a great distance to reach an eye clinic for surgery and follow-up visits. The difficulty of poor roads and extreme terrain (mountainous or desert) may make travel costs prohibitive compared to the perceived value of surgery. Also, civil war or other political instability may cause travel to be hazardous.

Opportunity costs are basically the cost the family suffers in lost income for an able-bodied member to take the blind member for surgery and follow-up. The opportunity costs are increased with increased travel distance and difficulty and again may be prohibitive compared to the perceived value of surgery.

Incentives for surgery are tied into the blind person's emotional state and desire for surgery, and the family's desire for a more independent member who can contribute to family productivity.

Older persons are considered to be less productive. Perhaps marketing for IOL surgery should be directly tied to some kind of "work-skills program." Such a program would address the re-adjustment of blind persons to sightedness, as well as the decreased productivity of older blind persons.

A large part of the reluctance that some patients have to IOL surgery may in fact be the lethargy that is part of depression. Studies of the blind performed in Australia show that older adults with severe visual impairment or blindness may suffer from decreased self-esteem and confidence, and increased frustration, embarrassment and social isolation [19]. Progressive onset of blindness is a risk factor for suicide among Australians of all ages [18]. Poor social support was associated with increased suicidal ideation among elderly individuals with mild and severe depression in the United States [17]. Studies performed in developing nations report psychosocial impairment due to blindness [25], which may account for part of the resistance to IOL surgery.

Other mitigating factors to patient incentive may include bad service from personnel, historically poor outcomes (lens removal with aphasic glasses and no lens replacement), and cultural bias against female gender [13], [24], [29]. Regional-specific culture can influence the impact of one barrier versus another, e.g., poor awareness and surgical and follow up costs were emphasized in studies done in Nigeria, whereas illiteracy and opportunity costs were emphasized in studies done in Nepal. However, the difference in literacy rates is small, Nigeria is 66.8% (2004) and Nepal is 53.7% (2001).

How do these barriers tie together to create incentive or lack of incentive in the individual and the family? Family decisions to support IOL surgery balance surgical and follow up costs and opportunity costs with family incentives and perceived benefit. The social psychology of this decision needs to be understood and addressed before the demand for IOL surgery will increase.

2. Framework for Sustainable International Medical Technology Transfer

2.1. The Role of Nongovernmental Organizations

Typically NGOs can be characterized as religion based or mission based. The advantage of religion based NGOs include a well established broad network of "actors" and continuity of presence (though not necessarily of personnel or of goals). The disadvantage of religion based NGOs is the potential of divisive polarity caused in multi-religion communities where they are present. The non-polarizing nature of mission driven NGOs in turn is an advantage, while its often temporary nature (because of inconsistent funding) is a distinct disadvantage.

One-dimensional political alliances with government officials can "politicize" religion based or mission based NGOs, changing them into instruments of public policy (and creating a disadvantage if there is a regime change) [30]. Strategic political alliances and involvement of local stakeholders can empower NGOs to be sustainable enterprises which benefit the community.

Unlike NGOs which depend solely upon donations to continue charitable work, self-sustaining entrepreneurial NGOs with local stakeholders have greater incentive to go beyond the transfer of basic essential medical services and technology (characterized by duplication) and develop new regionally tailored services and technology (characterized by adaptation and innovation) [31],[32].

NGOs undertaking medical technology transfer have an advantage over multinational enterprises in that while specific innovative medical products are patented, lifesaving surgical techniques and procedures are not (at least by the United States) and thus can be used without money being spent for licensing (which is a huge and hotly debated component of international technology transfer to developing nations) [31].

The motivations for multi-national enterprises to attempt international technology transfer, and, NGOs to attempt international medical technology transfer can be, on the outset, quite different. However, the language that Lall used and Wei modified to describe the technological content of transfer is still useful [21], [22].

2.2. Language of international medical technology transfer

Sustainable Medical Technology Transfer can be described in the language of international technology transfer in terms of:

- 1. Multi-national Enterprises/ Entrepreneurs = NGOs
- 2. Products = International Public Health Goods (surgical techniques, clinical procedures, preventive practices, biomedical devices and public health services)
- 3. Process Engineering = Surgical Techniques and Clinical Procedures; Health Education
- 4. Product Engineering = Biomedical Device Design and Fabrication (for surgeries, facilities, patient monitoring, disease maintenance and prevention and education)
- 5. Industrial Engineering = Information and Facilities Management
- 6. FLOW A = Medical Service and Public Health Goods
- 7. FLOW B = Human Capital, Medical Service Capacity
- 8. FLOW C = International Public Health Goods

The technological content of international medical technology transfer is shown in the Table 2 . In this table, Flow A, B and C are described in more detail.

2.3. Requirements for sustainable medical technology transfer

Sustainable medical technology transfer can occur under the following conditions:

- 1. Development of a coordinated framework, or, "context" where trust can be established, goals will be defined, and, knowledge will be transferred. [33]
 - a. By identifying shared organizational dimensions this context reduces the costs of cultural distance between transferring and receiving parties [34]. The seven key organizational elements as described by Santoro and Gopalakrishnan are: strategy, structure, values, support systems, style, skills and staff.
 - b. A coordinated framework serves the dual purpose of both allowing preeminent medical personnel to showcase the "true value" of their knowledge and techniques as well as increasing the access to new information and technology of medical personnel from developing nations.
- 2. National and international government technology policy that reduces costs of acquiring and absorbing existing technologies
 - a. The government of a developing nation needs to support the creation of infrastructure, human capital and R&D capacity. The most abstract of these concepts, R&D capacity, essentially can be described as a "context" for horizontal technology transfer between universities, public laboratories and domestic firms or NGOs [31].
 - b. Agreements need to be defined by the World Trade Organization, that allow developing nations to acquire existing medical technology without being crippled by licensing costs (and thus unable to sustain development) and at the same time respect the rights of multi-national enterprises to protect their valuable intellectual property
- 3. Support of sustainable entrepreneurship focused on domestic innovation as described above.

As shown in Figure 1, Flow A is dominated by transfer of knowledge and technology for essential medical services and public health goods from industrialized to developing nations.

As the level of difficulty of technology transfer increases from low to medium, it is further characterized as adaptive instead of duplicative imitation, creating and, or, training more of the developing nation's human and technological resources. This is shown in Figure 1 as Flow B having overlap in both the industrialized nation and the developing nation. Finally, Flow C is characterized by a high level of difficulty for vertical transfer of innovative public health goods from the developing nation back to the industrialized nation and to other developing nations.

3. Specific Cases of Intraocular Lens Replacement Technology Transfer

3.1. CASE I: NEPAL

In 1980, the population of Nepal was 18,916,000 and the blindness prevalence was 0.8%. The GNI per capita at that time was \$143 (1980 USD) [23]. An estimated 80% of blindness in Nepal is caused by bilateral cataracts [35]. Cost of IOL surgery is typically \$20-37 (USD) [28].

3.1.1. NGOs And Government

Foundation Eye Care Himalaya (Kathmandu, Nepal), Himalaya Cataract Project (Burlington, Vermont, USA) and The Fred Hollows Foundation (Sydney, Australia) are the main non-government organizations involved in IOL surgery in Nepal. The Fred Hollows Intraocular Lens Laboratory (established in 1994) in particular is known for its local production of high-quality single power poly methyl methacrylate (PMMA) lenses for \$7 (2000 USD) which takes advantage of economies of scale exporting thousands of lenses per year for \$10-12 (1998 USD) [28]. In collaboration with the Tilganga Eye Centre (Kathmandu, Nepal), it has also created low cost terrain-appropriate technology for IOL surgery including a portable operating microscope which costs \$3 000 (2000 USD) and a portable ophthalmic laser which costs \$12 000 (2000 USD) [12].

A study by the Tilganga Eye Centre found that 92.7% of Nepali patients require a lens strength between +22.5 and +23.0 diopters [36]. This power is larger than the North American standard of +21.0 diopters used in for mass production of intraocular lenses in Nepal. As myopia is considered better than hyperopia for vision correction, a new standard of +22.5 diopters has been determined as optimal for correcting the vision of Nepali patients.

The government of Nepal established the National Council for Science and Technology in 1976 and the Ministry of Science and Technology in 1996. The Ministry of Health and Population started the Nepal Health Research Council (NHRC) in 1991 "as an example of commitment of Nepal Government (NG) Nepal to promote scientific study and quality research in health in Nepal [W9]." However, there is little infrastructure for, or local or foreign investment in research and development, and what exists in local universities focuses on fundamental research [37]. The World Bank estimates that it takes 21 days to start a new business in Nepal [W6].

3.1.2. Barriers

Poverty (44%) and lack of family support (29%) are the two most important cultural barriers according to a survey conducted by the Tilganga Eye Center [26]. The statistical relevance of these responses is unknown. Approximately 50% of 78 patients surveyed were unwilling to pay more than \$13 for the surgery (with the average desired price of \$7). Typically, men were willing to pay more than women (indicating the value placed on gender in this patriarchic society). Men are typically better educated, being 65% literate compared to women only 45% of whom can read [W10].

Historically poor visual outcomes (from posterior chamber lens removal without replacement) may also play a role in discouraging patients from seeking treatment [20]. In summary, "The costs and efforts needed to undergo treatment seem greater than the perceived value of visual rehabilitation" for older family members who will not

necessarily require less economic support after surgery [13]. The rugged terrain of a country whose majority of GDP is dependent upon agriculture implies extremely high transportation costs. Also, the rising tension between the Communist Party of Nepal and government supported village defense forces may make travel prohibitive [W7].

3.1.3. Cataract Surgical Rate

Surgeons led by Dr. Ruit at the Tilganga Eye Centre has reintroduced the use of an innovative suture-less small-incision cataract surgery (SICS) that cuts fixed costs by almost eliminating use of expensive suture. While more technically difficult, the use of a surgeon's time is more efficient in SICS than typical IOL surgery, and good visual outcomes are maintained compared to more expensive surgeries performed in industrialized nations [12], [35], [24]. The Tilganga Eye Centre also reported acceptable visual outcomes from a remotely setup 4-day Eye Camp in Chaughada [28]. IOL surgery rates increased 10% from 1981 to 1995, mostly in affluent, literate, urban areas of Nepal. Less than half of the "population of illiterate farmers in rural Nepal, even when offered free transport [...] accept surgery within 1 year" and a surgical uptake of only 60% was reported in 1998 [13].

In 2005 the population of Nepal was 27 100 000 and the GNI per capita was \$270 (2005 USD) [W6]. According to the WHO SEARO Map, the 2003 Cataract Surgical Rate (or number of surgeries performed per year per millions of people) was 1000-1999 [W4]. Nepal is part of the WHO South East Asian Region – mortality stratum D (SEAR-D) which in 2002 had a blindness prevalence of 0.6% (51% due to cataract) [2].

3.2. CASE II: NIGERIA

In 1989, the population of Nigeria was 96 203 000 and the blindness prevalence was 3.3%. The GNI per capita at that time was \$327 (1989 USD) [23]. A randomized study of 15 villages in Katsina State (northern Nigeria) in 1999 resulted in bilateral cataracts being responsible for 44.2% of blindness (a population prevalence of 3.6%) [38]. A survey of performed at Otibhor Okhae Teaching Hospital (1995-2000) showed that 36.7% of blindness in Edo State (northern Nigeria) is caused by bilateral cataracts. This indicates little improvement from a previous study (1974) where 49.6% of blindness was due to bilateral cataracts. Cost of IOL surgery is typically about \$100 (USD) because of high fixed costs and low surgery demand [39].

3.2.1. NGOs and Government

Helen Keller International (New York City, New York, USA), Seeing is Believing/Sight Savers International (UK) and Christian Blind Missions International (Germany) are three of many non-government organizations involved in IOL surgery in Nigeria. None of the NGOs have a primary mission of eliminating cataract disease.

Onchocerciasis is a very significant cause of blindness in northern states of Nigeria [18],[40]. The control of this disease has been a major focus of eye care programs by the Federal Ministry of Health. Since 1995, the Christian Blind Missions International (or CBMI) in particular has worked closely with the health ministries of the northern states Kano, Jigawa, Yobe, the federal capital territory Abuja, and the southern state Taraba in an ongoing effort to control onchocerciasis. With onchocerciasis control programs being successful, in 2004 more attention has turned to eliminating avoidable

blindness from cataracts [W13]. An established network of volunteer community members trained to distribute drugs for onchocerciasis control have recently been retrained to identify and refer curable eye diseases such as cataract to CBMI outreach eyecamps [40].

The Federal Ministry of Science and Technology (established 1979) has created the National Biotechnology Development Agency (NDBDA) as well as the Nigerian Institute for Trypanosomiasis Research (NITR) (which conducts basic research on the pathology and immunology of trypanosomiasis and onchocerciasis) among many other institutes and technology incubation centers. The Federal Ministry of Health has created the National Institute of Medical Research and the National Institute of Pharmaceutical Research. The World Bank estimates that it takes 43 days to start a new business in Nigeria [W6].

3.2.2. Barriers

High Cost (61%) is the most important cultural barrier while lack of knowledge about where to get surgery (10%) is also important for those with bilateral cataracts according to a survey conducted by the National Eye Center in Katsina State. Previous poor visual outcomes from IOL surgery also caused 2% to indicate distrust in surgery [36]. However, with an estimated 1 ophthalmologist per 1 million people in the continent of Africa, the lack of service being available may currently be the biggest barrier. It was identified as the second biggest barrier (after cost) by 43% of people surveyed in 13 leper villages in northeastern Nigeria [41], [29]. There is also concern about rude staff or demands for bribes causing a mostly elderly demographic of potential patients to be wary of attempting IOL surgery [24], [36].

3.2.3. Cataract Surgical Rate

The NGOs in Nigeria have focused on building up eye care services in general, and in regards to cataract they have funded the training of several surgeons in ophthalmology diplomas and have paid to equip clinics and eye hospitals with the correct surgical equipment. In 2005, the population of Nigeria was 131 500 000 and the GNI per capita at that time was \$560 (2005 USD) [W6]. According to the WHO African Region Map, the 2003 Cataract Surgical Rate (or number of surgeries performed per year per millions of people) was 250-499 [W5]. Nigeria is part of the WHO African Region – mortality stratum D (AFR-D) which in 2002 had a blindness prevalence of 1% (50% due to cataract) [2].

4. Evaluating the success of Intraocular Lens Replacement Technology Transfer

The WHO Vision 2020 program provides the "context" for successful intraocular lens replacement technology transfer. Many of the organizational dimensions described by Santoro and Gopalakrishnan are addressed by the Vision 2020 goals.

Though the Vision 2020 program admirably focuses on preventive care, creating infrastructure, medical training, surgical volumes and statistical data collection, it still appears to lack a more concrete forum for knowledge transfer. The Community Eye Health Journal published by the WHO and the International Center for Eye Health (London, England) somewhat meets this need. However, the WHO should consider sponsoring regionally based semi-annual cataract disease specific conferences where

medical personnel, public health officials, and other local stakeholders might have access to anecdotal and technically based knowledge transfer in a way that further builds professional relationships. Tilganga Center has successfully mentored other eye hospitals through such a context [42].

4.1. CASE I: NEPAL

Over the last 13 years, Nepal has been very successful in Intraocular Lens Replacement Technology Transfer. In particular one should note the many journal publications in the British Journal of Ophthalmology (for such a small country), indicative of FLOW B and FLOW C and also, the quick ramp-up from duplicative imitation to adaptive imitation in the Fred Hollows IOL Laboratory (from using the North American Lens power standard, to performing a study on the best power for correcting the vision of Nepali). Adaptive imitation and innovation is shown by Dr. Ruit's reintroduction of suture-less IOL surgery and subsequent improvement of this surgical technique and FLOW C transfer of this international public health good through conferences and journal publications.

The Cost Recovery system which scales costs for IOL surgery depending upon patient income is a useful method to ensure clinic sustainability while keeping individual patient costs low. The minimum cost of \$20 for IOL surgery is about 7% of annual income - a little less than the average monthly income of Nepali.

The planned infrastructure expansion and training programs initiated by the Tilganga Eye Center are a sensible next step.

The medical personnel of the Tilganga Eye Center has shown a sensitivity in working within a multi-cultural society and have worked with both Hindu and Buddhist religious leaders to overcome barriers to eye surgery [43]. However, more emphasis will need to be placed on health education as smoking, a risk factor for cataract, has increased in the rural hilly communities (>62.4%) compared to national levels (38.4%) in 2000 [W10].

4.2. CASE II: NIGERIA

It appears that with onchocerciasis being such a debilitating disease in northern Nigeria, avoidable blindness due to cataracts has not received concentrated attention from the Federal Ministry of Health or collaborating NGOs before 2004 [W13], [W14]. With such a severe shortage of trained ophthalmology personnel and facilities in Nigeria, NGOs have been focused on building infrastructure and human capital. The number of IOL surgeries performed has increased, but not in a way that is significant to reduce the backlog of those blind from bilateral cataract [40], [W5]. The costs for IOL surgery, as indicated by Otibhor Okhae Teaching Hospital are disproportionate to annual income, almost 18%. Such a high cost, in addition to other cultural barriers, causes demand for IOL surgery to be very low. The clinics providing IOL surgery need to investigate alternative pricing schemes to sustain service.

The use of a previously well-established eye care service structure to increase demand for IOL surgery is indicative of FLOW B in that it is adaptive health care management [40].

5. Recommendations for continued development of technological capabilities and expertise for intraocular lens replacement

An interesting point about cataracts is that though it is easily corrected, the etiology of the disease is still poorly understood. However, IOL surgery is a huge part of the workload of ophthalmic departments around the world [44]. In the United States, the burden of cataract disease alone accounted for 4.8 billion (1999 USD) of 6.7 billion (1999 USD) in Medicare payments between 1996 and 2000. This amounted to 71% of Medicare spending on vision-related care, or, approximately 2.8% of total spending in those five years [45].

This poorly understood phenomenon occurring at such a large scale worldwide creates an opportunity for developing nations to take advantage of local resources (a large backlog of individuals with cataract) to make significant contributions to basic research and medical technology innovation. "Entrepreneurs that recognize complementarities between local needs and international objectives can design ways to produce international public [health] goods [32]."

5.1. "Applied" Clinical and Public Health Research

Several very specific suggestions for applied research that can be undertaken right away with resources currently available in developing countries (and will potentially yield international public health goods) are:

- 1. Investigation of the psychology of sensory deprivation from progressive blindness due to bi-lateral cataracts among the elderly (*Theories for Prevention, Counseling and Maintenance*)
- 2. Further investigation of posterior capsular plaque after surgery (*Surgical Techniques and Clinical Procedures*)
- 3. Further investigation and innovation of suture-less IOL surgery (*Surgical Techniques and Clinical Procedures*)
- 4. Investigation of how diet, in terms of anti-oxidants from vitamins A, C and E, and body mass index, correlates with age-related cataract (*Theories for Prevention, Counseling and Maintenance*)
- 5. Investigation of the relationship between lead concentrations in local water supply on cataract disease incidence (*Bioinformatics and Epidemiological Modeling*)
- 6. Investigation of how schemes which target individuals for IOL surgery based on visual acuity more efficiently reduce the backlog of cataract cases. (*Bioinformatics and Epidemiological Modeling*)

In support of "evidence for public health", models should be constructed, using the inputs of: surgical volume rates, outcome rates by degree of visual impairment (for blindness correction >3/60, severe visual impairment correction >6/60 and visual impairment correction >6/18), rate of increasing population age, and economic productivity burden of individual (by degree of visual impairment) to determine a targeting program that optimizes public eye health nationally and increases GNI per capita [23],[40],[46].

5.2. "Basic" Laboratory Research

In general it has been deemed very important by the US National Institutes of Health to investigate the mechanical, physiological and bio-chemical pathways for lens development, in order to better understand the etiology of cataract disease. Specifically of interest are those genes affecting lens crystalline, structural proteins, gap junction proteins and aquaporins [8]. This type of genetic research requires more extensive infrastructure in terms of laboratory space and expensive equipment.

Developing nations typically do not have the human capital or infrastructure to conduct such "basic" laboratory research. A way of further establishing the necessary "context" for successful transfer of laboratory research methodologies and skills might be sending promising local scientific personnel (previously trained within the developing nation) to industrialized nations – with a cooler-full of fresh human lenses – to perform short term (<1 month) research with preeminent surgeons, scientists and engineers as co-authors. An alternate method of building human capital may be to invite said preeminent personnel to conduct basic research with local personnel under the auspice of a 1 year research fellowship.

5.3. Infrastructure and Human Capital

One method of establishing the necessary infrastructure for basic research is foreign direct investment. However, it is debated in literature whether FDI promotes successful technology transfer to developing nations through diffusion, or, instead negatively impacts technology transfer [31]. *NGOs may be a more appropriate and sustainable way of involving local stakeholders in the development of infrastructure for basic research.*

An alternate method that would ensure continued support for both clinical infrastructure and associated human capital is to entice internationally renowned medical research universities to setup a "clinical outpost" in a developing nation. New surgeons from industrialized nations will benefit from 1-3 year "revolving residencies" which emphasize high volume surgical procedure experience. Local surgeons will benefit from constant infusion of up to date knowledge and procedures and international exposure through co-authoring in high profile medical journals. Agreements can be made between the university and developing nation government regarding patenting and licensing of any biomedical device innovation resulting from collaboration.

A method for creating basic research infrastructure and human capital that requires careful setup and upstream reflection because of the high potential for exploitation (and other ethical issues) would be to entice large pharmaceutical companies to work with local personnel and local populations to conduct research on possible pharmacological agents and gene therapies for cataract prevention and treatment.

6. Conclusion

The success of international medical technology transfer for intraocular lens replacement has been characterized by: very strong international monetary support of medical technology transfer entrepreneurship through NGOs and a coordinated framework for evaluation through WHO as a "context". This has been mediated by socioeconomic barriers to the surgical procedure, as well as, lack of infrastructure or trained medical personnel. It is clear that performing basic and applied research on the socioeconomics and science of the disease will benefit developing nations as well as produce international public health goods for consumption by other countries.

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Tables

 Table 1 Cultural Barriers to Intraocular Lens Replacement Surgery

Poor Awareness	Surgical and Follow-up Costs	Poor Family Support		
Zero knowledge	Human Capital	Opportunity Costs		
Some knowledge	Infrastructure	Travel Costs		
Complete knowledge without understanding benefits	Medical Supplies	Incentives		

Table 2 Modified Technological Capability Matrix, Adapted from Wei, L. "International						
Technology Transfer and Development of Technological Capabilities: A Theoretical Framework"						
Technology in Society, Vol. 17, No. (1995), pp. 103-120						

cess	Sustainable Development of	Content of Sustainable International Medical Technology Transfer				culty		
\Pr		Knowledge Transfer		Technology Transfer			iffi(Characterized
Transfer Process		Surgical Techniques and Clinical Procedures	Health Education	Information and Facilities Management	Biomedical Device Design and Fabrication	Linkages with Suppliers	Level of Difficulty	by
Flow A	Medical Service and Local Public Health Goods	Assimilation of Surgical Techniques and Clinical Procedures	Dissemination of Theories and practices for Preventive Care, Patient Counselng,	Service Capacity Measurement, Inventory Control	Design, Specifications, Standards, Quality Control	Feasibility studies, Cost Efficient Local production	Low	Pure / Duplicative imitation
Flow B	Human Capital, Medical Service Capacity	Training local medical and health services personnel	and Disease Maintenance	Service Quality Monitoring, Cost and Savings Analysis	Incremental Design Changes, New Designs and Specifications	Coordinated Parts Design, Reprocessed Medical Devices	Medium	Adaptive/ Creative imitation
Flow C	International Public Health Goods	Basic Research: Surgical Techniques and Clinical Procedures	Basic Research: Theories for Prevention, Counseling and Maintenance	Basic Research: Bioinformatics and Epidemiological modeling	Basic Research: Biomedical Product Development	Competitive Regional Supply Chain	High	Investigation and Innovation

Figures

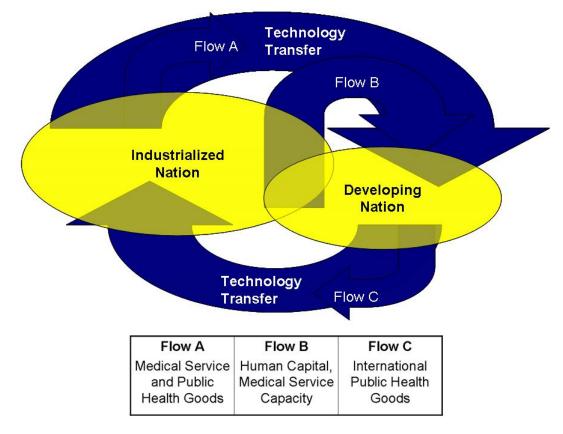


Figure 1 Sustainable International Medical Technology Transfer Flow Chart