5
Exporting Healthcare Services

Healthcare and life science services: emerging issues and conflicts

'Healthcare services outsourcing', 'healthcare exports' and 'medical tourism' are widely recognised terms used interchangeably. They embrace different activities, varying from simple medical transcription, to healthcare-related BPO (such as payroll, billing and patient records functions of hospitals) and the provision of a full range of complex surgery and medical services.

Sophisticated healthcare and life science services (HLSS) have been exported for over 150 years by OECD countries such as the US,[1] UK, France, Germany and Switzerland. However, until recently, these services were not recognised/quantified as 'healthcare service exports' explicitly. It was regarded as being in 'the natural order of things' for major metropolitan centres and imperial capitals to provide such services. Yet now, driven by the economics of globalisation and huge cost disparities, such services are being provided by emerging specialised corporate hospital groups – with a growing record of experience in healthcare services outsourcing – from **developing** countries.

These groups are establishing a global presence with recognised world-quality brands. Operating from developing countries like India, Malaysia, Thailand and South Africa, such groups are also based in the Gulf States and in newly developed economies (such as Singapore). Extending concepts of outsourcing/offshoring that have become established in sectors other than healthcare, their aim is to capture market share in global HLSS exports, especially in high-value medical activities such as: cardiovascular, neuro-, orthopaedic, obstetric, ophthalmic, urinary and paediatric surgery; long-term patient rehabilitation and psychiatric care; and increasingly in geriatric and terminal care. They are succeeding in doing so, despite facing many obstacles and barriers – ranging from the lack of portability of national healthcare insurance (especially when public) to accreditation and certification being used as protectionist barriers.

The healthcare/wellbeing sphere embraces more than allopathic (occidental) healthcare, including **alternative medicine** (homoeopathy, Ayurveda, acupuncture and acupressure) with oriental and natural origins, as well as cosmetic (e.g. plastic surgery, hair transplants, dermatology etc.) and **wellbeing therapies** (such as yoga, weight-loss, addiction treatment and meditation etc.) conducted in specialised spas or centres.

Often, 'export of healthcare services' includes implicitly **training** non-national medical personnel (doctors, nurses and paraprofessionals). This is because such training is highly specialised and invariably linked to, or dependent upon, a strong connection with healthcare delivery facilities such as teaching hospitals.

To explore opportunities for Mauritius in this burgeoning new global market, a symposium on the export of healthcare and life science services (HLSS) was held in April 2008. At that event, the case was outlined for Mauritius becoming: (i) a regional centre of excellence for medical tourism, medical and nurse training, and the outsourcing/export of a wide range of healthcare, life science and wellbeing services; as well as (ii) a regional centre for preclinical and clinical trials, and for particular phases of pharmaceutical and cosmetic-product research.

The symposium emphasised the willingness of the Government of Mauritius in general, and the Ministry of Health and Quality of Life in particular, to enact requisite legal, regulatory and policy changes to facilitate achieving this goal, in particular by encouraging public and private investment in the development of essential HLSS-related infrastructure. The importance of carefully structured public-private partnerships (PPPs) in facilities like hospitals and specialised clinics was underlined, as was the creation of dedicated zones and facilities to attract pharmaceutical firms to undertake preclinical/clinical trials in Mauritius. The government was committed to developing HLSS as a key area of new service export activity and was prepared to do whatever was necessary to achieve that goal.

Unlike the export of **financial** and **ICT/BPO services** discussed in previous chapters, **healthcare exports** are only incipient in Mauritius. For that reason, considerations concerning the **export** of HLSS – and the culture, policies and public, as well as private, institutional structures needed for that purpose – are invariably confused with **domestic** considerations and policies. Mauritian healthcare professionals (as well as political leaders, policy-makers, ministry officials and regulators) find it difficult to disentangle in their minds the distinct requirements of export markets from those of the domestic market for these services. Invariably, the implications of policy and practice aimed at encouraging HLSS **exports** spill over into concerns about what that would imply for the **domestic** healthcare domain.

In attempting to develop export capability for such services from Mauritius, this core confusion cannot be dismissed or overridden as a fearful protectionist response. It has to be anticipated and adroitly managed through a transitional phase. Given the diminutive size of the domestic Mauritian healthcare system and market – i.e. relative to the potential global market share (of 1–2 per cent) that Mauritius could capture for HLSS exports – it will, of course, be difficult to keep these two markets separate/distinct for all time. Indeed, it might be unwise and inefficient to do so. The domestic HLSS market was founded and has been run on UK/French-inspired lines – with 'free at the point of use' universal access to healthcare in government-financed clinics and hospitals. The HLSS export market is likely to be dominated

almost entirely by private players charging full payment for services rendered on a 'total cost recovery plus a profit margin' basis.

The presence of such private players in Mauritius will not be ignored by the domestic population, especially if they provide better facilities (hospitals, clinics) and better (global) standards of service delivery and care. Politically and practically, it will be impossible to keep the two markets separate. The local population cannot artificially be denied access to better HLSS services enjoyed by a transient foreign population.

Eventually, the domestic HLSS sector will be absorbed into a unified HLSS-delivery structure operating on global lines. Paradoxically, that opens up the possibility that the Government of Mauritius will be able to provide universal free healthcare by **financing local demand**, but **not necessarily providing local supply**, through the public-health system. It can rely instead on private HLSS infrastructure created for the global HLSS market. The government may save fiscal resources (capital and recurrent) by 'piggybacking' on a much larger and more diverse **private** HLSS industry, one that is created and evolves to service (and is driven largely by) the global export market.

This policy challenge is not imminent, and the dilemma it poses does not have to be resolved immediately. Indeed, it is unlikely to be addressed until the export-orientated HLSS industry grows to be of sufficient size to exceed the domestic HLSS-delivery system. That may not happen for a decade at least. Yet it is an issue for which political groundwork and administrative preparation needs to start now. Dealing with the issue honestly and openly may be an effective strategy for overcoming domestic (professional, union and civil society) resistance to change (based on fear of change and the unknown) and to opening up the HLSS sector for private entry, even if it is limited only to HLSS exports.

The global market for HLSS exports

Global healthcare expenditure was estimated at US$4.5 trillion in 2006. This figure accounts for about 8 per cent of global GDP, with **per capita healthcare expenditure** averaging US$800 worldwide. However, that average can be misleading. When disaggregated, the US$4.5 trillion figure shows up the following pattern:

- A spend of US$2.2 trillion in the US, with healthcare expenditure of US$7,200 per capita
- US$2.0 trillion in non-US OECD nations, with expenditure of about US$2,600 per capita
- A spend of US$300 billion elsewhere around the world: i.e. outside the US and the rest of the OECD, healthcare expenditures account for less than US$50 per capita

- The top (income) decile of the population accounts for about 80 per cent of healthcare spending in the developing world; this means five billion people account for an average healthcare spend of less than $15 per capita per year!
- Thus an average American spends 480 times more annually on healthcare than the average person in the developing world, while the rest of OECD spends 180 times more
- Paradoxically, these large disparities in global healthcare spending are resulting in OECD populations and societies facing more challenging demographic trends than non-OECD societies and populations, which are growing more rapidly; they are also driving cross-border HLSS.[2]

Cost differences in healthcare delivery between developed and developing countries is driving outsourcing and offshoring, while disparities in per capita health spending between poor and rich countries are driving the rapid growth of the overall global healthcare market.

Healthcare costs continue to rise rapidly in the US and the developed OECD world, with annual increases averaging about 7 per cent. Those costs are now unaffordable. Stresses and strains caused by public expenditure constraints are appearing in every OECD country's health system. There is increasing pressure to reduce costs, as demand for healthcare continues to grow with aging populations, the application of expensive new technologies and therapies, and higher expectations for quality care as a fundamental 'human right' on the part of OECD populations.

Developed OECD countries have less than 20 per cent of the world's population, but account for over 93 per cent of global healthcare expenditure.[3] This asymmetry reflects exploding healthcare costs in the developed world, which are leading to a rapid increase in HLSS exports. Such service exports (including outsourcing and offshoring healthcare services [BPO], as well direct medical services) are a relatively new – but rapidly growing – phenomenon. Continuing advances in ICT are making HLSS exports increasingly possible, attractive and competitive. They are being driven further by continuous advances in medical technology, globalisation, the entrenchment of service exports as a feature of world trade and large differences in the cost of healthcare delivery, as well as in the amount being spent on healthcare around the world.

At present, HLSS exports account for less than 0.5 per cent of global healthcare expenditures. By 2015, it is likely that they will account for 2 per cent of global health expenditure. That would mean HLSS exports accounting for about US$145 billion by 2015, compared to the US$25 billion they are estimated at today (in 1995 HLSS exports amounted to barely US$1 billion). There are few global industries with such rapid compounded annual growth.[4]

Given the multitude of activities involved in the HLSS domain, and accounting for the obvious duplication of what is counted as BPO revenue when it is related to

healthcare, the global HLSS export market was estimated in 2007 to be over US$25 billion.[5] Medical tourism alone accounted for about 80 per cent of that total. Some illustrative stylised facts about the potential for HLSS exports are recorded below:

- Medical tourists logged an estimated 19 million trips and spent over US$20 billion in 2008.
- In 2006, more than 50,000 people from the UK travelled abroad for some medical treatment.
- The UK figure is projected to increase to 200,000 by 2010, creating a UK-healthcare offshoring market of between £900–1,000 million (US$1.8–2 billion).
- Extrapolating for the EU, a conservative estimate would be US$6–8 billion in 2010, involving about 650,000 Europeans travelling abroad for treatment.
- In 2007, 150,000 Americans went abroad for treatment, driven by medical costs in the US, with healthcare expenditure abroad amounting to US$ 2.5 billion.
- The medical tourism industry from the US is growing by 15–20 per cent annually.
- Malaysia had over 85,000 medical tourists in 2006, spending about US$0.6 billion.
- India catered for 175,000 health tourists in 2007 and expected 200,000 in 2008, with health-tourism revenues expected to be US$2.4 billion in 2010.
- Thailand has a rapidly growing medical tourism industry. In 2005, one hospital in Bangkok catered for 150,000 tourists. The market was estimated to be worth about US$1.8 billion in that year.
- Singapore Medicine is a multi-agency government initiative. Some 374,000 health tourists visited Singapore in 2005. That figure increased to nearly 500,000 in 2007 and the country is targeting one million medical tourists in 2012 for export earnings of about US$5 billion.
- South Africa hosted 30,000 medical tourists in 2006.

Healthcare offshoring is being driven by demand, supply and cost factors. To illustrate, HLSS offshoring can result in lowering treatment costs by 50–70 per cent. For example, a breast implant in the US costs US$25,000 for the operation alone, with additional costs for hospitalisation etc. In India, the same implant costs US$8,000 **including** flights, two weeks in a 4-star hotel, surgery, hospital recovery, local transport and post-op consultation. Waiting lists for various treatments can vary from 5–12 months in the UK, Canada, Europe and Australia. Offshoring can reduce these times to less than two months, if not eliminate them altogether.

Table 5.1 Comparative costs of major surgery in different countries (US$)

Procedure	US cost	India cost	Thailand cost	Singapore cost	Malaysia cost
Heart bypass	>130,000	10,000	11,000	18,500	9,000
Heart valve replacement	160,000	9,000	10,000	12,500	9,000
Angioplasty	57,000	11,000	13,000	13,000	11,000
Hip replacement	43,000	9,000	12,000	12,000	10,000
Hysterectomy	20,000	3,000	4,500	6,000	3,000
Knee replacement	40,000	8,500	10,000	13,000	8,000
Spinal fusion	62,000	5,500	7,000	9,000	6,000

The main drivers of demand in the sector are: (i) **demographic differences** across the globe; (ii) a heightened degree of **'healthcare consumerism'**; (iii) changing **epidemiology**; (iv) **technological advances** in ICT and medical technologies; and (v) a **global shortage of workers** at all levels in the healthcare industry, resulting in a massive flow of such workers from the developing to the developed world. In an important sense, it is the last of these factors that is playing an important role in driving HLSS exports from developing countries, rather than continuing with the export of their people. The shortage is best portrayed in table 5.2, below.

In OECD countries, **demographic trends** are being determined by, and reflected in: (i) an ageing population; (ii) a substantial change in the role, structure and size of the family; (iii) extended families giving way to nuclear families; and (iv) a change in the role of women, a greater proportion of whom are working. All these factors are affecting healthcare trends and approaches to healthcare delivery. These trends are being felt more slowly in the developing world, with different ramifications for healthcare systems and for HLSS exports. In OECD countries, demographic trends are driving a shift in patient care from acute illness to chronic disease management

Table 5.2 Clinicians per 1000 population

	Physicians	Nurses	Dentists
Africa region	0.21	0.93	0.03
Americas	1.94	4.88	1.05
South Asia	0.52	0.81	0.06
Europe	3.2	7.43	0.52
Eastern Mediterranean	0.74	1.1	0.17
Western Pacific	1.1	1.7	0.17

Source: WHO Statistical Information System (2002). See http://www.who.int/research/en/ [accessed 6 January 2009]

and toward multidisciplinary care. There is an accompanying shift in care in hospitals, to care in the ambulatory and home setting with an emphasis on protocol-driven care.

Healthcare trends are also being driven by **heightened consumerism**. This is partly due to the larger role being played by instant global communications and the electronic/print media in influencing consumer information, expectations and demand. The result is a growing gap between rapidly rising expectations of 'healthcare consumers' and the ability of over-stretched healthcare systems in developed countries to meet those expectations at affordable cost. That gap is in turn creating large dichotomous 'divides' between rich and poor consumers and between urban and rural consumers.

Healthcare consumerism is encouraged by: the increased availability of medical information to patients; increased ability to receive care at home; increased desire to be informed and be part of decision making; increased costs driving consumer behaviour (i.e. 'shopping for value'), which includes medical tourism increasing on a global scale and patient resort to treatment outside of traditional medicine; and finally, there is increased consumer demand for 'transparency of outcomes' data. As more information about the outcomes of medical tourism and healthcare offshoring becomes available, the more this feeds back into increasing demand.

The inability of health systems in developed countries to meet consumer expectations, in real time at an affordable cost, is driving the growth of a **global** healthcare industry. Similarly, consumer dissatisfaction with allopathic medicine as practiced in the West is leading to challenges to conventional medicine and resulting in another significant divide: between Western (i.e. scientific or conventional) medicine on the one hand, and complementary or alternative therapies on the other. This divide will also influence HLSS exports.

Healthcare services demand (and therefore HLSS export potential) is also being influenced by changing **epidemiology**. This is reflected in a shift toward the management of: chronic diseases; smoking-related diseases, with an anti-smoking culture spreading around the world; growing **obesity**, which has become as much of a problem in the developed world as **malnutrition** is in the developing world; a growing incidence of stress-induced health problems, such as heart disease and diabetes; addiction management (smoking, drugs, alcohol etc.) around the world; and increasingly the global risk and impact of serious infections (including the risk of bioterrorism), which has been manifested in the HIV/AIDS pandemic, concerns about infections like SARS and bird-flu, and the return of diseases like drug-resistant tuberculosis (TB).

The fourth factor influencing global healthcare demand and HLSS export trends is **technology**. Rapid advances in ICT are resulting in new electronic devices emerging with capabilities that were unimagined before. Dramatic advances are also being seen in medical technologies such as: remote telemetry; minimally invasive

procedures (keyhole surgery) and robotics; biotechnology, resulting in new, more potent and targeted pharmaceuticals and pharmacogenetics; intelligent devices for all types of monitoring, as well as slow-release drug application; and the potential of nanotechnology for changing healthcare practices even more dramatically.

Apart from the influence of these different variables creating growing demand pressures, the supply side of the equation for value in healthcare offshoring has also changed rapidly. For instance, quality medical services are now available (on a limited and specialised basis to the affluent) outside OECD countries that are on a par with those available in OECD countries. There is also a growing resource pool of highly trained medical personnel in the developing world that has obtained the same qualifications as personnel in the developed world. The services of this resource pool are available at a much lower cost, owing to lower costs of living, and as a result, complex surgery can be made possible at a fraction of the OECD cost. There has also been a dramatic increase in computerised hospital information systems, while software technology is making remote treatment and distance monitoring possible. Private hospital groups (like Parkway, Apollo, Wockhardt, Saudi-German etc.) are now becoming – and operating on the same basis as – global corporations. They are creating state-of-the-art medical facilities (better than those available in the OECD) of great repute and globally recognised branding.

Yet, despite the obvious positive demand-supply-cost factors impelling greater outsourcing/offshoring of HLSS, there are many barriers that need to be overcome before it emerges as a global industry (as manufacturing and commercial services have). These barriers mainly include perceptions in source countries concerning the **quality** of care and service. Potential patients from developed countries seeking treatment abroad are concerned about:

- The quality of treatment, surgery, facilities and credentials of surgeons and medical personnel;
- Hygiene and modernity of healthcare infrastructure facilities (hospitals, clinics, laboratories);
- Recourse in the event that things go wrong and access to proper aftercare;
- Post-operative complications in the recovery/rehab phase at home, which may incur massive costs;
- The problem of emergency-repatriation costs, which are seldom built into overall cost calculations in 'packages' available for treatment abroad and for which insurance is not easily available;
- Implicit protectionism by national public health services (e.g. in the EU), which are often in two minds about healthcare offshoring: they want to reduce costs, but do not want to see a large service market (accounting for 10–15 per cent of GDP) migrating offshore at public expense;

- Protectionism manifested through accreditation difficulties (of medical facilities and staff);
- Home physicians refusing to become involved in post-op care for treatment received abroad, due to vicarious liability and insurance implications; and
- The lack of portability of private and public health insurance and exposure to legal liability risk.

These non-tariff barriers are gradually being reduced (through concerted action in source and receiving countries, as well as by the professional bodies involved) to develop globally recognised standards for accreditation, certification and qualification of facilities and people. Gradually, private insurance systems will evolve that provide for portability of treatment, although public insurance systems (*de facto* provided by national health services, as in the UK) will take longer to catch up. Nevertheless, the overall picture is one of HLSS service export potential that is likely to grow at a compound annual growth rate (CAGR) of about 60 per cent over the next decade.

Quality control issues

For growth in HLSS exports to be sustained through the next decade, the healthcare industry will need to resort to global 'standardisation' of products, services and quality, as has been done in other globalised service industries. For that to happen, global standards will be needed for accreditation of personnel and facilities, and certification by qualified regulatory authorities operating at global, regional and national levels. Such authorities will need to have adequate powers for outcome/performance monitoring and the enforcement of global standards wherever healthcare services are being provided to a global clientele.

Such quality control is likely to be easier in theory than it is in practice, especially with the globalisation of the labour market in healthcare services that has already occurred. **There is probably no healthcare system in the developed world that is not dependent on personnel from developing countries.** Without such personnel, most OECD healthcare systems would face breakdown or become uneconomic to sustain. However, the economics of compensation have globalised the labour market in an asymmetric manner, with the flow of professionals almost entirely one-way – i.e. from developing to developed countries. That direction of flow has several ramifications, especially for healthcare in labour-source (developing) countries.

HLSS exports can stem or reverse that flow. Instead of personnel moving from developing to developed countries, the creation of world-class facilities for HLSS exports in developing countries could result in patients moving in the reverse direction instead. After all:

- 37 per cent of physicians practicing in the UK are **international medical graduates** (IMGs)

- 40 per cent of the new annual intake of nurses in the UK is from other (usually developing) countries
- 25 per cent of physicians practicing in the US are IMGs
- 11 per cent of nurses practicing in the US are IMGs, while 35 per cent of nurses in the EU are from another country
- More than 60,000 non-resident Indian (NRI) physicians are practicing in the UK, Australia and North America, with 38,000 in the US alone (5 per cent of the US physician workforce)
- Of the 5,000 IMGs entering the US physician workforce annually, more than 20 per cent are non-resident Indians[6]

With developing countries providing 56 per cent of all migrating physicians (almost all to OECD countries), this of course raises a host of accreditation and regulation (A&R) issues, including *inter alia* issues of:

- Licensing
- Accreditation
- Recognition of foreign national qualifications
- Nationality and residency requirements
- State and provincial requirements
- Immigration regulations
- Access to examinations for completion of qualifications
- Foreign exchange controls etc.

Yet the broader question this phenomenon raises is: If nationals of so many countries can operate at high standards of qualification and certification in OECD countries, why can't such standards apply globally – for healthcare facilities, as well as the people working in them?

Two common features need to be counteracted to achieve this. First is the use of accreditation and certification by many countries (and by the professions practising in them) as **protectionist** devices to block foreign competition in the domestic healthcare services market, rather than applying A&R simply for quality assurance/control. Second is the reluctance on the part of developing countries to embrace global standards on the grounds that they are too high and too costly (for their economic circumstances) to adopt/implement. The issue of quality control, and the roles that A&R play in different parts of healthcare systems (especially those geared to cross-border HLSS exports), can be understood through the following four diagrams.

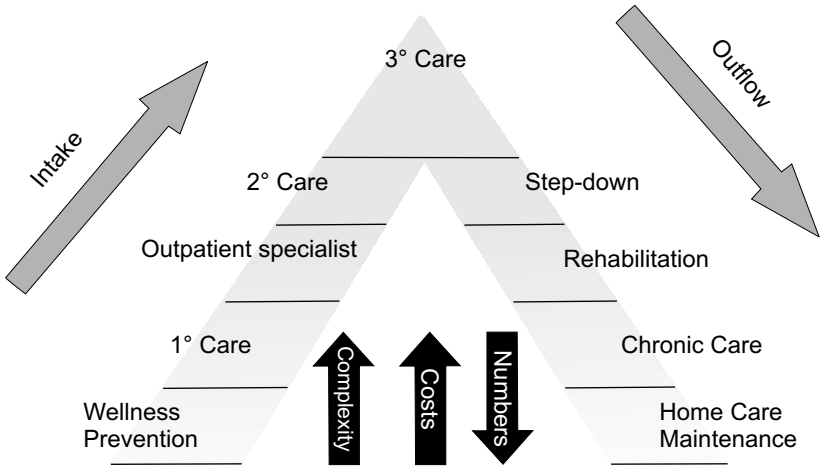


Figure 5.1 Level of care in healthcare system

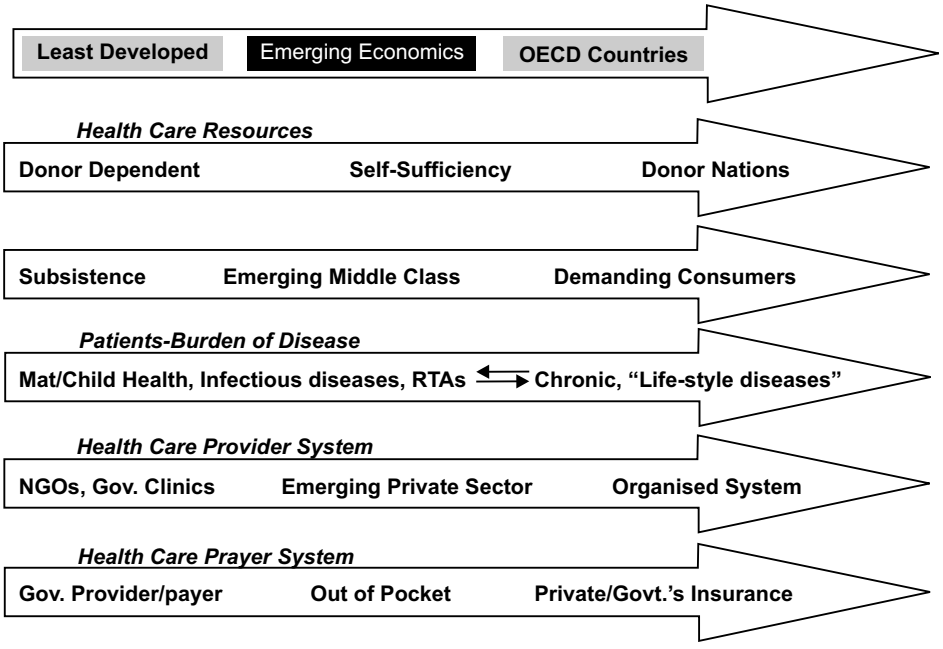


Figure 5.2 Economic development and health

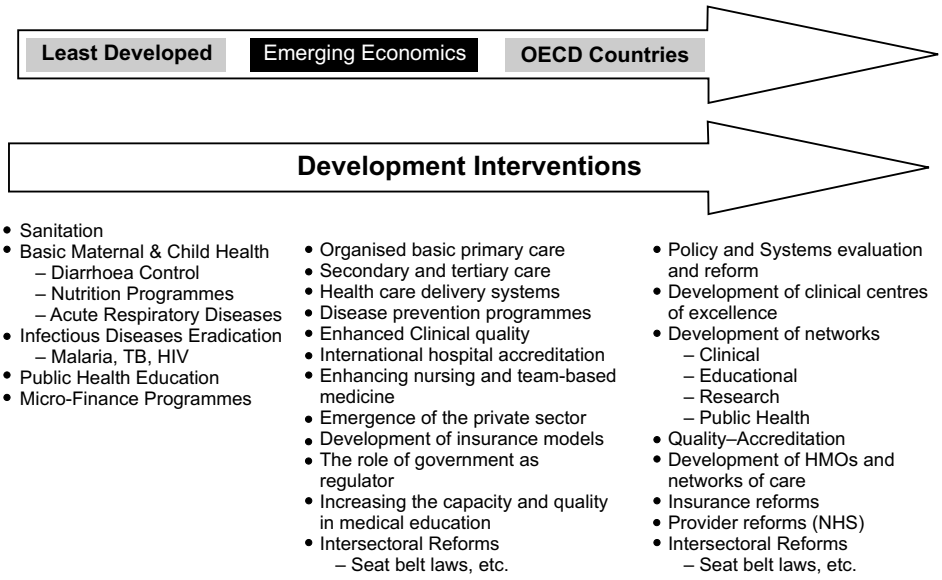


Figure 5.3 Economic development and health interventions

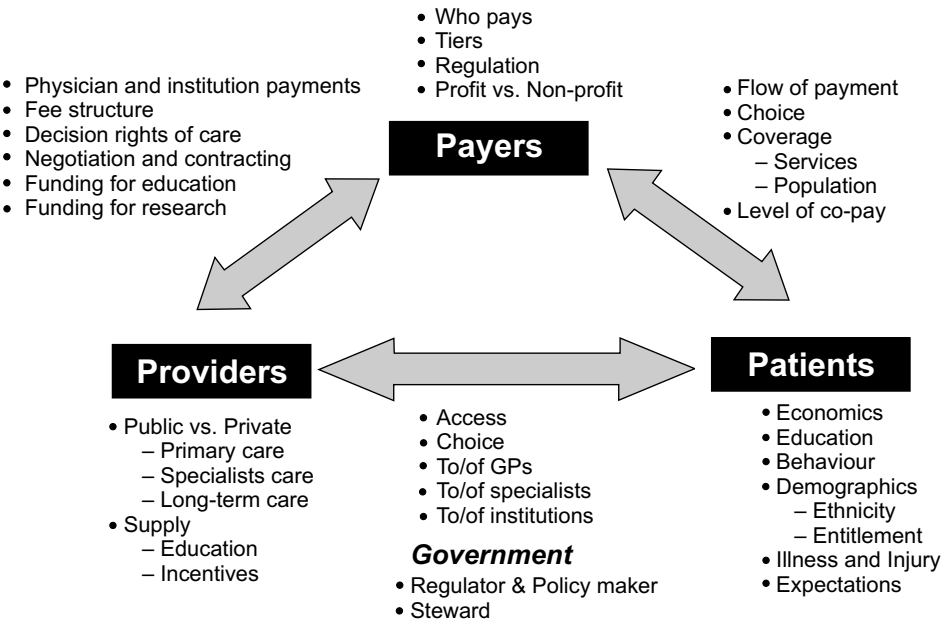


Figure 5.4 Health care system components

Every aspect of healthcare delivery requires A&R to be exercised in order to assure quality of service, protection of consumer rights and the protection of professional service providers from wrongful accusations of misconduct or malpractice liability. Consumers of healthcare need assurance that they are being treated by qualified professionals in certified facilities. By the same token, healthcare professionals need assurance that their qualifications are not subject to question, that they are widely recognised (across borders and around the world), and that they have protection from liability in the facilities they operate from. Facility managers as well as officials, regulators and policy-makers (not to mention insurers) need to be assured of quality control at every level for what they are managing, regulating, insuring and funding.

Effectively, A&R must influence (and be part of) overall healthcare system design, whether for the domestic or export markets. Usually, it is best not to have dual markets with dual standards (as, unfortunately, is the case in most developing countries). It is better to have single markets (for domestic and exported services) that are uniformly regulated, so as to avoid A&R arbitrage. The A&R regime must embrace performance assessment across providers, payers and purchasers of healthcare. It also has to incorporate priority setting from the top level, i.e. as part of the democratic political process whereby governments determine healthcare priorities and achieve them through their line ministry. However, A&R has to accommodate intersector priorities and advocacy (insofar as there are specific policies to assure equality of access and opportunity, equality of gender, race, caste, ethnicity or creed in access to healthcare services, policies to protect the rights of women and children and those of the aged).

The **regulatory** part of A&R has to assure: hygiene and sanitary regulation on the part of healthcare providers, and has to enforce standards that assure consumer protection, as well as maintaining a level playing field between consumers, providers and payers. To do this, it has to cover:

- Health institutions and their performance
- Development and management of health infrastructure
- Application and use of health technologies
- Private operators as natural persons, companies or legal entities
- Health business operations, including competition rules
- Prudential measures to protect the integrity of public health and malpractice[7]

In so far as gearing healthcare systems to exporting HLSS is concerned, the main barriers affecting A&R in the 'exporting' country are:

- Perceived quality of healthcare professionals
- Standards of quality assurance in healthcare facilities
- Mutual recognition of professional credentials

- Non-portability of insurance coverage
- Lack of standards for electronic medical records (EMR)
- Concerns over patient privacy and confidentiality in distance healthcare delivery
- Difficulties in cross-jurisdictional malpractice liability
- Potential negative effects of what is commonly recognised as 'brain-drain'

The **accreditation** part of A&R involves different considerations. It underlines the need for the continuous upgrading of healthcare facilities (hospitals, clinics etc.) **through accreditation** in order to: 'encourage those which are doing the best work, and to stimulate those of inferior standard to do better'.[8] Usually accreditation is a **voluntary** process by which a government or non-government agency grants **recognition** to healthcare institutions that meet certain **standards** that require **continuous improvement** in structures, processes and outcomes.

Improving accreditation has become a global trend. The picture around the world is as follows:

- The US, Canada and Australia have the oldest accreditation systems (the Joint Commission [JC] being the accrediting body since 1951)
- In Europe, Germany, France, Ireland and Spain have new accreditation systems
- In the Middle East, Egypt, Jordan, Saudi Arabia use the JCI for accreditation
- In India, the National Accreditation Board for Hospitals (NABH) is the principal accrediting body
- In South America, the *Instituto Técnico para la Acreditación de los Establecimientos de Salud* (ITAES) and the Consortium for Brazilian Accreditation (CBA) have been leaders
- The WHO, World Bank and development banks recognise and endorse the accreditation model

A common core of healthcare practice around the world ensures that accreditation is carried out by a recognised body which:

- Establishes and publishes standards
- Conducts objective, on-site evaluations
- Publishes accreditation decisions
- Requires across-the-board professional involvement of all professional categories
- Achieves consensus on standards of quality and safety
- Uses professionals to serve as external evaluators
- Focuses on continuous improvement of personnel and facilities

- Undertakes external, objective evaluations with qualified foreign peer evaluators
- Uses consensus standards
- Involves the health professions
- Is proactive, not reactive
- Applies benchmarks and standards on an organisation-wide basis
- Focuses on systems, institutions, structures, processes and procedures, not individuals
- Stimulates quality culture throughout healthcare organisations
- Undertakes periodic re-evaluation against standards, and reviews the standards as well
- Applies an appropriate 'risk reduction strategy': doing the right things well

Credible accreditation for countries planning to undertake HLSS exports

If each HLSS exporting country decided to adopt its own national A&R regime, while trying to make it compatible with similar regimes in other countries, major co-ordination problems and problems of reciprocity with mutual bilateral recognition would arise. To avoid that difficulty, an attempt has been made to facilitate the globalisation of the highest standards across the healthcare services industry in all countries. The Joint Commission responsible for accreditation in North America (i.e. US and Canada) decided unilaterally in 1997 to provide international accreditation through an affiliated body, the **Joint Commission International** (JCI).

That decision was based on work in over 50 countries and requests from healthcare organisations to be evaluated against JC standards, viewed as global 'benchmarks'. JCI has subsequently established a regime for achieving (through its accreditation) maximum quality standards that are: (i) patient centred; (ii) culturally adaptable around the world and in any country environment, yet which respect sufficient standardisation; and (iii) amenable to an accreditation process that incentivises and stimulates continuous improvement.

To achieve its goals, the JCI has developed a full range of international programmes, and established a number of international offices, with its standards and procedures being translated in 14 international languages (for the third edition of *Hospital Standards*). In addition JCI has appointed:

- An International Board of Directors (of JCI)
- International members on its Accreditation Committee
- An International Standards Subcommittee

- Regional Advisory Councils for Europe, the Middle East and Asia-Pacific regions
- A South American Regional Advisory Council in 2008

At the time of writing, the JCI had accredited over 140 hospitals in:

- The Gulf and Middle East: the United Arab Emirates (UAE), Saudi Arabia, Egypt, Jordan, Lebanon and Qatar
- East and South Asia: Thailand, China, Hong Kong, Taiwan, Philippines, Rep. of Korea, Singapore, Malaysia, India, Indonesia and Pakistan
- Europe: Italy, Spain, Ireland, Germany, Denmark, Austria, Czech Republic and Turkey
- Latin America and the Caribbean: Brazil, Chile, Costa Rica, Mexico and Barbados
- Several hospitals are preparing for JCI accreditation in Kuwait, Oman, Bahrain, Sudan, Nigeria, Bangladesh, Nepal, Iran, Israel, Colombia, Lithuania, Poland, Portugal and Switzerland

With the cross-country experience it has gained over the last decade, the JCI's accreditation standards now have a system-wide framework. They address all the important clinical and managerial functions of a healthcare organisation. They also:

- Focus on patients in context of their families;
- Have a balance of structure, process and outcomes;
- Are designed to be interpreted/surveyed within the culture and legal framework of a country;
- Are felt to be optimal, with achievable and measurable expectations;
- Contain many of the quality-control and quality-leadership International Organization for Standardization (ISO) 9000 criteria, as well as criteria of the European (the European Federation for Quality Management) and US (Baldrige) quality awards; and
- Are capable of evolving over time (third edition of *Hospital Standards*) as changing country and global circumstances demand.

Focus on patient safety

JCI's accreditation approach is focused primarily on assuring and protecting patient safety. To that end, it has adopted proactive strategies to reduce the risk of medical error and reflect good practices proposed by leading patient safety experts. It has taken a significant step toward incorporating these new tools into its accreditation requirements. The fact that its client organisations have voluntarily assumed responsibility for using JCI's **international patient safety goals** (IPSGs) to foster continuous

improvement is even more important. IPSGs involve: identifying patients correctly; improving communications between professionals and patients; improving the safety of high-alert medications; ensuring correct site, correct patient, correct procedure surgery; reducing the risk of infections; and reducing the risk of patient harm from falls. The critical steps to improvements in patient safety involve: the identification of all significant errors; analysis of each major error to determine root causes; compilation of data about error frequencies and root causes; dissemination of derived information to permit redesign of systems and processes; and periodic assessment of effectiveness of risk-reduction efforts.

Nonetheless, having described what is involved with JCI accreditation to achieve global standards in establishing a suitable healthcare system for HLSS exports, what has actual experience with such accreditation been? Is it worth the high cost involved? Does it make much of a difference? To answer these questions, the JCI has conducted research across a sample of accredited hospitals abroad to determine the value of accreditation. In doing so, it found that accredited hospitals reported significant improvements accruing from the accreditation process in: improving the quality of management and team leadership; medical records management; infection control; reduction in medication errors; staff training and professional credentialing; and quality monitoring.

The overall finding was that all stakeholder groups involved reported improvement in every dimension measured, with an overall improvement 49 per cent over the baseline. This raises an important policy question for Mauritius. **When it comes to A&R, should the government and the Ministry of Health & Quality of Life attempt to adapt its own extant A&R regime for the domestic healthcare system to comply with higher global standards, or should it simply adopt and apply JCI accreditation to establish its credentials firmly and unquestionably in the HLSS export space?** This is an important issue, upon which some time needs to be spent to consider the pros, cons and costs involved.

Medical tourism

Medical tourism is growing rapidly and turning out to be an immense business opportunity for nations that are positioning themselves correctly. Examples of countries promoting medical tourism include India, South Africa, Malaysia, Thailand, Israel, Hungary, Turkey, Jordan, Lebanon, Lithuania, Cuba and Costa Rica. With medical travel spends growing at 20 per cent plus year-on-year,[9] what potential does Mauritius have to become another destination for **medical tourism** on a significant scale? Can Mauritius capture 1–2 per cent of the global market for medical tourism and make healthcare and life science services exports as significant as exports in other service industries?

Oddly unrecognised, Mauritius has already become a destination for 'medical' tourism on a highly specialised and limited scale: it has established a global reputation

for hair transplants. However, it is unclear what amount of total revenues, export revenues and value-addition Mauritius derives from these services. This is an area in which official statistics need to be greatly improved. Yet Mauritius does have the potential to become a destination for medical tourism in both the regional and global contexts. The arguments favouring this view are outlined below.

'Medical tourism', as the term is commonly understood, involves travel from a place of residence to a destination at which medical or surgical treatment is provided, and involves more than one night away from the country of residence. Generally the term applies to patients from developed countries going to less-developed countries for medical treatment (usually surgery), although there is probably an equal flow of medical tourists in the opposite direction. Some advertising is involved in attracting medical tourists, as it is for attracting tourists in general.

Medical tourists are usually able to obtain treatment of the same or higher quality at home, unless they are from a developing country. They are not referred by a physician, and do not receive any medical follow-up at home. By and large, medical tourism is cost-driven. It affords privacy along with a holiday. The fees charged in the destination where treatment is received are usually lower than in the home country. Within this broad field, there are a growing number of specialised sectors of medical tourism, including: surgery, cosmetic treatment, wellness/spa treatment, dental treatment and infertility and reproductive treatment.

Countries that have succeeded in exporting HLSS usually organise around a narrow set of services; they provide specific high-value services for niche local/regional markets. They compete on the basis of strength in specific clinical service lines adopting a Centre of Excellence (CoE) approach. Only with a critical mass of patients for individual services are they able to achieve competitive quality at reasonable cost. Inviting private companies to provide specific services for the public health system can create a springboard for these services to be provided to foreign patients. The countries listed above are actively promoting medical tourism as a service export activity. A number of other countries are also involved, including Argentina, Bangladesh, Bulgaria, France, Switzerland, Russia, Australia, the UK and the United States.

The areas that suggest themselves for medical tourism in Mauritius include, among others: (i) e-medicine and Telemedicine for the African region; (ii) specialisation in stem cell transplants for patients with sickle sell anaemia (prevalent in Africa) and thalassaemia (prevalent in South and South East Asia, the Middle East, Mediterranean and North Africa) and (iii) for intensive diabetes care. In addition, Mauritius might build on its successful experience with hair transplantations by promoting a wider range of cosmetic surgery (including plastic surgery and dermatological clinics), dental surgery (with new prosthodontic facilities and laboratories), infertility treatment, diagnostic imaging and medical spa treatment.

Possible further areas for exploration include the creation of purpose-built facilities for long-term addiction treatment, long-term psychiatric care and terminal care. Mauritius could choose to add to the facilities that Switzerland and the Netherlands are providing to EU citizens suffering from incurable illnesses and facing a lifetime of fatigue, stress and pain, to seek voluntary euthanasia at a time and in a manner of their own choosing in special facilities that provide supervised care and treatment in the final stages.

Relying on these specific activities, the Government of Mauritius (through the Board of Investment and the Ministries of Tourism and Health working together) might consider developing **integrated health tourism packages** that emphasise the cultural and ethnic strengths of the island by marketing in specific geographies (right column, below) to play to particular language skills and ethnic connections (left column):

- French – Europe
- English – UK, Singapore, Australia, South Africa
- Indian – India and South Asia
- Chinese – ASEAN and East/North East Asia
- Muslim – North Africa, the Middle East, the Gulf Emirates, Saudi Arabia

However, for Mauritius (along with South Africa, which has made rapid strides to establish itself) to become a medical tourism CoE for Africa, the Indian Ocean Rim and proximate Asia, it needs to combine three core elements and become a CoE simultaneously for: medical education, life sciences services and a selective range of healthcare services. Success in these three elements will create a self-reinforcing virtuous circle.

As in other service industries, Mauritius cannot aspire to be 'everything to everybody' in the way that larger countries like India can. It has to focus on niche specialisations that play to its strengths. Mauritius does not have – in the case of any of these three core elements – a sufficiently wide or deep domestic healthcare system, medical educational or research base, or a sufficiently large economy, population or environment. It does not have a large enough base of healthcare professionals, although it has exported a number of these and continues to do so. For that reason it cannot export HLSS from its extant resource base in the healthcare system. It can only do so by creating a convenient 'plug and play platform' for operators from elsewhere to establish themselves in Mauritius to export the services that are needed from that location and to provide labour market entry/exit conditions that permit total openness and flexibility.

To take advantage of global medical tourism export opportunities, Mauritius may need to create a specific medical tourism programme (MTP) driven by a dedicated taskforce involving all stakeholding organisations embracing: a **medical** cluster, a

tourism cluster and a business services-cum-retirement cluster. Such a taskforce would aim to bring all stakeholders together to solve problems, create new protocols, and adapt continuously to changes in the global healthcare industry that may affect Mauritius's competitive position.

The base (policy, institutional and infrastructural) for engaging in medical tourism does not appear to be particularly strong at present. However, it has much potential that can be developed relatively swiftly through appropriately structured partnerships with foreign players:

- A few globally recognised facilities (e.g. Darne, Apollo) already exist and can super-specialise even further
- New specialist services can be built up rapidly in the areas of orthopaedic, cardiac and general surgery
- The medical tourism market should be developed in outward concentric circles, beginning with local areas and spreading to wider regional neighbourhoods, then to the EU and rest of the world. The initial focus would be on:
    - Indian Ocean Rim Islands
    - Africa (around South Africa) – all SADC
    - India and South Asia
    - The Gulf countries (with which complementary partnerships can be developed)
- Reliance needs to be placed on corporate partnerships with globally recognised and branded hospital groups in South Africa, India, Malaysia and Singapore to capture a 1–2 per cent share of the medical tourism market worldwide.

Alternative medicine and drug research

Mauritian resorts are already investing in wellness and spa treatments, and they are attracting a broad clientele from their traditional tourist client base. Yet Mauritius has unexploited potential for offering alternative therapeutic treatments in Indian Ayurveda as well as Chinese acupuncture and acupressure. Both are becoming increasingly popular worldwide. The Indian Kairali Clinics group (which has established a global reputation for Ayurvedic treatments and has invested in spa franchises in the UAE and Japan) has indicated its interest in investing in a facility in Mauritius.

Mauritius as a centre for natural drug research

Apart from these obvious opportunities for offering alternative medicine treatments, Mauritius may be able to exploit opportunities for research and development into the role of traditional/alternative medicine in pharmaceutical drug development

and healthcare. The potential in this niche is considerable. To illustrate: **Bionovo**, an unconventional drug company specialising in this area of natural drugs research and development, observed that eight out of 29 small molecule drugs launched in 2000 were derived from natural products (NPs). Large drug companies did not have a significant role in deriving these drugs. For cancer, the percentage of small molecule, new chemical entities that are non-synthetic has remained at 62 per cent averaged from 1981–2002. In the antihypertensive area, of the 74 formally synthetic drugs, 48 can be traced to natural product structures/mimics. To date there is no *de novo* combinatorial compound approved as a drug. In infectious diseases, over 75 per cent of the drugs were shown to be of natural origin.[10]

Moreover, resort to some form of alternative medicine is growing rapidly in the EU and US, in fact at a faster growth rate than is seen in the use of conventional allopathic treatment. Again, to illustrate with some stylised facts regarding the US market:

- About 34 per cent of Americans used some form of alternative medicine (Eisenberg, 1997)
- In 1994, the Dietary Supplement Health and Education Act (DSHEA) 1994 created the Office of Dietary Supplements within the National Institute of Health (NIH)
- Post-DSHEA supplements grew from 4,000 to 30,000
- In 1998, National Center for Complementary and Alternative Medicine (NCCAM) was formed
- In 2003, the NCCAM budget was US$113 million
- In June 2004, the Food and Drug Administration (FDA) published 'Guidance for Industry: Botanical Drug Products'
- The botanical/dietary supplement industry in the US is estimated to be worth US$50 billion
- About the same amount is true for the EU; the total US+EU industry is worth more than US$100 billion
- At the time of writing there were 50 active commercial investigational new drug applications for botanical drugs granted by the FDA
- Chinese pharmacopeia contains 14,000 substances
- There may be problems translating the traditional tenets into modern biomedicine

In this particular area of drug development, what is needed in a country environment is:

- Sophisticated intellectual infrastructure

- A collaborative/integrative scientific environment
- 'Bricks and mortar' scientific space, preferably connected to a university research cluster
- A favourable and proper regulatory environment for drug development and healthcare
- Strong IPR protection by global standards
- Access to hospitals and patients with target indications

Developing such an environment has a high pay-off, but it involves a considerable amount of upfront investment in hard and soft infrastructure. For Mauritius to become a Centre of Excellence for this purpose, it will need to:

- Support the build-up of the necessary intellectual infrastructure (a long-term task)
- Legislate strong IPR protection/enforcement (there is already a good regime, which can be strengthened)
- Build bricks and mortar scientific space (this can be done through PPPs)
- Provide access to hospitals and patients with target indications (this is limited at present)
- Attract collaborations with pharma/biotech companies (the BoI needs to work on this)
- Provide pharma/biotech services by creating contract research organisations (CROs) and contract management organisations (CMOs)
- Collaborate with academic/industry affiliates to guarantee long-term interests
- Serve as international hub as well as a regional centre

The overall conclusion at the symposium was that for Mauritius to engage in this space it would need to take a number of actions on the policy, investment and educational/research frontiers. None of these could be accomplished in the short term. However, the long-term objective had to be kept in view as being desirable to reach given the considerable pay-off and spin-offs that could result.

Clinical trials

What is involved with clinical research and what would Mauritius need to do to establish more contract research organisations (CROs)? In answering these questions, it has to be recognised that there are presently a number of barriers between clinical and basic research in pharmaceutical drug development. There are also increasing complexities involved in conducting clinical research and it has become more difficult to translate new knowledge to the clinic and back again to the bench.

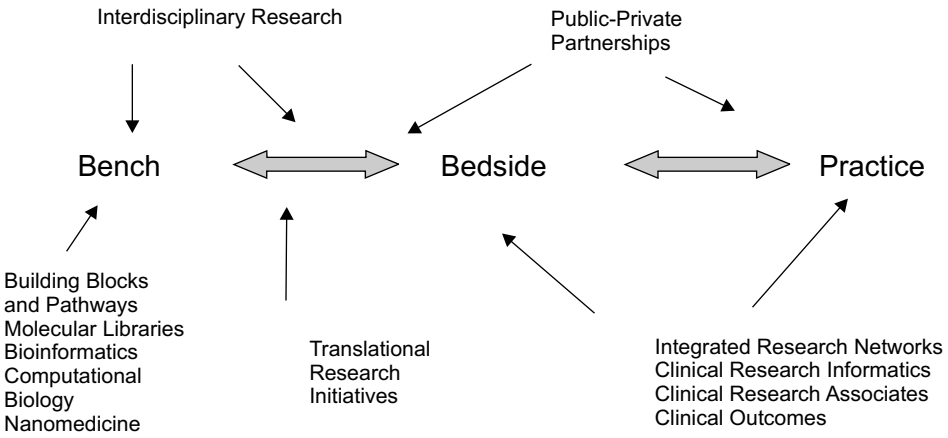


Figure 5.5 Re-engineering clinical research

Source: Presentation by Dr Kok Wei Yap at the Symposium on the Export of Healthcare and Life Science Services

The research and development functions of the pharmaceutical industry have become phenomenally expensive in relation to new drug approvals.[11] There is also a fundamental shift occurring in the geography for CRO from OECD to developing countries, which is being driven by regulatory requirements.[12]

Mauritius has a history of limited clinical research from 1971 through 2006. The most recent research was done on the chikungunya virus epidemic. Up to the late 1980s, health research was carried out mainly by the Ministry of Health (MoH) to provide the necessary knowledge and background to facilitate the design of public health programmes. The lack of such knowledge often imposed constraints on improving the way in which these programmes were formulated. Research was scanty and geared particularly towards communicable diseases and fertility control. The financial input for research was mainly from overseas (usually through aid-funding).

Currently, Mauritius is undertaking biomedical research in: genetic factors intervening in breast cancer and diabetes, infectious diseases (AIDS and chikungunya) and sexual and reproductive health. However, the research being carried out is characterised by non-invasive investigations, no administration of drugs and no experimentation with new surgical techniques. The research is also limited to studies of strictly national (not international) relevance, and is based on observation, carried out on

small samples of the population and driven by academic requirements. The principal institutions undertaking such research in Mauritius include:

- The Mauritius Institute of Health
- The University of Mauritius
- SSR Medical College
- Central Health Laboratory (MHQL)
- Mauritius Research Council
- Mauritius Family Planning
- Cardiac Centre Pamplemousses
- The Cambridge Infectious Diseases Consortium (CIDC) specialising in trials on cosmetics

Whether Mauritius can become a Centre of Excellence for clinical research depends on the following factors influencing drug research in general and Mauritius's attributes in particular:

- The ability to bring new drugs to the market faster (simultaneous development)
- Faster growth in pharmaceutical global markets
- Genetic ethnic and racial diversity of the population yielding better results at lower costs
- A relatively large, treatment-naïve patient pool (especially if Africa is included as Mauritius's hinterland)
- A high prevalence of certain diseases in Mauritius and its Africa and Indian Ocean Rim (IOR) hinterlands
- Relatively good quality of extant medical infrastructure
- Implementation of International Clinical Health-General Council of Practitioners (ICH-GCP) guidelines
- Relatively lower cost per patient trial cost
- An environment that allows that 'one-dose-for-all' may not suitable (i.e. the island does not insist on a uniform rigid approach to clinical trial design)
- Trained clinical research investigators can easily be imported from South Africa and Asia
- A multilingual population
- Limited time difference with Europe (+2h in summer and +3h in winter)
- Availability of trained persons in biological sciences and informatics

- The high literacy rate of the population
- A good number of doctors per 1000 population
- Good training facilities in the paramedical field
- A well-regulated domestic pharmaceutical market
- Existence of high-quality health services in the private and public sectors
- Updated law on protection of intellectual property rights for confidentiality of data (2002)
- Lower turnover rates of skilled staff than, for example, in India and other CRO countries
- Availability of good epidemiological data
- Cancer register established since 1989
- Excellent data on diabetes and cardio-vascular disease arising from non-communicable disease (NCD) surveys 1987, 1992, 1998 and 2004
- A morbidity pattern that is similar to developed countries
- Diseases with urgent demands for better therapies in the EU/US are also prevalent in Mauritius
- A naïve population with respect to experimentation (i.e. the island has a varied and mixed native population that represents much of the world at large in terms of race and ethnicity)
- Lower drop-out rates than elsewhere
- Managing the supply chain and transport are easier given the island's geography
- Excellent scope to set up a solid chain of custody
- No problems with the customs department
- Corruption of officials is not an issue (although in fairness some foreign investors feel it is)
- The possibility of having purpose-built sites for clinical trials
- Excellent communications with foreign countries
- Existence of a high-calibre courier service
- Good facilities for commissioning of specialised clinical research sites
- All biomedical studies are submitted to the Ministry of Health and Quality of Life (MHQL) for approval (including soft trials on cosmetics)
- Scientific validity is vetted by the sponsor and the Biomedical Research Committee of the MHQL

- Ethical aspects are cleared by the Ethics Committee, set up under the MHQL
- Essential clinical research aspects are properly catered for, such as informed consent, confidentiality of data, protection of minors and vulnerable groups and ownership of samples

During the symposium, Mauritius's potential for contract research organisations (CROs) was explored further via the illustrative example of South Africa (RSA), which has a larger economic, educational and established research base. In South Africa, clinical research capability was established in the past because of a clear strategy by government and industry to make South Africa a Centre of Excellence for CRO, leveraging of some core advantages and its intellectual capital, human capital and infrastructure. There was also a competitive rand to US$ exchange rate, the country formerly had a well-regulated environment for the industry and medical innovation capacity is highly regarded worldwide. However, the dynamics influencing South Africa's supposed advantage in CRO have changed and there is now a major problem with 'brain drain' of high-level human capital. Meanwhile, tertiary care budgets and the attention of academia are shifting to primary care, there has been a shift from institutional teaching and research priority into service provision, the South African rand has appreciated too much against the US$ and regulatory agencies have become less capable.

Given the reversal in the South Africa environment for retaining CROs, and looking at the potential that Mauritius had, it was suggested at the symposium that there might be some benefit to be derived from a strategic South Africa-Mauritius partnership focused on CRO. Such a partnership would enable stakeholder congruence, especially between both governments and their private sectors and sustainable, long-term strategic partnerships between relevant pharma CRO groups and Centres of Excellence – i.e. academic institutions and private organisations. It would also be of benefit in terms of clustering of similar minded countries (regionalisation), access to new patient populations (niching) and sharing of best practice (hubbing). An EU mutual recognition process could be facilitated, while the partnership would also encourage more informal communication e.g. with Kenya, Uganda, Tanzania and Zimbabwe and best practice sharing (hubbing) of regulatory activities.

The advantages of such a co-operative arrangement for Mauritius would be:

- Access to capacity building and hubbing
- Access to larger pool of intellectual property
- Access to regulatory best practice knowledge, procedures and functions
- Expanded export of health services
- Import of research and investment capital from the global pharma industry
- Significant upward leveraging of health tourism potential
- Critical mass development in institutions, people and infrastructure

Conversely the advantages for South Africa would be:

- Access to a pool of new 'niche' patients
- Broader opportunities for health tourism
- Opportunities for exchange of knowledge and information
- Opportunities for new strategic alliances
- Centres of Excellence
- Better risk management for retaining CRO capabilities

However, there are also constraints and concerns in developing Mauritius's role as a CRO centre. These include difficulties with recruitment/training of staff at regulatory and operational levels, commitment to ensuring that legislative timelines are met and limitations of existing physical infrastructure and the administrative set-up. Further constraints include complications in setting up adequate clinical trial sites, harmonisation of procedures and guidelines with SADC countries, keeping the Mauritian public fully informed (it is a small place and bad news travels quickly) and competition for highly skilled staff between government and the private sector. There also exists the risk of the island being flooded with demands for soft trials of limited interest or for dubious studies or that trials driven by sponsors' needs may be unconnected to the health interests of the country. Finally there may be concerns about: continuity of treatment at the end of the trial and equity issues, limited transfer of technology, the time needed to meet international standards and shortage of staff experienced in toxicology, pharmacovigilance and clinical pharmacy.

These constraints notwithstanding, there has been an increase in the number and complexity of tests being conducted in Mauritius on both cosmetics and dermatological preparations. At the time of writing, applications were in the pipeline (for approval) for studies in pharmacogenetics, especially for NCD and anticancer drugs and on drugs causing photosensibilisation. Studies have been commissioned by the WHO on anti-retro-virals (ARVs) and an important CRO in Montpellier is focusing on Hepatitis B research.

If clinical trials are to have a sustainable future in Mauritius, the government and the private sector will need viable partnerships, with established institutions, experienced in the field. Compromising on standards to meet timelines or to attract investors is not a solution. The principle of precaution has to prevail in case of doubt. For Mauritius to become a CRO, a considerable amount of specialised training will be necessary in clinical pharmacy, pharmacovigilance and toxicology. What is needed even more is 'joined-up government', in which a clear vision and strategy for the future, coupled with inter-ministerial co-operation rather than conflict, drives the pace of progress in this domain.

Finally, in considering the potential for Mauritius as a CoE for clinical research, what might be learnt from the example of Singapore's extraordinary ambitions and

achievements so far in becoming a global CRO and creating a new Biopolis for healthcare services, research and intellectual capital? That example illustrates clearly what can be achieved with the right commitment on the part of government and industry, and the right strategy being put in place with the right people to execute it.[13] Singapore had set up the Institute of Molecular and Cell Biology before 2000. The Genome Institute of Singapore was established in 2000, followed in 2001 by the Bioinformatics Institute, and the Institute of Chemical Engineering Sciences in 2002. Other institutions, such as the Singapore Institute for Clinical Sciences and the Institute of Medical Biology have followed more recently. Singapore has developed research and development human capital using both a pro-global and a pro-local approach: pro-global through international talent recruitment, creating a diverse multinational R&D hub; and pro-local through its scholarships and fellowships programme, building a pipeline of well-trained local scientists. This has led to exceptional biomedical manufacturing growth.

Pre-clinical research

What is the difference between **preclinical** and **clinical** trials in R&D for drugs for the pharma industry? Before a new drug can be put into use for human consumption it undergoes several phases of preclinical and clinical testing (after discovery) in the development and market approval stages. These stages of research are heavily proscribed and tightly regulated (in OECD countries, but increasingly in developing countries as well) to assure patient safety and avoid malpractice and legal liability claims from arising over time with extensive use and experience.

Pre-clinical trials are carried out on a variety of animals and (in later stages) on primates whose anatomies resemble that of humans. Clinical trials then follow on human subjects. Pre-clinical trials involve both breeding and supplying animals and primates, and conducting drug tests on animals and primates. These activities must be conducted along lines that use appropriate standards and are subject to various stages of regulation.[14]

The different phases of trials result in tested compounds numbering in the tens of thousands in the early stages, but boiling down to one or two at the end of the process. That adds enormously to R&D cost, which can amount to US$1.5 billion or more per new drug brought to market. Given the draconian regulatory approval standards that are now in force in OECD countries, it can take 10–15 years to bring a new drug to the approval stage and up to 20 years to obtain an international patent right (IPR). Such economics have now become prohibitive for global pharmaceutical companies, who are now actively seeking other options to reduce the time and cost involved in the process from discovery to use approval.

A direct consequence of the industry's quest for greater efficiency and economy in the R&D phase is resulting in a shift in the geography of CROs where preclinical and clinical trials are conducted before drugs are approved for human use. The

1950s
Kidney transplants
Polio vaccine
Replacement heart valves
Hip replacement surgery
Drugs for high blood pressure

1960s
Heart bypass operations
Drugs to treat mental illness
Rubella vaccine

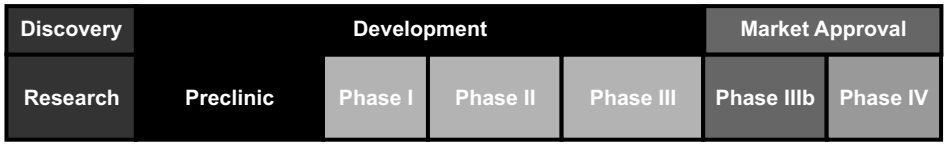
1970s
Chemotherapy for leukemia
Drugs to treat stomach ulcers
Inhaled asthma medication

1980s
Drugs to control transplant rejection
Life support systems for premature babies
Hepatitis vaccines
Treatment for river blindness

1990s
Meningitis vaccine
Combined drug therapies for AIDS
Drugs for breast and prostate cancer

Figure 5.6 The importance of animals in biomedical research

Source: Presentation by Mrs Mary-Ann Griffiths at the Symposium on the Export of Healthcare and Life Science Services



"Preclinic" = "prior clinic" = before human studies

⇨ Animal testing = regulatory required safety assessment

Clinic = " with humans in the hospital"

Phase I	Healthy, mostly male volunteers
Phase II and III	patients
Phase IIIb and IV	patients / case reports

Figure 5.7 The development pathway

Source (Figures 5.7, 5.8, 5.9): Presentation by Dr Rainhard Korte at the Symposium on the Export of Healthcare and Life Science Services

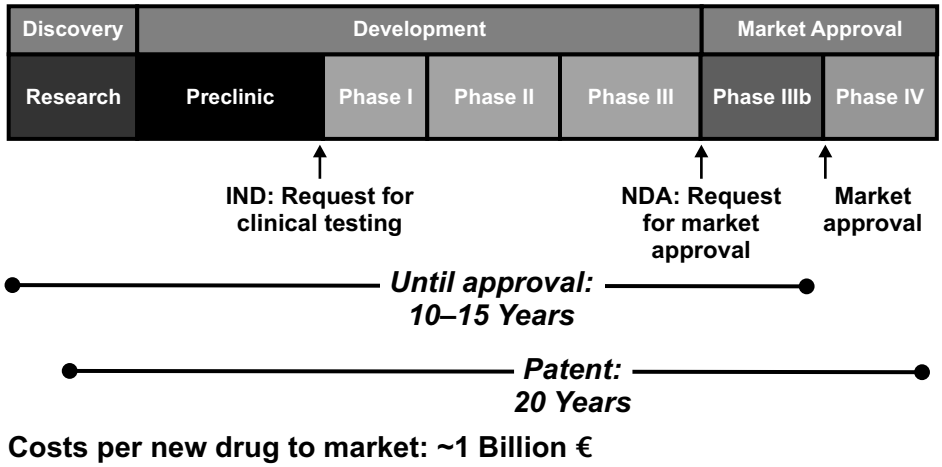


Figure 5.8 The way to market approval

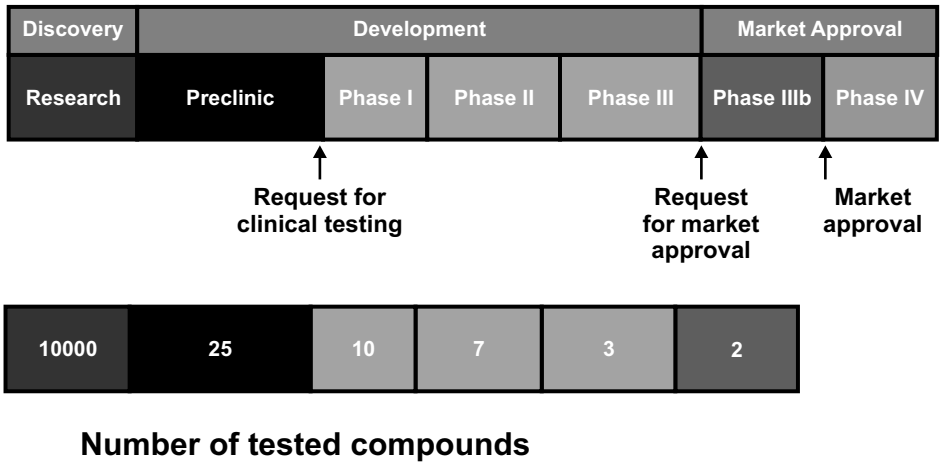


Figure 5.9 Success rate for new drug substances

locations of CROs is shifting from the USA, Europe and Japan to India, China, Taiwan, Vietnam and possibly Mauritius. East and Central European countries are barred from competing in this area by their quest for entry into the EU, which is governed by common regional standards and regulation.

While there may be possible competition for CRO status in a number of emerging markets, there are still minimum requirements that the pharmaceutical industry needs to be met for regulatory purposes. For example, the non-clinical safety

requirements for market approval of a drug involve: single and repeated dose toxicity studies, reproduction toxicity studies, genotoxicity studies, assessment of carcinogenic potential, safety pharmacology studies, local tolerance studies, pharmacokinetic and toxicokinetic studies, absorption, distribution, metabolism and excretion (ADME), immunotoxicity and phototoxicity, with provisions for special populations, e.g. children and juveniles.

These demanding requirements notwithstanding, preclinical studies, especially toxicity studies in primates, can be a valuable addition to the healthcare portfolio of the Government of Mauritius. However, the success of a venture in this area will be depends on the market situation, competitive investments, quality and time. At present, the dominant view among global pharma firms is that the highest potential for CRO industry lies in China and India: together they account for 38 per cent of the world's population and their rising incomes and rapid development make these two countries the most interesting growth areas for the pharmaceutical industry. For that reason, it should come as no surprise that the pharma industry is focusing on these markets when it comes to conducting R&D.

Yet Mauritius is closely connected with both countries. It has a sizeable, representative sample of the Indian and Chinese ethnic populations with the same genetic traits. For that reason, and given other attributes, Mauritius could be a useful microcosmic practical laboratory for pharma firms to carry out applied research. Even so, the investment required for the requisite facilities and qualified staff is high. The relocation of specialised staff from Europe and the US may be difficult, but perhaps less so in the case of Mauritius. A ten-year period from start to international acceptance (by governments and pharmaceutical industry) may be needed before a conclusion can be made about the quality and profitability of a preclinical facility in Mauritius.

More than 20 million animals of various species are used for preclinical testing by the cosmetics and pharma industries every year. Of these, about 60,000 (0.3 per cent) are primates. Despite that small percentage, trials on primates have resulted in fundamental medical breakthroughs, such as the eradication of small pox, polio and viral diseases (measles, rubella, whooping cough) through the use of vaccines developed as a result of such testing. Ongoing studies on primates hold the promise of vaccines or cures being developed for HIV, Parkinson's disease and Leukaemia.

Mauritius already breeds primates for preclinical research and exports them around the world. The Mauritian primate breeding industry has steadily expanded over the last 25 years. It includes five suppliers exporting 10,000 primates annually. They have come to be recognised (in the EU and Japan) as among the best for preclinical testing. The conduct of preclinical trials in Mauritius would be a step toward vertical integration of an industry that is ready to, and capable of, blossoming – probably more quickly than clinical testing. With greater volumes of preclinical packages being outsourced to CROs by the global pharma industry, and a supportive government ostensibly encouraging development of the HLSS sector, a shift to preclinical

contract research would appear to be an opportunity that Mauritius could grasp and develop. It should be relatively simple to tailor the development of legislation and industry capabilities to meet current and future needs of the pharmaceutical and biotechnology industry. With the Mauritian primate breeding and export industry having established a worldwide reputation, it would be a natural next step to locate preclinical trials in Mauritius and tap into an existing resource.

For that aspiration to be translated into reality, the Government of Mauritius needs to create an environment that enables the island to become a centre of excellence in certain areas of preclinical research. Its limited resources require a sharp and narrow focus that plays on its existing strengths. Its strategy for locating preclinical trials on the island through domestic and foreign CROs must combine clinical research with clinical services. It must address regional needs, and explore/exploit all available sources of funding, whether financed by not-for-profit NGOs, private pharma corporations or multilateral organisations and governments.

The strategy must seek to develop suitable infrastructure based on models such as Cape Town in South Africa, with over 25 biotech firms established in a research park, the Biopolis in Singapore, Scripps in Florida and European biotech clusters such as Cambridge, Munich, Paris, Medicon Valley (Denmark & Sweden), Biovalley (around Basel in Switzerland) and Oxford. Obviously dedicated infrastructure in Mauritius will need to be adapted to reflect its own circumstances and realities, and should be financed in partnership with the private sector with the government's role being limited to partnering through land contributions on appropriate terms.

An effective strategy would incorporate the following features and aim at:

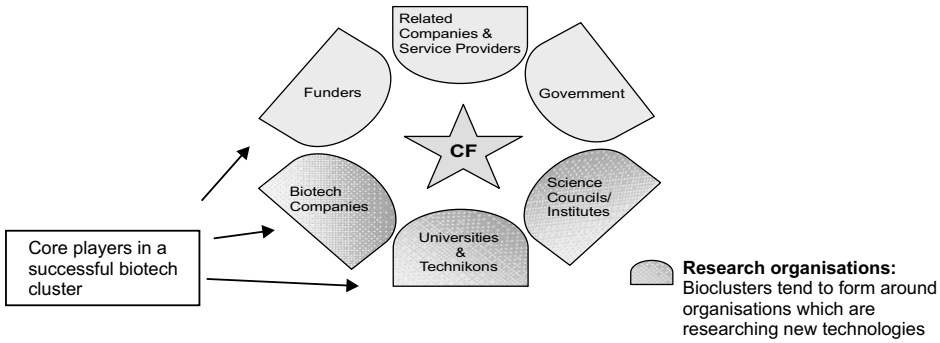
- Forming alliances with overseas institutions such as Scripps, Harvard, NIH, Cleveland Clinics, Mayo Clinics and Institut Pasteur
- Forming corporate alliances with large pharma firms, technology companies, service companies and financial sponsors
- Providing land on appropriate terms for the initiative to take off e.g. Biopolis Singapore
- Providing good general infrastructure e.g. University of Mauritius for Biotechnology and Healthcare Campus
- Ensuring quality of service, quality of care, General Council of Practitioners, good laboratory practices (GLP) standards etc.
- Providing and attracting the necessary funding: Government of Mauritius, World Bank, Bill and Melinda Gates Foundation, private equity, sovereign wealth funds and banks
- Forming an international advisory board

- Starting discussions (in parallel) with leading institutions with respect to alliances, with corporations, not-for-profit organisations, financial sponsors, sovereign wealth funds, banks and international organisations.

However, such a strategy is more widely applicable to developing HLSS exports as a whole and not just one confined exclusively to developing preclinical research capabilities in Mauritius. Ideas were exchanged between the Board of Investment (BoI) and a European corporate finance group that offered to assist with articulating such a strategy and directly assisting the government/BoI to implement it. It will take experienced people to make these ideas a practical reality. The government/BoI should not hesitate to find and work with such people. The Ministry of Finance and Economic Development (MoFED) must make available the necessary budget resources. These ideas should be followed up and put into practice sooner rather than later.

Next steps (roadmap) for HLSS exports

In considering a roadmap and next steps for developing the HLSS sector in Mauritius and gearing it to maximise service export potential perhaps something can be learnt from the example of South Africa, which undertook a similar exercise recently. This approach can (and should) be suitably adapted in formulating a more tailor-made roadmap for Mauritius. The foregoing is confirmed by the experience of many countries that have also attempted to develop an HLSS industry and encourage HLSS service exports. A detailed review of best practices in biotech clusters allows a pragmatic positioning of the Mauritian context[15] (Figure 5.12) Globally there are over



Cluster Facilitator (CFs) are critical elements of modern clusters:

- Their role is to identify issues faced by stakeholders and facilitate a more competitive cluster.
- CFs are organised efforts to increase growth and competitiveness of clusters within a region, involving cluster firms, government and/or the research community. CFs have become a central feature of microeconomic policy in the last decade

Figure 5.10 Structural components critical to a successful biotech cluster

Source: Presentation at the Symposium on the Export of Healthcare and Life Science Services, adapted from Cluster Initiative Greenbook

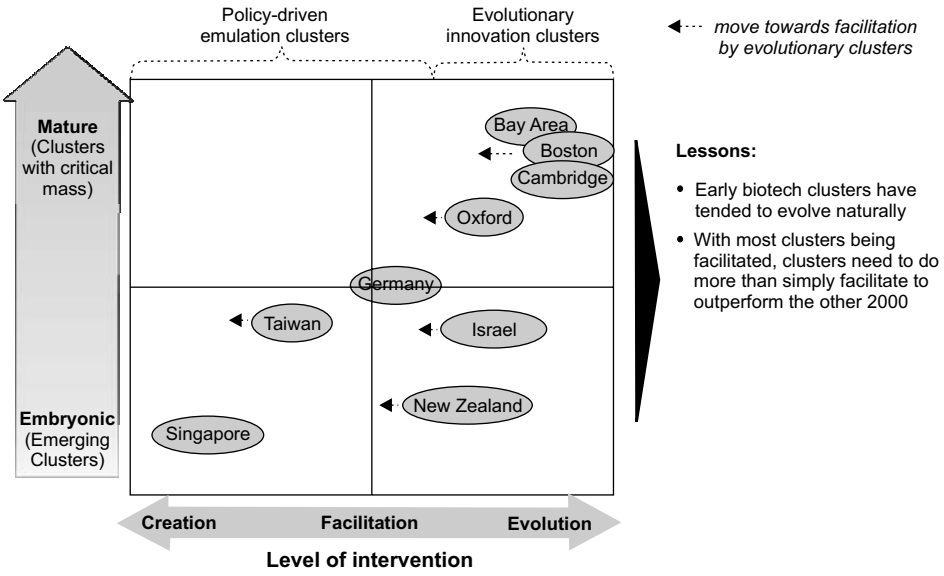


Figure 5.11 It is becoming accepted practice amongst regions and countries to actively promote the growth of their biotech clusters

Table 5.3 Key success factors for biotech clusters

Key success factor	Description
Strong science base	Leading research organisations, critical mass of researchers, world leading scientists
Skilled workforce	Skilled workforce, training courses at all levels
Ability to attract key staff	Critical mass of employment opportunities, image as biocluster, attractive place to live
Entrepreneurial culture	Culture of commercial awareness and entrepreneurship, role models, second generation entrepreneurs
Effective networking	Shared aspiration to be a cluster, trust, frequent collaborations, trade associations, shared infrastructure
Availability of finance	Venture capitalists, business angels, government seed funding
Premises and infrastructure	Incubators, premises with wet labs and flexible leasing arrangements Good transport links: motorways, rail, international airport Business support services and large companies Specialist business, legal, patent, recruitment and property advisers services Large companies in related sectors (healthcare, agriculture, agrifood)
Supportive policy environment	National and sectoral innovation support policies, and fiscal and regulatory framework Support from RDA and other development agencies, sympathetic planning authorities
Growing company base	Thriving spin-out and start up companies. More mature role model companies

Source: Dr Mark Fyvie, biotechnology consultant, presentation at the Symposium on the Export of Healthcare and Life Science Services

4,400 biotech companies, with those in North America and Europe earning over 97 per cent of global biotech revenues. More than one hundred cities and regions worldwide are now attempting to establish biotech clusters, to join the existing 150–200 clusters, most of which are only five to ten years old.

The HLSS market holds considerable promise for Mauritius in diversifying and enhancing its service exports. Mauritius is already involved in limited service exports such as hair transplants, primate breeding and cosmetic contract research being undertaken by CIDC in Ebene. However, there is more that the Government of Mauritius can do in increasing HLSS value-addition and exports. It can realign its policies and enter into appropriate partnerships with a number of domestic and external players and stakeholders. Areas in which Mauritius could benefit from exploiting a small but significant share of the rapidly growing global market for medical tourism have been highlighted above. This is also the case for medical education, alternative medicine and a larger presence in the preclinical and clinical trials domain for contract research.

In view of the potential that HLSS holds, the government and Ministry of Health have been focusing more clearly and defining a timeline for much needed (and much delayed) action on the legislative and policy fronts. Hopefully, the new timelines established and conveyed to the world at large will be met by appropriate and timely actions taken by parliament and the government. Some potential investments have been lined up in the expectation that such action will be taken (e.g. Saudi-German Hospital Group and the Kairali Clinics). Clearly more needs to be done in attracting a wider range of investments in all these areas. The way forward was pointed to by corporate finance and investment banking experts who participated in the symposium. Their active involvement and inward investment will need to be secured to make things happen.

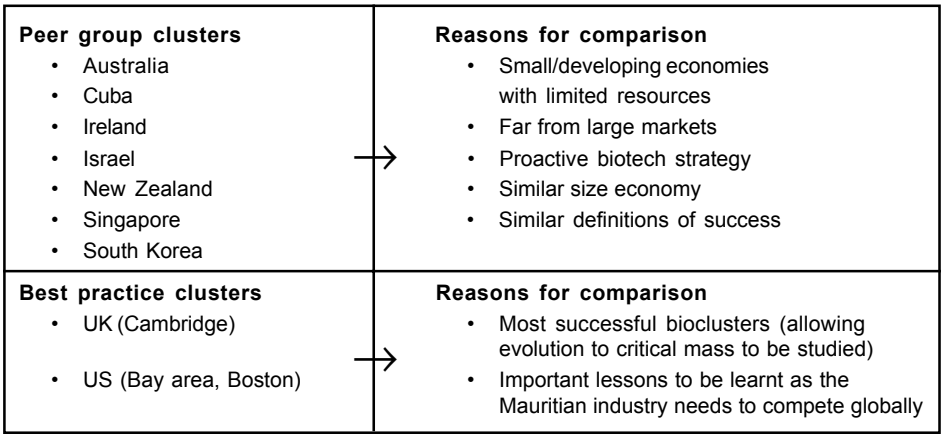


Figure 5.12 A detailed review of best practices in biotech

Notes

1. For example, US healthcare firms and hospitals (e.g. the Mayo Clinic or the Cleveland Clinic) export services by treating foreign patients in American healthcare facilities. The 2006 revenue for the Mayo Clinic was US$6.3 billion and that of the Cleveland Clinic was US$4.4 billion. American companies and hospitals also maintain 'on-ground' operations abroad. The most common is the operation and management of hospitals and clinics in other countries, followed by managed care and emergency evacuation ventures. US providers are also active in home healthcare, dental care, health insurance, strategic planning and pharmaceutical retailing activities abroad. US firms annually collect international licensing fees and royalties for healthcare expertise and information technology provided.
2. See, for example, http://ucatlas.ucsc.edu/spend.php [accessed 6 January 2009] and other sources such as OECD and UN/WHO/World Bank databases on country healthcare indicators and expenditures which are continuously updated.
3. Dr Derick Pasternak, Managing Director, Middle East International Office, Joint Commission International. Figures presented at Symposium on the Export of Healthcare and Life Science Services, April 2008.
4. Projections made by author based on trends emerging from the source data referred to in the previous footnote.
5. Some estimates are as high as US$40 billion, but those double-count revenues already being counted as health service related ICT-BPO revenue.
6. See, for example,

   http://www.lse.ac.uk/collections/pressAndInformationOffice/newsAndEvents/archives/2007/EurohealthJuly.htm or

   http://www.hse.gov.uk/migrantworkers/healthcare.htm [both accessed 6 January 2009].
7. For more details on the complexity of a sophisticated regulatory system such as that of the UK, see presentation by Mr Harry Cayton, Chief Executive, Council for Healthcare Regulatory Excellence (CHRE), at the Symposium on the Export of Healthcare and Life science Services, April 2008.
8. Quote from the American College of Surgeons, 1918.
9. Sobhi Batterjee, Symposium on the Export of Healthcare and Life Science Services.
10. Dr Isaac Cohen, Chairman and Chief Executive Officer, Bionovo, USA, at the Symposium on the Export of Healthcare and Life Science Services.
11. See presentation by Dr Mark Fyvie, Symposium on the Export of Healthcare and Life Science Services.
12. See presentation by Dr Kok Wei Yap, Symposium on the Export of Healthcare and Life Science Services.
13. For more details on this see presentation by Dr Kok Wei Yap at the Symposium on the Export of Healthcare and Life Science Services.
14. For more details see presentation by Dr Rainhard Korte at the Symposium on the Export of Healthcare and Life Science Services.
15. Full details can be found in the presentation by Dr Mark Fyvie at the Symposium on the Export of Healthcare and Life Science Services.