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WORKING PAPER NO. 111

THE ROLE OF INFORMATION TECHNOLOGY IN DESIGNS OF HEALTHCARE TRADE

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SEPTEMBER, 2003



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Foreword

The analysis in this study focuses on the nature and scope of the expanding role of information and communication technologies (IT) in the design and development of healthcare products and services, delivery systems and healthcare administration. The study traces the potential impact of IT on costs, efficiency and equity as a driver of cross-border trade and investments and notes that IT can play an important role in enabling the world's poor to access essential healthcare products and services in new innovative forms if the challenges that inhibit its diffusion in developing countries can be addressed through appropriate policy choices. The study points to the need for further research of how IT affects costs of diagnosis and treatment with respect to specific disease burdens at particular locations to resolve tensions between efficiency and equity.

The study highlights policy choices at national and international levels for the various unresolved challenges associated with distributed enterprising that concern vulnerabilities for public health because TRIPS, CBD and BWC do not apply in equal measure in all WTO national jurisdictions. The study is a welcome addition to policy research on the impact of IT on design and development of trade in healthcare products and services.

Dr Arvind Virmani Director and Chief Executive ICRIER, New Delhi

September 2003

Abstract

Information Technology (IT) is poised to revolutionise healthcare trade through new thresholds in human connectivity. This paper focuses on the expanding role of IT in three distinct but related categories: (a) design and development of healthcare products and services, (b) delivery systems, and, (c) healthcare administration. Through information power that IT enables, capacities of decision-makers are continually transformed in how they link with each other, in the here and now. This not only promotes conventional trade in services and e-commerce and facilitates worldwide convergence in several aspects of healthcare management and organisation. However, this process also raises fears and anxieties because the pervasive nature of IT and its uneven diffusion increase some vulnerabilities where policy safeguards would be needed. The process of IT diffusion occurs at many different points of impact in the international economy. Thus, policy choices have to cater to a wide range of national and regional needs and circumstances concerning rights to health, rights to trade and rights to development. National policies and international regimes need to strike a harmonious balance between these sets of rights.

The persistence of unresolved conflicts of rights and conflicts of interests point to the need for new international arrangements to be mandated and resourced. The extent to which this can be achieved is uncertain. This uncertainty is traceable to the ways *responsibility* for healthcare, *authority* to design healthcare products and systems, and the *power* to organise healthcare delivery remain separate or come together. The restructuring of private investments to integrate IT with life sciences in public-private partnerships is a sign of the growing significance of IT in healthcare. It is also a reminder of how powerfully IT could be harnessed in pursuit of millenium development goals.

The Role of Information Technology in Designs of Healthcare Trade^{*}

I Nature and Scope of Present Trends in IT and Health

Healthcare needs cannot be met in most countries for the vast majority of the world's population from within the prevailing structures of resource allocation. There are several potential sources of conflict among countries for making and observing rules of international trade in healthcare goods and services. However, promoting trade and protecting health need not be viewed as incompatible goals. Shared commitments on the use of global healthcare resources can be a powerful uniting force in the world. Consensus is constrained by glaring disparities in different regions of the world on quality and reliability of basic infrastructure, healthcare resources, differences in exposure to disease and disease burdens, shares of world trade in health services and inadequate awareness, that adversity anywhere affects prosperity everywhere as amply demonstrated during the recent SARS epidemic. The enthusiasm for global convergence on healthcare trade is dampened by differences in national regulations and comes bundled with efficiency, cost and equity considerations.

Information and communication technologies (IT¹) could revolutionise healthcare. With the right policy choices, IT is able to promote new thresholds of human connectivity and is a powerful tool of global convergence through cross-border supply of services. Firstly, IT enables new opportunities for production of knowledge, the only factor of production not subject to the economic laws of diminishing returns, and to trade in it for direct economic benefits. Secondly, international diffusion of new knowledge and best

This paper was invited by the Indian Council for Research on International Economic Relations as a contribution to the synthesis report of Working Group 4 on `Health and the International Economy' for the WHO Commission on Macroeconomics and Health chaired by Jeffrey Sachs. I thank the many persons who made helpful comments and suggestions on earlier versions. This revised version has benefited from suggestions and comments received from Arvind Virmani, Isher Judge Ahluwalia, Risto Nuolimaa, Vineeta Mathur, Jacob Matthan, K. Vijayaraghavan, Zahid Shah and an anonymous referee.

¹ The abbreviation 'IT' refers to information and communication technologies(ICT) throughout this paper.

practice opens new ways of improving the performance of health systems. This paper focuses its inquiry into healthcare problems and solutions impacted by Itwith a view to help evaluate policy choices. To put this another way: What difference can IT make to worldwide production and trade in healthcare commodities and services ? Can IT's role in designs of healthcare trade raise revenues and improve healthcare in developing countries ? Will commercial interests claim priority over people's health ?

The most significant feature of IT is its capacity to enable reliable storage, retrieval and instantaneous transfer of text, sounds, images and numbers as audio, visual and data communications. This substitutes and supplements face-to-face contact and transportation. Due to this, spatially distant resources and needs connect easily and add new links to productive capacity in all aspects of healthcare-development, delivery and administration. When this productive capacity is recognised as a shareable and exchangeable resource to be accounted for, IT products and processes acquire a currency akin to money. Producers of healthcare products and services – regardless of location – can design the outcome of their efforts to be combinable with each other' s efforts and their contributions can also be electronically traded. In this manner, IT reinforces incentives for trade and investment and for sharing and distribution of work in ways, for purposes, and with consequences that cannot fully be envisaged in advance. Thus, IT raises hopes but it also triggers anxieties over how world health resources and architectural dimensions of cross-border transactions of the international economy would enmesh with each other.

Cross-border supply is the least developed mode of healthcare services trade whereas the movement of patients across borders, foreign commercial presence and the movement of natural persons have hitherto been, in that order, the three more important ways of services supply in the sector. IT was first introduced in healthcare at medical facilities and in medical systems at a time when efficiency at the delivery-end mattered the most². Trade in IT-assisted healthcare (health resources that use, apply or are facilitated by IT) and in healthcare-related IT (IT that arises from, in or for healthcare commodities and

² World Bank (1993)

services including powerful diagnostics and investigative tools) expanded rapidly in the 1990s. Much of this expansion occurred in healthcare development and healthcare administration pointing to the need to systematically explore the two-way linkage between IT and healthcare. However, intangible and invisible services are not easily tracked because (a) they usually come bundled with products, and, (b) due to differences in national accounting conventions. The linkages remain under-researched at a time when both IT and health sectors are in the process of restructuring to converge in important respect. The role of information technology in healthcare is not well documented and several important questions arise which are not easily answered.

- 1. Under what conditions does IT diffusion promote health, trade and development ?
- 2. How may policies ensure that higher healthcare costs attributable to IT are commensurate with benefits ?
- 3. Would trade based on IT diffusion for healthcare development in business-tobusiness mode and for healthcare delivery to patients be efficient and equitable in developing countries ?
- 4. Does IT diffusion in healthcare mitigate disease burdens by reductions in cost per diagnosis or cost per treated/cured illness ?
- 5. What lessons can be learnt from the experience of uses and abuses of IT in healthcare in developed and developing countries ?
- 1. Do new risks and vulnerabilities require new policy safeguards ?

This paper is a modest attempt to fill some of this void with a special emphasis on research and policy issues of particular relevance to less developed countries.

IT touches all aspects of healthcare and at many different points of contact. However, this paper limits its scope to six of the most significant issues arising from IT's role in healthcare trade. These are (1) IT's role in design of healthcare products and services (2) IT's impact on design of healthcare systems (3) Information power effects (4) IT's facilitating role in strengthening public-private partnerships (5) IT-induced vulnerabilities and IT-aggravated risks, and (6) Need for global governance.

These issues concerning the impact of IT on healthcare are analysed in the following sections. Section 2 presents IT's role in the design of products and services following the genomic revolution which has completely transformed drug development and affected many aspects of cross-border supply of healthcare products and services. Section 3 discusses how and why new ways of organising work locally, nationally and globally impact healthcare systems when they seek to improve price/quality ratios through crossborder supply of services. Section 4 sets out some of the important dimensions IT impacts by bringing the power of information within grasp of individuals, enterprises, and, governments. Section 5 spells out the rationale for policy options and potential for partnerships noting some of the conflicts that need to be resolved through new arrangements. Section 6 presents the evidence on vulnerabilities induced by or enhanced with the use of IT for which appropriate policy safeguards must be designed. Section 7 spells out the rationale for global governance in several respects due to unsolvability of certain problems within national policy frames. The cumulative impact of IT, relevant to priorities and perspectives of national and international policy makers, consumers, service providers, and insurers is evaluated under performance criteria set out in Section 8 emphasising that ITliberates trade in healthcare services from many conventional shackles but noting that its potential benefits would best be reaped with global solutions and international safeguards. Section 9 concludes with recommendations emphasising the need for more research to evaluate policy outcomes and further policy choices.

II IT's role in design of healthcare products and services

IT has created opportunities for optimising linkages between domestic markets and exports/imports which is reflected in the design of healthcare products and services. The notion of `TeleMedicine' thus emerged as the practice of using audio, visual and data communications for medical consultations, diagnosis, treatment, nursing care, medical education and transfer of medical data together with a broader concept of `TeleHealth' which includes TeleMedicine and healthcare management, surveillance, literature and access to knowledge from a distance, using ICT. The notion of E-health has gradually emerged to describe the combined use of electronic communication and information technology to enable transfers and interactivity.

In the post-genome era, the search for new therapies based on the study of genes and proteins linked to diseases has caused an explosion in genetic data. IT-enabled tools are indispensable for testing large portions of DNA and protein quickly. The new requirements of speed, economies of scale, standards, simulation and security have rapidly transformed healthcare into an information-based science driven by IT which is global in scope³. New medicines and treatments develop faster and better with cross-border sharing of work across time-zones and simultaneous clinical testing in trials covering a wider geographical area-all of which is IT enabled. Trade in genomic databases involves high stakes ever since the human genome was decoded. The correspondence between the capacity of IT and the economic use of IT lies at the heart of the matter since information easily loses meaning, validity, relevance and the taste for it changes rapidly. It is noteworthy that even at the cutting edge of IT in healthcare development in genomics, leading firms like Celera could not sustain a business model based on priced information through online subscriber services for genome databases and were forced to diversify into more value-adding services.

³ Poste (2001) presents a succinct analysis of how IT and healthcare industries intertwine globally.

In 2001, the size of IT-enabled healthcare services is estimated to be about \$ 3.1 billion, of which about 80 per cent are in developed countries⁴. On-line consultations by patients and doctors through websites and email, distance referrals, emergency evacuations, and advance transmission of images and data of patients from ambulances can reduce lead times of intervention in emergency wards of hospitals. Treatments administered in a shared mode, distance surveillance of convalescing patients, risk assessments by insurers, distance consultations on symptoms revealed by patients and observations noted by doctors with the aid of transferable data from image scanning machines, processing of medico-legal documents, and cross-border networking for TeleEducation are some of the ways IT's contribution to new products and services is expanding rapidly.

In less developed countries, such innovations are mainly offered at urban locations in the quality conscious segment of private healthcare. Some aspects of TeleHealth such as TelePathology (requiring special cameras to digitalise specimen slides) and TelePsychiatry (requiring two-way interactive video conferencing) would remain limited in the near future, to developed country locations where sophisticated equipment can be maintained and its costs afforded. Applications like TeleEducation for medical degrees of renowned universities in partnership with local institutions and for continuing medical education of professionals in hospitals, medical colleges and healthcare centres have great demand in developing countries.

Healthcare delivery is not the most significant cross-border trade contribution of IT's role, constrained as it is by lack of widespread harmonisation of medical curricula and qualifications, approved drug lists, benchmarked standards, market access barriers such as economic needs tests (ENTs) and portability of healthcare insurance. Cross-border trade has been left "unbound" (i.e. countries are free to regulate entry of foreign services) by World Trade Organisation (WTO) members in commitments under the General Agreement on Trade in Services (GATS). Outsourced healthcare administration made up of backroom operations including medical transcriptions, invoicing, collections, purchases and inventory

⁴ *Poste* (2001).

management, accounting, payroll management, continuing education networks linking hospitals and medical schools, surveys, and research networks presently are a bigger segment of domestic business and trade where IT's role is significant and growing.

These opportunities represent potential services exports not only among developed countries (for example between Norway and Sweden for prenatal chekups and nursing care in Lapland or between Australia and Canada for TeleConsultations among physicians), but also from developed to developing countries (for instance, Japan to Thailand, U.S.A to Mexico, U.K. to Kenya, France to Ivory Coast and Singapore to Indonesia for TeleDiagnostics and TeleRadiology), from developing countries to developed countries (for example, Srilanka/India to U.K., U.S.A, Australia and New Zealand for healthcare administration services which could in future be extended to TeleDiagnostics when professional qualifications are mutually recognised or harmonised) and among developing countries (Bhutan, Thailand, Argentina, Nigeria, India, Brazil, China, Nepal, Bangla Desh, Tanzania for a range of telemedicine applications)⁵. Improved career prospects of doctors in short supply in developing countries enabled to export their services without movement as natural persons or foreign commercial presence would reduce the brain drain

IT has enabled doctors and paramedics to use diagnostic packages and decisionsupport tools based on the system of international classification of diseases (latest is ICD-10). Diagnostic measures on ICD-10 were among the first services to be e-commercialised in Europe. In Japan and Finland, early warning signalling of infectious disease epidemics is done from patterns of database searches of physicians trying to diagnose from symptoms at the time of the outbreak of disease⁶. This kind of IT application could be transported to any developing country or rendered in a distance mode enabling quicker intervention when epidemics break out although safeguards would be needed to ensure it does not trigger panics or false alarms.

⁵ Mandil (1998)

⁶ Jormainen et. al (2001) explain how physicians' database searches can be a powerful tool for early detection of epidemics.

III IT's impact on design of healthcare systems

IT enables new ways of working and organising work locally, nationally and globally.

IT is an important consideration in the design of public health systems in less developed countries where governments need to simultaneously pursue agenda related to healthcare, development, and trade. Declining budgets and rising costs of healthcare encourage these innovations also in developed countries. This has significantly enhanced trade potential. Medical costs in OECD countries have risen to over 10 per cent of GDP and could reach 15 per cent in the next decade High cost medical procedures, increased longevity, ageing populations, and costly medicines are the main reasons patients, national public health systems and health maintenance organisations seek cross-border supplies offering more advantageous price/quality ratios. Within domestic economies of U.S.A., Canada and Japan, TeleMedicine services halved traditional costs and increased the productivity of medical professionals. TeleExpertise has evolved as the basis for branded healthcare chains with an international scope. Cross-border trade also flourishes within enterprises following the establishment of foreign affiliates. Corresponding to innovations in products and services introduced by IT, designs of healthcare systems could be simplified to reflect organisational forms based on syndication to reduce financial and administrative burdens. Resource combinations needed for vast undertakings such as development of new vaccines, testing new procedures for isolating genes and proteins or proving new specific treatments become organizable, bypassing difficulties associated with movement of natural persons and foreign commercial presence that restrict inter-firm and intra-firm service deliveries across national borders. Problems of transferring patient records, communication of new medical know-how through dissemination of scientific publications and sharing in peer group for a among medical practitioners are solved. Instant portability is organised at low cost and electronic storage makes physical acquisition and storage redundant.

Public healthcare systems can be significantly rationalised with IT. Robotics and Artificial Intelligence applications enable the positioning of automatic analysers of biotic material such as blood, oral fluids and excretions at remote locations. Radiological scanners in rural areas enable distance consultations with organ specialists. Delivery of healthcare expertise can be networked through health centres in villages and beyond extending the reach of healthcare to places where it does not exist. Emergencies can also be handled more efficiently in countries deficient in transport infrastructure.

Medical professionals such as doctors, nurses, surgeons, anaesthetists, laboratory pathologists and medical technicians can pool their expertise in new forms and link in ways that save costs and time. IT enables inexpensive arrangements directly and indirectly through partnerships, branches, representation offices, subsidiaries, affiliates, franchises, licences and alliances through on-line tele-services and data transfers and there are numerous ventures in India, Pakistan, Srilanka, Kenya, and Mexico where transfers of know-how have been so arranged. The TELEMED project in the European Union has promoted collaborations in Europe and among African, Carribean and Pacific Basin countries. New arrangements of profit-sharing are also being structured between medical practitioners, chemists, pharmaceutical firms, those providing medico-technical services and medical education institutions. Facilities in developing countries have been quick to seek affiliation with well known medical schools and hospitals to be able to offer superspecialisations and also to enhance their image as in the case of Duncan Gleneagles, Apollo Hospitals and Escorts in India.

The greatest impact is and would remain on the way healthcare development is organised where the most significant transformative role of IT is observed in how it induces :

- (a) new ways of discovering, synthesising and testing therapeutic products where IT enables scale, speed, simulation and synergies;
- (b) intra-firm cross-border transfers as a source of profitability and growth with important implications for how costs are absorbed under differential pricing; and,
- (c) through the design of collaborations that support (a) and (b).

Trade in healthcare development is typically characterised by firm to firm arrangements. Less developed countries are weak in basic telecom and energy infrastructure and do not have many scientific laboratories endowed with adequate financial and human capital. In the past, this made them less likely nodes for linking in healthcare development networks. Three aspects have changed this now. The drug discovery process in the new biotechnologies is IT-intensive. It is necessary to process vast amounts of information at high speeds by distributing the work. Secondly, the drug development process involves clinical trials in targeted pre-selected populations based on isolating disease genes among populations with higher than normal susceptibility to disease. Thirdly, in trying to exclude those contra-indicated by the composition of a therapeutic substance to prove a drug's safety within limits of notified exclusions calls for IT-intensity in global trials where IT-assisted screening reduces the scale of clinical trials as in the case of Genentech's Herceptin drug for breast cancer treatment⁷. Such developments increase IT intensity in healthcare development and promote trade across borders to developed and developing countries. Intra-firm cross-border transfers are the preferred mode in the design of such healthcare development networks and contribute to the feasibility of differential pricing when final products are developed and test-marketed

IT enables many different forms of cross-border cooperation that could bring down the high costs of innovation from about \$ 500 million per medicinal drug developed to less than half of that cost while reducing the lead time of about twelve to fifteen years, on average, to less than five years in many cases. The logic of profitability in this situation

warrants a calculus that increases consumer spending and margins while costs of development and delivery are brought down. Firms syndicate risks in the design, development, production and distribution of healthcare products and services where profits are indicated. This is particularly the case with new drug developments and new treatment procedures for non-communicable diseases [such as cardio-vascular diseases with

⁷ The process of genetic screening to reduce clinical trials, technically known as pharmacogenomics hastens the introduction of new drugs and opens new niches for trading in high-priced proprietary diagnostic products according to Aitken (2000).

respiratory complications and malignant neo-plasms], which cause three times more deaths than communicable diseases⁸. In communicable diseases, an important application of IT has arisen in mapping out characterised vectors using satellite remote sensing data to study the spread of vector-borne diseases such as Malaria and Plague.

IT contributes profoundly in expansion of choice for design of research networks in discovery of new medicines, design of partnerships for testing new therapeutic methods, in marketing and distribution of prescription drugs, instruments, medical systems as well as investments by successful health maintenance organisations, managed care systems, and incorporated forms of general and special healthcare facilities.

Insurers can use IT to pool information and syndicate risk through consolidation if the insurance sector is open to foreign trade and investment. Cross-border mergers in the insurance industry for life and non-life businesses are prompted by new ways to assess acturial risks based on more reliable data and larger data sets through IT. The price differences for health insurance reduce. Insurers have an incentive to encourage "managed care" facilities to harmonise standards, standardise costs, and reduce the power of other service providers through consolidated contracts with or as Health Maintenance Organisations (HMOs). The policy implications of this are discussed in a later part of this paper (Section 6).

Trade in healthcare administration is, typically, a business to business activity in which "covered entities" in developed countries (and elite institutions in urban centres of less developed countries) meet obligations related to record-keeping and support services by farming out work to "business affiliates" at lower wage locations or to the informal sector in their own countries in a bid to reduce their costs. The role of IT is significant here because time and cost advantages accrue from distributed enterprising across two or more time zones. Data processing and transfers can go on 24 hours a day, 7 days a week, 365 days in a year with increased efficiency and reduced cost. Whether this reduction in cost is

⁸ WHO (2000)

passed on to the consumer or not would depend on policies governing such transactions and regulations governing prices where applicable. Governments in services exporting countries also need policies to encourage innovation so that wage cost differentials are not the only reason for trade and the trade remains sustainable with positive spillover effects.

The dominant mechanism of cooperation in drug discovery is driven by economies of scale. Consolidation of enterprises of similar business profiles through mergers and acquisitions is replacing affiliates with more intra-firm transfers among developed countries. In drug testing, principal firms located mainly in developed countries do most of the research and development. They are now able to organise division of work differentiating tasks of different stages and outsource some of the stages to establishments functioning as affiliates and agents. Human clinical trials are typically first conducted in developing countries due to fewer restrictions and lower costs. While positive spillover effects occur in all value chains and consolidations, investments in healthcare development were unnevenly spread. This is partially offset by research and development capacities created in developing countries like India aided by technology and scale acquired through process patent regimes and generic manufacturing for domestic market and exports. Policies can ensure that developing countries have incentives to undertake IT investments and participate in international networks of collaborators for drug discovery and development⁹.

The demand for increased IT-intensity in healthcare development is stimulated by service providers who stand to gain from 'biopower'¹⁰ when databases designed by or on behalf of pharmaceutical firms, managed care enterprises and insurance agencies become available to a large transient population of commercial subscribers. New information

⁹ The least developed countries have a reprieve from product patents (inapplicability of Sections 5 and 7 of Part II of TRIPS) until 2016 but it is doubtful that their market size would allow profitable investment in generic production by domestic or foreign investors without the possibility to export part of the output.

¹⁰ 'Biopower' refers to bio-information as an alternative means of domination to territories or commodities.

increases the number of target molecules at which drugs are aimed¹¹. This reduces the cost of drug development if the identified target molecules could be proved or disproved quickly¹². The rate at which candidate molecules are disproved is presently twice the rate at which new candidate molecules are reported¹³

Until recently (1999), pharmaceutical companies typically spent less than 5 per cent of revenues on IT (compared with 10 percent for other data intensive industries such as financial services). Since then, they have increased their IT budgets to over 20 per cent of revenues to compete for *in silico* research. According to a Frost & Sullivan Study, the bioinformatics market was estimated to be about \$ 3 billion in 2001 (60 per cent of which is in the U.S) and projected to grow to about \$12 billion by 2007¹⁴ Estimates published by two reputed journals 'Science' and 'Nature' several months earlier independently confirm these estimates. International trade in bioinformatics accounts for less than 25 per cent of this value since most of it is located as domestic business in the U.S. To bioinformatics must be added other segments to compare the size of the IT-related healthcare development industry with IT-related healthcare administration and IT-related healthcare delivery. Table 1 presents the three segments of the IT-related healthcare markets in U.S.A.) , and the rest of the world.

¹¹ Target molecules are usually proteins. Only about 500 proteins are presently known although there are between 600,000 and 1 million proteins and protein mutations in humans. The use of IT to map protein databases in the search for new medicines gave rise to the science of proteomics.

¹² IBM was among the first companies to design and market a computer known as "Blue gene" for this specific purpose in 1999 and diversify into lifesciences with an investment of about \$ 700 million. Since then, several big IT firms have formed life science divisions. These include Compaq, HP, Motorola, Sun, Fujitsu and Hitachi.

¹³ See Neil Holtzman, "Will the Human Genome project revolutionise medicine ?" http://www.mhsource.com/pt

¹⁴ Cookson (2001) quantified the IT business in healthcare on the basis of field surveys.

HEALTH CARE	USA	OECD (excl U.S.A)	OTHERS	TOTAL			
DEVELOPMENT	7.2	3.8	1.2	12.2			
ADMIN	3.1	2.8	0.8	6.7			
DELIVERY	1.2	1.3	0.6	3.1			

Table 1: IT-RELATED HEALTHCARE TRADE YEAR 2001 (Figures in \$ billions)

Source: Author

Notes:

- (1) These are DELPHI estimates of commercially assessable transactions (including contracts) on an annualised basis for 2001 based on five independent surveys (Science, Nature, Frost and Sullivan, Poste and Financial Times).
- (2) Reliance has not been placed on values of market capitalisation of biotech firms (\$200 billion) or sales of biotech products (\$ 50 billion) for the purpose of estimating IT-related healthcare.
- (3) Trade values are highest in the OECD column at about 50 %. of output.. The corresponding figure for U.S.A. is about 25 % and for others less than 10 %.
- (4) About \$ 82 billion per year worth of patented medicines are to go off patent by 2007. Together with the emergence of bioinformatics, pharmacogenomics and proteomics, this has spurred the healthcare development segment to become the fastest growing segment of the industry.
- (5) The annual gross value of all electronic transactions was estimated to be \$ 95 billion in Year 2000.

At a global level, the value of IT in healthcare development (and its costs) exceeds the value of IT in healthcare delivery and healthcare administration put together. There are significant differences in the composition of IT in healthcare development, delivery and administration between developed and developing countries. Differences in ways in which healthcare services trade is accounted and recorded make comparisons difficult. Decentralised networks and IT reinforce each other, whereas IT costs and risks require syndication. These two contrary tendencies pull in different directions. When higher ITintensity affects the creation of value in the industry, it is pertinent to investigate whether this is associated with concentration of economic power, given the incentives for syndication of risk under conditions of higher IT intensity. Healthcare as an industry could undergo restructuring away from what are termed "cathedral" kind of corporate structures towards more "bazaar" kind of networks¹⁵.

There are a number of reasons for IT-intensive distributed enterprising to become the norm.

Firstly, international production and trade in healthcare services is designed around the concept of sharing in innovation through networks where the registered office is typically located in a country other than country of origin, with multiple share listings, cross-holdings based on alliances, sourcing of inputs from multiple sources and the extensive use of transfer pricing on intra-firm trade to minimise tax exposure.

Secondly, policies conducive to such arrangements require bargaining power with host governments, and well established intellectual property rights. Trends towards increased consolidation through mergers and acquisitions and divestments for arms length relationships to satisfy competition policies and anti-trust legislation are part of acquiring size and scale to be both cost-efficient and profitable¹⁶.

Biotech is a high risk-high payoff business where IT intensity can make or break a company. There are over 150 biotech drugs on the market. Some biopharmaceuticals have sales of over \$ 1 billion. About a third of all new drugs in Year 2001 arose from biotechnology. However, the number of new medicines approved in the U.S. was down from 53 in 1996 to 27 in 2000 to just 9 in 2001. In Europe, biotech firms like Cybio, Genescan, Lion Bioscience and Medigene lost over 90 % of their value in Year 2001 whereas many U.S. biotech firms continued to command higher price-earnings ratios than

¹⁵ Raymond (1999)

¹⁶ Data-based analysis of industrial restructuring trends in healthcare as reflected in asset management strategies of the biggest 100 firms presented in two tables in an earlier version of this paper was excised for the sake of brevity and can be separately made available to interested readers upon request to the author.

traditional pharma companies¹⁷. However, the biotech firms havent yet grown to the size of pharma firms (See Table 2 for a comparison of the top five firms)

	SALES OF TOP FIVE BIOTECH FIRMS, 2002-03 (\$ BLN)		SALES OF TOP FIVE PHARMA FIRMS, 2002-03 (\$ BLN)
AMGEN	6.3	MERCK	53.0
GENENTECH	2.8	JOHNSON &JOHNSON	37.4
SERONO	1.7	PFIZER	33.0
BIOGEN	1.2	NOVARTIS	32.3
CHIRON	1.2	ROCHE	29.7

Table 2: BIOTECH AND PHARMA FIRMS: A COMPARISON

Source: BusinessWeek, June 2, 2003, p.46

IT has enabled licensing of drug development including the phases of its clinical trials. When a promising pharmaceutical compound is discovered, it is now the norm to auction rights to its development. An obesity-related gene discovered by scientists at a University was auctioned for about \$ 20 million¹⁸. In this case, the buying firm then contracted out its clinical trials and recouped on its investment by value-adding into the asset with each progressive phase of clinical trials. In another case, Pfizer paid Searle \$ 225 million to develop *celecoxib*, an anti-arthritis compound and farmed out the job. Inlicensing by firms for rights to development is regarded more profitable than outlicensing of know-how for a fee. The bigger firms usually have large sales and distribution networks worldwide to exploit their investments on a global scale. Out of fiftyfive "blockbuster

¹⁷ Reinhardt (2001)

¹⁸ Aitken et. al, 2000

drugs" (each contributing to revenues exceeding \$ 500 million in a year) marketed in 1998, fourteen drugs were developed this way¹⁹. Among these fourteen drugs, the cholesterol-reducing Lipitor tops the list with sales of \$2.2 billion. Almost half of the profits of the world' s ten largest pharmaceutical firms arise from such arrangements over externally sourced products and externally sourced services brokered together to gain time and cost advantages through substantial cross-border supply of services through IT. In some cases, as much as 95 % of revenues are derived from such arrangements. It is apparent that this model is sustainable only if firms quickly spot and capture compounds. If contract R&D organisations become credible with IT, biotechnology firms would not sell out their discoveries. IT also enables large firms to target molecules through bigger networks and laboratories in situations where asset specificities and past human capital investments matter.

From the published financial statements of pharmaceutical firms, it is noticeable that the five largest pharma firms significantly increased overseas presence as measured by foreign assets to total assets ratios, taking advantage of cross-border supply of services.

According to the National Human Genome Resource Institute in U.S.A., genes contain codes for more than 50,000 proteins in the human body and drugs on the market presently target only 10 per cent of these. Moreover, the functions of 95 per cent of human genes are not yet known. This means that firms need to go beyond narrowly researching one gene at a time and investigate the interplay of genes and proteins along the entire cellular pathway of a disease. This calls for unprecedented co-operation across a range of locations, and a range of sciences, using gigantic data-sets at different locations.

Insurers and actuaries are able to use IT to pool records and databases for costeffectiveness analysis. Bio-information and medical databases have been commodified and are tradable. Comparisons of relative efficacy of alternative treatments on a large scale adds to knowledge that brings down costs of diagnosis and treatment, besides enabling effective risk syndication by health insurers-domestic and international. This is trade-

¹⁹ Aitken et.al, (2000).

promoting because there is a growing demand for private insurance in all countries where public healthcare systems are weak or non-existent (including those developing countries where incomes are rising and there is demand from urban elites). The use of IT in structuring premia and settling claims encourages firms to set up 24-hour helplines offering year-round health insurance coverages, which may extend from national to international through partnerships and direct commercial presence involving foreign direct investments. The consolidation of micro-insurance units for healthcare can be enabled the same way as IT enabled dairy co-operatives in rural areas of less developed countries to achieve economic scale. Schools that have IT infrastructure readily become nodal points for adult literacy and adult healthcare too. School-based health insurance schemes with IT systems have been tested successfully in Egypt in remote locations Field studies from Uganda and Philippines suggest that reinsurance possibilities can also be introduced in such ventures although the cost-neutrality in such schemes is not easily achieved ²⁰. IT has made it possible for moral hazards and adverse selection to be regulated so that insurance firms can take into consideration pre-existing disease conditions and public health vulnerabilities to

structure risks properly and yet be supervised for not profiling only those insurance targets that have low health costs, in the interests of consumer protection.

IV Nature and scope of information power conferred by IT

New networks, contracts and licenses, organisation structures, control systems and management processes enabled by IT expand choices and reduce response times for all concerned. Patients, doctors, hospitals, pharmacies, statutory health authorities and health insurers can quickly avail, adjust to and offer new responses interactively and rearrange their responsibilities towards each other. Information power encourages new ways of exercising power, authority, and responsibility to emerge around combinations and trade-offs involving *choice, costs, efficiency* as the criteria by which performance is judged. Performance comparisons promoted through openness and accountability raise the incentives for private and public health systems to compete and perform better.

²⁰ Dror (2001) has analysed what IT is doing to reinsurance markets by enabling fragmented markets to be consolidated.

Hospitals, medical schools, pharmaceutical companies, related enterprises as well as local health authorities and health journals and advisory services have all developed and maintain web pages accessible through internet. About 25 per cent of the content of the world wide web deals with health and health-related topics covering conventional and alternate healthcare possibilities which has expanded choice enormously.²¹ Millions of individuals visit world wide web sites for information which would enable them eat intelligently, learn to exercise their bodies and to find out other healthcare information²². IT enables links to nutrition, diet, exercise, primary healthcare, ante-natal and post-natal care, hygiene and sanitation to be located in the proximity of other healthcare and medical information with obvious synergies. The awareness of alternate medicine, and nonallopathic medical systems is expanding rapidly due to IT. In developing countries, this is important because the majority of registered medical practitioners (between 56 percent and 80 percent in different developing countries) do not practice allopathy and three out of four patients turn to medical systems other than allopathy. Websites enable people to be more aware of medical systems such as homeopathy, ayurveda, unani, kampo, acupuncture, herbal medicines and to know where these are available. Alternative medical systems can be evaluated publicly whereby experiences shared and facts documented quickly separate biases, conjectures and quackery from what is reliable. Websites get rated for their quality. Rating agencies like Internet medicine.com and Healthgrades.com provide comparative performance data for thousands of hospitals and medical centres. At the consumer delivery end, e-healthcare players are generally hospitals or medical centres with solid reputations where the web is used as a supplementary channel rather than a substitutive one.

²¹ Mandil (1998)

²² Websites like Dynamed databases offer links to the International Classification of Diseases (ICD). Pharmainfonet provides pharmacopia listings. Korean sites like Medmark have links to hospitals, research centres, patient/consumer information and diseases. Webmedlit, a Canadian supersite links to 23 medical journals and a Doctor' s Guide to the Internet. An Indian site DoctorNDTV.com with more than 150 experts whose credentials are posted on the site with links to drugs, therapies, medical research and clinical resources was cited in Lancet which has begun to recognise such websites (Lancet, Volume 358, 9281, 18.8.2001). These developments reflect very profound changes in credentialling medical resources and for price/quality comparisons.

In enabling doctors, paramedics, patients, insurers and regulators everywhere (including less developed countries) to become aware of new information quickly, classification of disease and statistics become more accurate. Timely and precise information is a pre-requisite of good stewardship and IT provides means to evaluate responses and establish mechanisms in all areas where logic of decision-making is data-based. Market failures like non-availability of medicines at health outlets and pharmacies could also be prevented with better information. Open information flows on deliveries and deliverables would set norms, standards and new forms of partnership between private, voluntary and public sectors. A remarkable feature of IT is its capacity to establish and disseminate publicly accessible global databases of prices of healthcare commodities and services.

The risk of erroneous patenting of therapeutic substances in one country of what is in the public domain in another would also be reduced. For instance, information about the patenting of' haldi' (turmeric), as "Use of turmeric in Wound Healing" granted by the U.S. Patent and Trade Mark Office (U.S. Patent 5401504 dated 28.3.1995) spread quickly through the world wide web of the internet which spawned campaigns culminating in successful action by a developing country government (India) to redress the wrong.

V IT's facilitating role in strengthening public-private partnerships

Private sector participation in financing, production and delivery of healthcare products and services is a welcome addition to the resource-starved healthcare sector but also a challenge to the regulation of public health and in ensuring equitable access to the poor and needy. The sharing of information about facilities, performance, resources, costs and prices among health authorities, planners, contributors, governments, service providers and patients is an important aid to promoting better management of healthcare systems with shared perspectives developed through interactive communications. This reduces the chance of missing opportunities of trade promotion in healthcare that require businesses and governments to act in concert.

The capacity of different people and organisations to work together across complex networks is an important element in novel and experimental advances. If communities of expertise can be connected and resources mobilised together with public interest, political energies and accountability, IT diffusion could play an important role in public-private partnerships in managed healthcare²³. Success in any form of accountable and responsible public-private partnership is based on ongoing reviews, feedbacks and consultations where informed participation is the key to success. IT connectivity provides an interactive platform to exchange ideas and information at low cost which encourages participation and acts against exclusion. By this process, IT facilitates participation in collaborations by spawning communications networks with strong incentives to move away from isolated systems towards risk syndications and risk exchanges, harvesting value through designs of communications networks.

Aided by IT, the success of Merck' *slvermectin* drug donation for curing river blindness enabled a hundred million people to be treated in 31 countries with credibility of the programme based on communications networks which enabled wide participation and lots of feedback. This success later spawned one of the biggest public-private partnerships when Merck joined hands with the Gates Foundation for more such initiatives. In contrast, Glaxo-Wellcome' s anti-Malaria*Malarone* drug donation programme in Kenya suffered from inadequate communication and participation and lack of sufficient information to conduct a reasoned discourse²⁴ Failures experienced in drug donation

²³ The kind of proposals Sachs (2001) advocates would be greatly facilitated by IT-aided participation.

²⁴ See Shretta et. al. (2001).

programmes due to communication gaps could be easily remedied by IT ²⁵. IT connectivity would have enabled facts of the Malarone case to be known at the time it happened with scope for timely intervention by all concerned instead of the public remaining unaware for four years until details were published by scholarly journals like Lancet. Electronic archiving accessible through internet could simplify dissemination of new knowledge published by scientific journals.

The core role of IT in healthcare may be understood from the way designs of healthcare development and delivery enabled and supported by IT include or exclude people and encourage or discourage their participation in influencing decisions about allocation of healthcare resources. Participation is a vital aspect of healthcare because health consumption requires participation in its production at every level starting from individual persons (diet, hygiene, lifestyle, belief and trust in one or more medical systems) to communities (safety, pollution control, sanitation, public hygiene), and nations (healthcare standards, budgetary allocations, medical education, support to research and innovation in diagnosis and treatment, and availability of medicines) rendering it uniquely amenable to communicative technologies, horizontally and vertically in and between these aggregations.

Public-private partnerships are also required to cope with trading in bioinformatics and clinical databases. Significant transactions costs arise when contributions are sourced from a wide range of value creators using different platforms of data transfers and with multiple claims to proprietary rights over fragments of a whole process before a marketable product arises. This creates incentives for venture capital, pharmaceutical firms, biotech

Malarone had not received regulatory approval as a safe drug in its home country and the need for mass chemoprophylaxis was not established in Kenya; nor was this drug likely to be an affordable long term solution in any poor country. The risk of premature development of drug resistance was exported to Kenya (after Thailand turned down a similar offer) for the firm to accumulate experience through clinical data on this drug being developed mainly for affluent tourists and military overseas missions. The publicity highlighted that one million doses were offered free but Shretta et. al (2001) have documented that immediately after 189 courses of treatment in the first six months, Glaxo-Wellcome obtained the government' s permission to sell the drug at its market price, causing a diversion of the medicine from the welfare sector to the private sector for profit, defeating the stated purpose of the donation..

start-ups and the State (and its marketised counterparts such as health maintenance organisations) to make new forms of partnerships in predictive medicine and treatments. Alliances of universities and research centres with drug developing and clinical trial enterprises are being established within developed and developing countries and also between organisations in developed and developing country locations. IT-intensity sustains such networks contributing to efficiency and equity through rationalisation of financial constraints as well as non-financial constraints.

VI IT-induced vulnerabilities and IT-aggravated risks

IT is distinguishable from other technologies because it is process oriented and transformative in its effects on production, consumption and organisation. Connection speeds are constrained by availability of bandwidth spectra and the risk of data loss from contamination by viruses and bugs can only be minimised but not altogether eliminated. While information that IT produces is easily commodified, much of the knowledge that IT-driven biotechnology incubates is tacit and not eassily reducible as information. This is the reason that biotech requires science parks and trustful networking anchored in a location.

Placing information on the web poses risks to ownership of intellectual property. Nor can all information belong to everyone being unsustainable even in its elements, without being hosted or sponsored. IT products are excludable, divisible and ownable through introduction of filters, but cyberspace does not create a domain governed from within itself insulated from other jurisdictions²⁶. The reliance on IT obliges adaptation to ever-changing new technical norms and to new rules introduced by regulators or censors. Policies and safeguards need to be envisaged to harmonise private and public interest so that IT is not used as a tool to propagate harmful substances and drugs. There could be four different ways in which IT as a media channel could be protected from undesirable traffic:

²⁶ The declaration of independence of cyberspace by Barlow (1996), which is part of the folklore of IT is flawed because IT flows depend on what regulators would allow and the conditions they impose.

- 1. International legal agreements on e-commerce prohibiting certain products and services as 'global public bads" from the purview of e-commerce.
- 2. Introduction of rules by regulators with enforceable penalties.
- 3. The use of IT itself to neutralise the canvassing of "sins and bads" with counter-campaigns disclosing more information on health hazards.
- 4. Censorship of cyberspace through filters

IT has enabled screening of people for susceptibility to diseases and also the targeting of new drugs to pre-defined genetic profiles. Policies must ensure that genetic stratification does not create new social class structures with genetic upper classes and genetic lower classes. Priorities of healthcare developers and deliverers would need to be harmonised within the budgetary constraints of healthcare contributors and recipients in different countries with different quanta of healthcare resource availability.

Healthcare needs, resources and IT capacities in less developed countries differ from developed countries although IT-enabled resource linkages and exchanges could impact quality, efficiency and equity dimensions of healthcare everywhere. The globalised healthcare industry is growing faster than any other industry and offers incentives to participate in its designs. Imminent restructuring of authority and responsibility in national spaces forces all concerned to respond in self-interest. Resource constraints in less developed countries pull investments into IT to the extent allocation of scarce resources can be improved on efficiency and quality considerations in private healthcare and on grounds of efficiency and equity in public healthcare. Safeguards are needed to ensure that global solutions for market standardisation and control (of health norms or IT standards and specifications) are not limited to a few players with greater access to healthcare or IT resources.

Since IT-intensity is one of the causes of rising healthcare expenditures, policies would need to ensure, through appropriate cost-benefit analysis, justifications and

affordability of such increases on grounds of efficiency or postive externalities, particularly in the case of less developed countries²⁷. If IT attracts resources away from actions which have large positive externalities (or the benefits to those who derive livelihoods from IT's role in healthcare are less than the increased costs of healthcare commodities and services), Specific regional studies at the level of local communities would be useful to understand and evaluate these processes because the available data is meagre.

IT has enabled certain kinds of abuses that would have previously not been possible to execute on a large scale. Pharmaceutical firms provide incentives to pharmacies to sell prescription drugs over the counter without prescriptions in less developed countries. IT has made it possible for chemists, pharmacies, and extension counters of clinics and hospitals to build databases and push products using retail store models of incentives -something that would be impossible in developed countries where firms target doctors, not individual chemists or pharmacies. This is also a source of concern to health insurers organising the contribution side of such a market through health insurance schemes.

Overconsumption of medical products and services is one of the leading causes of rising healthcare costs. Health insurance schemes get dragged into bearing the burden due to improvements in medical procedures to prolong life, ageing populations and the tendency of buying insurance according to needs without necessarily contributing to it on the basis of means. There is also the danger of supply-induced demand. For instance, schools that introduce school-wide healthcare insurance schemes are pressurised in direct marketing campaigns to dispense medicines and treatments with little regard to needs. The marketing of Ritalin, Metadate and Adderall (through commission agents armed with IT-databases) to school authorities for "attention deficit hyperactivity disorders" in school children to make children more docile for teachers has already occurred without parents' knowledge in some instances. Such malpractices would be difficult to control in societies where establishments like schools have power over parents as in cities of developing countries where demand for places in private schools exceeds supply. IT-enabled databases have also been used to target

²⁷ See Fuchs and Sox (2001) for their detailed critique. particularly relevant to less developed countries.

school children covered by health insurance through commission agents acting together with school systems to push children into medical treatments they do not need by inducing them through small treats as incentives. Similarly, "managed care" alternatives could take perverse forms for adults too when IT promotes disease management models bypassing medical expertise by conducting what is termed in medical parlance as "wallet biopsy" (scrutiny of the means to pay).

The recording of health data does not merely concern medical histories, medicine inventories and doctors' addresses maintained for the benefit of patients. Clinical and personal data of patients and doctors routinely stored in medical facilities could be traded without informed consent for market research, insurance and other commercial purposes to target profiles. IT has enabled this to be done in centralised databases on a large scale for whole communities, regions and countries. Some governments already directly trade in their monopoly of control over such information as in UK and China. Other governments as in Estonia, Kenya, Nigeria, Tonga and Iceland license this trade through firms registered in off-shore or other grey and distant jurisdictions²⁸. The licensing of healthcare databases for commercial profit with or without the prior consent of individuals whose data is so traded enables collecting or trading DNA information on specific groups and communities without their knowledge or consent.

New vulnerabilities point to the need for policy safeguards to deal with the following problems:

(a) Rights to privacy and personal data protection are easily breached because healthcare databases have to be kept open for updating old records and for initiating new records and entries. So confidentiality cannot be secured by coding the data or disconnecting the data from personally identifiable features. Patients could lose trust in the confidentiality of their conversations with their doctors unless this problem is solved. Demands of payment

²⁸ For instance, the Swiss firm Hoffman-La-Roche (20 % owned by Novartis) funded deCode Genetics, a firm with a 'Delaware registration' to link with subsidiary affiliates for healthcare database trading start-ups in third countries on the basis of 'presumed consent' of subjects[Bear,(2001)].

for parting with bio-information could arise.

- (b) Medical databases are easily linkable to databases of genealogy, castes, tribes, clans, ethnicity, and genetics. The principle that such data be stored only at its place of origin and used only for the original purpose for which it is collected is difficult to enforce. Personal data on whole nations and ethnic groups could be exploited in ways that endanger public health (Mathur, 2002). Without enforceable international agreements, no individual or social institution is in any position to supervise the use of healthcare databases. In the hands of mercenaries and rogue states, healthcare databases could be misused to trigger complex humanitarian emergencies or for fostering permanent dependencies using biopower as a means of disruption.
- (c) The scientific and commercial value of health databases is limited to those who have the means to maintain and update these databases and link them to other databases in their possession. This could accentuate the information and technology gaps between developed and less developed countries²⁹.
- (d) IT enables decoding of personal data using genotypes and phenotypes as personal identifiers and the design of novel organisms against which vaccines or antibiotics would be useless. When private information held in public databases is commercially traded by privatising public domains, rights of natural persons get transposed with rights of artificial juridical entities. Since intellectual property rights are private rights, international regimes for e-commerce in healthcare and consumer protection are needed for what remains outside the public domain.
- (e) The risk is greatest when exclusive ownership or control of healthcare databases is lawful. The entirety of medical records of a community are a non-renewable single good. Yet, the incentive for governments in less developed countries to sell or license such information to raise resources from the private sector is considerable. This is particularly

²⁹ Feachem (2001); Fox-Rushby, Mills and Walker,(2001).

the case when therapies are developed on the basis of databases of communities offered free drugs in exchange. There is growing awareness that firms need to repay communities for vital bio-information. DNA information of an individual is worth about \$100,000 in commercial value which could be greater than the cumulative income receipts of individuals in poor countries over a lifetime³⁰. This clearly points to the need for biobanks which could profitably and securely be designed and constituted under international control as independent global healthbanks or by extending WHO's mandate to accommodate them within its umbrella.

- (f) Unrestrained IT in healthcare implies the end of privacy. If the restraining instrument is government executive control as in Malaysia and the U.K, the danger is arbitrariness. In contrast, IT restrained by parliamentary laws could lead to wasteful litigation. If restrained only by market incentives it would make it too easy and too profitable for businesses to act contrary to the interests of other constituents. This situation urgently requires new forms of public-private partnership.
- (g) If it is known that normal data protection controls can be easily bypassed by powerful interests in a vital area like health in any particular country, it would also have consequences for trade and development in other sectors due to loss of confidence in that country's capacity to provide adequate data protection for business secrets and intellectual property rights.
- (h) With IT, the inventory of possible symptoms, physiological and mental, is quickly recognised also in patients who suffer from minor ailments and who could recover anyhow, with or without treatment. When treated, such patients recover rapidly. This sort of change in diagnosis rather than in treatment may re-allocate healthcare resources and increase costs. IT could also increase the cost of healthcare in other ways when "internetpositive patients" confront doctors with medical information obtained from the web which doctors themselves may not have found time to evaluate.

³⁰ Bear (2001) explains details of this calculation.

- (i) With reference to insurance consolidation in Section 2, trading in clinical and genetic databases enables insurers to acquire information to exclude beneficiaries of specific profiles who pose higher risks to predictable disease susceptibilities. Secondly, centralised healthcare databases of more than one million records cannot be securely designed and administered³¹. Due to these hazards, the role of IT in organising the contribution side of healthcare remains undeveloped for the present.
- (j) The promotion of IT as a means to stimulate cross-border connectivity for growth and employment through trade and foreign investment cannot be easily accomplished when international networks bypass locations where doctors, IT specialists and other scientists and technologists do not already relate to each other. According to the reports of the European Union's TELMED project, there is little evidence even in developed countries of any strategic development of telematic healthcare outside pilot programmes, except in medical imaging, community health applications, and health care administration systems involving smart cards and electronic patient record transfers.

VII Need for global governance

The responsibilities for healthcare and IT are naturally global in certain respects although not well reflected in the organisation of either of them. Healthcare policy is conventionally the responsibility of local and national governments whereas IT is mainly innovated through private initiatives. Research and Development costs have risen and risks are greater because much of the work is on diseases which are not well understood and a large number of patents are due to expire by 2005, forcing the pace.

Cross-border data transfers in healthcare development, delivery and administration and have increased manifold and continue to grow. The normative aspects of these data transfers (and authority to exercise control over them) are designed to technical standards

³¹ Anderson (1996) provides a technical explanation of why security of clinical information is compromised when records are consolidated beyond this critical maximum threshold.

but are not determined by technology $alone^{32}$. These flows are governed through conceptions of what transactions are regarded fair on the basis of negotiated

international regimes such as the General Agreement on Trade in services (GATS) and Trade Related Intellectual Property Rights (TRIPS). Such arrangements at the national and international level need to cater to concurrent pursuit of rights to health, rights to trade and rights to development while striving for a dynamic balance between these sets of rights. There is acute concern for what the TRIPS regime would do to availability of affordable essential drugs for the poor and whether it would adversely impact health or trade or development.

Historically, healthcare was descriptive with a legacy of disarray in data management including storage and annotation with no agreement on standards for shared databases and software designs. Several standards persist for transmitting images, data and for making electronic medical records. Comparability of care is not assured. The present approaches of Bio-ontology consortium, Bio-pathways Consortium, Life Sciences Domain Task Force and the Object Management Group differ very much from each other and consensus is not imminent³³. An indirect recognition of this IT problem in healthcare comes from the plan made at the BIO 2001 San Diego Conference by over fifty pharmaceutical, biotech and IT firms to work together to develop bioinformatics standardisation to end the chaos, confusion and avoidable high costs presently caused by use of dozens of incompatible data platforms.

GATS commitments on telecom access could facilitate or preclude cross-border trade in health services and are also a cost factor. The protection for IT itself was legislated in TRIPS and computer programmes brought under Article 2 of the Berne Convention, 1971 as literary works by the 1996 Geneva Amendment with separate further protection for databases (but not for data) under Article 5 of the Geneva Amendment. Programme carrying signals transmitted by satellite were already covered under the Brussels

³² Richardson (1995) cites the case of how TeleMedicine is routinely practised from U.S.A. to Saudi Arabia and other gulf countries but any practice in the reverse direction is regarded as a crime.

³³ Poste (2000) analyses the costs and consequences of lack of convergence.

Convention of 1974 (Brussels Convention Relating to the Distribution of Programme-Carrying Signals, May 21, 1974) to prevent distribution of signals except to intended recipients. The implementation of the Ministerial Declaration on Trade in IT products (known as ITA-I) concluded in Singapore in December 1996 among 29 countries (including all 15 EU countries and U.S.A and Canada, among others) was delayed because signatories did not have the threshold proportion of world trade in information technologies required for the agreement to take effect which had to wait for an adequate number of countries representing IT trade (China, India, Thailand) to join the agreement. The ITA-II round for zero tariff on an expanded product coverage could not be concluded and the non-tariff measures work programme adopted on 13.11.2000 remains a modest step. The Washington Treaty on Intellectual Property in Respect of Integrated Circuits, 1989 (under WIPO) protecting topographical designs of integrated circuits has not entered into force, to date. The Rome II recommendations on enforceability of consumer rights for cross-border supply in national jurisdictions are contrary to the EU Directive on Electronic Commerce which recognises enforceability only in jurisdictions where the service provider is located. Thus, there are several unresolved IT problems awaiting global solutions.

The authority for one's own well-being is partly delegated by individuals as "consumers" (paying and non-paying customers) to governments, doctors, nurses, hospitals and clinics, insurers, employers etc. intermediated by information brokers and bridging institutions. The ways in which such authority is pooled or divided is determined by market power and negotiated arrangements which may be understood as designs or patterns. Such patterns corresponding to or conceived as an information network consist of "designers", "processors" "senders", "carriers", "conduits" and "receivers" which may be human or machine and involve transfers of digitalised information between them. This complicates the pinpointing of responsibilities and liability risks. Moreover, information confers power in immediate interactions, in hierarchies inside networks and in hierarchies of networks which call for privacy, secrecy, codes, passwords, and firewalls. Ownable and lockable databases protected by firewalls are incompatible with the notion of open seamless webs. If digitalised information transferred by "IT" is prized as a commodity, the

battle over its control to negate its process aspects becomes a cost burden, as observed by the founder of cybernetics half a century ago in a seminal observation which holds true also today³⁴. This complexity points to the need for global governance to reap the maximum benefits of IT diffusion in healthcare.

There is a good case for competition policy harmonisation at the international level without which comparisons of role of IT on costs, prices, profits and volumes entail significant effects of subsidies in developed countries that protect competitivenes. TRIPS caters to this circumstance through the enabling Article 31 (k), relevant excerpts of which state:

"Members are not obliged to apply the conditions.....where such use is permitted to remedy a practice determined after judicial or administrative process to be anticompetitive"

Federally funded pharmaceutical inventions in U.S.A. subsidise about half of the American Pharmaceutical industry' s research costs with State-aid. Wherblind-alleys have been eliminated by the application of federal funds, gifts of drugs developed in the national institutes and laboratories are made to enable private capital to develop and commercialise the final product³⁵. Pharmaceutical companies' costs mainly consist of expenses to acquire patent rights, obtain FDA approval and preserve exclusive marketing rights. Universities pledge exclusive rights to the outcome of their government funded research to private firms in exchange for cash incentives and financing of buildings and laboratories as in the Wisconsin-Geron, Berkeley-Novartis, Washington-Pharmacia and Colorado-Ribozyme collaborations. These are about 130 such instances of co-operation in U.S.A. and cross-border collaborations of this nature are emerging outside America too in developed and developing countries³⁶.

³⁴ Wiener (1949,1950)

³⁵ Evidence of this is recorded in the Testimony of Ralph Nader and James Love before the Special Committee of the U.S. Senate on February 24, 1993 (<u>http://www.cptech.org/pharm/pryor.html</u>)

³⁶ Reinhardt (2001)

The reluctance of National Institutes of Health in U.S.A. to dilute intellectual property rights in commercial licenses to final products developed by firms through parallel licensing of therapeutic agents and compounds to WHO or some similar other global institution is understandable. The Bayh-Dole Act (P.L. 96-517, December 12, 1980) was aimed at enhancing American competitiveness, not healthcare and it need not come in the way of a global compact in the war against disease. Whether new public-private partnership initiatives of the kind envisaged by Sachs (2001) may circumvent this technicality, remains more uncertain than the continued existence of statutes (in U.S.A, Italy, Australia, Philippines, India, China, Malaysia, Singapore, New Zealand, Ireland, Switzerland and the U.K.) whereby governments may lawfully ignore patents if public interest requires them to do so. The situation is complicated further by the inviolability of independent justice systems to interpret national public interest when writs of mandamus are invoked against governments by individual citizens or in class action suits.

All kinds of services are marketed as "products". Whether they are regarded patentable or not could make a difference to market structures, intensity of competition, cost and price structures for such services and to incentives for pre-emptive patenting. The need to distinguish the exploitation of patents subsidised by State-aid from those that reflect investments in R & D by companies is important. It is not clear whether compulsory licensing is automatically hindered in the case of the former by the application of Article 5 of the Paris Convention for the Protection of Industrial Property (once three years have elapsed from the date of patent) and whether Article 28 of TRIPS would stand in the way of production for exports (the article only mentions import restrictions) as in EU' sdispute case against Canada at the WTO (WT/DS/114). In this situation, a patent looks less like a certificate of ownership and may at best be regarded as a ticket to litigation. A weak patent backed by a big firm is more effective than a strong patent held by

a small firm which cannot afford to defend it³⁷. Almost half of the litigated American patents (46 % to be precise) were invalidated by courts between 1990 and 1998. Pharma patents disputes have invariably required IT in the courtrooms too³⁸. Thus there is a need for policy convergence at the global level so that IT and IPR issues may be harmonised in the interests of trade and healthcare.

VIII The Evaluation If It's Impact

The role of IT in healthcare and its impact through services trade depend on three inter-related aspects:

- (1) power and reach of telematic connectivity which determines who would be included,
- (2) legitimacy of service providers seeking returns on investments, and,
- (3) structure of responsibilities for healthcare which are part of the governance frame in local and national jurisdictions.

Healthcare systems must perform at a "fair" cost to preserve and augment human capital which is impossible to arrange without cross-border trading in healthcare commodities and services and some degree of harmonisation of standards. From the preceding discussion, what consumers, service providers, insurers, governments would value by the criteria of choice, efficiency and costs is summarised in Table 3 below:

The five leading private patenters of human gene uses (Incyte Genomics, Human Genome Sciences, Celera Genomics, Hyseq and Millenium) are altogether estimated to have made about 27,500 patent applications and between them obtained 812 U.S. patents upto February 2001.

³⁸ To quote the Judge in the AZT case," The administrative complexity of conducting a trial of this magnitude has been enormous for the court and the parties. The sixty year old courtroom in New Bern, North Carolina has been converted into a high-tech facility using six computer-integrated video display monitors..."

HEALTHCARE STAKEHOLDERS	CRITERIA: CHOICE	CRITERIA: EFFICIENCY	CRITERIA: COST
CONSUMERS	DOES CHOICE OF HEALTHCARE COMMODITIES, SERVICES, FACILITIES EXPAND ?	COUNTERVAILING INSTITUTIONS ? QUALITY STANDARDS ? COMPETITION ?	PRICING ? SAFETY ? DATA PRIVACY?
SERVICES PROVIDERS	WHICH CROSS-BORDER NETWORKS ?	SYNERGY EFFECTS IN INNOVATION OF PRODUCTION AND DISTRIBUTION ?	REDUCED COSTS ON DEVELOPMENT AND DELIVERY?
INSURERS (firms, employers)	DATA-BASED CALCULUS FOR FINANCING ? CONSOLIDATION ?	SCALE EFFECTS ? CROSS-BORDER DELIVERY?	REDUCED COSTS ?. HEALTH MAINTENANCE ORGANISATIONS ? MORAL HAZARDS ? LEAKAGES ?
GOVERNMENTS	DESIGNING HEALTH SYSTEMS WITH NATIONAL/ GLOBAL SCOPE ?		BURDEN ON PUBLIC FINANCES ? TRADE BALANCE? INVESTMENT FLOWS ? HUMAN CAPITAL?

TABLE 3 STAKEHOLDER GOALS BY PERFORMANCE CRITERIA

Note: The design of healthcare products, healthcare systems and healthcare policies is influenced by motives, preferences and expectations of different stakeholders as above.

In Figure 1 above (with its 25 synoptic points of reference), the concerns of the various interest groups are noted. The rest of this section is concerned with analysing how IT would affect all the various interest-groups and their goals and preferences.

Doctors and patients benefit from the way IT enables records to be safely stored, efficiently retrieved easily updated and quickly transferred. IT promotes awareness. People easily obtain information concerning diseases, treatments and facilities. Discerning consumers get to understand their own responsibility as co-producers of their health, and to evaluate choices. Studies have established that small inputs of TeleHealth resources contributed to huge gains in access to healthcare for consumers in Bhutan, Ethiopia, Sri Lanka, South Africa, Argentina, Mozambique, Taiwan, Saudi Arabia, Thailand and Jordan ³⁹. The participation of individuals in networks as special interest groups where experiences are shared worldwide strengthen countervailing institutions through which patient's rights may be effectively asserted. Service providers respond to incentives to produce, trade, and link at competitive cost.

Investments in telematic capabilities can strain public finances but these would be justified where efficiency and equity gains enable returns on such investments through improved healthcare or reduced costs as attempted in Thailand, South Africa, Brazil, China, India, Srilanka and Mexico. The question of whether IT adds to costs or reduces costs could yield different answers depending on how this issue is examined.⁴⁰ If we focus on disease burdens and assess how use of IT affects cost per diagnosis or cost per treated illness, it would be important to factor in the quality and reliability dimension that IT brings to healthcare. The weightage to be assigned to quality is not easy to specify because the greater part of IT's contribution occurs in healthcare development and healthcare administration, not in healthcare delivery. Yet healthcare delivery which is directly experienced by patients is usually the starting point of cost-benefit analysis.

³⁹ Mandil (1998) presents the early international experience of how telehealth propels cross-border trade in health services.

⁴⁰ Fuchs and Sox (2001) present a physicians' perspective of the usefulness of thirty medical innovations facilitated by IT and Fox-Rushby, Mills and Walker (2001) propose cost-effectiveness league tables.

The calculus of costs is altered when IT enabled healthcare databases in genetically coded information of groups and communities (required by drug developers) are traded as a *quid pro quo* to access to healthcare or if tools of IT are used to optimise revenue models for services providers against consumer needs and interests. Questions of safety, privacy, data protection and public health that arise in such contexts were discussed in Section 6. Although these problems are universal in nature, it is necessary to develop safeguards for them particularly from the perspective of less developed countries where resource scarcity could render abuses and misuses harder to prevent or remedy. Costs to consumers in the form of what IT adds to prices of hospital care, outpatient care and prescription drugs or other costs in the form of loss of privacy and data protection would need to be addressed by policy measures in all situations where the demand side is poorly organised and public healthcare not well resourced.

The prospects of widespread use of IT in healthcare delivery in less developed countries ought to be viewed with caution. Policies would be needed to ensure that rural populations are able to afford costs long after short term pilot projects with external assistance are demonstrated to be feasible.⁴¹ The scope of IT in healthcare would also be constrained by infrastructure (electricity, telecom bandwidth, maintenance of equipment etc) and cost in less developed countries and substantial investments would be needed need to overcome this limitation. TeleHealth services supporting many forms of medical services including storage, retrieval and transmission of data and images would be very expensive. Specific targeting of applications which save time, transport costs and have high positive spillover effects may need to be prioritised. The labour intensity of health services is to the

⁴¹ IT has not been used for healthcare delivery to remote locations even in developed countries where advanced public health systems backed by welfare state guarantees are in place such as Finland, where such technologies are highly advanced and can be afforded privately as well as publicly. The remote Lapin Province of Northern Finland spanning the Northern latitudes between 67,25 (Sodankyla) and 69,52 (Utsjoki), has no hospital. Local health centres are understaffed by more than 60% of authorised strength. The reach of telemedicine from the nearest hospital in Rovaniemi cannot take care of any serious emergencies, maternity cases, or surgeries. All diagnostics requiring pathological tests or radiological scanning and any medical emergencies require patients to travel to Rovaniemi, involving road journeys of upto 15 hours from Utsjoki.In contrast, Norway, Scotland, and Russia introduced trade in telemedicine successfully. Tromso (Norway) and Archongelsk (Russia) are teleconnected with growing two-way trade..

advantage of developing countries which can promote trade while strengthening national health systems at the same time.

Diagnosis and treatment practices evolve from a complex mix of regulatory procedures, disease burden circumstances and the load on service providers. Many less developed countries lie in climatic zones that produce a wide range of infections from bacteria and viruses. It is difficult to expect convergence in medical practice in some diseases. It is doubtful that IT could significantly improve the diagnostic context for infectious diseases except to the extent of enabling quick second opinions, or transferring results of pathological tests. However, in applications like heart surgery, cancer treatments, immunisation procedures, use of diagnostic equipment in surgeries and in the provisioning and distribution of life-saving medicines, convergence is promoted by information flows. New epidemics of non-communicable diseases such as diabetes, cancer and heart disease spread faster with IT transmissible life-styles and consumption cultures according to researchers who point to "fragility of recent health gains" and emphasize the importance of prevention and public health surveillance in less developed countries where the rising burden of non-communicable diseases presents a double burden of disease⁴².

Healthcare spending is not promotable as a goal in itself and such spending, except in its preventive or prophylactic aspect, is unrelated to good health, a promotable goal. Secondly, healthcare spending is context-sensitive to the cost of diagnosis and treatment of specific illnesses which differ in propensity across countries and also regions within countries. International comparisons on the basis of spending per capita say nothing about how much of the health need was met and at what cost per diagnosis or what cost per treated illness.⁴³ Fairly detailed cost information on these lines would be needed to know whether IT has added to costs or reduced costs in relation to the burden of disease. Also, such data would require to be obtained consistently over a period of time to know how the cost changed. With

⁴² Brundtland (1999) and Beaglehole and Bonita,(2001) have drawn attention to the dilemma of the double burden of disease facing developing countries.

⁴³ Navarro (2000) and Rosen (2001) cite these benchmarks to question healthcare rankings in the World Health Report 2000.

reference to Figure 1, IT has raised the costs of drug discovery, increased efficiency and reduced costs in drug development and health diagnostics leaving choice largely unaffected, whereas in healthcare delivery, IT has increased choice and costs but efficiency gains are marginal and uncertain.

The real gain from connective IT technologies lies in the expansion of choice for diagnosis and cost-effective treatment of those communicable diseases and non-communicable conditions which are hard to diagnose or difficult to treat and for which gestation periods of treatment innovation may be shortened. The rising incidence of the non-communicable disease burden can be checked when data on risk factors in less developed countries is properly recorded with the help of IT and analysed (Beaglehole and Bonita, 2001).

Solutions for regions with a preponderance of communicable disease and low production and IT capacities would need to differ from regions where non-communicable diseases are the bigger menace and production capacities can be created to cope with this aided by a higher quality of IT penetration. The latter category would include Argentina, Brazil, China, India and Mexico. Problems with so-called "neglected diseases" are not the responsibility of any particular country nor attributable only to non-availability of medicines. The introduction of the TRIPS product patent regime may require firms in these countries to step up research and development activity or sell-out to foreign firms, independent of the resources of global funds for which they may compete.

IT has made marketisation of household production through home workers, call centres and backroom paperwork possible in ways previous studies could not anticipate but this has not improved the situation in most of the least developed countries.⁴⁴ There remain

⁴⁴ Reynolds' s "turning point" conjecture when intensive growth overtakes extensive growth (Reynolds, 1983) applied to a sample of 41 less developed countries, each with population over 10 million persons, shows that 7 countries in this sample could not reach the turning point mainly because of "remoteness" or "absence of infrastructure" or both. These seven are Afghanistan, Nepal, Ethiopia, Sudan, Zaire, Mozambique and Bangladesh. Two decades later the position on remoteness and infrastructure for these countries is not much improved.

more than 80 countries where it should now be possible to introduce trade based on IT's role in healthcare but IT presence is barely noticeable. The scale and sophistication of markets required for IT services to be domestically viable without cross-border trade are rarely present in least developed countries except for a limited range of business-to business and enterprise resource planning applications. Firm level data from the chemical, pharmaceutical, biotechnology, and bioinformatics industries in South Korea, China, Singapore and India suggests that joint venture subsidiaries with foreign majority control are associated with greater knowledge transfers and associated spillover effects consistent with the findings in earlier Moroccan and Venezuelan studies⁴⁵.

This brings pressure on governments to act on their obligations concerning public health and healthcare in a manner consistent with policies for trade, investment and development. The expansion of cross-border parallel trade in intermediate IT services and products where intellectual property rights are weak and the attempt to stop cross-border parallel trade in final pharmaceutical products are known to be at the core of this controversy.

The next generation of life saving medicines would come mainly from IT-induced advances in genomics and proteomics involving genetically modified microorganisms. The same knowledge can also be used to increase microbial virulence and to bioengineer microorganisms resistant to drugs and vaccines, which have new ways of spreading, can escape detection by the body's defence system, and if desired can also remain latent until triggered at some later time. While countries may find reasons or loopholes to deny patents for diagnostic, therapeutic, surgical methods, plants and animals, and biological processes for the production of plants and animals, the category "microorganisms and microbiological processes" cannot be denied patents.

In Section 6, it was noted that countries are vulnerable because databases of whole populations can be maintained privately to target specific populations or ethnic groups⁴⁶. This

⁴⁵ Haddad and Harrison (1993)

⁴⁶ The human genomes of the populations of Tonga, Estonia and Iceland have been bought and patented by private companies (<u>http://vector.cshl.org/eugenics.html</u>)

implies that for the first time in history, 'ethnic cleansing' and 'civil wars' can be started without conventional weapons. One of the dangers of the otherwise welcome public-private partnerships in the offing is the nature of license they provide to firms building databases by conducting long-distance large scale clinical trials in less developed countries which could have uses in eugenics or bioterrorism to their detriment if global health databases remain under private ownership or monopoly control ⁴⁷.

The Biological Weapons Convention (BWC) prohibits stocking any microorganisms unless they have therapeutic value. It is very difficult to establish usefulness before clinical trials are completed. The facilities to stock microorganisms and the rights to hold them are governed under the Budapest Treaty on Microorganisms and arise in the context of the Convention on Biological Diversity, 1992 (Biodiversity Treaty) which recognises the country of origin of genetic resources. Article 7(d) of the Biodiversity Treaty explicitly provides for maintaining and organising data with regard to conservation of life forms. Further, its Article 16(3) caters for developing countries to be provided access to biotechnology protected by patents. But U.S.A, the only country with access to all microorganisms is not a signatory to the Biodiversity Treaty, signed and ratified by 157 countries and has refused international inspections under the Biological Weapons Convention. International consensus is needed for global databases to be legitimately shared and for countries to adhere to international regimes. If legitimate access to biological information remains skewed, and without adequate international safeguards, the biological divide would grow and so would the risk of accidental or deliberate disease from the actions of terrorists and rogue States.

IT intensity has spread to investigative tools and procedures which can be patented before biotic matter has been probed. Also, genetic information is patentable as soon as its elements are identified even before its uses are found or functions decoded. This confers advance exclusive property rights on potential disease genes⁴⁸. The use of IT complicates

⁴⁷ 'Bioterrorism' is malevolent use of bacteria, viruses or toxins against people, animals and plants (NLM, 2000).

⁴⁸ U.S.A. banned frivolous patenting on January 12, 2001 because every protein molecule target is at least passable as an additive for hair shampoo and dog food, or more creatively as low-cholestorol cat food.

intellectual property rights in genetic material if DNA sequences of identified elements are treated as separate inventions, because any useful product is likely to cross boundaries of several patents⁴⁹. An international consensus needs to be evolved so that IPR issues do not slow down IT-intensive global medical research ⁵⁰.

If there is a consensus that TRIPS causes welfare losses of different magnitudes to different countries due to differences in nationally subsidised IT-intensity in healthcare,

either TRIPS could be renegotiated and modified, or supplemented by a scheme of international credits and debits to cater to the differential impact on costs and benefits for developing countries requiring differential treatment. This could take an innovative form, for instance in pooled funds for common causes under international regimes. TRIPS could also be left as it is but that could force WTO dispute panels of the future to re-write TRIPS and encourage countries to make their own national interpretations of it until then⁵¹. Questions about affordable medicines and the incentive for innovation require recognition of IT's role in healthcare and agreement on criteria for making the trade- off between static equity and dynamic efficiency.

IX Conclusions and Recommendations

What difference does IT make to worldwide production and trade of healthcare commodities and services ? This central question was examined by analysing the embeddedness of IT in development, delivery and administration of healthcare commodities and services in cross-border value chains of the international economy with the following conclusions and recommendations:

1. TeleHealth provides means by which the allocation of healthcare resources can be improved together with trade promotion. In linking individuals, groups, communities,

⁴⁹ Bobrow and Thomas, 2001 question the wisdom of granting patents before anyone including the patentholder has any clue to the therapeutic significance of what is sought to be protected.

⁵⁰ Barton (2001) also cautions against this danger.

⁵¹ A compromise introduced for least developed countries to kick-start the Doha Round in November 2001 absolves them of responsibilities under Sections 5 and 7 of Part II of TRIPS until 2016.

organisations and governments in complex value chains across borders, IT can play an important role in enabling the world's poor to access essential health products and services in innovative forms as discussed in Sections 2 and 3 of this paper. IT has promoted efficiency by enabling information to be available and cheaply distributed and improved the prospects for countervailing institutions to function for reasons detailed in Section 4. These benefits are observable in less developed countries too with IT diffusion. Information is a pre-requisite of good stewardship and IT enables governments to know what to regulate and how best making it less likely that commercial interests would claim precedence over people's health. More open information flows on deliveries and deliverables would set norms and standards and new forms of partnership between private, voluntary and public sectors could be created.

Old institutionalities like *Hisba*, *Ombudsman*, *Panchayat* could be revitalised as stewards in local communities or new ones built if even 5 % of total resources allocated to country specific projects were earmarked for investments in action-research to organise IT's role in efficient ways of delivery under local control. This will also help compare performances, conduct reasoned discourses on alternatives and provide feedbacks on much needed public-private partnership experimentation. Decentralised networks and IT reinforce each other whereas IT costs and risks require syndication and these two contrary tendencies pull in opposite directions. Investments in IT for healthcare could be treated as global public goods and financed internationally.

2. Telematic connectivity conferred by IT is easily diffused technically but structural impediments inhibit its diffusion in less developed countries. Since the new generation of healthcare commodities and services are IT-intensive and access to naturally occurring and mutated microorganisms highly skewed, the digital divide could aggravate the biopower divide. However, this could be mitigated by aligning financial means and bio-information needs of firms in developed countries with financial needs and information rationalised in developing countries through new global institutions and partnerships.

- **3.** The tension between efficiency and equity is at the core of how IT affects designs of trade in healthcare services in several important ways:
 - (a) in design of therapeutic products due to new ways of discovering, synthesising and testing drugs but incentives require to be structured for IT-intensity to be used for underfinanced neglected diseases;
 - (c) in design of networks where transfer pricing of value created at different locations and e-commerce are a crucial determinant of profitability and growth through cost control and differential pricing and can reduce response times for development, delivery and administration of healthcare;
 - (d) in design of healthcare systems where developing country governments struggle to build national health systems with strain on public finances while at the same time investing in telematic capabilities, IT and human capital for cross-border services trade in healthcare. Attention to the framework presented in Section 8 would call for policies that ensure that higher healthcare costs induced by IT are commensurate with benefits by spreading the costs.
- 4. Policy conflicts between health, trade and development goals over rights and interests require international regimes for distributed enterprising, particularly with regard to how biological resources are shared. The dissolution of traditional industry boundaries between pharmaceuticals, biotechnology and IT for life sciences has irreversibly transformed the contestable healthcare arena changing its scope from national to global. Cross-border trade in health-related IT services has attracted record amounts of FDI for healthcare development and healthcare administration but not as much for healthcare delivery. The scale and scope effects for industrial structures point to continuing consolidation and a reduction in the number of global players in healthcare businesses.

This poses new challenges to anti-trust legislation and competition policies which would need to be harmonised globally.

5. IT enables distance consultation and cross-referrals among professionals where density of

medical professionals is highly variable across urban and rural areas and the expertise of specialism difficult to replicate at every location. By promoting low cost distance interaction among groups for exchange of information, IT expands choices, enables more productive use of medical resources, and encourages innovations in cross-borde supply of services as detailed in Sections 2 to 4. Alternative forms of medical treatment such as *kampo*, *homeopathy*, *ayurveda*, *unani*, *acupuncture*, *herbal medicine* etc. would be more thoroughly scrutinised and facts separated from conjectures on the basis of information and experiences shared on websites and in internet discussion groups.

6. Digitalised connectivity has improved transparency, expanded choice and created new value chains for all concerned but its impact on costs of healthcare is unclear. This deserves to be researched further with respect to disease burdens, cost per diagnosis and cost per treatment for more clarity on policy perspectives. All the potential gains from the role of IT in healthcare in less developed countries are not yet visible in actual gains to date. This is partly because stewardship requirements in less developed countries are greater and different from developed countries and because IT is not a substitute for some of the critical factors contributing to healthcare such as safe drinking water, nutrition, hygiene and sanitation or poverty. The diffusion of IT to rural areas is also constrained by non-availability of electricity and the difficulties of maintaining computer equipment in dust-free and humidity-free settings. The positive impact of IT on healthcare exports, growth, and employment has to be weighed against resource diversions, depletions and strains on public finances. In countries where global networks present limited points of contact, the positive spillover effects for human capital and infrastructure are negligible. The reach and power conferred by IT does not translate easily into capacity creation. Not much can be concluded about motives and powerbases of those influencing policy without better clarity through more research and empirical analysis at disaggregated levels in specific developing countries and in specific kinds of IT applications among clusters of healthcare service providers and communities. The questions raised in Figure 1 of Section 8 constitute an ongoing research agenda. More research is needed to understand how market and non-market solutions proposed would actually work. Governments need to

encourage experimentation on syndication of risks across public systems and private enterprises through innovations in health insurance and IT investments for healthcare.

- 7. The use of IT has spawned and proliferated new fields of knowledge for profit in healthcare. These have prompted discussions on international collaborations (including public-private-voluntary inter-sectoral partnerships) for transnational governance of new risks for the bundling of product-services linkages as analysed in Section 5. The involuntary extraction of data from humans across borders requires a review of standards of privacy and data protection laws. Complex questions of personal data protection, privacy, remote liability and vicarious liability where national treatments are yet to be harmonised must remain on the research and policy agenda of the WHO. Considerable uncertainty remains about prospects for IT-enabled global databases concerning microorganisms from which the next generation of IT-assisted life-saving medicines would emerge. This poses health security hazards on an unprecedented scale, besides rendering TRIPS partially unimplementable. The normative aspects of digitalised transfers of data are not determined by IT alone and government scrutiny over such communications are constraints for the notion of seamless connectivity. The responsibility for healthcare and for IT is naturally global in certain respects. Global governance and public-private partnerships need to be designed to secure public health, human privacy, data integrity, intellectual property rights and telematic trade as discussed in Sections 6 to 8 of this paper.
- 8. Information and communication technologies now enable abusive experimentation to be undertaken *from a distance* in the twentyfirst century. The perversion of medical knowledge and skills towards involuntary, uninformed and coercive participation in trade of genetic material, expropriation of organs, biological experiments in eugenics, human safety and ergonomics, is very hard to prevent. In the twentieth century such experimentation occurred on minorities in a number of countries on a large scale. The greatest transformative impact of IT has arisen in robotics involving the design of expert systems approximating artificial intelligence with learning capability. IT systems, on the

basis of learning, could be making decisions not under the control of identifiable humans or collectivities of human agents and be communicating amongst themselves in languages not immediately intelligible even to their original programmers⁵². The solutions to introduce human supervision to mitigate this would further complicate issues of privacy and data protection⁵³. There are also implications for the law of extra-territorial liability and the doctrine of remoteness and international agreement would be needed to keep pace with differing national interpretations and avoid the pitfalls listed in Section 6 and analysed further in Sections 7 and 8.

9. Independent healthcare standards and regulations bodies are required for the establishment and interpretation of healthcare trade rules including dispute settlement. This could be a joint undertaking of WTO and WHO. Similar to the way fiscal domains provide for model codes and mutual convergence (for instance in the treatment of non-residents), international private and professional bodies or inter-governmental bilateral and multilateral mechanisms are needed to harmonise professional qualifications, curricula, standards and regulations concerning rights and obligations related to healthcare. Mutual recognition of healthcare systems and standardisation of data transfers and telematic platforms are also needed.

IT blurs the boundary between the real and the virtual world. A clarification of the *locus standi* principle in private and public law is required to enable foreign national, supranational or international regulatory authorities concerned in a healthcare matter to prosecute in national jurisdictions in matters arising from IT based healthcare development and healthcare delivery. Agreements/Protocols are required whether actions could be initiated where cause of action has arisen or where the party liable for the action is located involving some degree of joint regulation among treaty countries on identified sets of healthcare commitments. The need to create supranational judicial and executive authorities with powers to require bio-defaulters to be accountable to international control

⁵² Warwick (1998) and Aggarwal (1998) analyse the perils of unsupervised artificial intellligence applications.

⁵³ Perri 6 (1999, 2001) discusses the problems of human supervision over aertificial intelligence applications.

as has been done for genocide and war crimes, merits serious consideration. At the same time national extra-territoriality as in current U.S. trade laws would require to be circumscribed, supported by agreements on which flows may take place under what conditions and to what degree of openness and transparency. The danger that e-business standards could evolve to reflect the concerns only of developed countries must be countered through appropriate international regimes in IT consortia as well as WTO for reasons discussed in Sections 7 and 8.

10. A new international civil service of transferable regulators under international control of the WHO or UN as <u>health keepers</u> (like peace keepers) could be created to observe violations, share information, help develop policies, systems, actions for cooperation at national and international level and to announce early warning signals before complex health emergencies arise. The creation of international insurance markets against regulatory failure also deserves consideration. Health-keeping responsibilities could initially be limited to liberal democracies willing to subscribe to international codes of governance conduct and able to underwrite financial guarantees in favour of independent international bodies such as globally mandated healthbanks or healthfunds, with WHO facilitation. The same healthbanks could act as clearing houses for biobanks, other healthcare resources and IT-intensive databases held in public-private partnerships. Since IT standards are not made at the WTO or WHO, globalising the control of healthcare data sets could end the conflict between seamless connectivity and firewall solutions. Healthbanks could also fund the identification and disclosure of genetic information and microorganisms in the public domain with proper safeguards.

The imminent expansion of cross-border trade in health related IT and IT-related healthcare may or may not significantly alter the calculus of costs and benefits of saving or prolonging human life and alleviating suffering caused by diseases, accident-inducing hazards, ageing, improper nutrition, lack of hygiene, disability, humiliation and despair. The reasons for this uncertainty are traceable to the ways *responsibility* for healthcare, *authority* to design its value chains, and the *power* and *capacity* to organise its delivery

remain separate or come together. The challenging task of creating and resourcing new international institutions to overcome this uncertainty remains.

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