

# Strategies for solving wicked problems of true uncertainty: Tackling pandemics like Covid-19 (Version: April 13, 2020)

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### Strategies for solving wicked problems of true uncertainty: Tackling pandemics like Covid-19

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### Abstract

This paper has three objectives: first to locate Covid-19 as a 'wicked problem' characterized by 'true uncertainty' that challenges strategists and unrolls new research agenda; second, to examine the inter-disciplinary and multi-disciplinary dimensions of the endeavours to contain the pandemic that point to the need for new conversations beyond national boundaries; and thirdly to propose, based on interpretive pattern recognition methodologies, a five pronged approach for the immediate future after the lockdown. The study points to the need for further research on how epidemiological imperatives, disease burdens, economic adversities, civic community cohesions and political compulsions come together to resolve tensions between costs, efficiency and equity in formulating responses to emergencies.

Keywords: Covid-19, pandemics, strategies, wicked problems, true uncertainty

JEL Classification Codes: D23, D39, F02, I10, I28, K42

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### INTRODUCTION

On 14<sup>th</sup> April 2020 (tomorrow), India's 21-day lockdown to fight the Covid-19 pandemic is scheduled to end. China, South Korea, Singapore, Italy and Spain are also partially relaxing their lockdowns. Countries such as Sweden did not have any lockdown. Several States in the Union of India (West Bengal, Maharashtra, Punjab, Delhi and Puducherry) have announced extensions of the lockdown until the end of April. Some States may announce their respective decisions today or tomorrow and yet others may be waiting to follow the Central Government's new guidelines. Any decision to extend the lockdown nation-wide will have costs and consequences but it is one way forward of buying more time in the hope that the infection curve would flatten in two weeks giving more time for shoring up supply chains, providing for the poor, the vulnerable and the needy, and for enhancing medical preparedness. Are there other strategies to be discovered or designed? This paper concludes by flagging a five-pronged geographically decentralized approach for consideration for after the lockdown ends, whether tomorrow or after two more weeks as is rumoured, drawing attention to the complexities of the problems and noting the medium term and long term policy challenges.

Healthcare needs cannot be satisfied in most countries for the vast majority of their populations from within the prevailing structures of resource allocation. 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. There is inadequate awareness, that adversity anywhere affects prosperity everywhere. The enthusiasm for global convergence on healthcare policies has always been sparked when there have been pandemics like Ebola, HIV/AIDS, SARS, MERS, and now Covid-19 but gets dampened by differences in national regulations and comes bundled with efficiency, cost and equity considerations. Will commercial interests always claim priority over people's health?

### **WICKED PROBLEMS**

In strategy, the genre of what are termed 'wicked problems' are the most challenging because they require comprehensive simultaneous solutions to a basket of problems. If any problem were to be sequenced or prioritized or a solution applied to any of the problems in the set, the 'wicked problem' as a whole becomes more intractable. This is because some of the solutions could conflict with each other and the solution to one problem may aggravate one or more of the other problems. Hence 'wicked problems' can only be resolved fully or not at all. But there is at least a clear enough future. The strategy literature has known of 'wicked problems' as a genre since 1973 (Rittel and Webber, 1973). When resources are limited and responses are constrained, there is a temptation among economists to begin discussing inevitability of 'trade-offs'.

Recognising trade-offs is useful when the future is clear enough. When the future scenarios are few, finite and familiar, risks can be computed based on the laws of large numbers and possible outcomes can be ranked, often by invoking unmeasurable values based on ethical notions, social choice models, personal preferences and utilities. Even if the future scenarios were not clearly articulable as discrete options, there could be a range of choices that could be assumed. An example of this is the use of information and communication technologies (ICT) in healthcare for drug discovery and vaccine development which concern the long term.

### ICT IN HEALTHCARE DESIGN

In the post-genome era, the search for new therapies based on the study of genes and proteins linked to diseases caused an explosion in genetic data. ICT-enabled tools became indispensable for testing large portions of DNA and protein quickly. The new requirements of speed, economies of scale, standards, simulation and security rapidly transformed healthcare into an information-based science driven by ICT which is global in scope<sup>2</sup>. 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 ICT enabled. Trade in genomic databases involves high stakes ever since the human genome was decoded. The correspondence between the capacity of ICT and the economic use of ICT 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 ICT in healthcare

<sup>&</sup>lt;sup>2</sup> Poste (2001) presents a succinct analysis of how IT and healthcare industries intertwine globally.

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.

ICT has enabled doctors and paramedics to use diagnostic packages and decision-support 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 by tracking database searches patterns of physicians trying to diagnose from symptoms at the time of the outbreak of disease. Jormainen et. al (2001) explain how physicians' database searches can be a powerful tool for early detection of epidemics.

### TRUE UNCERTAINTY

If past patterns are not a reliable indicator or if the nature or scope or magnitude of a problem makes it impossible to forecast what may happen because the actors trying to solve a 'wicked problem' have different motivations, preferences and powerbases, we encounter 'true uncertainty'. None of the previous pandemics the world has experienced travelled so fast and so wide in so short a time. Covid-19 poses 'true uncertainty' different from the Level 4 uncertainty in the strategy literature called 'true ambiguity' which was limited to the difficulty of having to anticipate institutional changes (Courtney, Kirkland, and Viguerie, 1997). For example, structuring a commercial investment in a location at a time when the country risk and political risk were both likely to change because governance institutions were in a flux due to impending changes.

The challenge for strategists is to focus on understanding what lies in the intersections set of 'wicked problems' and problems characterized by 'true uncertainty'. Problems that would locate in this intersection-set are rare but this is not a null set historically. The Keynesian question, 'How to pay for the war?' (Keynes, 1940) arose in the context of 'Who shall survive?" (Moreno, 1934) and was precisely one such moment when a lot depended on what State actors would agree to do jointly and severally in the future and for the future. Often, humanity has turned away from doing anything about wicked problems because the costs and consequences

are incalculable, or the processes of engaging with them painful, unpleasant and politically unpalatable.

Let me mention just a few. Consider the stickiness to and also the departure from the Gold Standard (both decisions of Imperial Britain after each World War) and also Nixon's unilateral abandonment in 1971 of the American assurance of fixed parity of 35 dollars to an ounce of gold as a quid-pro quo to the world not creating an international reserve currency. When IC 814 was hijacked from Kathmandu, no country was willing to assist India in storming the aeroplane when it was on Indian soil or even in Dubai where US skymarshalls were present. And the Indian commandos waited for instructions to take action for hours, a short flight away. The five terrorists released in exchange for hostages were the very persons who masterminded the 9/11 attack barely two years later. Perpetrators of genocides like Pol Pot completely escaped justice because nobody, not even the UN, would touch this wicked problem (Pol Pot lived to the ripe old age of 72 and died in 1998). The problems of climate change and planet sustainability have failed to muster adequate inter-governmental support through the Convention on Biodiversity.

Micro-organisms constitute 20% of the mass of the planet. In 1995, the signatories to TRIPS at WTO agreed that intellectual property rights of private parties isolating or mutating microorganisms (viruses included) would be universally recognized in patents. Viruses in categories V-3, V-4 and V-5 are not held under international control and they can be patented or left unpatented. When patented, the specimen is held under the Budapest Treaty. There are very few countries that have technical capacity to hold or work with V-3, V-4 and V-5 viruses. In the whole of Western Europe, only Necker Institute in France and the Karolinska Institute in Sweden have V-3 capabilities and even they lack V-4 and V-5 capabilities. Only five countries are known to have V-4 and V-5 capabilities. The world has a nuclear non-proliferation treaty (with some nuclear countries outside it) but there is not even a figleaf of any biological germs non-proliferation and safeguards treaty. This is one of the biggest threats to peace in our times. There has been speculation ever since the Covid-19 outbreak whether the Covid-19 is a naturally occurring mutation or an engineered one that got accidentally leaked

and may keep mutating and spreading<sup>3</sup>. According to a study published in the Lancet, 14 of the first 41 Corona infected patients (including Patient Zero) had no connection with the Wuhan food market (Huang. et. Al, 2020; Boyle, 2020). Curiously, the only official V-4 facility in China is located in Wuhan. It is noteworthy that Francis Boyle is the American Law Professor who drafted the Biological Weapons Anti Terrorism Act of 1989 and that YouTube deleted Francis Boyle's statement from its site. There has also been speculation that the Coronavirus originated in Canada's only V-4 lab, the National Microbiology Laboratory circa 2012. <sup>4</sup>

This is hardly the time to believe or debunk conspiracy theories but it would be useful to remember that mutated microorganisms are capable of unleashing virulent infections and there are documented instances to the knowledge of the Government of India of such attacks on local populations in India in 1994. Countries are vulnerable because databases of whole populations can be maintained privately to target specific populations or ethnic groups<sup>5</sup>. 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 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 <sup>6</sup>.

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

<sup>&</sup>lt;sup>3</sup> https://www.siasat.com/covid-19-biowarfare-says-bioweapon-creator-dr-francis-boyle-1866058/

<sup>&</sup>lt;sup>4</sup> https://greatgameindia.com/coronavirus-bioweapon/

<sup>&</sup>lt;sup>5</sup> The human genomes of the populations of Tonga, Estonia and Iceland have been bought and patented by private companies (http://vector.cshl.org/eugenics.html)

<sup>&</sup>lt;sup>6</sup> 'Bioterrorism' is malevolent use of bacteria, viruses or toxins against people, animals and plants (NLM, 2000).

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.

### INTERPRETING THE PATTERNS

In India, according to the Government of India Ministry of Health data, about 230,000 COVID-19 tests would have been administered to people by midnight tomorrow night. This is based on the number of about 185,000 tests done until 11.4.2020 and a testing rate of about 15,000 per day this week. The cumulative number of positive Covid-19 cases confirmed to date was 9352 today and the number hospitalized was about 1650 excluding those recovered (979) and dead (324) leaving about 8050 active cases. There is some flattening out of the infection rate reported from Kerala, Madhya Pradesh and Telangana. There are various estimates made of how much reduction in the infection rate the lockdown has helped with. However, the lockdown was also marked by some planning deficiencies, unintended consequences and surprises. Assuming that everyone is learning from these experiences, let me only encapsulate what challenges remain.

The availability of personal protective gear to doctors, nurses and paramedics remains a challenge as does testing, tracing and treating in the 601 hospitals the government has so far organized with a bed capacity of over 100,000 (of which about 2000 only has been needed so far). There was inadequate attention and communication to vulnerable sections of the migrant worker population who were not informed of what the government was doing for them and what the government expected from them. Besides the police and local government officials, local community leaders have a role to play here without introducing party politics into it. The supply chain of perishable products took time to be secured and with the Rabi crop waiting to be harvested and brought to the market, there is a risk of food wastage and loss of income to

farmers. The reaching of essential supplies for people locked down or interned was slow, disrupted, unpredictable. There have been riots in Surat, Delhi, Bhiwandi etc. and clips of the police misbehaving with vendors, migrants, and other poor require confidence building measures among those most vulnerable. Attention is now also required to gradually and safely restore farming, manufacturing and services to shore up the economy. In the medium and long term other measures and policies and systems would also be needed.

Geographically, India could be configured into five kinds of zones, each designated by a colour for ease of identification and also to note the change in status with time:

Zone I (WHITE ZONE) States/Districts where there are zero active cases could go into a SHUT-IN area quarantine such that lockdown is completely lifted inside but going in and out of these States/districts such as Sikkim can be restricted for another 14 days.

Zone II (GREEN ZONE) States/territories/districts where the hospital system is strong and death rate has been low despite an infection rate and the infection curve is flattening, For example, Tamil Nadu, Kerala, Goa and Laddakh. In such States/territories/districts also there can be a lifting of the lockdown with sealing zones only for specific containment areas to be identified.

Zone III (PURPLE ZONE) States/Territories/Districts/Areas temporarily placed in this category where the situation is unclear where ingress and egress would have to be regulated with more testing.

Zone IV (ORANGE ZONE) Cluster Outbreak zones where containment efforts are continuing and situation is hovering between cluster outbreak and community transmission.

Zone V (RED ZONE) States like Maharashtra and areas like Dharavi where the peak has not been reached and the situation needs reviewing.

For each of these zones, the decentralized arrangements for supply chains, essential supplies, tracing, testing, and treating would have to be differently organized in a humane and efficient

manner. The critical challenge will be the reliability and speed with which COVID testkits are used because antibody testing can give false positives and also miss out until the 5th day of infection and would be useful only to track community level incidence. It is not clear why India has not imported the Roche PCR machines and kits and is relying mainly on Chinese imports with low reliability according to experts. Although Plasma Technology has not gone through full and extensive trial, based on application on small samples it is working and now Indian scientists in Delhi are already attempting it with ICMR approval. Hydroxylchloroquine and HIV anti-virals have also been tried in Rajasthan but there are also reservations about their use due to unpredictable side effects. Research with sub-populations would have to establish levels of vaccine doses and treatment doses.

### **MEDIUM TERM ISSUES**

The Government of India's response to the Covid-19 outbreak has its origins in the first measures undertaken by the Ministry of Health from January 8, 2020 onwards. Passenger flights from China and other Covid-19 countries were stopped and thermal screening of arriving passengers at all international terminals begun. But it is well known that thermal screening was never useful in any country even during the SARS pandemic. Canada had 48 deaths from cases of SARS arriving in Canada and none of them were detected even after 100% thermal screening. The shortfalls in preparation required for doctors and nurses and other administrative-medical and para-medical personnel, adequate stocks of personal protective equipment, test kits and instituting the system and pricing with subsidies, organizing for displaced personnel showed up how much healthcare had been neglected. Testing, Tracing and treatment facilities could have been organized more easily if there had been better provisioning, training and administrative procedures. These can be addressed in the medium term beyond the emergency ad hoc responses now made.

Supply chains of perishable commodities, cold chains, capacity for communicating and organizing deliveries of essential supplies, local radio, public announcements and community radio stations all require fresh thinking. The most revolutionary idea would be to acknowledge that creating entitlements from categories of deprived and disadvantaged groups by sectoral profiling or income profiling or caste profiling are all inferior to the country-wide creation of

'communities of habitat' with civic rights and responsibilities for all people who happen to be there for living or working or even visiting.

### LONG TERM MEASURES

The long-term policies would require attention to health care development, and to delivery. A Disability Adjusted Life Years (DALY) approach is needed to organize universal healthcare with understanding of how disease burdens of contagious diseases and non-communicable conditions should be driving allocation of healthcare resources and infrastructure. By revisiting the size, scope and responsibility of public sector and private sector institutions, efforts to build bridges of collaboration between them are required. For example, all hospitals of a city or town should have a system to pool blood plasma for diagnosis and treatments. Diagnostic services, immunization programmes, vaccine development, drug discovery, drug price control, pharmacy regulation and participation in international networks and collaborations for research, clinical trials, expertise development, biomaterials procurement functioning of the Medical Council of India, integration with AYUSH etc. are some of the issues that require long term policies and systemic investments. We also need to understand why India's ICT strengths have not played a big role in life sciences.

## WHY IS INDIA WEAK IN DRUG DISCOVERY AND VACCINE DEVELOPMENT DESPITE ICT

The greatest impact of ICT is on the way healthcare development is organised where the most significant transformative role of ICT 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. The drug discovery process in the new biotechnologies is ICT-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, 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 ICT-intensity in global trials where ICT-assisted screening reduces the scale of clinical trials as in the case of Genentech's Herceptin drug for breast cancer treatment<sup>7</sup>. Such developments increase ICT 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.

ICT enables many different forms of cross-border cooperation that can bring down the high costs of innovation from about \$ 500 million per medicinal drug developed to less than half of that while reducing the lead time of about twelve to fifteen years, on average, to less than five years in many cases. However, when it comes to clinical trials, developed countries and less developed countries present different horizons. Many developed countries pharma firms do human clinical trials in less developed countries such as India due to fewer restrictions and lower costs, officially and unofficially. Now comes the paradox. India does not allow animal-testing which precedes human clinical trials. This inhibits end-to-end value chains for new vaccine development or new drug development in India.

Moderna from Boston, USA and Gileard from San Francisco FO, USA are active in vaccine development. Moderna has a vaccine in a developmental stage based on miRNA and genes in Stage 2 clinical trials. But even if it were to clear Phase III, it will take at least 12 months for US FDA approval because it would be the first of its kind using human genome. Moreover, a robust delivery mechanism would have to be developed using GalNac. Innovassynth Technologies of India is among the three companies in the world who could supply GalNac bringing India prominently into the Covid-19 vaccine chain. Antibody-based vaccines are also

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).

under development by Glaxo Smith Kline and Johnson & Johnson. Scaling up after FDA approval would also pose challenges where India can play a part. However, the cost of these vaccines is likely to be prohibitive for general use in India, unless subsidized or placed under compulsory licensing. Gilead already has a vaccine for flu based on viral treatment which could be both cost effective and manufactured quickly on a large scale. Here is potential for an Indian partner to collaborate. Bharat Biotech and Seram Institute Pune who are also in vaccine development could be potential collaborators of foreign vaccine firms. In Japan, an anti-influenza treatment with Favipiravir has been introduced into clinical trials. Since Japan has an Indo-Japanese V-3 facility in Kolkata of the same level as India's other V-3 facility in Pune, this could also form part of a collaborative chain.

Firms syndicate risks in the design, development, production and distribution of healthcare products and services where profits are indicated. In communicable diseases, an important application of ICT 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 and this can be done also for viruses such as the Covid-19. Policies can ensure that developing countries have incentives to undertake ICT investments and participate in international networks and collaborations for drug discovery and development<sup>8</sup>.

The demand for increased ICT-intensity in healthcare development is stimulated by those who stand to gain from 'biopower' Databases designed by or on behalf of pharmaceutical firms, managed care enterprises and insurance agencies can become available to a large transient population of commercial subscribers. New information increases the number of target molecules at which drugs are aimed <sup>10</sup>. This reduces the cost of drug development if the

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The least developed countries had a reprieve from product patents (inapplicabilty of Sections 5 and 7 of Part II of TRIPS) until 2016 but their market size did not allow profitable investment in generic production by domestic or foreign investors without the possibility to export part of the output.

<sup>&</sup>lt;sup>9</sup> 'Biopower' refers to bio-information as an alternative means of domination, to territories or commodities.

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 ICT to map protein databases in the search for new medicines gave rise to the science of proteomics.

identified target molecules could be proved or disproved quickly<sup>11</sup>. The rate at which candidate molecules are disproved is presently twice the rate at which new candidate molecules are reported<sup>12</sup> Gene based approaches needs Deoxy and RNA amidites and there are firms in India such as Innovassynth Technologies that are part of international value chains.

### THE CHANGING NATURE OF BIOPHARMA INNOVATIONS

When a promising pharmaceutical compound is discovered, it is the norm to auction rights to its development. An obesity-related gene discovered by scientists at a University was auctioned for about \$ 20 million<sup>13</sup>. 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 antiarthritis compound and farmed out the job. In-licensing by firms for rights to development is regarded more profitable than out licensing 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 fifty five "blockbuster drugs" (each contributing to revenues exceeding \$ 500 million in a year), fourteen drugs were developed this way<sup>14</sup>. 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 ICT, biotechnology firms would not sell out their discoveries. ICT also enables large firms to target molecules through bigger networks and laboratories in situations where asset specificities and past human capital investments matter.

<sup>&</sup>lt;sup>11</sup> IBM was among the first companies to design and market a computer known as "Blue gene" for this specific purpose and diversify into lifesciences with an investment of about \$ 700 million. Since then, several big ICT firms have formed life science divisions. These include Compaq, HP, Motorola, Sun, Fujitsu and Hitachi. Also Bill Gates set up the Gates Foundation noticing the synergy between ICT and BT.

<sup>&</sup>lt;sup>12</sup> See Neil Holtzman, "Will the Human Genome project revolutionise medicine?" http://www.mhsource.com/pt

<sup>&</sup>lt;sup>13</sup> Aitken et. al, 2000

<sup>&</sup>lt;sup>14</sup> Aitken et.al, (2000).

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. 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.

### CONTAGIONS, TRIALS AND TREATMENTS

Aided by ICT, the success of Merck's Ivermectin 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 discourse. 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.

Failures experienced in drug donation programmes due to communication gaps could be easily remedied by ICT. ICT 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 Lancet. The downside of ICT is that it can promote disease management models bypassing medical expertise by conducting what is termed in medical parlance as "wallet biopsy" (scrutiny of the means to pay).

### NEED FOR GLOBAL GOVERNANCE

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 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 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. 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 ICT produces is easily commodified, much of the knowledge that IT-driven biotechnology incubates is tacit and not easily reducible as information. This is the reason life sciences R&D requires science parks and trustful networking anchored in a location.

ICT has enabled screening of people for susceptibility to diseases and also the targeting of new drugs to pre-defined genetic profiles. Policies would have to 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 and budgets.

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. Safeguards are needed to ensure that global solutions for market standardisation are not limited to a few players with greater access to healthcare or ICT resources.

ICT 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. ICT 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. Overconsumption of medical products and services is one of the leading causes of rising healthcare costs. A higher aggregate health expenditure or even health expenditure per capita does not necessarily imply better healthcare. 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.

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 jurisdictions<sup>15</sup>. 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.

The responsibilities for healthcare and ICT 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.

### FALSE TRICHOTOMY: HEALTH or GROWTH or TRADE

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 but are not determined by technology alone<sup>16</sup>. 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.

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)].

<sup>&</sup>lt;sup>16</sup> 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.

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 competitiveness. TRIPS cater 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 anti-competitive"

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. Federally funded pharmaceutical inventions in U.S.A. subsidise about half of the American Pharmaceutical industry's research costs with State-aid. When blind-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 product<sup>17</sup>. 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 countries<sup>18</sup>.

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

<sup>&</sup>lt;sup>17</sup> 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 (http://www.cptech.org/pharm/pryor.html)

<sup>18</sup> Reinhardt (2001)

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.

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 imminent<sup>19</sup>. An indirect recognition of this IT problem in healthcare comes from the plan made by over fifty pharmaceutical, biotech and ICT 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.

### DISTRIBUTED ENTERPRISING

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

<sup>19</sup> Poste (2000) analyses the costs and consequences of lack of convergence.

transferred by "ICT" is prized as a commodity, the battle over its control to negate its process aspects becomes a cost burden. This was observed by the founder of cybernetics half a century ago in his seminal work on human uses of human beings<sup>20</sup>. It is impossible to desire a universal solvent and a national or other proprietary container to hold that universal solvent. This complexity points to the need for global governance to reap the maximum benefits of IT diffusion in healthcare.

From the preceding discussion, what consumers, service providers, insurers, governments would value by the criteria of choice, efficiency and costs is summarised in Table 1 below (Mathur, 2003):

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<sup>&</sup>lt;sup>20</sup> Wiener (1949,1950)

### TABLE 1 STAKEHOLDER GOALS BY PERFORMANCE CRITERIA

HEALTHCARE STAKEHOLDERS	CRITERIA: CHOICE/EQUITY	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?	SIDE-EFFECTS/ SPILLOVERS ?  EQUITABLE NORMS ?	BURDEN ON PUBLIC FINANCES ? TRADE BALANCE? INVESTMENTS ? HUMAN CAPITAL?

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.

ICT 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 genes<sup>21</sup>. The use of IT complicates 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 patents<sup>22</sup>. An international consensus needs to be evolved so that IPR issues do not slow down IT-intensive global medical research <sup>23</sup>.

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 then<sup>24</sup>. 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.

<sup>&</sup>lt;sup>21</sup> U.S.A. banned frivolous patenting 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.

<sup>&</sup>lt;sup>22</sup> Bobrow and Thomas, 2001 question the wisdom of granting patents before anyone including the patent-holder has any clue to the therapeutic significance of what is sought to be protected.

<sup>&</sup>lt;sup>23</sup> Barton (2001) also cautions against this danger.

<sup>&</sup>lt;sup>24</sup> 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..

### **CONCLUSIONS**

1. The immediate problem of tiding over the Covid-19 pandemic requires a five pronged approach after the lockdown. There is a need to distinguish populations geographically by separating, isolating territories based on where normal life can be gradually restored with safeguards as white zones from others, the green zones, where clearly more time is needed to let the infection curve flatten out from yet others where the death to infection ratio can be used as a proxy indicator of medical infrastructure and readiness. Hotspots where the risk is greatest require to continue as red zones with more lockdown and close attention not only to tracing, testing and treating but also to reaching essential supplies to people in these containment spaces. The areas where the status is of cluster outbreak with risk of community contagion would have to be orange zones. Where there is doubt, it should be declared a purple zone as a transitional classification. More nuanced analysis based on patient profiles with respect to pre-morbidity indicators, age and susceptibility would sharpen the analysis to determine in which zone a particular locality, region, district and State should be placed. For each of the five zones recommended, a different operational and tactical set of guidelines would be needed.

- 2. In the medium term, policy choices would 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 have failed to strike a harmonious balance between these sets of rights.
- 3. In the long term, the persistence of unresolved conflicts of rights and conflicts of interests within and among countries point to the need for new international arrangements to be mandated and resourced and existing institutions to be bolstered. 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, services and systems, and the *power* to organise healthcare delivery remain separate or come together. The restructuring of private investments to integrate ICT with life sciences in public-private partnerships is a sign of the growing significance of how powerfully resources and responses can be harnessed.

4. However, ICT also enables abusive experimentation to be undertaken *from a distance* in the twenty-first 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 programmers<sup>25</sup>. The solutions to introduce human supervision to mitigate this would further complicate issues of privacy and data protection<sup>26</sup>. 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.

- 5. Independent healthcare standards and regulatory 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. Since a pandemic like Covid-19 also affects the future of work, this is a great opportunity for ILO and WHO (both have their headquarters right next to each other in Geneva) to collaborate. 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.
- 6. 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

<sup>&</sup>lt;sup>25</sup> Warwick (1998) and Aggarwal (1998) analyse the perils of unsupervised artificial intellligence applications.

<sup>&</sup>lt;sup>26</sup> Perri 6 (1999, 2001) discusses the problems of human supervision over aertificial intelligence applications.

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 health banks or health funds, with WHO facilitation. The same health banks 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.

- 7. The demands of the Covid-19 emergency and the demands of private consumption will need balancing. Nobody can be certain of when the health crisis would end and when the economic and social crises left behind would heal. To paraphrase Keynes (1940), the best way to be secure would be to plan for a long endurance. Social justice may require sacrifices by the rich and prosperous. Taxes, borrowing and new creative financial instruments would have to finance public expenditures and compensate somewhat for lost private consumption of the poor and vulnerable. Compulsory savings schemes of the kind experienced in the past can be reintroduced. Voluntary savings can be encouraged too. It may be time also to introduce a fiscal domain for local governments, municipalities and panchayats to have the possibility of investing in soladaristic community building with which communities of habitat can identify.
- 8. The imminent Covid-19 crisis is an opportunity but overloading it with unrealistic expectations would be unreasonable. It cannot solve all the problems of the world or even alter the calculus of costs and benefits of saving or prolonging human life and alleviating suffering caused by poverty, migratory distress, refugee displacement, 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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