Introduction

The Coronavirus disease 2019 (COVID 19) pandemic has posed fresh challenges pertaining to the prevention, control and management of infectious diseases in the medical innovation landscape all over the world. Although the emergence and resurgence of communicable diseases have been serious health concerns, especially for poor regions and populations across the globe, these diseases did not receive adequate attention in medical innovations due to various political economy reasons and their confinement to limited (poor) regions. For instance, we have seen outbreaks of Ebola haemorrhagic fever in African countries, cholera in African and Asian countries, dengue haemorrhagic fever in India and other South Asian countries, Japanese encephalitis in India and Nepal, and influenza and malaria in African and South Asian countries in the recent past that perhaps did not receive sufficient attention of the vaccine, drug or medical equipment industry. Similarly, the worldwide severe acute respiratory syndrome (SARS) outbreak in 2002 and the Zika virus epidemic in 2016 also did not significantly change the priorities of medical innovations, which are mostly concerned with non-communicable diseases. However, the COVID 19 pandemic has exposed the lack of preparedness to emerging communicable disease problems across the world and compelled us to revisit the threat of communicable diseases in a globalised world since the infection changed the prevailing risk perceptions by crossing the binaries of rich and poor and exposing the entire humanity to infection. The COVID 19 pandemic thus poses certain questions on the epistemological base of the present organisation of medical innovation, which is built around the principles of techno-scientific capitalism and setting of priorities in medical innovation. This book attempts to discuss the mismatch between public health priorities and medical innovations which can have implications for the health of the global population in the future.
The last four decades have witnessed several path-breaking innovations in healthcare, particularly in drugs, vaccines and medical technologies. Advancements made in the research in health and life sciences across the world have played a conspicuous role in medical innovations. The proliferation of biotechnology and its associated streams of biomedicine, bioinformatics, genomics and advancements made in the field of synthetic biology have widened the scope of medical innovations to the next level. The competitive market regime, product patent protection and the facilitating policy environments in several countries for entrepreneurial research, especially for the patenting of publicly funded research outputs and the academia–industry collaborations, have indeed contributed to this new wave of biomedical research in many parts of the world. One of the major developments in the course of these changes and advancements in healthcare research and development (R&D) was the near complete dominance of the private sector and the emergence of venture capital as the most important players in health research funding. Along with these developments, there has been a sharp decline in the share of public funding in health R&D except for the research on neglected diseases, which is usually carried out through health departments, universities and research institutes.

Needless to say, innovations in healthcare have substantially contributed to the control, cure and management of diseases. Laal (2012: 471) listed out drugs including penicillin, aspirin, insulin, oral contraceptive, vaccination, statins, smart pill and Viagra in the group of innovative drugs; technologies including electrocardiography, X-ray, nano-healing, electric health records, laser surgery, MRI (magnetic resonance imaging), ultrasound, organ transplant; and devices including artificial hearts, robotic catheter, handheld medical scanner, bone injector drill, dialysis machine, lens implants, artificial joints and skin antennas as the major medical innovations. It is true that the human genome discoveries have opened up enormous possibilities in medical science. The human genome project has opened up what scholars noted as the ‘post genomic era’ that expanded the scope of medical innovation in personalised medicine, risk prediction and its management. Similarly, stem cell research, targeted therapies for cancer and combinational drug therapy for HIV (human immunodeficiency virus) survival were also significant innovations in healthcare. For instance, institutions such as the Harvard Medical School did pioneering research
in the areas of cancer diagnosis and therapy, vaccines for diphtheria, causative features of Alzheimer’s disease and its treatment, multiple organ replanting, identification of pathway linked to cartilage deterioration and bone attrition of rheumatoid arthritis, prediction of the chances of heart diseases, production of functional blood cells for the growth and regenerative therapy of skin and several internal organs, vaccines for herpes that stimulate the immune system from inside host cells, DNA-sequencing technologies for risk prediction of certain diseases, new cancer drugs targeting proteins that support survival of cancer cells, risk prediction of kidney failure in diabetic patients, RNA signature pathogens to determine best treatment options for infectious diseases, identification of a substance that thickens heart muscles often leading to heart failure, potential new therapies for osteoporosis, and vaccines to protect transmission of Zika virus from animals to humans, to list a major few.¹

Such laboratory researches have contributed immensely to drug, vaccine and medical technology development through successful academia–industry collaborations. However, the increasing thrust of academia–industry collaborations in medical innovations and the rigorous commercialisation of innovations raise several crucial public health questions as well. Who decides the priorities of innovation and what are the considerations that go into the disease/health focus and target groups of these innovations? Do these innovations really add value to healthcare? Who are the beneficiaries of these innovations? Does it lead to social inequalities? Do such technologies lead to medicalisation/pharmaceuticalisation and, if so, who bears the burden more? What are the new discourses of health that these technologies bring in?

Fuchs and Sox (2001) identified thirty major innovations in the recent past from the original articles published in the Journal of the American Medical Association and the New England Journal of Medicine as part of their study on the views of practitioners on medical innovations. Practitioners who participated in the study considered MRI and computed tomographic (CT) scanning, ACE (angiotensin-converting enzyme) inhibitors, balloon angioplasty, statins and mammography as the major five innovations in terms of their usefulness. The least significant five innovations for them

were bone marrow transplant, non-sedating antihistamines, sildenafil (Viagra), IV-conscious sedation and calcium channel blockers. These rankings may be questionable since they are conducted in a particular healthscape and are largely based on the experiences and perceptions of practitioners; however, the significance of the larger questions on the public-health relevance of medical innovations remains. Apart from the questions of their usefulness and probable contributions to population health, innovations in pharmaceutical and biopharmaceutical sectors across the world generated considerable scholarly attention for several reasons. Scholarly engagement on medical innovations dealt with a wide range of issues including their epistemological shifts, political economy, co-production and implications on access, affordability and the medicalisation of body and society (see Waldby 2002; Rose 2007; Clarke et al. 2009; Cooper 2011; Birch and Tyfield 2013). Among others, one of the compelling analyses was on the well-established interconnectedness of science and technology and capitalism (Levins and Lewontin 1985). Singer (1992) elaborated the observations of Levins and Lewontin (1985) on the interconnectedness between science and capitalism which is quoted here

… by the mid-point of the 20th century, science itself had become a commodity on a massive scale with the following characteristics: (1) research has become a business investment; (2) scientific discovery has become quantifiable (enabling an estimation of associated costs and benefits of investment and economically based investment decisions); (3) scientists have become ‘scientific personnel’ with associated proletarianization, loss of control and rational management; and (4) scientific labour must itself be produced, with the expectation that university training must be cost efficient. (Singer 1992: 400)

The commodification of science has also led to setting the priorities of research on a large scale as ‘research itself has become a business investment’ (Levins and Lewontin 1985). There is a growing literature on the political economy as well as bio-political economy of medical innovations in general and biomedical technology and life sciences in particular and the way through which such technologies can lead to patient–customer subjectification in advanced capitalistic societies. Waldby
(2002) by introducing the concept of biovalue attempted to understand the linkages between biotechnology, life science and capitalism, drawing from both Marxian notions of value and Michel Foucault’s concept of biopolitics. The linkage of modern day capitalism and biomedical research and innovations in healthcare was extended by Rajan (2006) in his work on biocapital and the constitution of post genomic life by carefully invoking the Marxian political economy and Foucault’s concepts of biopower and biopolitics together. He illustrated how the new knowledge base of medical innovations triggered by the advancements made in biomedical research and new technology develops a technocapitalistic paradigm of healthcare, which tends to shift the notions of health to risk management and simultaneously construct a new genre of patient–consumer subjects, which he called the ‘patients-in-waiting’. He attributed it to the ‘co-production of the market, state, and technology with their strategies, agents and policy institutions’. Birch and Tyfield (2013), however, did not view concepts such as biovalue, biocapital and biopower as something not entirely different from the Marxist framework of value of labour. They argued that biovalue is nothing but knowledge value, which is produced or co-produced, exchanged and circulated with several processes and institutions. Hence, for them ‘there is nothing intrinsically valuable or capitalist about natural or biological materials without a number of supporting economic and extra economic processes and institutions’ (Birch and Tyfield 2013: 313).

Despite this disagreement on the formulations of ‘bioconcepts’ they also recognised the power of the (bio)knowledge economy to shift the social determinstic model of health and well-being to biomedical reductionism and individualised care.

Several studies attempted to understand the epistemic shift that the technocapitalistic biomedical paradigm brings about in the domain of health as well as the nature of capital and its strategies of circulation, co-production, accumulation and subjectification of patients/consumers (Jasanoff 2004; Rose 2007; Clarke et al. 2009; Cooper 2011; Birch and Tyfield 2013; Strasser 2014; Rajan 2017; Stevens and Newman 2019). Rose (2007), invoking the concept of biopolitics, elaborated how biomedical epistemologies project a ‘molecular self’, which ensembles body as a collection of several parts and micro cells that could be viewed and approached separately. He argues that the epistemological base of biomedicine is nothing but biomedical reductionism, which essentially
endeavours to shift the ‘corporeal self’ to ‘molecular self’. This molecular view of self opens possibilities for a wide landscape of innovations that can customise bodily appearances, redefine normalcy, medicalise body, predict risks and manage risks. Clarke et al. (2009) argued that the advancements in the ‘technoscientific innovation’, organisation and practice of biomedicine led to the ‘biomedicalisation’ of society in countries such as the United States (US). They explained the processes of biomedicalisation in the US and the epistemological shift that has come along with biomedicalisation and the processes through which it got consolidated, hegemonised and legitimised in the US. The increased focus on health risk and surveillance in the biomedical paradigm shifted the approach of healthcare to ‘treatment of risk’, which for them (Clarke et al. 2009) commodifies health and lifestyles. It also led to customisation of health with the focus on individualised medicines and technologies. The coming up of biomedical organisations, privatisation of research projects and the university–industry collaborations, technologies to zero in on to individualised traits and division of the population based on such attributes were also part of the processes of biomedicalisation (Clarke et al. 2009) that opened up the commercial frontiers of this discipline. They also explained the processes of ‘technoscientisation of biomedicine’ with the help of bioengineering, nanoscience, bioinformatics, genetic engineering, and so on. Another integral part of biomedicalisation is its normalisation and legitimisation with the proliferation of knowledge and information on the possibilities of biomedicine to the masses through various channels of communication. The latest contribution of medical sociology and anthropology, which attempted to expand our knowledge on the linkages of technology, capitalism and social control, is ‘pharmaceuticalisation’ (Abraham 2010; Williams et al. 2011). The concept of pharmaceuticalisation is invoked in medical sociology literature to explain the expansive efforts of pharmaceutical companies through the network of state, private institutions, media and other influential agencies. William et al. (2011) explained the major processes of pharmaceuticalisation such as ‘reconfiguration of health problems as pharmaceutical solutions, mobilisation of patients or consumer groups around drugs, the use of drugs for non-medical purposes and the creation of new consumer markets and drug innovation and colonisation of health futures’, among others.
For Cooper (2011) the epistemological shift that biomedicine and *biocapitalism* strive to bring in the notions of health is its technological innateness which sees ‘life as a technological creation’. Using a Marxist political economy framework, she discussed the knowledge base, processes and actors behind the emergence of *biocapitalism* with the biotechnology revolution, its nature, reproduction and accumulative powers. She has illustrated how value creation and circulation happen in the life sciences with the integration of the latter into speculative markets and translation into marketable commodities.

In short, there is a general agreement that global health research views health as a technical response to disease instead of contextualising health within a social context. Thus global health research is involved in biomedical research that focuses on technological innovation rather than always directing research and policies towards the health needs of the population. This emphasis highlights the change in social relations and the behaviour of the state, business and people at large.

**Medical innovations and public health priorities**

Public health priorities of medical innovations have been a critical question in the scholarship of science and technology. It is already illustrated that infectious diseases are less prioritised in health R&D worldwide (Viergever 2013; George et al. 2018). The Global Observatory on Health R&D of the World Health Organization (WHO) provides the recent trend in global health R&D and innovation. The WHO Global Observatory data show that only 13 per cent of the global ongoing clinical trials are for communicable diseases (see Figure I.1). Data on R&D funding for neglected diseases provided by G-Finder (https://www.policycuresresearch.org) show that the major part of the funding for infectious diseases comes from the public sector, bilateral institutions and philanthropies. As per these data, the private sector contributed only 16 per cent of the global funding for neglected diseases of which the major part of the investments was from multinational companies. The data further show that HIV/AIDS (human immunodeficiency virus/acquired immunodeficiency syndrome) received nearly 35 per cent of global funding for neglected diseases in 2017. Within that 56 per cent was for the research on developing preventive vaccines of HIV.
Malaria and tuberculosis received 17 per cent and diarrhoeal diseases received 5 per cent of the total funds.

Nearly 72 per cent of the ongoing clinical trials are for non-communicable diseases (NCDs) (see Figure I.1). Within NCDs there is an added focus on oncology R&D worldwide which does not match the public health need of many countries including India where cardiovascular diseases (CVDs) were the major causes of morbidity and mortality among NCDs (Dandona et al. 2017; Milne and Katin 2019). For instance, the data on registered clinical trials across the world available on the WHO Global Observatory show that out of the 175,848 registered clinical trials as of January 2019, nearly 37 per cent were for oncology (see data for different types of cancers given in Figure I.2). CVDs, on the other hand, constituted only 9 per cent of the global clinical trial. The WHO data also show that the preventive focus of global healthcare R&D is too little. For instance, the data show that nearly 92 per cent of the ongoing global R&D was for drug development whereas the share of vaccines was nearly 6 per cent (see Figure I.3). The regional distribution of global healthcare R&D is also important in this context to understand the priorities of healthcare R&D. As it is clear from Figure I.4, Europe and North America together dominate the R&D innovations in healthcare with a share of nearly 59 per cent. Across countries, the US dominates with a share of nearly 23 per cent of the global ongoing R&D, followed by Japan (7.8 per cent), China (6.6 per cent), Germany (6.5 per cent) and United Kingdom (UK) (6.1 per cent).

Figure I.1 Number of products in pipeline by health category

Source: WHO Global Observatory on Health R&D (data as of January 2019).
Figure I.2  Global clinical trial by disease or condition

Source: WHO Global Observatory on Health R&D (data as of January 2019).

Figure I.3  Type of health products in the pipeline from discovery to market launch for all diseases

Source: WHO Global Observatory on Health R&D (data as of January 2019).
Health R&D in India

The pharmaceutical/biopharmaceutical sector is one of the fastest growing industrial segments in India. The structure and the composition of the industry since independence have changed over the years. As already well known, the structure of this industry in post-independence India has changed significantly, especially with the introduction of the Patents Act of 1970 which helped the industry develop into a strong generic manufacturer through the reverse engineering process. The composition of the industry was mainly foreign owned and controlled until 1970 (Joseph 2016). The Patents Act of 1970 changed this composition and led to the formation of a large generics industry in India and the structure further underwent a change in 1990, which is largely attributed to the World Trade Organization (WTO) agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) (Joseph 2012). The post-product intellectual property rights (IPR) regime, however, has taken away this significant advantage that India had. The policy reforms placed the Indian

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2 For a discussion, see Grace (2004), Dhar and Gopakumar (2011) and Mondal and Pingali (2017).