

State of Finance in India Report

2021-22

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ACKNOWLEDGEMENT

We are happy to present the first edition of the State of Finance in India Report which comes after our struggles against the multiple waves of COVID-19 in the past two years. The pandemic also laid bare many pressing matters in the economic landscape of the country that we attempted to address as we reshaped the edition to unravel those questions.

We are grateful to our authors who were able to contribute to the edition despite the constraints of their time and the immediacies of the health emergency. We thank them for their patience and also apologise for the delay that the many phases and faces of the pandemic forced upon us.

We are also grateful towards our publisher, Yoda Press for bringing this together with rigour and grace and materialising this. We particularly thank Arpita Das, Ishita Gupta and Chitraksh Ashray for navigating the course towards the publication.

We would also like to thank [Anirban Bhattacharya](#) who coordinated this edition, helping in conceptualising the Report, patiently following up with each author at all stages, as well as liaising with Yoda Press.

INTRODUCTION

Economic development is actively influenced and informed by the reforms and regenerations in financial systems. India is no exception to this. The economic narrative of India is integrally linked to the hyper financialisation of the global economy and the unbridled growth of its prime movers, namely, the financial institutions, actors and markets. While the basic tenets of the global economic order still affirm allegiance to principles like shared welfare, synchronised stability and universal environmental sustainability, the emerging economies like India are fast plummeting into a neo-liberal crisis, manifested best in its financial instability and unequal living standards. This makes it important to deliberate and debate on the role played by finance in the economic development of India as only a systematised financial model can promote sustainable economic growth in the country by bolstering actual investments in constructive capital generation.

It is essential in these times to think through the kind of authority wielded by the global and local financial markets over the economic ecosystem of India to be able to analyse the (non) prioritisation of equitable growth and distributional goals in the country that could have ensured the majority a respectable living standard. The economic

experiences of India, like many other emerging economies, have been shaped and reshaped by the permutations and combinations of financial flows within the international markets and across borders. Both the rise in the flow of capital during the good times and the sudden reversals of the demanding times have had deep seated repercussions on the developmental patterns of the country; along with pushing the country in to an arena of international competition by opening up the indigenous financial markets to global reach, the globalisation of finances has also engineered financial crises in India, thereby threatening the survival of a vast majority within a highly disproportionate financial ecosystem.

The State of Finance in India Report 2021–22 seeks to initiate a dialogue on the effect and influence of financialisation and policy changes on the economic growth of India wherein the leverage of private capital has soared substantially over the years in comparison to the bargaining power of labour. Such a state of affairs has undoubtedly placed the concept and intent of “growth” in India at the mercy of imprudent resource extraction and heightened energy consumption, thereby widening the gap between the rich and the poor in the country. The report also seeks to demystify the world of finance by demonstrating the very

concept of finance as the driving force that steers development models in the country.

Towards that end, the report is a first of its kind that expands the domain of finance and economics beyond the confines of ivory tower experts and invites writings from a cross section of academics, policy makers, activists, social practitioners and of course eminent economists who engage with the questions from ground. Given that finance and money touch and shape our lives in more ways than one, this ensemble of authorship gives the report a certain multidimensional character that allows us to explore the concerns of the day in a much broader as also deeper sense. Wearing a critical, alternative and bottom-up lens while looking at finance and economy, the compilation stands out as it gives us an opportunity to critique the mainstream/dominant view in a language and form (each piece is no more than 2500 words on average) that is accessible to a larger audience. The report is a result of the combined efforts of Centre for Financial Accountability, the Economic Research Foundation and Focus on Global South. The editorial board comprises C. P. Chandrashekhar, Jayati Ghosh, Shalmali Guttal, Nitin Sethi, Joe Athialy, Bhargavi Rao and Benny Kuruvilla.

This, the first edition of the State of Finance in India report, comes at a juncture when the people and the economy are still in the long shadow of the pandemic. The viral waves in fact also played a role in interrupting the process of compilation of the report. The theme in focus in this edition is in fact The Viral Waves and the Aftermath. The shelf-life of news these days is such that public discourse has “moved on” from even the biggest humanitarian crisis of recent history, and with that we have forsaken, rather squandered, the opportunity to take the right lessons from the crisis for a more resilient future. As such, this edition gives us the right amount of distance from the peak

of the tragedy to take a holistic view of the fractures and failures that precipitated the crisis and the misplaced priorities of the public finance that we witness. Some of the key learnings (or unlearnings) that emerged in the aftermath of the pandemic were in the areas of the dismal public health, the digital divide in education, the vulnerable informal sector, and the importance of deepened social protection and universal rights. The analysis in the sections also attempts to unravel the particular vulnerabilities of the marginalised sections in terms of caste, tribe, gender and minorities. Under “In Focus”, we have authors contributing to all of the above with insights from the ground giving us a sense of the urgent relook needed at our public finance.

The theme “In Focus” would change every year, the next edition being on Climate Finance. But this is followed by a second segment called Sectoral Overview. Herein the attempt would be to highlight from a critical point of view of finance and economy, the developments at the given point in time across a broad stroke of sectors. There would be some sectors that we would like to cover in each of our editions, namely, banking, agriculture, infrastructure, energy, labour, health, education, social security, marginalised sections and international finance. Commentaries highlighting and analysing specific aspects of the developments under these segments may give a reader a quick grasp over the present contentions in the sector from a people’s perspective. Over and above in some of the editions we would also try to cover at least a few from among the areas of taxation, fintech, defense, share market, climate concerns, commons and local governance.

The lead article in every edition would be a bird’s eye view of Indian finance written by the editors. In this edition Prof Jayati Ghosh and Prof C. P. Chandrasekhar wrote this overview of the

state of finance in India by locating the present exigencies and crisis within broader adherence to the neoliberal macro-economic trends set in motion since the last three decades that have contributed towards rendering the Indian financial sector extremely vulnerable and fragile.

Because questions around finance touch almost every aspect of our lives and future, we believe it should not be treated as a domain left to the experts alone. We need participative deliberations and

debates about the financial choices being made on our behalf. At a time when fundamental economic issues are either obscured or are distorted or simply drowned under loud rhetoric which is far from ground reality, there is a need to carry on with our interventions, our discussions and keep building spaces that can hold critical thinking on the myriad ways in which the very character of finance, its ebbs and flows are shaping the lives of millions in this country. *The State of Finance in India* is a small effort towards that direction.

A BIRD'S-EYE VIEW OF INDIAN FINANCE

C. P. Chandrasekhar and Jayati Ghosh

The period of COVID-19 pandemic has been devastating for the people of India and for the Indian economy. The pandemic brutally exposed and exacerbated existing inequalities of class, occupation, gender, caste and region. It also brought into sharp relief the major flaws in the country's recent development trajectory, which had resulted in falling investment and stagnating mass consumption demand, falling employment, poor human development indicators and persistence of extensive undernutrition. While much of this was the result of the accumulation of past economic policies and processes, various government policy actions over this period affecting both finance and the real economy did little to alleviate these problems; rather, prior problems were aggravated by state policy and acts of both commission and omission.

This year's report traces how these processes played out in terms of macroeconomic and sectoral trends and their impacts on different sections of people. In this introductory chapter, we provide a brief appraisal of financial policies in India, relating to both financial intermediation and public finance.

THE FINANCIAL SYSTEM AND POLICIES

As 2021 drew to a close, there was a sense that the Indian financial system was at a tipping point.

The structure moulded with policy initiatives beginning at Independence and culminating in bank nationalisation in 1969 was not only under strain but well under way to being dismantled by a neoliberal state. The Independence-to-nationalisation policy journey had put in place a structure that, until the 1990s, successfully mobilised a dominant share of the nation's financial savings, allocated it in ways that ensured that the distribution of credit across sectors and segments of the population became progressively broad-based and inclusive, and regulated financial institutions in ways that ensured relative stability. The financial framework was a central instrument of the state's development policy. A crucial component of this was that it built and relied on diverse institutions—such as banks, development banks, nationalised insurance agencies and refinancing channels—that were each subject to different degrees of state support and regulation. There were silos separating commercial banks, financial units focused on long-term finance and markets allowing for speculative activities.

This structure is now under threat. The neoliberal agenda of restoring corporate (as opposed to state) control over the nation's financial savings means 'fixing' something that was not broken. The financial system has been forced to begin an unfortunate return journey from the heady environment of nationalised banking to the

predatory and crisis-ridden context that prevailed in the early 1950s.

A number of developments resulting from the pursuit of the neoliberal agenda have combined to bring about this retrogressive transition.

The first is the weakening of the fiscal powers of the state. These fiscal powers should enable the state to provide direct financing of investment, by mobilising resources through taxation and additionally supporting expenditure through borrowing. Such borrowing would be expected to be serviced in the future with enhanced tax revenues and additional resource mobilisation. However, the neoliberal agenda has been eroding the tax base of the state, with its commitment to “incentivising” private investment with lower tax rates and subsidies and concessions of various kinds. It has stuck to fiscal conservatism, even when there is no economic logic to this—which means that the government has chosen to rein in its fiscal deficit. The result is that investment in areas such as infrastructure that, in the early post-Independence years, were expected to be funded by the state can no longer be driven by a proactive fiscal policy. This not only constrains such investment but implies that, to the extent that it occurs, such expenditures will have to be supported with credit flowing through intermediaries populating the financial system outside the fiscal realm.

The second was the neoliberal decision to obliterate the segment of the pre-existing financial system consisting of public development banks and state-sponsored, specialised long-term financing institutions supported with concessional credit or implicit/explicit state guarantees aimed at ensuring access to low-cost finance. These were the institutions within the financial framework that were expected to meet a part of the requirements of finance for capital intensive projects with long maturities, especially such as were undertaken

by risk-averse private investors. The official Narasimham Committees of the 1990s, focused on privatising India’s largely public financial sector, had recommended that these institutions be shut down or converted into commercial banks to ensure a level playing field for the private sector banks it believed must come to dominate the financial sector. In the years that followed, leading development finance institutions (DFI) were allowed to set up banking subsidiaries into which the DFIs were reverse-merged. In other cases, such as the Industrial Finance Corporation of India, the institution was stripped of its development financing role.

The third development consisted of moves to liberalise banking while the system was still largely under state ownership. Banks were allowed greater flexibility to invest in or lend to the retail market for personal loans, to sensitive sectors such as stocks and commodities and to areas like infrastructure characterised by long maturities, significant illiquidity (since exposures cannot be easily wound down) and higher risks. Moreover, strong exposure limits to individual borrowers or sets of borrowers belonging to the same business group were formally and informally relaxed. These changes not only whetted the appetite of banks to move to new areas but also the government started to nudge banks they still controlled to lend large sums to corporates investing in areas like infrastructure, even though this would involve significant maturity, liquidity and risk mismatches given the substantial dependence of banks on short-term deposits for their loanable funds.

Global policy shifts facilitated the liberalisation-induced transformation of banking. Those shifts have ensured that large foreign capital inflows have been, thus far, the norm in the years since the early 2000s. Foreign investment inflows (portfolio and FDI), that amounted to \$6-8 billion a year during 2001-03, rose to \$15-20 billion a year during

2003-06, \$30-60 billion during 2006-14 and \$40-70 billion during 2014-19. With an open capital account, India has been a major “beneficiary” of the surge of cross-border flows of capital triggered by the easy money policies adopted by developed countries’ central banks, especially after the 2008 financial crisis. The resort to quantitative easing and setting near-zero interest rates saw cheap capital seeking high returns in emerging markets, with India receiving an exceptionally large share. The surge in inflows resulted in a spike in domestic liquidity, reflected in a sharp rise in the deposit base of the banking system that triggered a credit boom. That only intensified the diversification in lending to the retail market and the corporate sector, especially to corporates investing in infrastructure.

The fourth development of relevance was the mistaken plan to make liberalised equity and bond markets, with flexible rules favouring the participation of foreign institutional investors, mutual funds and retail investors, an important source of long-term finance. That has not worked, except perhaps for a few very big players. Many years after that plan was implemented, stock exchanges largely remain sites where shares are traded in secondary markets, with the market for new finance through public offerings open only to large, well-established firms, except in periods of speculative frenzy that culminate in a market collapse. On the other hand, corporate bond markets remain underdeveloped, showing some buoyancy only in periods where the flow of liquidity into markets is too large to be accommodated in the secondary equity segment.

Finally, having reduced its own fiscal flexibility, the government chose to adhere to a neoliberal macroeconomic stance in which the principal lever for macroeconomic management was a monetary policy, as opposed to a fiscal policy. Measures to infuse liquidity, drive credit growth and keep interest rates down were seen as the best devices

to address any downturn, including in situations like the contraction induced by the COVID-19 pandemic and the brutal lockdowns that were the government’s response. Instead of substantially enhanced government expenditures to finance transfers to and budgetary support for the worst affected, special liquidity windows to banks to fund targeted sectors, with limited guarantees, were the favoured instruments in relief and revival packages.

This combination of developments precipitated tendencies that have significantly increased the fragility and vulnerability of India’s financial sector. Though the credit boom led to an acceleration in GDP growth, many projects undertaken by corporate groups with the large volumes of finance that were made available failed to deliver expected profits and the revenue streams needed to meet the debt servicing commitments that large-scale borrowing implied. This tendency was, however, not the focus of public attention for long since, having unleashed this trajectory, the government and the banks sought to tide over the problem by restructuring bad debts and treating them as standard rather than stressed assets. The restructuring involved some combination of concessions such as an extension of the duration of the loan, reduction of the applicable rate of interest and conversion of part of the loan into equity. But in most cases, even such restructuring did not help, and the loans reappeared as stressed debt. But because of lax norms, a significant share of such debt was not recognised as such till the Reserve Bank of India stepped in and issued stricter guidelines, resulting in a spike in non-performing assets (NPAs) starting in 2015.

Once recognised as NPAs, these debts had to be provided for, with attendant implications in terms of losses on the banks’ books that eroded bank capital. In time these loans were “technically” written off and fully provided for, though they were still slated for recovery through the multiple

mechanisms available for the purpose—Debt Recovery Tribunals, proceedings under the SARFAESI Act and finally, the Insolvency and Bankruptcy Code. But recovery rates in most cases were pathetic, with banks forced to take large haircuts, either in their own settlement efforts, proceedings under the company law tribunals or the operations of Asset Reconstruction Corporations. Some of the losses and erosion of capital resulting from this were covered by the government's recapitalisation drive. But given the government's self-imposed fiscal conservatism, there were limits to such recapitalisation, and in time the drive lost all momentum. Banks burdened with bad debt—provided for or otherwise—found themselves vulnerable and weakened.

The tendency of the government and, for long, the Reserve Bank of India to bury the bad debt problem also had a behavioural effect. 'Entitled' corporates began to believe that it is their right to be spared when defaulting on debt. As former RBI Governor Raghuram Rajan (2005) was pushed to admit: "Regulatory forbearance, where RBI makes it easy for banks to 'extend and pretend', is not a solution. Since no other stakeholder—such as the promoter, tariff authorities, tax authorities, etc.—contributes to resolution, the real project limps along, becoming increasingly unviable. ...Also, some large promoters take advantage of banker fears about assets turning non-performing to extract unwarranted concessions without any sacrifice in the value of their stake. Regulatory forbearance, therefore, ensures that problems grow until the size of the provisioning required to deal with the problem properly becomes alarmingly large—which then prompts calls for yet more forbearance."

It was at a time when bank balance sheets were damaged by these developments that the COVID-19 crisis struck. Given the government's tendency to privilege monetary over fiscal measures, as noted earlier, the government's policy response

emphasised the provision of credit to a range of sectors hurt by the crisis. Since the crisis that affected these borrowers adversely has persisted to varying degrees, the probability of defaulting on the debt service payments due on the enhanced credit flow has increased. Not all of the special-purpose loans the public banks were called upon to deliver were guaranteed. And even in the instances they were, delays in monetising the guarantee in case of default are inevitable given the fiscal position of the government. Since the rules on when the debt would be considered non-performing had been loosened, given the impact of the crisis, it is still not clear how much more damage bank balance sheets have suffered. But by all accounts, another spike in NPA levels seems inevitable.

In time, not only are banks vulnerable, rendering the financial system fragile, but they are unable to sustain the credit boom on which growth rode. A credit crunch and contraction follow. The banking system is unable to play the role assigned to it either before or after liberalisation. The problem does not stop with the banks. Regulatory forbearance affects non-bank financial companies (NBFCs) as well. The NBFC crisis stems from two different sources. First, as happened in the case of IL&FS, there is the possibility that projects that were funded with borrowing went bad or did not deliver the returns they were expected to generate. Things worsened when, in order to prevent these loans from going bad and affecting the solvency of the institution, more loans were advanced, either to the defaulting firm or to others who moved those funds to the potential defaulter in the form of investments or payments so that the loan could be serviced. The NBFC, in turn, in order to remain in business and service the loans which helped finance these projects, borrowed more. The spiral of debt had to unwind.

The problem partly was that being implicitly government-sponsored, IL&FS not only received

financial support from other public institutions like the LIC but was also seen as being government guaranteed. Banks not only lent to infrastructure directly but to such institutions and through them indirectly to infrastructure. Unfortunately, investments in infrastructure have proved to be extremely bad bets for multiple reasons. IL&FS had to crash and it did.

The second source of trouble, which seems to be relevant to failed housing finance company DHFL, is that even when the projects financed by the NBFC may not be going bad, the fact that it is using short-term borrowing to provide long-term loans to its clients requires it to roll over its own debt, or borrow again, to sustain its operations while repaying old loans that fall due. If for some reason the market is unwilling to roll over loans and advance additional loans for expansion, the NBFC faces a liquidity problem. Being tied into long-maturity assets, it does not have the money to repay its own loans, leading to default. The credit crunch resulting from the banking problems can cause trouble for the NBFCs.

What about fraud? It cannot be denied that it played a role in IL&FS. But in a financially liberalised world, identifying where bad practices favoured by liberalisation end and fraud begins is difficult. If, for example, a financial institution which is heavily exposed long-term to a group or a project is faced with potential default that can have extremely bad repercussions for its own books of accounts, should it lend more to the entity concerned or let it default? If rules and monitoring do not prevent further lending, many managers may choose the soft alternative of keeping the project alive and prevent default, in the hopes that matters would improve. It is another matter that in a climate like that, some managers, looking for illegitimate gains or even their “performance-related” payment prospects, may choose to indulge in fraud. The causes of the crisis run deep, and the

use of words and phrases like “fraud”, “liquidity shortage” and “environmental factors” only conceal the fact that deregulation and liberalisation explain India’s own financial meltdown.

The vulnerability stems not only from failure. Success may also be riding on increased vulnerability, as in the case of the unprecedented boom in India’s stock markets till recently, which occurred alongside a real economic contraction or recession and high unemployment. The very same liquidity surge, driven by foreign capital inflows, has kept the market buoyant, with valuations at levels that cannot be justified even by optimistic projections of growth in future earnings. With cheap money policies in the developed countries expected to end, bringing to a close the opportunity to borrow cheaply in developed country markets and invest for high returns in emerging markets, an outflow of capital may ensue. That would unwind the stock boom that is bound to have ripple effects on the country’s currency and financial markets.

Overall, the Indian financial system is indeed at a tipping point. The solution the government is seeking to the prevalent fragility is to wash its hands of the financial sector through the privatisation of banks and insurance companies. But with banks burdened with bad debt and markets expected to slip, selling out the public financial sector may not be easy. Financial instability with collateral damage in the real economy is inevitable, with signs of the latter already visible.

PUBLIC FINANCE

Matters are rendered worse by the conservative fiscal stance of the state. It is known that economic activity in India had been slowing down much before the disruption caused by the pandemic. The massive impact that demonetisation and GST had on smaller and informal units was one major cause, affecting informal employment and livelihoods and

leading to declines in mass consumption as wages and self-employed incomes were suppressed. This was an important reason for declining investment along with the financial factors mentioned above. It was ironic—but predictable—that the strategy to deliver more profits to corporates by suppressing wages ended up reducing total profits by shrinking the market. The focus on large companies also left out the small and medium enterprises that provide the bulk of employment in the country; they also suffered a lot due to demonetisation and the GST imposition. After 2011, both labour force participation and employment fell relative to the working-age population. Real wages started decelerating from 2015 onwards and declined from 2017. The systemic problems in agriculture worsened, which meant that cultivators fared even worse than casual rural wage workers.

In such a context, it could have been expected that the government would adopt a more proactively expansionary fiscal stance to counter the recessionary tendencies in the economy. Unfortunately, public spending was not increased to counter the decline in demand elsewhere; rather, tax rates for corporations were lowered in the (vain) hope that this would cause private investment to revive. And the obsession with reining in the fiscal deficit meant that the loss in tax revenues resulting from such concessions was countered by restraining public spending.

This unjustifiable conservatism persisted throughout the pandemic, worsening the impact of the health emergency and imposing long-term costs on the Indian people. Indeed, the Indian government's fiscal reticence has made it a significant outlier in the world. Advanced economies have gone all out in terms of expanded public spending. Their governments quickly abandoned the (flawed) arguments about the dangers of large fiscal deficits when large capitalists realised that they would also suffer from the

closures and downturns created by the spread of the coronavirus. Even governments in developing countries constrained by external debt overhang and fear of capital flight increased their spending despite declining revenues, both to provide some relief and social protection to their populations and to shore up domestic demand that would otherwise collapse completely. While their additional spending was only a tiny fraction of that in the rich world, and not even very much in relation with their GDP, it was nevertheless, on average, a notable increase over the immediate past.

Not so in India, unfortunately. The Indian government is one of the few in the world that voluntarily reduced its total spending in this crisis period. And it did so even though it was not constrained by sovereign debt concerns or conditionalities imposed by multilateral organisations. The central government is so obsessed with the need for fiscal discipline, no matter what the context or requirements of particular exigencies, that any reduction in total revenues causes it to cut down on its spending.

It was entirely predictable that the questionably harsh yet ineffective lockdown in mid-2020 and the spread of the second wave from early 2021 would severely impact economic activity. This obviously led to declining revenues for the government: in 2020-21, total receipts of the government fell by more than 30%, although tax revenues fell by only around 22%. This lower impact on tax revenues was partly because of the revenues from enhanced levies on petrol and diesel that the centre did not share with state governments and partly because large companies continued to flourish and even benefited at the expense of smaller companies in this period. Even though the economic and health crises clearly warranted higher public expenditure, the Indian government actually spent Rs 5,300 crore less in the pandemic year 2020-21 than in the previous year. This was notwithstanding the claims

made in the various relief packages announced over the year. For example, the Atmanirbhar Abhiyan package of May 2020 was claimed to amount to an additional Rs 10 lakh crore, or 10% of India's estimated GDP. Obviously, this was nothing more than a smoke and mirrors exercise, as the government cut down on other (often crucial) areas of spending to compensate for small increases, such as in the rural employment programme (Ministry of Finance, n.d.).

Since then, as the economy was allowed to open, central government spending has remained low even though revenues have been much more buoyant, driven by an increase in direct tax receipts of 84% compared to the previous year. This increase could reflect a bigger cause for worry: a dramatic increase in economic inequality. Income concentration has been rapid and extreme, with the top 10% and even 1% grabbing larger shares of the pie. Meanwhile, micro and small enterprises have been closing in droves, and self-employed people have been losing their incomes, with their market shares being taken over by large companies that pay more direct taxes. Restrained spending and rising revenues have led to a significantly lower fiscal deficit, which seems to have been the government's primary aim, regardless of the economic cost to the citizenry.

To this must be added the implications of fiscal centralisation, which also had severe consequences since state governments are largely responsible for providing essential public services to the citizens. While the initial lockdown was imposed without any consultation, state governments were made responsible for implementing it as well as for essential public health measures and all the measures required to deal with the economic effects of the lockdown, but they were completely strapped for cash. The central government provided very little by way of additional resources and avoided its constitutionally mandated requirement to share

tax revenues with state governments by classifying new taxes as cesses and surcharges on existing tax rates and central fuel taxes, all of which do not need to be shared with the states. After invoking the centralising National Disaster Management Act to declare a national lockdown, the centre left the state governments to deal with the additional health spending and the measures required to deal with the increased economic distress as best as they could. Not only did the central government refuse to spend more itself, it also forced the state governments to base their additional required spending on borrowing that would be difficult to repay. The centre even refused to pay the full dues that it owed to the states, resulting from a prior agreement negotiated in 2017 when the introduction of a national Goods and Services Tax deprived state governments of their own revenue-raising powers. When it became evident that all this was completely unfeasible and would lead to major humanitarian crises, in late July 2020, state governments were allowed to borrow more—but knowing that they would have to repay later with little or no help from the centre.

This is bad news for the macroeconomy. The impact may be temporarily disguised by the greater profits made by some large corporates and rising asset values driven by growing inequality, but soon enough, the overall impact of low public spending on depressed domestic demand and inadequate infrastructure will be felt. Low spending also affects the public provision of essential goods and services.

The pattern of public spending is an indication of the extent to which citizens' rights are met by the state. Some of the starkest indicators relate to central government spending on programmes that directly provide employment, food access, health and education. Most countries increased spending on both health and education during the pandemic, which created more demands on health services and required large investments to compensate

for school closures and enable the sudden shift to online learning. Not so in India (Government of India, n.d.) Health spending by the central government has remained pitifully small and even fell in nominal terms in the first half of this year compared to last year. (Note that it is around half of the spending of the Ministry of Home Affairs—truly remarkable in a country where state governments are supposed to be responsible for security.) Education spending by the Ministry of Human Resource Development fell sharply during the pandemic instead of increasing and still remains at less than two-thirds of pre-pandemic spending, meaning that we are effectively denying a generation of children and youth their right to education. The spending on women and children, which provides essential nutrition to mothers and infants, was similarly cut and remained well below pre-pandemic spending. Spending on agriculture fell this year in the teeth of the ultimately victorious farmers' struggle. In the peak of the first wave, spending on MGNREGA increased—but this has been short-lived. But labour market conditions are still terrible in rural India, and the total spending on this has fallen sharply in the current year. Spending on public provision of food appears to have increased in the current year, but this is really a statistical artefact: it reflects the fact that the central government finally paid up some of the

longstanding dues it owes to the Food Corporation of India from previous years.

The consequences of these financial and fiscal developments are the concern of this report. Individual chapters in the report provide a much more detailed examination of the implications of these policies and processes for various sectors and segments of the population.

REFERENCES

- Government of India. (n.d.) *Government Of India Union Government Accounts At A Glance As At The End Of September 2019*. <https://cga.nic.in/MonthlyReport/Published/9/2019-2020.aspx>
- Ministry of Finance. (n.d.) *Statement on half yearly review of the trends in receipts and expenditure in relation to the budget at the end of the first half of the financial year 2021–22*. Government of India. <https://dea.gov.in/sites/default/files/H1%202021-22%20FRBM%20English.pdf>
- Rajan, R. (2005, August 24) *Strong sustainable growth for the Indian economy* [Speech transcript]. RBI Docs. <https://rbidocs.rbi.org.in/rdocs/Speeches/PDFs/SPFIB08A57E6BFBD2E545D488962C43CF3A85B9.PDF>

SECTION 1

In Focus: The Viral Waves And Their Aftermath



Public Health



HEALTH SYSTEM STRENGTHENING THROUGH PUBLIC FINANCING IN INDIA

A Priority for Civil Society Advocacy Efforts in a Post-COVID-19 World

Philip Mathew

The COVID-19 outbreak in India has been a major disrupter for the economy and a rude wakeup call for the Indian healthcare delivery system. The desperate scenes which unfolded on the streets in front of major private hospitals and in the intensive care settings of public hospitals, showed an underfunded and inefficient healthcare system on its knees. At the peak of the second wave in April-May 2021, there were shortages of almost everything—right from hospital beds to oxygen to essential medicines required to treat severe cases of COVID-19.¹ A few months down the line, the government was audacious enough to declare that there was no shortage of oxygen even during the peak of the pandemic.² This takes away even the remotest possibility of fixing accountability issues or having a critical evaluation of the policies adopted at different stages of the pandemic. However most public health experts see the entire fiasco as the sign of a deeper malaise, which is the chronic lack of investment in our public healthcare system.

The World Health Organization's Global Health Expenditure Database can give us a broader picture of the nature of investments in

our healthcare system.³ India's Current Healthcare Expenditure (CHE) is around 3.5% of its Gross Domestic Product (GDP) which is down from 4.2% in the early 2000s. Compare this with other members of the BRICS grouping—Brazil spends around 9.5%, China 5.3%, South Africa 8.5% and Russia 5.3%. If we look at the per-capita CHE (Current Health Expenditure in Purchasing Power Parity), it is more than \$1,500 in Brazil while it is as low as \$275 in India. Even though there is no global consensus on the minimum threshold for healthcare spending in a country, it can reasonably be assumed that India is not spending enough when compared to similarly placed countries. Another disturbing statistic is the government's domestic general healthcare expenditure as a proportion of CHE. The latest figures show that it is around 28%. It was as low as 18% in 2004, before rising rapidly to almost 29% in 2011. Since then, it has either fallen or stagnated and is much lower than the global average of 59.5%. All of this indicates one thing—we have failed to invest adequately in improving our healthcare delivery system.

The southern states have always performed well in terms of most governance parameters,

including indicators which assess the robustness of healthcare delivery like Infant Mortality Rate, Maternal Mortality Rate, Under-5 Mortality Rate and Health Workers per 1000 population.⁴ The last time National Health Accounts were published, it showed that southern states have been spending more money on health than most other parts of the country. This is reflected in Total Healthcare Expenditure (THE) per-capita, Government Healthcare Expenditure (GHE) per-capita and Out-of-Pocket Expenditure (OOPE) per-capita. The official case-fatality rates for COVID-19 infections have also been consistently lower in southern states than the rest of the country.⁵ Besides, most of the southern states of India did not see the kind of desperation scene that was seen on the streets of the Hindi heartland. Though this evidence is purely anecdotal and most of the states have been notoriously efficient in undercounting COVID-19 deaths, it is indeed a pointer towards a better-equipped healthcare system moderating the impact of the pandemic. There are several factors which affected the death rates in the COVID-19 pandemic and the comparison between states may not be logically possible based on one indicator alone. But largely, we can assume that access to healthcare during the peak of the pandemic was determined by the overall healthcare spending in that state.

Once we reasonably conclude inadequate healthcare spending as a significant risk factor for poor access to healthcare and probability of death during a pandemic, we need to assess the reasons for this chronic lack of investment. India has a three-tier system of healthcare delivery, which places enormous importance on primary care.⁶ The Primary Health Centres (PHC), which are supposed to serve a population of 30,000 in rural areas and 20,000 in Tribal areas or hilly terrains, form the mainstay of the primary healthcare

system. These centres are supposed to provide promotive, preventive, curative, rehabilitative and palliative healthcare services, and deal with the various dimensions of health. Those who designed the system had also envisaged sub-centres, which cater to the healthcare needs of small habitations up to 5,000 in population. Having said that, even 75 years post-Independence we are yet to fully operationalise these PHCs across the country. It is estimated that India has a vast network of more than 200,000 government run PHCs. However, if we look at the services other than the Maternal and Child Health (MCH), these PHCs account for only 11% of the total outpatient services in rural India, indicating their non-functional or dysfunctional status in many parts of the country. The utilisation of services from these PHCs and their functionalities tend to be better in southern and north-eastern parts of the country. But there are several studies and reports indicating their dire conditions such as lack of staff, drug shortages, poor oversight, low quality of services etc. in many of the north Indian states. However, the root cause of these problems could be the lack of real public pressure on the government machinery to improve service delivery. If the services at the PHC are deficient, the public seek out other forms of healthcare services. In most parts of the country, there is a large system of informal practitioners who take care of the needs of a certain section of the population. These informal practitioners may not be qualified in any way to deliver healthcare, but they satisfy the demand for medical attention. We also have a large network of traditional practitioners and Ayurveda, Yoga, Unani, Sidha and Homeopathy (AYUSH) doctors who deliver good quality healthcare services. In a country where the rise in the price of onions has pulled down governments, healthcare issues have almost never featured as an election issue anywhere. Therefore,

the political capital available for healthcare issues is abysmally low except in times like these. This is probably the reason why government spending on healthcare is stagnant at around 1.3%, when the National Health Policies in 2002 and 2017 recommended it to be raised systematically to 2% and 2.5% respectively.⁸

Another facet of our healthcare system is the concentration of these facilities in urban areas, especially in the private sector. In most of the populous states, the private healthcare facilities far outnumber the public ones. The Centre for Disease Dynamics, Economics and Policy (CDDEP) estimated that more than 60% of the healthcare facilities in the country are privately owned and that only around one-third of these are situated in rural areas. It means that 65% of India's population who live in villages have access to only around one-third of the healthcare delivery facilities.⁹ Therefore, the actual brunt of chronic underspending in the publicly owned healthcare facility is finally borne by the rural poor. Having been physically and economically deprived of access to essential healthcare services, the overall productivity of this demographic group will come down further. This sets in motion a vicious cycle—poor health contributing to lower productivity, which further disrupts the household food security and access to healthcare. Catastrophic Health Expenditure is defined as the out-of-pocket expenditure on health that accounts for over 10% of the annual household expenditure. Traditionally, Catastrophic Health Expenditure was higher in richer households in India, but these numbers have been rising rapidly in low-income households since the last one decade, something which can push people back into poverty.

The lack of access to healthcare is most evident among the country's most vulnerable groups. Even some of the government documents like

the 12th Five Year Plan published by the erstwhile Planning Commission of India acknowledges it. It lists out groups like internally displaced people, nomadic tribes and de-notified tribes as the most vulnerable.¹⁰ Other observers have even suggested that all the scheduled castes and scheduled tribes and women are among the vulnerable in the Indian context. These groups generally have lower access to healthcare services and the utilisation rates tend to be poor. The choices available to them are low and the financial access to healthcare services may be poor. Studies have shown that provisions for free medicines and laboratory investigations significantly increase healthcare utilisation rates in public health facilities, showing the importance of tackling issues of financial access. These access issues among the vulnerable groups have become more glaring when it comes to major illnesses than minor conditions such as acute illnesses, musculoskeletal pain, etc. The treatment rates tend to be more or less similar between different socio-demographic groups in the case of minor illnesses, while the disparity in health seeking behavior is quite significant for major illnesses like cardiovascular disease, diabetes, etc. We can safely hypothesise that this discrepancy is due to the differences in access, both physical and economic, that is starkly present in these groups.

The solution to most of these issues is increased government spending on healthcare, focusing more on the improvement of primary healthcare.¹¹ Some studies have shown that more than one-third of the demand for curative services can be handled by primary healthcare. The promotive and preventive services rendered through PHCs are also cost effective, even when we consider a range of outcome indicators. A robust primary healthcare system should be complemented by a well-functioning referral system. Therefore, geographically accessible and adequately equipped secondary and tertiary

health services should be made available throughout the country. This should be funded by tax revenues and not any forms of insurance which come with co-payment riders and the probability of rejection of claims. A Beveridge model, in which healthcare is financed and provided by the government, should be the right system for developing countries like India. With this model, the likelihood of market failure is low and the government can effectively control the tariff structures. Any insurance system, which requires registrations, periodic renewals, co-payments, etc., are inherently biased against the most vulnerable sections of society. There are several innovative financing options proposed for developing health systems, which include social impact bonds, healthcare focused investment funds, micro-credit schemes to stimulate demand for healthcare services, etc. But none of this can replace the impact of increased investments by the government into the health system. In an ideal scenario, this government investment would come from general taxation or specific cess/tariff imposed on specific goods or services. Besides, the increased investment should not happen through a mission or project mode. We have seen a rapid increase in government spending on healthcare after the launch of National Rural Health Mission (NRHM) in 2005. But the increases plateaued out by 2011–12, once the mandate of the mission was temporally completed.¹² We have seen in the past that there is a definite shelf life for initiatives managed in project mode.

The political declaration of the United Nations' High Level Meeting on Universal Health Coverage (UHC) laid down an ambitious roadmap to achieve UHC by 2030.¹³ It recognised that Health-for-All is an integral part of the UN's 2030 Sustainable Development Agenda and stated that, "health is an investment in the human capital

and social and economic development, towards the full realisation of the human potential." The declaration called for resilient, accountable and people-centered health systems, which are capable of maintaining the highest levels of quality and equitable access. The declaration acknowledges the critical role of the governments in ensuring UHC and calls on governments to prioritise health in public spending. Though this was a pathbreaking document, this has been largely forgotten after the outbreak of COVID-19. Several important reports prepared in the light of COVID-19, speak the language of securitisation and conveniently push the health system strengthening narrative into the background. The Independent Panel on Pandemic Preparedness and Response and the G20's High Level Independent Panel calls for establishment of structures which look at global health security. Though there is a lot of favourable text on health system strengthening, these reports lack any solid recommendations on increasing the investments in healthcare delivery structures in Low-Middle Income Countries (LMICs). The global policy community cannot allow the narrative around pandemic preparedness to be dominated by health securitisation. Rather, it is in the interest of LMICs to actively seek out a global consensus on channeling greater investments to advance the UHC agenda. A holistic approach in which UHC and health systems strengthening is highlighted as the cornerstone for pandemic preparedness, may be the only pathway in which there is a direct benefit to low-resource settings. There is no place for under-funded piecemeal approaches like the Pradhan Mantri Jan Arogya Yojana, which aims to cover 100 million underprivileged families in the country through a health protection scheme.¹⁴ This is to be implemented in collaboration with the states, with the central government contributing

60% of the finances. But if we look at the allocation for this flagship scheme for 2020-21, it was a paltry 6400 crore. Even after accounting for the contribution from states, the overall allocation for the health of a family is as low as Rs 1,000 per year for a health protection of 5 lakhs. It also carries all the baggage of traditional insurance models—rejection of claims, irrational selection of hospitals, registration issues, etc.

The third international conference on Financing for Development came out with the Adis Ababa Action Agenda in 2015.¹⁵ It called for nationally appropriate spending targets for investments in public services, including healthcare. The agenda reiterated the importance of investing in health system strengthening and affirmed the right of World Trade Organization members to take advantage of the flexibilities in Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. Cohesive, nationally-owned, sustainable development strategies, supported by integrated national financing frameworks will form the core of Agenda 2030, as per the Adis Ababa Action Agenda. Though this important policy document did not lay down any specific threshold for healthcare spending, the broad call was to increase the money allotted for health strengthening in national budgets. That leaves the question of how much is adequate spending? Can we have a target, at least for advocacy purposes in country contexts? The Abuja Declaration of 2001, in which the Heads of States of African Union countries committed to spending at least 15% of their national budgets on healthcare, may be the only document with an international consensus.¹⁶ But it's troubling to note that only two countries have managed to achieve the ambitious target by 2018.

It is a fact that South Asian governments spend less on health, education and social assistance, as

compared to their peers in other regions. Though this region has experienced strong economic growth since the 1990s, the focus has been on infrastructural improvements and defense modernisation and not on social sector spending. Even in countries like Bangladesh, which has done very well in several health and social indicators in the last two decades, the social sector spending is way behind what we see in South-East Asian Countries or Latin America. This is probably a reflection of the poor importance accorded to health and social development, in the rapidly transforming political landscape of South Asia. The relative importance accorded to the health and wellbeing of a person during the time of Nehruvian socialism, has been more or less replaced by the individualism propagated by votaries of capitalism. Even in the vast networks of public healthcare facilities, several states in India have been very enthusiastic in designing systems for collecting user fee or co-payments. Most of these changes have been under the insistence of the Bretton Woods twins or other neo-liberal international financial institutions. This argument for "minimal government, maximum governance" falls flat when we look at the market failure which happened during the initial phases of the COVID-19 outbreak. Erratic supply of essential medicines, instances of mediocre quality treatment given at private institutions and overcharging for services show that market forces cannot be a solution for all governance issues. There is a need for strong government intervention, either as a regulator or service provider, in low-resource settings. This should be complemented by increased public spending in the social sector. As an immediate action, India should be able to raise the spending on health, education and social assistance to at least 10% of GDP by 2025. This will also help to cushion the socio-economic impact

of COVID-19 and ensure that people do not fall back into poverty. We can also assume that it will increase human productivity and make a conducive environment to harvest the demographic dividend that a young population has to offer.

In some states like Kerala, the utility of grassroots workers like Accredited Social Health Activists (ASHAs) and Angawadi workers was quite evident during the early phase of the COVID-19 outbreak. When the government system was in disarray, these workers were the vital link between the public and the formal health system. They were crucial in educating the public about the disease, providing intelligence to the health system and identifying beneficiaries for government schemes during the pandemic. The UHC system suitable for a country like India would be based on strengthening this system of community health extension workers and improving the service delivery in PHCs. For this purpose, we need more resources in the healthcare system, right from training of healthcare professionals to making the supply chains resilient. But the take-home message is that there is no UHC without a strong PHC.

REFERENCES

- Pandey, V. (2021) Coronavirus: How India descended into Covid19 chaos. *BBC News*. 5 May. <https://www.bbc.com/news/world-asia-india-56977653>
- Press Trust of India. (2021) No deaths due to lack of oxygen specifically reported by states, UTs during second Covid wave: Centre. *Indian Express*. 20 July. <https://indianexpress.com/article/india/covid-oxygen-deaths-india-centre-7414128/>
- World Health Organization. *Global Health Expenditure Database*. <https://apps.who.int/nha/database>
- Niti Aayog, World Bank, Ministry of Health and Family Welfare. (2019) *Healthy States, Progressive India- Report on the ranks of States and Union Territories*. Niti Aayog: New Delhi.
- Government of India. Covid19 state-wise status. <https://www.mygov.in/covid-19/>
- Chokshi, M., Patil, B., Khanna, R., Neogi, S.B., Sharma, J., Paul, V.K., Zodpey, S. Health systems in India, *J Perinatol*. 2016 Dec;36(s3):S9-S12. <https://pubmed.ncbi.nlm.nih.gov/27924110/>
- Garg, S., Basu, S., Rustogi, R., Borle, A. Primary Healthcare Facility Preparedness for Outpatient Service Provision during the COVID-19 Pandemic in India: Cross Sectional Study. *JMIR Public Health Surveill* 2020 Jun 1;6(2):e19927. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7265797/>
- Mann, G. (2020). Demand for Grants 2020-21 Analysis : Health and Family Welfare. *PRS India*. 12 February. <https://prsindia.org/budgets/parliament/demand-for-grants-2020-21-analysis-health-and-family-welfare>
- Kapoor, G., Sriram, A., Joshi, J., Nandi, A., Laxminarayan, R. (2020) COVID-19 In India : State-Wise Estimates Of Current Hospital Beds, Intensive Care Unit (ICU) Beds and Ventilators. CDDEP. <https://cddep.org/publications/covid-19-in-india-state-wise-estimates-of-current-hospital-beds-icu-beds-and-ventilators/>
- Planning Commission of India. (2013) *Twelfth Five Year Plan: Social Sectors*, SAGE Publications India: New Delhi. https://niti.gov.in/planningcommission.gov.in/docs/plans/planrel/fiveyr/12th/pdf/12fyp_vol1.pdf
- Jaffrelot, C., Jumle, V. (2020) Private Healthcare in India: Boons and Banes. *Institut Montaigne*. 3 November. <https://www.institutmontaigne.org/en/blog/private-healthcare-india-boons-and-banes>
- Macrotrends.net. (n.d.) India Healthcare Spending 2000-2020,. <https://www.macrotrends.net/countries/IND/india/healthcare-spending>

13. United Nations. (2019). Universal health coverage: moving together to build a healthier world, United Nations. <https://www.un.org/pga/73/wp-content/uploads/sites/53/2019/07/FINAL-draft-UHC-Political-Declaration.pdf>
14. National Health Authority. *About Pradhan Manthri Jan Aarogya Yojna*. <https://pmjay.gov.in/about/pmjay>
15. United Nations. *Financing sustainable development and developing sustainable finance*. <https://www.un.org/esa/ffd/ffd3/wp-content/uploads/sites/2/2015/07/DESA-Briefing-Note-Addis-Action-Agenda.pdf>
16. Gatome-Munyua, A., Olalere, N. (2020) Public financing for health in Africa: 15% of an elephant is not 15% of a chicken. *Africa Renewal*. <https://www.un.org/africarenewal/magazine/october-2020/public-financing-health-africa-when-15-elephant-not-15-chicken>

THE COVID-19 VACCINE STORY

The Abandonment of Process and Protocol, and the Demise of the Scientific Method

D. Jacob Puliyel

Twenty-fourth August 2021 marks a milestone for vaccine science in India. On this day, the world's first DNA vaccine, developed indigenously, was given emergency use authorisation (EUA) by the Drug Controller General of India (DCGI). It is also perhaps the second time in the history of modern medicine that a drug manufacturer has been granted this approval without publishing any evidence from Phase III trials in peer-reviewed literature.

Conventionally, a killed or attenuated form of the infectious agent is used to make vaccines. Its effect is relatively short-lived because activated lymphocytes destroy the pathogen-infected cells, limiting the duration of the effectiveness of the vaccine. DNA vaccination, on the other hand, involves the injection of a piece of DNA that contains the genes for the antigens of the virus. This enters the host cell nucleus, and it is hoped that it remains as an episome without getting integrated into the host cell DNA. The inserted, cloned DNA will direct the synthesis of the antigen it encodes. The immune system is activated by this antigenic stimulus. The manufacturers call it "plug-and-play" technology. The plasmid DNA platform used to

facilitate the entry of viral DNA into the host nucleus can be adapted to deal with mutations in the virus quite easily. As no infectious agents are used, they are not capable of precipitating the infection it is meant to protect against, the way live attenuated vaccines do oftentimes.

The reason this has not been used in humans previously, in other parts of the world, is because of the huge risks involved (World Health Organization, 2007). The worst of these risks may not be evident till many years later. It is for this reason that the world has exercised great circumspection with the use of this technology.

The expression of a foreign antigen, in the long run, may result in an undesired immunopathological reaction. Anti-DNA antibodies can result in diseases like Systemic Lupus Erythematosus (SLE). We also know that the antigen expressed in the new COVID-19 DNA vaccine (spike protein) has biological activity and could cause thrombosis (Kowarz et al., 2021). However, the injected DNA may not remain an episome, it may integrate with the host's chromosome, causing a permanent mutation of the person's genome. Germline alteration can be

caused by integration into reproductive tissue. This can affect fertility and reproductive function. There are also considerations of embryo-foetal and perinatal toxicity.

If, on account of pure fortuitousness, we avoid a great human tragedy with the use of this vaccine, one hopes the lesson we learn is not that due process and protocol are redundant or unnecessary!

INDIA'S FIRST VACCINE

This is the second vaccine developed entirely in India. India's first fully indigenous vaccine is Covaxin. It is a killed vaccine using beta-Propiolactone to inactivate the virus. It was developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR). Bharat Biotech was given the COVID-19 virus strain for making the vaccine by the ICMR around 9 May 2020 (ICMR [@ICMRDELHI], 2020). Within two months of providing them with the virus strain, the Director-General of the ICMR Balram Bhargava wrote Bharat Biotech a letter dated 2 July 2020. It said that the vaccine would be launched on 15 August 2020 and that the project was being watched by the "topmost level of the government". He warned that if the investigator did not begin recruiting trial participants within a week, it would be "viewed seriously".

That tryst with destiny did not happen as scheduled for the 74th independence day of the country, but by December that year, Bharat Biotech applied for regulatory approval without publishing efficacy data in any peer-reviewed journal. The approval was given on 3 January 2021 (Press Information Bureau Government of India, 2021). Vinod K. Paul, a paediatric doctor and member of the government's think tank, NITI Aayog, commended the Atmanirbhar programme for

developing the vaccine in record time. Even before the safety tests were complete, the DCGI claimed Covaxin was "110%" safe.

On 30 March 2021, the Brazilian drug regulator, Anvisa, conducted an onsite evaluation because the country had plans to place an order to buy the Indian vaccine. Anvisa noted serious problems with the manufacturing process—they were not sure that the SARS-COV-2 virus was completely killed and that it was free of microbial contamination. This suggests that one ran the risk of getting COVID-19 from the vaccine itself or developing bacterial sepsis. Furthermore, Anvisa noted that there was no standardisation of potency from dose to dose (G1, 2021).

There were also allegations of corruption and bribing (Wikipedia, 2022). The Brazil government decided to drop its plan to buy 20 million doses of Covaxin.

This is a risk with triumphalism in science.

VACCINE EVALUATION

All vaccines have to be tested for safety (they must not cause more serious adverse effects than the disease they are supposed to prevent) and efficacy (that they are effective in preventing the disease being targeted). We will discuss each separately. For this discussion, it is important to view this from an international perspective.

Vaccine safety issues

Antibody-Dependent Enhancement (ADE)

Antibodies produced against the virus are generally protective and control viral infection. However, we now understand that some antibodies, paradoxically, help the virus, and the presence of

these antibodies make for a more serious disease (Tirado & Yoon, 2003).

The mechanism for this is not clearly understood, but neutralising antibodies are usually protective. When the levels of neutralising antibodies are low, other antibodies, called binding antibodies, begin to manifest, and this causes serious disease. The binding antibodies don't eliminate the virus but merely stimulate a 'panic button' in the immune system. The resulting unregulated cytokine storm can overwhelm the body and result in multiorgan dysfunction (MODS) and even death.

In the past we've seen this phenomenon with other vaccines, such as the vaccine for the Respiratory Syncytial Virus (RSV). Vaccinated children had more severe bronchiolitis than unvaccinated children (Fulginiti et al., 1969). Some studies during the 2009 H1N1 pandemic had shown people with previous vaccination against influenza fared worse than the unvaccinated (Lansbury et al., 2017).

The quadrivalent live attenuated dengue vaccine Dengvaxia evoked a good antibody response in recipients, but the vaccinated had a more serious disease when exposed to the virus in the next dengue season. Coronavirus is notorious for causing ADE. ADE has been reported in both SARS-CoV and MERS-CoV (Lee, 2020).

Spike Protein as Pathogen

Existing use of the spike protein is to stimulate immune protection. It has been suggested that the spike protein is a toxin, and if it gets into the blood, it can cause blood clotting and bleeding problems, namely Vaccine-induced Thrombotic Thrombocytopenia (Barnes et al., 2021) and also heart problems (myocarditis) (Tercatin, 2021; Lei et al., 2021; Hippisley-Cox et al., 2021).

These have been reported among the vaccinated.

VACCINE EFFICACY

Waning Immunity

The United States Food and Drug Administration (FDA) had stipulated that a COVID-19 vaccine's efficacy must be at least 50% for approval (U.S. Department of Health and Human Services et al., 2020). The AstraZeneca vaccine was said to have 63% efficacy, and the vaccines of Pfizer and Moderna were said to be 95% effective. However, The British Medical Journal (BMJ) reports that the protection with the Pfizer and the AstraZeneca vaccines wanes rapidly

(Iacobucci, 2021).^c Peter Doshi, a senior editor with the BMJ, notes that in Israel, which has used the Pfizer vaccine, protection from infection and symptomatic disease was 64% in the early part of July, and it dropped to 39% by the end of the month (2021). According to his analysis of a preprint by Pfizer, the rapid fall of efficacy was noticed even before the Delta virus became widespread (Thomas et al., 2021).

Viral mutation and immune escape

At the beginning of the COVID-19 vaccination programme, virologist Geert Vanden Bossche (2021) warned that mass vaccination during a pandemic was inadvisable, as the vaccine could drive the virus to mutate and make the vaccines ineffective – a phenomenon called an immune escape. This is now realised with the international spread of the Delta strain of the virus, which has resistance to the present-day vaccines (Callaway, 2021).

Person-to-person spread

As predicted by virologists like Geert Vanden Bossche, the virus has evolved vaccine-resistant mutations like the Delta strain. According to the

CDC (2022), a high amount of the Delta variant was seen in the unvaccinated people as in fully vaccinated people. The vaccine is, however, said to protect against serious illness.

This ability of the vaccinated to spread the disease demolishes one of the main justifications for enforcing vaccine mandate—the need to protect the vulnerable. The unvaccinated are no more a risk to others in society than the fully vaccinated.

SERIOUS DISEASE AMONG VACCINATED INDIVIDUALS

On 18 August 2021, President Joe Biden announced that persons who received the Pfizer and Moderna vaccines would be given a third dose eight months after they had been given their second dose (Subramanian, 2021). Hilariously, he has updated it to five months now (Mendez, 2021)!

Intriguingly, he made the announcement even before the FDA had evaluated the need for this extra dose. Ostensibly, this decision was taken to stymie the spread of the highly contagious Delta coronavirus variant. This, however, does not ring true because it is known that the vaccine does not prevent person-to-person spread, and in any case, the Delta variant is resistant to the vaccine.

Rochelle Walensky, the Director of the Centre for Disease Control (CDC), was more forthcoming with the truth when she admitted that vaccine protection was waning. She said that data from Israel showed an increased risk of severe disease among those vaccinated early (Reuters, 2021).

This leads one to speculate that AED may have set in. As the neutralising antibodies produced by the vaccine wane, binding antibodies are causing the dreaded disease enhancement. This has probably created panic in the US government, which led it to announce the need for the third dose before approval by the FDA. A study published recently

in the *Journal of Infection* lends credence to the COVID-19 ADE theory (Yahi et al., 2021). It is hoped that more booster doses will boost the levels of neutralising antibodies, and these antibodies will prevent binding antibodies from causing serious disease on exposure to COVID-19. This is what PE Fine (1997) describes as a salesman's dream and an epidemiologist's nightmare. There is, as yet, no evidence that repeated boosters can keep AED at bay.

VACCINE MANDATES

Another interesting feature of this COVID-19 pandemic is the threat of vaccine mandates. Vaccination certificates (vaccine passports) are being demanded as a condition of employment and travel (India Today, 2021; Mai-Duc & Chapman, 2021; Schneider et al., 2021)

The vaccine under Emergency Use Authorisation is not considered a fully licenced vaccine but an experimental vaccine. In the absence of a licenced vaccine, such mandates violate the Helsinki Declaration (1996). Article 25 decrees "The participation of persons capable of giving informed consent to medical research must be a voluntary act. No person capable of giving their informed consent can be involved in a search (experiments on humans—an explanation not in the original quote) without giving their free and informed consent."

FDA LICENCED VACCINE

On 23 August 2021, the FDA approved a Pfizer COVID-19 vaccine called Comirnaty (O'Shaughnessy, n.d.). This approval was given when only 13 months of its two-year trial period had been completed. Approval was given without convening the FDA's "Vaccines and Related Biological Products Advisory Committee (VRBPAC)"—a body of independent experts that

was set up to ensure that data from COVID-19 vaccine trials are reviewed in a transparent, deliberative manner (Shah et al., 2020). The committee will be presented with a *fait accompli* at its next meeting.

Now that the vaccine had been fully licenced, it was felt that it could be mandated legally (Lovelace, 2021).

Kennedy and Nass (2021) note that the FDA approval statement mentions that the licenced vaccine Comirnaty was in short supply while the old Pfizer-BioNTech COVID-19 vaccine approved under EUA was available for use interchangeably with the licenced Comirnaty. However, the old vaccine was still under EUA.

Pfizer licenced vaccine Comirnaty is subject to strict product liability laws, and persons injured by the vaccine can sue for damages. People who take the vaccine labelled Pfizer-BioNTech COVID-19 have very limited protection in the event of serious adverse events under EUA rules. Kennedy and Nass argue that the FDA's rush to licence Comirnaty knowing full well that the approved drug cannot be used, being in short supply, is a cynical scheme to encourage vaccine mandates and to enable Pfizer to quickly unload inventories of vaccines (Pfizer-BioNTech COVID-19) which the Delta variant has rendered obsolete and which is known to have caused numerous serious adverse effects.

LACK OF TRANSPARENCY

Real data is not being made available. The incidence of adverse events is not being reported faithfully (Nambiar, 2021). Vaccines have been approved without publishing any Phase 3 data in peer-reviewed journals. Regulators seem to be colluding with vaccine manufacturers to keep the

public in the dark by not insisting on publicly reviewable data on safety and efficacy.

The BMJ has gone a step further and argued that journal publications are not sufficient in themselves. They are asking for "release of underlying data from clinical trials to allow for independent verification of results, assessment of heterogeneity of treatment effects for specific subgroups, and facilitate the formation of new research questions" (Tanveer et al., 2021).

Insisting on raw data implies a distrust of peer-reviewed literature. This is justified in the light of recent events when widely trusted, high-profile medical journals had to admit to publishing non-verifiable data (Mehra et al., 2020) and the non-disclosure of conflicts of interest by prominent authors (Editors of The Lancet, 2021).

SCIENTIFIC METHOD

The biggest casualty in this pandemic is the scientific method. The scientific method involves the generation of the hypothesis that the author tries to falsify himself. Only if it proves impossible to falsify does he accept the truth of the hypothesis and publishes it to his peers. His peers must necessarily challenge the findings and try to independently falsify the premises and inferences. In this way, by challenging and verifying findings, science can self-correct and makes slow but steady progress. All forms of censorship and everything that retards the open exchange of ideas saps the very essence of scientific enquiry. Assuming that any one authority or organisation has a monopoly on truth against which all other opinions must be "fact checked" is an anathema to science.

The WHO, however, has a contrary view (Pan American Health Organization & World Health Organization, n.d.).

It believes that the COVID-19 outbreak has been accompanied by what it calls “a massive infodemic: an overabundance of information—some accurate and some not—that makes it hard for people to find trustworthy sources and reliable guidance when they need it”. It has spent effort and money to combat this by censoring social media and the press. There seems to be no room for scientific views that challenge the accepted truth (Corbett, 2021). They are ignored, undermined, and suppressed. Scientists are afraid to speak up. Doctors like Pierre Kory, a highly published and renowned critical care specialist of the Front Line COVID-19 Critical Care Alliance (FLCCC), have had to resign their hospital appointments for not towing the official line on treatments for COVID-19 (McGinley, 2021).

“Scientists shouldn’t be censoring themselves,” says Alina Chan, a Harvard scientist who has contributed to unravelling the COVID-19 origin mystery. “We’re obliged to put all the data out there. We shouldn’t be deciding that it’s better if the public doesn’t know about this or that. If we start doing that we lose credibility, and eventually, we lose the public’s trust. And that’s not good for science.” It would cause an epidemic of doubt, and that wouldn’t be good for any of us (Jacobsen, 2020).

We urgently need to restore the sanctity of process and protocol and revitalise the scientific method if we are to survive this and other pandemics. Pandit Jawaharlal Nehru famously said, “Who lives if India dies? Who dies if India lives?” We may well say: Who lives if science dies? Who dies if science lives?

REFERENCES

- Barnes, G. D., Cuker, A., Piazza, G., & Siegal, D. (2021, June 8). Vaccine-induced Thrombotic Thrombocytopenia (VITT) and COVID-19 Vaccines: What Cardiovascular Clinicians Need to Know. *American College of Cardiology*. <https://www.acc.org/latest-in-cardiology/articles/2021/04/01/01/42/vaccine-induced-thrombotic-thrombocytopenia-vitt-and-covid-19-vaccines>
- Bossche, G. V. (2021, May 13). *Predictions on outcome of mass vaccination during a pandemic of more infectious Sars-2-CoV variants*. Voice for Science and Solidarity. <https://www.voiceforscienceandsolidarity.org/scientific-blog/predictions-on-outcome-of-mass-vaccination-during-a-pandemic-of-more-infectious-sars-2-cov-variants>
- Callaway, E. (2021, June 22). *Delta coronavirus variant: scientists brace for impact*. Nature. https://www.nature.com/articles/d41586-021-01696-3?error-cookies_not_supported&code=d47d613d-66b4-4b3e-bd43-023d37065fb8
- CDC. (2022, April 26). *What You Need to Know About Variants*. Centers for Disease Control and Prevention. <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html>
- Corbett. (2021, March 12). *Hello, I Must Be Going! - The Corbett Report*. The Corbett Report - Open Source Intelligence News. <https://www.corbettreport.com/hello-i-must-be-going/>
- Covaxgate. (2022, July 2) In *Wikipedia*. https://en.wikipedia.org/wiki/Case_Covaxin
- Doshi, P. (2021) Does the FDA think these data justify the first full approval of a covid-19 vaccine? *The BMJ*. 6 September. <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/>
- Editors of The Lancet. (2021) Addendum: competing interests and the origins of SARS-CoV-2. *The Lancet*, 397(10293), 2449–2450. [https://doi.org/10.1016/s0140-6736\(21\)01377-5](https://doi.org/10.1016/s0140-6736(21)01377-5)
- Fine, P. E. (1997) Adult Pertussis: A Salesman’s Dream—and an Epidemiologist’s Nightmare. *Biologicals*,

- 25(2), 195–198. <https://doi.org/10.1006/biol.1997.0083>
- Fulginiti, V. A., Eller, J. J., Sieber, O. F., Joyner, J. W., Minamitani, M., & Meiklejohn, G. (1969) Respiratory Virus Immunization. *American Journal of Epidemiology*, 89(4), 435–448. <https://doi.org/10.1093/oxfordjournals.aje.a120956>
- G1. (2021, March 30) *Anvisa nega certificação de boas práticas a empresa fabricante da Covaxin, vacina da Índia para Covid-19*. <https://g1.globo.com/bemestar/vacina/noticia/2021/03/30/anvisa-nega-certificacao-de-boas-praticas-a-empresa-fabricante-da-covaxin-vacina-da-india-para-covid-19.ghtml>
- Hippisley-Cox, J., Patone, M., Mei, X. W., Saatci, D., Dixon, S., Khunti, K., Zaccardi, F., Watkinson, P., Shankar-Hari, M., Doidge, J., Harrison, D. A., Griffin, S. J., Sheikh, A., & Coupland, C. A. C. (2021) Risk of thrombocytopenia and thromboembolism after covid-19 vaccination and SARS-CoV-2 positive testing: self-controlled case series study. *BMJ*. <https://doi.org/10.1136/bmj.n1931>
- Iacobucci, G. (2021) Covid-19: Protection from two doses of vaccine wanes within six months, data suggest. *BMJ*. <https://doi.org/10.1136/bmj.n2113>
- ICMR [@ICMRDELHI]. (2020, May 9) @ICMRDELHI has transferred the #Covid_19 strain isolated at @icmr_niv to @bharatbiotech. We will be partnering [Tweet]. Twitter. <https://twitter.com/ICMRDELHI/status/1259139533754400769>
- India Today Web Desk. (2021) Mumbai local trains to resume for fully-vaccinated passengers; here's how you can get your passes. *India Today*. 9 August. <https://www.indiatoday.in/information/story/mumbai-local-trains-to-resume-for-fully-vaccinated-passengers-1838696-2021-08-09>
- Jacobsen, R. (2020) Could COVID-19 have escaped from a lab? *Boston Magazine*. 9 September. www.bostonmagazine.com/news/2020/09/09/alina-chan-broad-institute-coronavirus/
- Kennedy, R. F., Jr., & Nass, M. (2021) 2 things mainstream media didn't tell you about FDA's approval of pfizer vaccine. *The Defender*. 24 August. <https://childrenshealthdefense.org/defender/mainstream-media-fda-approval-pfizer-vaccine/>
- Kowarz, E., Krutzke, L., Reis, J., Bracharz, S., Kochanek, S., & Marschalek, R. (2021) "Vaccine-Induced Covid-19 Mimicry" Syndrome: Splice reactions within the SARS-CoV-2 Spike open reading frame result in Spike protein variants that may cause thromboembolic events in patients immunized with vector-based vaccines. *Research Square*. <https://doi.org/10.21203/rs.3.rs-558954/v1>
- Lansbury, L. E., Smith, S., Beyer, W., Karamchic, E., Pasic-Juhas, E., Sikira, H., Mateus, A., Oshitani, H., Zhao, H., Beck, C. R., & Nguyen-Van-Tam, J. S. (2017) Effectiveness of 2009 pandemic influenza A(H1N1) vaccines: A systematic review and meta-analysis. *Vaccine*, 35(16), 1996–2006. <https://doi.org/10.1016/j.vaccine.2017.02.059>
- Lee, W. S. (2020, September 9) *Antibody-dependent enhancement and SARS-CoV-2 vaccines and therapies*. *Nature*. https://www.nature.com/articles/s41564-020-00789-5?error=cookies_not_supported&code=6f5c33a4-72d1-42a6-ae8a-19f7f3f8f19e
- Lei, Y., Zhang, J., Schiavon, C. R., He, M., Chen, L., Shen, H., Zhang, Y., Yin, Q., Cho, Y., Andrade, L., Shadel, G. S., Hepokoski, M., Lei, T., Wang, H., Zhang, J., Yuan, J. X. J., Malhotra, A., Manor, U., Wang, S., ... Shyy, J. Y. J. (2021) SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE 2. *Circulation Research*, 128(9), 1323–1326. <https://doi.org/10.1161/circresaha.121.318902>
- Lovelace, B., Jr. (2021) FDA grants full approval to Pfizer-BioNTech's Covid shot, clearing path to more vaccine mandates. *CNBC*. 23 August. <https://www.cnn.com/2021/08/23/health/fda-pfizer-biontech-covid-19-approval/index.html>

- www.cnn.com/2021/08/23/fda-pfizer-biontech-covid-vaccine-wins-full-approval-clearing-path-to-mandates.html
- Mai-Duc, C., & Chapman, B. (2021) All California Teachers Must Be Vaccinated or Tested Weekly for Covid-19. *WSJ*. 12 August. <https://www.wsj.com/articles/california-teachers-must-be-vaccinated-or-tested-weekly-for-covid-19-11628705928>
- McGinley, L. (2021) Supporters tout anti-parasite drug as covid-19 treatment, but skeptics call it the 'new hydroxychloroquine.' *Washington Post*. 8 April. <https://www.washingtonpost.com/health/2021/04/08/ivermectin-covid-drug/>
- Mehra, M. R., Desai, S. S., Ruschitzka, F., & Patel, A. N. (2020) RETRACTED: Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis. *The Lancet*. [https://doi.org/10.1016/s0140-6736\(20\)31180-6](https://doi.org/10.1016/s0140-6736(20)31180-6)
- Mendez, R. (2021) Biden says U.S. health officials are considering Covid booster shots at 5 months, moving up timeline of third shot. *CNBC*. 27 August. <https://www.cnn.com/2021/08/27/biden-says-us-health-officials-are-considering-covid-booster-shots-within-5-months.html>
- Nambiar, N. (2021) Adverse events reporting by states 'not satisfactory', says AEFI. *The Times of India*. 22 July. <https://timesofindia.indiatimes.com/city/pune/adverse-events-reporting-by-states-not-satisfactory/articleshow/84623666.cms>
- O'Shaughnessy, J. A. (n.d.) *Letter from US FDA to Pfizer, Inc.* FDA. <https://www.fda.gov/media/150386/download>
- Pan American Health Organization & World Health Organization. (n.d.) *Understanding the infodemic and misinformation in the fight against COVID-19 | Digital Transformation Toolkit*. PAHO. https://iris.paho.org/bitstream/handle/10665.2/52052/Factsheet-infodemic_eng.pdf
- Press Information Bureau Government of India. (2021, January 3) *Press Statement by the Drugs Controller General of India (DCGI) on Restricted Emergency approval of COVID-19 virus vaccine* [Press release]. https://www.icmr.gov.in/pdf/press_release_files/HFW_DCGI_emergency_use_authorisation_03012021_2.pdf
- Reuters. (2021) CDC says vaccine protectiveness slipped amid Delta variant. *Reuters*. 18 August. <https://www.reuters.com/business/healthcare-pharmaceuticals/cdc-says-vaccine-protectiveness-slipped-amid-delta-variant-2021-08-18/>
- Schneider, J., Kaufman, E., & Stracqualursi, V. (2021) Pentagon mandates US military service members get Covid-19 vaccine after FDA approval - CNNPolitics. *CNN*. 25 August. <https://edition.cnn.com/2021/08/25/politics/us-military-covid-vaccine-mandate/index.html>
- Shah, A., Marks, P., & Hahn, S. (2020) Ensuring The Safety And Effectiveness Of A COVID-19 Vaccine. *Forefront Group*. <https://doi.org/10.1377/forefront.20200814.996612>
- Subramanian, C. (2021) COVID-19 booster shot for Pfizer, Moderna vaccines will be available Sept. 20. *USA TODAY*. 18 August. <https://eu.usatoday.com/story/news/politics/2021/08/18/covid-vaccine-booster-shots-coming-sept-20-biden-administration-says/8178505002/>
- Tanveer, S., Rowhani-Farid, A., Hong, K., Jefferson, T., & Doshi, P. (2021) Transparency of COVID-19 vaccine trials: decisions without data. *BMJ Journals*. <https://doi.org/10.1136/bmjebm-2021-111735>
- Tercatin, R. (2021) COVID-19: Israel finds possible link between vaccine, myocarditis cases. *The Jerusalem Post*. 25 April. <https://www.jpost.com/health-science/covid-19-israel-finds-possible-link-between-vaccine-myocarditis-cases-666237>
- Thomas, S. J., Moreira, E. D., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Polack, F. P., Zerbini, C., Bailey, R.,

- Swanson, K. A., Xu, X., Roychoudhury, S., Koury, K., Bouguermouh, S., Kalina, W. V., Cooper, D., Frenck, R. W., ... Jansen, K. U. (2021) Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine. *medRxiv*. <https://doi.org/10.1101/2021.07.28.21261159>
- Tirado, S. M. C., & Yoon, K. J. (2003) Antibody-Dependent Enhancement of Virus Infection and Disease. *Viral Immunology*, 16(1), 69–86. <https://doi.org/10.1089/088282403763635465>
- U.S. Department of Health and Human Services, Food and Drug Administration, & Center for Biologics Evaluation and Research. (2020, June) *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry*. <https://www.fda.gov/media/139638/download>
- World Health Organization. (2007) *Guidelines for assuring the quality and nonclinical safety evaluation of DNA vaccines* (No. 941). https://cdn.who.int/media/docs/default-source/biologicals/vaccine-quality/guidelines-for-assuring-the-quality-and-non-clinical-safety-evaluation-of-dna-vaccines70ee1b3e-88a6-40af-8989-fbff8304a377.pdf?sfvrsn=521ee591_1&download=true
- Yahi, N., Chahinian, H., & Fantini, J. (2021) Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? *Journal of Infection*, 83(5), 607–635. <https://doi.org/10.1016/j.jinf.2021.08.010>



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