

TIF - Vaccine Conundrums

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Vaccine blunders: In front of a vaccination centre in Mumbai that is closed for the day because of a lack of supplies (3 May) | Ashish Vaishnav/Alamy

The government lost an opportunity to dampen the second wave but it should at least protect us from the third wave. For that it needs to revise its 'liberalised' vaccine policy, which with its array of complicated procedures will not aid rapid vaccination.

Much has been written about India's latest iteration of its policy on vaccination to prevent the incidence of mortality and reduce severe morbidity due to Covid-19. It is not just media articles that have carried comments on the policy. On 2 May and again on 12 May, leaders of opposition political parties wrote to the prime minister requesting a rethink of a policy that has a strange procedure of procurement and a confusing array of prices unilaterally fixed by the companies. It is interesting that not one newspaper article has been able to discern plausible reasons for the new strategy. Even the central government's affidavit filed in the Supreme Court does not indicate how this policy will help the citizen, justifying a departure from settled policy.

Since control of infectious diseases is a shared responsibility of the states and the centre — it is on the Concurrent List of the Eighth Schedule of the Constitution — the central government has always procured vaccines and supplied them to the states according to the needs of the target groups. In fact, it is the central

government's grants that have enabled states establish cold chains, train vaccinators, provide consumables like disposable needles, lay down protocols to be followed, and, most importantly, ensure quality assurance and follow up on adverse events following vaccination. Over the decades of implementing this policy, it is the central government that has acquired the infrastructure capacity and technical capability to ensure a timely supply of vaccines according to a prefixed schedule and take corrective or legal action in the event of slippages or contract violations by vaccine producing companies.

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On their part, the state governments are responsible for the proper implementation of the vaccination programme: establishing vaccination sites, identifying vaccinators and ensuring their training and supervision, maintaining the infrastructure, developing and disseminating communication material, tackling issues related to vaccine hesitancy, engaging community and other societal resources to ensure maximum coverage, and so on. If each item of past vaccination programmes is costed, the resources shared between the the centre and the states would be roughly 50 : 50.

The current controversy

There are four components of the new "Liberalized and Accelerated National COVID-19 Vaccination Strategy" announced on 20 April that have caused a certain amount of consternation:

- (1) The central government has ordered that the vaccine companies earmark half of their production for the use of the central government at a fixed rate of Rs 150 per dose
- (2) The remaining 50% may be sold to the state governments and private parties
- (3) The companies may announce the sale prices of the vaccine to the buyers. There is no mention of meeting foreign obligations and so it is assumed that the companies are forbidden from exporting their production or fulfilling their commitments to organizations like COVAX, the international initiative for vaccine equity
- (4) Extension of vaccination to all adults above the age of 18.

As the law stands, neither the Drugs Act nor any other act bestows any power or authority on the central government to issue such directives, except under a national public health emergency when a vaccine becomes a public good that has to be made available for use by governments. That is why governments issue tenders and place orders that consume almost the entire manufactured quantity. Such a monopsony gives governments the bargaining power required to beat down prices.

Under the Universal Immunisation Programme, India procures almost 14 varieties of vaccines for children every year. The most expensive is the injectable polio vaccine that is procured for Rs 198. As against that, the prices under the centre's new policy on Covid-19 vaccines were initially:

Name of Vaccine	Price to Central Government	Price to State Govts	Private companies
Covishield (Rs/dose)	150	400	600
Covaxin (Rs/dose)	150	600	1200
Doses to be provided	50% or 30 million/month	Unclear	Unclear

It is significant that in response to an uproar after the policy was announced, the prime minister intervened to 'request' the companies to revise their prices, which they then did. Serum Institute of India (SII), which produces Covishield, brought down the price to state governments to Rs 300 and Bharat Biotech, which produces Covaxin, brought its price down to Rs 400. At these prices, the people of India are paying the highest amount per dose in the world, since Covishield is available for an equivalent of Rs 160 per dose in Europe and is being supplied at Rs 210 per dose to GAVI, the global vaccine alliance that is a key member of COVAX. Almost all countries in the world vaccinate the rich and poor free of cost. It is ironical that the government of the country that has been the most affected, both economically and by incidence of disease, is making vaccines available at the highest price in the world for its people and its governments.

Justification

While there has been no detailed explanation offered by anyone about the benefits of the government's vaccine policy, a clue to the policy intention can be gleaned from the public statements of owners of the two Indian manufacturers of vaccines, Adar Poonawalla of SII and Krishna Ella of Bharat Biotech. Both have clearly stated that they need to make super profits to be able to use those surpluses for reinvestment in their companies. Such statements did raise hackles as they sounded insensitive, the statements being made at a time when almost all sections of society are economically, socially, and emotionally traumatised. In allowing such profiteering, the central government has also been accused of abdicating its responsibility towards people when it needed to be shown the most.

The universal demand from all quarters has been for free vaccination. It is justified as both SII and Bharat Biotech have received substantial financial assistance from the government (Rs 4,500 crore) and Rs 22,000 crore as advance purchase support from the Gates Foundation and GAVI. In addition to significant technical help from publicly funded research organizations (Indian Council of Medical Research and Oxford University), the government regulator also extensively bent procedures to enable them to market their products, notwithstanding the several unknowns in their vaccines. For example, the length of time for which their vaccines offer immunity is not known, nor whether they will be effective against the new mutants, nor whether a booster dose would be required later, and so on.

How does the policy affect access or availability?

The combined manufacturing capability of SII and Bharat Biotech is now about 64 million doses a month. Despite being provided funds by GAVI in September 2020, SII has not significantly ramped up capacity. It is now being said that both these companies will expand their monthly capacity by end July: SII to 100 million from 60 million, and Bharat Biotech to 20 million from 4 million. So, from August, it is expected that 120 million doses may be produced. Due to non-availability of accurate figures in the public domain, it is unclear as to what the exact quantities will be available domestically, especially for the states. Do these figures include or exclude the quantities that have to be provided to COVAX? Do they take into account other contractual obligations? Assuming that the 50% rule for the central government was on total production and that these external obligations had not been factored into account, the availability of vaccines to the states will be squeezed further.

The central government has been very ad-hoc in deciding the population groups eligible for vaccination. Initially, healthcare and frontline workers were made eligible. The government then included the elderly (60+) and those above 45 with comorbidities. Such targeting had a scientific basis since data showed that nearly 88% of mortality during the first wave was amongst this age category. These groups are estimated to add up to 300 million of the population (250 million above the age of 45, and 50 million in the defence forces, healthcare sector, etc.¹) Since the launch of vaccination on 17 January, about 17% of this particular target group have been covered with a single dose and about 10% with two doses.

Under the new policy, the 18-44 age group was made eligible for vaccination from 1 May. The government's

expansion of its target population was done without any connection to the supply of vaccines. Due to the huge dose of complacency amongst policymakers in January, there was an understanding that since the pandemic was on its way out, the two companies would be able to produce enough to meet the country's needs. This led to the government not placing any advance orders or purchase agreements with any other company, not drawing up a policy on stockpiling, and even shipping 66 million doses (out of the 200 million it procured) to 90 countries as grants or on commercial terms.

What remains unclear is why the central government not place orders earlier and why later it placed orders in such small installments that made it impossible for the companies to plan production. At first, orders for 10 million doses were placed with SII at Rs 200 per dose. This was later revised to 200 million doses that brought the price down to Rs 150 per dose. The third order was only placed on 26 April, for another 150 million doses. The rationale for such a procurement policy is befuddling.

Against this background of demand and supply, the extension of eligibility and the liberalising of the vaccine procurement to give play to market forces is confusing for three reasons:

(1) There is no market as such that has been stimulated since there are only two companies currently supplying vaccines (unless India issues a global tender). States have to vaccinate 500 million persons out of the estimated 550 million in the 18-44 years age group (as the remaining 50 million, presumably of the health and other frontline workers and defence forces, are covered by the centre under its 300-million target). So states need to procure a total of 1 billion vaccine doses. At the current rate of production and the 50:50 formula, it will take many months before the population is vaccinated.

(2) States will now have to compete with each other and with private providers of vaccines. Even among private providers, only big corporate hospitals with deep pockets can afford to buy vaccines at the rates now marked and bear the risk that there will be enough takers at the higher prices.

(3) There are now raised expectations, more so due to the other government order that has stated that only those registered under the COWIN can be vaccinated and not walk-in persons. On 1 May—the first day of the new policy—133 million individuals did register, causing crowding at the registration points. As younger people signed-up on COWIN in large numbers after the centre made registrations mandatory for the 18-44 age group, “no vaccines available” boards sprang up. Under pressure from vocal groups, some states are rumoured to have diverted vaccine supplied by the centre for the 45+ group to the younger age groups. Other states, like Andhra Pradesh and Telangana, have confined vaccination until now to the 45+ target group.

Only the affluent can afford vaccines at private hospitals where they are priced at between Rs. 850 and 1,500 a dose. Making COWIN registration mandatory further favours the better off — those with access to computers, smart phones, and technology — leaving out a large number of the poor living in urban slums and rural areas. Overall, this will lead to a skewed selection of the vaccinated, an outcome that will neither flatten the trajectory of the epidemic nor address concerns of equity.

Price is a significant barrier in health-seeking behaviour, particularly when it pertains to prevention and not immediate treatment. Notwithstanding the issue of supply being out of sync with demand, there is a need to make available vaccines for free at the point of supply so as not to leave out large swathes of the poor. In response to the Supreme Court seeking to intervene in this matter of vaccine equity, the centre has haughtily asked it not to interfere in its domain of policy. The centre explained away its stand saying that since many states would provide the vaccine free, it should not be of any concern to the court or citizens how the financing is done. This is a facetious argument, since there is no justification as to why the same product should be sold at three different prices in the same country. Can the centre's stand be right if the policy is bad and can impact peoples' health security and fundamental right to life?

Differential pricing is a routine strategy that companies adopt across countries. Paracetamol that costs less than Rs 10 in India may cost Rs 150 in the US. But in the case of the Covid-19 vaccine in India, the differential pricing is

within the same geography and is likely to hamper the smooth administration of the vaccination programme. First, there will be the administrative burden on the state government machinery to maintain separate accounts of the volume of vaccine doses supplied by the central government for one target group and the state government-procured doses for another target group. Second, the state governments will have to deal with leakages and black-marketing between the three markets created by the centre's policy.

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Even as states now find themselves without vaccines, private hospitals have stocks, forcing many not-so-affluent — for whom vaccination is of immense value for their and their families' survival — to spend money for the vaccine. The rationale for having doses made available for the private sector was that it would expand the reach of the vaccination efforts — but amongst whom? A real scale up can happen only be when the entire private sector is incentivised to partner with the government, when vaccination sites are doubled to over 1 lakh from the current 44,000 and when daily vaccinations are increased to over 10 million from the present average of 3 million.

What the government clearly seems to miss is that success in beating back the virus lies in speeding up vaccination. We are in the midst of the second wave. Vaccination will have only some impact on flattening this wave. After it subsides, there is likely to be a small window before a predicted third wave could hit us. It is during that window between the second and third waves that we need to ensure that 70% of our population are covered. For this, decentralisation is key. District level micro-plans have to be prepared; there must be operational flexibilities to use civil society, gram panchayats, and other stakeholders; and epidemiological evidence should drive the prioritisation of shots. Not all younger people need the vaccine at the same time. Those in regular contact with others need it more urgently— teachers, sanitation workers, taxi drivers, home-delivery workers, industrial workers, amongst others. Detailed planning and education of the people is essential to reduce anxiety and panic.

The key, however, is the supply of vaccines. In accepting a position that the vaccine production will be restricted in the main to two companies, we concede defeat. The centre is fully empowered, and not as weak as it makes us believe, to impose compulsory licensing on Bharat Biotech, and to get India's more than half-a-dozen vaccine manufacturing companies to ramp up production capacity to at least 300 million doses a month. Besides, not everyone needs to manufacture the vaccine – several can also fill and finish. India has that infrastructure and capability.

It is confusing as to why the centre is not using that advantage and those powers to achieve vaccine security for all within the next six months. This is doable and does not need the consent of other countries. The obdurate reluctance to use India's sovereign powers in the face of so much untold human suffering is inexplicable.

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The central government must procure vaccines centrally and supply them to the states. It is simply unwise to force states to go to the market as some are issuing global tenders that may result in a variety of vaccines, such as the Chinese vaccines, in India without having gone through rigorous regulatory approval. Such a confusing situation is clearly avoidable.

Finally, the differential pricing that forces states to cross-subsidise the central government is bad policy and must be opposed as a matter of principle. The burden is unfair and unequal. To vaccinate 300 million people, the centre, at Rs 150 per dose, will spend Rs 9,000 crore. State governments, having to vaccinate 500 million people at Rs 350 a dose, will have to spend Rs 35,000 crore, double the Rs 17,500 crore that they would have had to spend if the unit price was the same as that for the centre. Pharma companies will now get a bonanza of an estimated Rs 17,500 crores simply because the centre refuses to use its powers to issue a tender and get a market-driven price instead of an administered one. This at a time when the state governments already have huge expenditures to incur, including those related to Covid-19 relief. That said, even if the centre feels states need to share the expenditure, it could be on the pattern as in centrally-sponsored schemes.

The central government needs to get realistic and put peoples' welfare upper most. Vaccines are a public good and even capitalist countries like the US are providing them free. India's logic seems misplaced. It is now for the Supreme Court and the people to compel the central government to revise its policy and ensure every rupee so saved is spent on strengthening the broken health infrastructure—so that we never ever have to again face a situation where thousands lose their lives for want of oxygen.

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Footnotes:

1. The population sizes in the 45+ age group and the 18-44 age group are based on estimates of the Registrar General of India's projections of the total population in 2020 and the corresponding age distribution