

# South Africa's vaccine quagmire, and what needs to be done now

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South Africa's approach to its Covid-19 vaccine programme has been characterised by a large number of missteps. In aggregate it has left the country behind many others on the continent, and essentially left millions unvaccinated as a savage third wave descends on the country.



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This has happened despite an established vaccine procurement and distribution network, access to the first large batch of vaccines on the continent, and a large number of pandemic and vaccine experts.

As the country battles a <u>severe third wave crisis</u>, at great cost to health, economy and society, the rollout of a vaccine programme remains the only sustainable means to protect the population against Covid-19 severe disease and death and return to some level of acceptable economic activity.

Strategically, therefore, policy needs to be hyper-focused on the delivery of a responsive vaccine programme to protect especially high risk groups against severe disease and death.

In this article, we outline the history of the vaccine strategy and its pitfalls. We also suggest a way forward.

#### Some context

As the pandemic first unfolded South Africa had, from a vaccine perspective, a number of things going for it. It has a large childhood vaccine programme although with weaknesses in <u>overall coverage</u>. It also has a private sector able to distribute adult vaccines, and experience of rolling out large programmes, such as antiretrovirals.

While reeling from a devastating first wave and associated lockdown in this period, the country was well poised to rapidly implement a mass vaccine programme.

In September 2020, for instance, a vaccine subgroup (the MAC Vac) of the Ministerial Advisory Committee on Covid-19 (MAC) was set up. It was made up of a small group of virologists, regulators and other public entities. It recommended supporting Covax, a pooled procurement and distribution initiative aimed at securing large volumes of vaccines for countries that might struggle with bilateral agreements.

But during early December 2020 it became worryingly clear that government had <u>no vaccine strategy</u> at any level of maturity apart from the fragile Covax arrangement.

To quote the deputy director general of the Department of Health, <u>Dr Anban Pillay</u>:

We have not delayed the procurement at all. We took a decision at the time we will go to (sic) Covax facility because Covax was purchasing vaccine (sic) from multiple vaccine producers, rather than taking the risk and going with one vaccine supplier.

Despite also asserting that individual companies had in fact been approached, there was no evidence of this, including within the publicly released MAC Vac advisories.

In late June 2021 the first 1.4 million doses of Pfizer vaccine were <u>finally delivered</u> to South Africa through the Covax facility. It still remains unclear what will be delivered of the roughly 10.6-million doses still owed to South Africa during 2021.

As no signs of a coherent strategy by the government were surfacing, a group of academics drafted a <a href="10-point vaccine">10-point vaccine</a> strategy in early December 2020 to prompt a strategic response from government.

But no strategy emerged during that month.

# January - February 2021

In frustration a group of South Africa's health academics and activists published an article <u>in early January 2021</u> condemning the absence of a vaccine strategy. They raised the concern that South Africa would enter the winter wave of SARS-CoV-2 infections without a significant part of the population vaccinated against infection or severe illness.

The article provoked a response. The health minister called <u>a news conference</u>, announcing that a strategy would be forthcoming and that confidential bilateral negotiations were in fact under way.

He failed to disclose any details.

A day later, on 4 January 2021, the Department of Health for the first time began belated bilateral negotiations of any seriousness with the Serum Institute of India for whatever doses they could make available of the AstraZeneca vaccine.

Within a week a commitment of some 1.5=million doses was made for delivery during February and March, with the potential option to purchase another 1.5 million.

This revealed what was possible if government began to act with purpose.

Also, within a relatively short period, an application for registration was submitted to the South African Health Products Regulatory Authority and emergency approval provided.

However, there was no rollout strategy, with no vaccine sites or registration system to manage the process. The <u>first</u> <u>AstraZeneca vaccine batch then arrived</u> on 1 February 2021 with much fanfare and was immediately transferred to the Free State for quality assurance.

As there was no other commitment to purchase, until this period no other <u>vaccines were being evaluated by the regulatory authority</u> apart from a rolling application by Johnson & Johnson. And as government had indicated it would be the sole purchaser and distributor of Covid-19 vaccines, no other party had applied for registration.

Despite the rolling application, the Aspen facility in Gqeberha was set to fill and finish 300 million doses of Johnson & Johnson vaccine in 2021. But there were no plans to use these in South Africa as the government appeared to show little interest up to that point.

A 26 January 2021 statement by Aspen's chief financial officer appeared to confirm this. It stated that:

Aspen confirmed it had the capacity to make up to 300-million doses of the vaccine, in a Port Elizabeth plant, and that all those doses would be earmarked for export.

Confusion then ensued when the health minister announced that due to the AstraZeneca vaccine not demonstrating efficacy against mild to moderate Covid-19 against what is now referred to as the Beta variant in the small South African AstraZeneca trial, the rollout of the vaccine <u>was put on ice</u>. The decision was criticised by <u>local scientists</u>, and not supported by the <u>World Health Organisation</u>.

#### **March 2021**

Due to the intervention of researchers involved in the Johnson & Johnson vaccine trial in South Africa <u>a workaround was quickly negotiated</u> for 500,000 trial doses to be made available. These would be prioritised for health workers with implementation in March 2021.

However, this was an expanded observational trial (Sisonke trial), not a rollout. It could only rely on trial sites for expansion, severely restricting the scaling up of the programme.

Nevertheless, the Sisonke workaround was a local initiative that spared the lives of many frontline health workers.

## **April 2021**

The minister of health then controversially chose to discard the initial one-million AstraZeneca doses rather than use them. It is our understanding that this was based on the MAC VaC advice.

He also took a decision to forgo the additional doses that would have been made available from the Serum Institute of India in terms of both bilateral agreements and the first round of Covax. This was despite the World Health Organisation position that while not effective against infection by the Beta variant, it would be effective against the original wild-type variant still prevalent in South Africa and would probably offer protection against severe illness due to the Beta variant, which was subsequently corroborated in animal model studies. The protection against Beta-variant severe Covid-19 in the animal model study was evident despite the low levels of neutralising antibody induced by the AstraZeneca vaccines against the Beta variant, indicating such protection is likely mediated by CD4+ and CD8+ cellular immune responses that are largely unaffected even due to mutations in the Beta variant.

A number of experts were critical of this decision. They argued that South Africa should urgently use all available vaccines.

The minister also indicated that South Africa would not make use of <u>Novavax</u> either, <u>despite it being the only vaccine</u> shown to protect against mild to moderate Covid-19 from the Beta variant and considered in the same league as the mRNA vaccines for efficacy against severe Covid-19. No evidence was offered for the decision.

The AstraZeneca decision effectively knocked South Africa out of the running for the first round of Covax doses, which were made up of AstraZeneca (237-million doses) and some Pfizer (1.2 million doses).

The decision not to pursue the Novavax vaccine potentially explains why they did not seek authorisation through the South African Health Products Regulatory Authority.

While the South African government did begin to take bilateral contracts seriously, our understanding is that substantial negotiations with Johnson & Johnson and Pfizer only began from February 2021.

This guaranteed that South Africa would face a winter wave of the epidemic with most of the 17-million or so high risk population unvaccinated.

The bilateral negotiations bore fruit with both Johnson & Johnson and Pfizer making significant commitments. But delivery was to be spread out intermittently through the remainder of the year – largely missing the predicted winter wave.

## May - July 2021

South Africa officially started its rollout in May 2021 with Pfizer. But it did so with limited sites.

Expansion to scale is now restricted by the availability of doses rather than the ability to expand the number of sites.

The achievement of scale during June was then scuppered by the <u>Federal Drug Administration's (FDA) determination</u> that the very 2.2-million initial Johnson & Johnson doses earmarked for South Africa by Aspen were contaminated and needed to be destroyed.

Despite the very long lead time to this decision, no apparent contingency arrangements were negotiated in the meantime. This resulted in a scramble to compensate for the failure of Johnson & Johnson to deliver on time.

Although replacement doses were subsequently made available, South Africa's already belated vaccination drive was substantially diminished.

By the end of June 2021 South Africa had administered only 3-million doses, 480,000 of which were from Johnson & Johnson through the Sisonke trial and the remaining 2.2 million from Pfizer.

The end of June target for vaccinations was however 5-million outside of the Sisonke trial. Going into July 2021 South Africa should therefore have stock of around 4.3-million doses available if the 6.5-million doses promised by the end of June have arrived.

However, this stock is largely due to the slow pace of vaccinations. We should have had only around 1.7-million doses available at the end of June if everything had gone according to plan.

The bungling continues. Vaccines have moved up to around 100,000 doses administered per day. But, inexplicably, virtually no vaccinations occur over weekends at the majority of sites. And government has not made arrangements for non medical scheme members to make use of private sector vaccination sites.

## What has been learned?

Without a proactive strategy government will perpetually respond to events. Any reasonable strategy must account for contingencies.

What could go wrong? What is not yet known for certain but may be true?

This requires combining evidence with hedging decisions for unknowns where no evidence is yet available.

In this pandemic, as in many other aspects of government policy, decisions have to be made even when perfect information is unavailable.

With this in mind four strategic errors were made.

First, vaccine nationalism was plainly the greatest risk to securing doses in late 2020. Without timely and assertive bilateral contracting beyond Covax it was guaranteed that South Africa would be at the back of the international queue when it began to realise its mistake.

Second, low vaccine efficacy, especially when confronted with variants, is a contingent risk you have to mitigate through careful vaccine candidate selection (for procurement) together with diversification – booking multiple candidates. This includes the advance contracting of booster doses updated for variants of concern.

Third, the ground-game – or rollout process – requires advance preparation to rapidly achieve scale. However, scaling up requires that you start early and learn from mistakes. South Africa has started. Finally. But it is nowhere near the levels required before the winter wave of infections.

Fourth, a substantial winter third wave was predictable and every effort was required to vaccinate the high risk population, particularly for those over the age of 60 and with co-morbidities, by May 2021 with at least one dose of a vaccine that could prevent severe illness. South Africa unfortunately gave this option away despite a contingent probability that AstraZeneca vaccinations would protect against severe Covid-19.

## A look at the strategy for 2022?

South Africa has clearly suffered the consequences of poor strategic decisions to this point. It doesn't need to continue along these lines.

But strategy going forward needs to account for three key factors.

First, from the end of July 2021 many of the advanced countries will have surplus doses and are likely to shift their focus to updated vaccines that address variants of concern. It is therefore probable that the Covid-19 vaccine world will be characterised by a simultaneous glut of original vaccines and constrained supplies of updated booster shots.

Second, global herd immunity, even though an aspirational goal, is unlikely to materialise with the current generation of Covid-19 vaccines and the ongoing evolution of the virus. Instead the objective should be centred on protecting against severe illness and death despite ongoing transmission. One possible contingency is that a single complete mass vaccination programme permanently reduces Covid-19 to a mild illness – with ongoing infections acting as a booster to immune responses. The alternative, less likely contingency is that new variants emerge that evade even natural infection and vaccine induced immunity against severe illness. Both contingencies need to be prepared for.

Third, the pace of vaccinations remains constrained by access to doses rather than the capability of the public and private health systems to administer vaccines. Addressing these supply constraints is therefore a priority.

Taking account of these factors, the following four considerations should form part of the strategy for 2021 and into 2022:

- Bilateral negotiations need to be assertively pursued despite the doses already booked. These should focus on the
  more effective vaccines that are likely to move into surplus during the latter part of 2021 and into 2022. Therefore
  negotiations need to be ongoing with proactive procurement for both 2021 and the whole of 2022.
- 2. South Africa should be advance purchasing the updated vaccines which could have higher effectiveness against the variants of concern. These should include agreements well into 2022.
- 3. Rather than advance purchasing too few doses, or just enough, consideration should be given to purchasing more than is required. This would cater for the contingent risk of ongoing transmission resulting in severe illness in the vaccinated population. It would be a mistake for South Africa to again take its foot off the pedal when the opportunities for bilateral contracting are increasing. But the window for astute early action is closing.
- 4. Greater transparency in strategy, implementation, and the strategic rationale for decisions is required, given the importance these decisions hold for the well-being of the country.

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