Practical Lessons for LMICs' Introduction of Pfizer's COVID-19 Vaccine

This version was prepared in March 2022, and some recommendations may become out-of-date over time.

The following note is based on the experience of several technical partners and consultants who have supported the preparations for the introduction of Pfizer's COVID-19 vaccine[1] across sub-Saharan Africa in Q4 2021-Q1 2022. While the introduction of this vaccine represents a major opportunity to accelerate COVID-19 vaccination coverage, it also presents a number of risks. This note aims to share some lessons learned to date to support countries in their preparations. It should be taken as complimentary to existing guidance from Pfizer, COVAX/GAVI, and UNICEF/WHO. Ultimately, countries must plan based on their own contexts and some of the recommendations below may not be applicable in all cases.

The note is divided into 3 sections: (I) Strategy and Service Delivery; (II) Cold Chain and Logistics; and (III) Demand Promotion.

[1] This note refers primarily to the vaccines targeting the 12+ age group. Pfizer vaccines for the age group 5-11 years have different characteristics and considerations; anticipated vaccines for children below 5 may also have their own requirements. Please see I.6 for more details.

(I) Strategy and Service Delivery

1. **Pfizer as part of a broader vaccine portfolio.** Most countries currently planning for Pfizer introductions already have several other COVID-19 vaccines in the system, including AstraZeneca, J&J, Sinopharm, Sinovac, and others. It is therefore important to consider the comparative advantages of each vaccine type and use them accordingly. It is also important to anticipate in advance the impacts of Pfizer introduction on the overall campaign, for example in terms of pressure on the distribution system, complexity of vaccine management at peripheral levels, or even impact on the demand for other COVID-19 vaccines. *Several countries that have focused too narrowly on Pfizer without considering the overall system have encountered difficulties in the Pfizer roll-out and/or have seen negative impacts on delivery of other COVID-19 vaccines.*

   ➔ Countries are encouraged to have a short paper/policy[2] outlining the role that Pfizer is expected to play within the broader campaign, including target population and vaccine management considerations, and outlining any measures that need to be in place (regarding Pfizer or other vaccines) to maximise the positive impact of Pfizer introduction. This would complement but go well beyond what is currently included in the Pfizer introduction checklist shared by COVAX/Pfizer.

2. **Vaccine shelf life.** Although Pfizer vaccines have a theoretical shelf-life of up to 25 weeks, many countries have seen recent deliveries of doses with only 15 weeks' validity. This places serious pressure on fragile health systems to administer a large number of doses in a short period of time. *This creates greater risks of wastage, as well as pushing countries towards campaign modes of service delivery which are costly and may weaken routine immunization.*

   ➔ Countries are encouraged to proactively discuss their preferences in terms of vaccine shelf-life with GAVI/COVAX. In the event that longer shelf-lives cannot be guaranteed, countries may consider reducing the size of shipments, spreading them over time, or requesting delays until such time as Pfizer/COVAX can provide vaccines that meet countries' needs and realities.

3. **Prioritize high-volume vaccination centers/teams.** Given the overall shelf-life issue mentioned above, the 31-day shelf-limit of Pfizer once passed into the +2°C-+8°C cold chain, and the fact that the vaccine presentation is a 6-dose vial, the Pfizer vaccine is most appropriate to be used in high-volume/high-traffic vaccination centers or outreach teams. This will help reduce both open and closed-vial wastage, as well as the complexity and cost of reallocating vaccines close to expiry to alternative locations in order to avoid wastage.

   ➔ Pfizer vaccines should be prioritized for high-volume vaccination sites and teams. Low-turnover sites – often located in hard-to-reach areas where the health system is weakest – should be prioritized to receive other COVID-19 vaccines with longer shelf lives and fewer doses per vial to reduce wastage.

[2] This could be a standalone document, or part of a revision to countries' NDVPs.

4. **Resource mobilization.** The arrival of substantial number of Pfizer doses provides an opportunity for countries to significantly increase the pace of COVID-19 vaccination, previously hampered in part due to lack of vaccines at the global level. It is however important to recognize that most countries will need to allocate additional resources in order to significantly increase the pace of vaccination. *Several countries have found themselves with large numbers of Pfizer doses in addition to the large quantities of other vaccines but lacking the funding required to cover increased operational costs of delivering these doses. This is particularly true for the many countries that have not updated their operational budgets since the last update of their NDVP, many of which did not anticipate the introduction of Pfizer. In some cases, they have found themselves paying more to quickly administer Pfizer while reducing administration of other COVID-19 vaccines, thereby not significantly increasing the overall rate of vaccination. In other cases, Pfizer doses have remained in central UCC stores for weeks without being deployed, further reducing their shelf-life.*

   ➔ Countries are strongly encouraged to assess the operational resources that will be required to increase the pace of vaccination overall, as well as costs that may be specific to Pfizer (see section II below). This updated budget can serve as a basis for dialogue with development partners to mobilize necessary resources *before* the vaccines arrive.

5. **Trainings as an opportunity.** Countries introducing Pfizer generally plan refresher trainings for vaccinators who will be administering the new vaccine. In addition to covering topics specific to the Pfizer vaccine (dynamic labeling and stock management, dilution, etc.) these trainings can be a strategic opportunity to update practitioners on other aspects of the COVID-19 vaccination campaign. *Selected countries have used these trainings as opportunities to build capacity on related topics including countering common anti-vaxx myths, changes in vaccine eligibility since the previous training (pregnant and breastfeeding women, new age cohorts, etc.), strengthening AEFI reporting, etc.*

   ➔ Countries are encouraged to think strategically about the opportunity to use Pfizer introduction training to strengthen the broader COVID-19 vaccination campaign by building capacity of vaccinators/service providers at the peripheral level**.**

6. **Considerations on boosters and age eligibility.** For many countries, the Pfizer vaccine may be the first COVID-19 vaccine they receive which has SRA approval for use in children under the age of 18. This, combined with emerging evidence on the declining protection afforded by the primary vaccine course has led countries to question the balance to be struck between primary or booster vaccination and vaccination of different age cohorts. Based on WHO SAGE latest guidance (January 2022), countries with lower levels of coverage are encouraged to focus on increasing coverage of (i) primary vaccinations among high- and highest priority groups; and (ii) booster doses for these groups. These are prioritized over the extension of coverage to medium priority groups (including children and adolescents). While it is not yet clear how long immunity from booster doses may be maintained, many countries have already begun planning for the integration of regular boosters for COVID-19 into routine immunization provision.

   ➔ Countries are encouraged to follow WHO SAGE guidance on prioritization of different population groups for both primary and booster doses. Countries are also encouraged to begin consideration of cost-effective and sustainable strategies for provision of booster doses.

(II) Cold Chain and Logistics

1. **Vaccine forecasting – cold chain and delivery capacity.** Most countries' forecasting and modelling exercises have narrowly focused on UCC storage capacity for Pfizer, creating a number of problems. First, many countries continue to use tools that do not enable them to model storage capacity for all vaccines in the country – including routine immunizations, multiple COVID-19 vaccines, and any planned SIAs – resulting in under-estimation of storage capacity, particularly in the +2°C-+8°C system at peripheral levels. Furthermore, focusing only on storage capacity without considering the pressure that Pfizer vaccines will put on service delivery (to avoid vaccine expiry) has also resulted in countries overestimating the number of doses they were ready to receive.

   ➔ Countries are encouraged to use tools such as WHO's Cold Chain Equipment Inventory and Gap Analysis that enable more comprehensive assessment of cold chain capacity. They are also encouraged to analyze critically the current rate of vaccination and consider in advance the resource that might be required in order to augment the vaccination rate to that which would be required to effectively use all anticipated Pfizer vaccines before their expiry date (without negatively impacting delivery of other COVID-19 vaccines).

   ➔ Teams are encouraged to adapt a supply planning approach to consider all vaccines in country, those allocated, and the absorption capacity to strategically plan the timing and quantity of shipments to match what the country is capable of in terms of service delivery while striving to reach the goals of coverage.

2. **UCC Installation and Maintenance.** For many countries, the Pfizer vaccine is the first vaccine requiring ultra-cold chain (UCC) equipment. Countries are therefore considering how and where to integrate UCC equipment into their vaccine cold chain system. An important point to consider is that if a country does not have the capacity to transport vaccines at ultra-cold temperatures (-80°C), it doesn't make sense to install UCC equipment at the regional level.[3] Given the complexity of managing and maintaining UCC equipment – including electrical stability – many countries have opted at the initial stage to install UCC at the national level and to transport the Pfizer vaccine to lower levels within the normal 2°-8°C cold chain. Some countries have also had to rewire the electrical circuits at vaccine stores due to the significant power demand of UCC equipment.

   ➔ Countries are encouraged to carefully consider the siting of UCC equipment, keeping in mind the stringent operating requirements and their own capacity for transporting vaccines at (-80°C). In many cases, it is not advised to install UCC equipment at regional or sub-national levels.

3. **Temperature monitoring.** There is a temperature tracking device from Parsyl that can track the dynamic labeling required for Pfizer. This should contribute to improving routine temperature monitoring across the entire supply chain. Even where such specialized devices are unavailable, use of normal temperature tracking devices (e.g. fridge-tag) is strongly encouraged to ensure vaccine quality. *Some countries have faced shortages of temperature monitoring devices as these had only been procured in sufficient quantities to cover routine immunizations.*

[3] The exception to this would be if regional-level UCCs could be supplied directly from the international port of arrival using the Softboxes in which they are shipped. Softboxes can maintain temperature for 24 hours after arrival, beyond that they require re-icing.

➔ Countries are encouraged to plan for and ensure the availability of temperature monitoring devices for the +2OC-+8OC distribution of the Pfizer vaccine.

4. **Dynamic labelling.** The Pfizer vaccine should be delivered with stickers/labels to use for the dynamic labelling to place on the actual vials, but these are often missing from the shipment. Other options could be small Ziploc bags with the expiry written on the outside or a pen that can write on the vials directly. *Although the shelf-life of Pfizer vaccines has been extended, several countries report that logistics staff and service providers are uncomfortable with administering vaccines beyond the expiration date printed on the box. Staff trained in first in-first out may need to be retrained to employ first-expiring-first-out instead.*

   ➔ Countries are encouraged to plan carefully for the human resources required to appropriately manage the dynamic labelling of Pfizer vials. Training and communications are necessary to ensure that logisticians and service providers administering vaccines understand and are comfortable with the expiration dates indicated by dynamic labelling as opposed to those printed on the box and prioritize vaccines appropriately to avoid expiry/wastage.

5. **Distribution and Delivery.** Many countries' vaccine distribution systems are set up for deliveries every 2-4 months based on storage capacities at local level. Delivery systems have often been optimized for cost or factors other than speed, since most routine antigens have several months' shelf-life under standard (+2^{O}C-+8^{O}C) cold chain conditions. *Given that the Pfizer vaccine has a more limited shelf-life of 30 days once removed from UCC, many countries will need to revisit their distribution plans. Effective use of Pfizer vaccines may require changes such as (i) more frequent deliveries (monthly or bi-weekly); (ii) deliveries of smaller numbers of doses (to ensure they can be fully utilized in 30 days); and (iii) bypassing regional and/or district levels or ensuring 'push' delivery all the way to the service delivery level in order to reduce the time lost in transit. All of the above may have significant cost implications.*

   ➔ Countries are encouraged to revisit their distribution plans in advance of Pfizer arrival, and to ensure that these vaccines can be distributed to service delivery levels in a timely manner to minimize the risk of expiry/wastage. This may require distribution approaches which are significantly different to those used for routine immunization or other COVID-19 vaccines, and it is important to anticipate and budget for any additional costs.

(III) Demand Promotion

1. **Importance of social mobilization.** Because of the limited shelf-life of Pfizer vaccines under normal cold chain conditions, social mobilization is of increased importance in order to ensure that demand is sufficient to use the vaccines within their shelf-life. *Several countries have neglected to prepare social/community mobilization plans in advance, and have faced low levels of demand for Pfizer in the initial weeks following introduction, placing these doses at risk. In others, delays in printing and distributing informational materials has negatively impacted demand for Pfizer.* In addition to broad-based social mobilization to support demand for all COVID-19 vaccines, additional efforts may be focused on specific vaccination centers where Pfizer vaccines will be offered.

2. **Anti-vaxx sentiment specific to Pfizer.** While anti-vaxx messages and myths vary from country to country, they remain a challenge for COVID-19 vaccination in general and Pfizer is no exception. *In some countries, little effort has been put into countering Pfizer-specific vaccine myths due to the lack of Pfizer in the country, allowing these to gain widespread exposure and traction.* For this reason as is the case for any New Vaccine Introduction, it is critical to actively monitor Pfizer-related anti-vaxx myths and begin efforts to debunk them before Pfizer is launched.

3. **Potential impact of Pfizer on demand for other vaccines.** COVID-19 vaccine preferences vary significantly by country and even within countries. *Several countries have observed a notable decrease in demand for other COVID-19 vaccines after the introduction of Pfizer. This can create major difficulties to the overall COVID-19 vaccination effort which for most countries will continue to rely on a portfolio of vaccines.* In addition, if Pfizer vaccines are preferentially allocated to certain locations for strategic and operational regions, this may be misinterpreted by the public with the risk of further undermining confidence in all COVID-19 vaccines.

   ➔ The three factors point to the urgent need for countries to assess, plan, prepare, and implement demand promotion/social mobilization activities related to the Pfizer introduction well in advance of the actual arrival of the vaccines in country. If needed, these communication needs should be communicated with technical partners and donors to ensure that required human and financial resources are allocated in a timely manner. These communications should be considered as part of the broader COVID-19 communications strategy, which may also require adjustments.

Do you have comments, feedback, or questions? Please share with us at info@jsi.com and ssternin@gmail.com specifying that your feedback refers to this document.

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