Autodisable syringe gap analysis

May 25, 2022



The auto-disable (AD) syringe gap analysis combines syringe supply capacity collected from manufacturers with estimated syringe demand from all countries known to use AD syringes globally, including demand for both COVID-19 and non-COVID-19 immunizations. The model forecasts supply and demand on a quarterly basis and extends through the third quarter of 2023.

AD syringe demand forecast

Three potential scenarios for AD syringe demand are forecasted to reflect the uncertainty in future demand. Demand estimates for COVID vaccination syringes are based on country-level projected uptake of vaccine doses considering current vaccination rates,¹ dose deliveries² and allocations,³ and global COVID-19 vaccine coverage targets. Demand for non-COVID-19 immunizations (such as routine childhood immunizations and vaccine campaigns) is based on PATH analysis of the pre-COVID-19 AD syringe market size⁴ and considers expected increases in non-COVID-19 syringe demand to make up for routine immunizations missed during the pandemic.

 The low demand scenario reflects syringes needed for COVID-19 vaccine doses that have already been delivered to countries but not yet used, as well as existing COVAX allocations. This scenario assumes

- a 5% increase in routine immunization syringe needs over pre-COVID levels for the remainder of 2022.
- The moderate demand scenario includes syringe needs of the low scenario and also assumes additional doses will be used from bilateral deals, future COVAX allocations, and/or donations to reach 40% population coverage in all countries. Furthermore, this scenario assumes 5% of the population in all countries receives one booster dose by the end of Q1 2023. The moderate scenario assumes a 15% increase in routine immunization syringe needs over pre-COVID levels for the remainder of 2022.
- The high demand scenario includes syringe needs of the low and moderate scenarios and assumes additional doses will be used from bilateral deals, future COVAX allocations, and/or donations to reach 70% population coverage in all countries. Furthermore, this scenario assumes 10% of the population in all countries receives one booster dose by the end of Q2 2023 and an additional 10% of the population is boosted the following year to account for the possibility of more booster doses or recurring booster doses. This scenario assumes a 25% increase in routine immunization syringe needs over pre-COVID levels for the remainder of 2022.

Figure 1: AD syringe demand is based on vaccine dose data for COVID-19 immunizations and the pre-COVID-19 syringe market size for routine immunizations. Three scenarios were forecasted to reflect uncertainty in future demand.

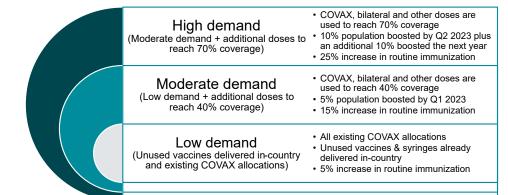
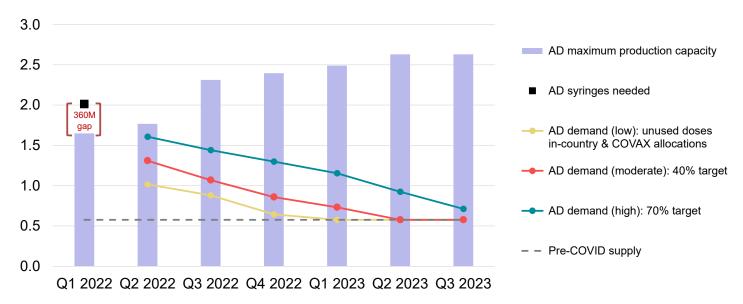


Figure 2: Global production capacity of AD syringes is expected to be adequate in all demand scenarios.



Current vaccination progress is accounted for in population coverage calculations for primary series and booster COVID-19 vaccinations, and a 2-dose primary regimen is assumed. Each scenario assumes different vaccine wastage rates, with a higher wastage rate applied to doses already delivered to countries based on typical shelf life for COVID vaccines. The syringe wastage rate is assumed to be 10% in all scenarios based on historical vaccination campaigns.

AD syringe supply forecast

The supply forecast reflects maximum production capacity reported by WHO-prequalified AD syringe manufacturers in the second quarter of 2022. However, manufacturers may not be able to produce at maximum capacity if orders are not received with sufficient lead times. Production capacity is shifted ahead 1 quarter to reflect typical shipping times for sea transport.

AD syringe shortage in early 2022

Over 2 billion AD syringes were estimated to have been needed in Q1 2022 based on reported COVID-19 vaccinations in countries that use AD syringes, routine immunization syringe needs and syringe wastage. This indicated an estimated gap of 360 million units in Q1 2022. Manufacturers' nearly threefold ramp up of production capacity was essential to respond to the large surge of demand.

New AD syringe volumes

All primary series COVID-19 vaccines for adults with WHO emergency use listing (EUL) as of May 20, 2022,

can use 0.5 mL AD syringes, with the exception of Pfizer, which requires a 0.3 mL AD syringe.5 Moderna booster and pediatric doses (still awaiting WHO EUL) have a dose volume of 0.25 mL, and Pfizer pediatric doses are 0.2 mL, requiring novel volumes of AD syringes that were not previously manufactured.^{6,7} Multiple brands of 0.3 mL syringes have been prequalified to deliver Pfizer adult doses since early 2021, and additional AD syringes of 0.2 and 0.25 mL volumes were prequalified in May 2022.8 Demand for these new syringe volumes is uncertain due to pending COVAX allocations of pediatric doses, poor visibility into bilateral pediatric dose deals, and undetermined COVID-19 immunization practices for new child cohorts. In the case that novel sizes of AD syringes are not available where or when they are needed, the WHO has recommended that 1 or 2 mL re-use prevention (RUP) syringes with appropriate graduations and dead space be used instead.9

Gap analysis

Global production capacity for AD syringes is expected to be sufficient for all potential demand scenarios given reductions in demand and manufacturers' substantial ramp up in production capacity. In a low scenario, syringe demand is expected to approach pre-COVID levels towards the end of 2022, and in a high scenario, is expected to remain slightly above pre-COVID levels through 2023 to achieve the 70% target in all countries and continue booster campaigns. However, the evolution of the pandemic and the emergence of new variants, among other factors, may bring about sharp increases in syringe demand in the future.

Table 1: Key inputs and assumptions for three demand scenarios.

| Assumption | Low syringe demand | Moderate syringe demand | High syringe demand |
|---|--|--|---|
| COVID-19 vaccine uptake | Doses already delivered in-country, but unused, are administered in Q2-Q3 2022 with 60% wastage. Existing COVAX allocations are administered in Q2-Q4 2022 with 30% wastage. No further booster doses. | Doses already delivered in-country, but unused, are administered in Q2-Q3 2022 with 40% wastage. Existing COVAX allocations are administered in Q2-Q4 2022 with 20% wastage. Bilateral doses and additional doses (COVAX, donations, etc.) are administered in Q2 2022-Q1 2023 to reach 40% population coverage and 5% boosted in all countries. | Doses already delivered in-country, but unused, are administered in Q2-Q3 2022 with 20% wastage. Existing COVAX allocations are administered in Q2-Q4 2022 with 10% wastage. Bilateral doses and additional doses (COVAX, donations, etc.) are administered in Q2 2022-Q2 2023 to reach 70% population coverage and 10% boosted in all countries. An additional 2.5% of the population boosted in Q3 2023. |
| Syringe wastage rate | 10% | 10% | 10% |
| Routine immunization increase above pre-COVID-19 levels | 5% throughout 2022 | 15% throughout 2022 | 25% throughout 2022 |
| Doses for COVID-19 vaccination | Population coverage calculations assume 2-dose primary series and 1-dose boosters. | | |
| Non-exclusive AD countries | Countries that use AD syringes non-exclusively (in addition to other syringe types) for immunizations are assumed to need AD syringes for 60% of their forecasted immunizations. | | |

Table 2: Key data sources.

| Data source | Forecast input | Date updated |
|-------------------|--|----------------|
| Our World in Data | COVID-19 vaccinations ¹ | End of Q1 2022 |
| UNICEF | COVID-19 vaccine dose deliveries ² | April 27, 2022 |
| COVAX | COVID-19 vaccination allocations and forecast ³ | April 11, 2022 |



¹Source: <u>https://ourworldindata.org/covid-vaccinations</u>

 $^{^2} Source: \underline{https://www.unicef.org/supply/covid-19-vaccine-market-dashboard}$

³ Source: https://www.who.int/publications/m/item/decision-of-the-independent-allocation-of-vaccines-group-on-the-allocation-of-covax-facility-secured-vaccines--11-april-2022

 $^{^{4}} Source: \underline{https://path.azureedge.net/media/documents/PATH_Global_COVID_syringe_supply_assessment_path.org_3.8.21.pdf$

 $^{{}^{5}}Source: \underline{https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued}$

⁶ Source: https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf

 $^{^7} Source: \underline{https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1$

⁹ Source: https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy_brief-Vaccination-Injection_safety-Addendum-2022.1