

# What We Know (and Don't Know) About Global Vaccine Manufacturing Capacity

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## Abstract

Global vaccine manufacturing capacity remains poorly defined, inconsistently measured, and insufficiently understood—limitations that undermined the COVID-19 response and, without progress, will constrain responses to future pandemics too. This paper synthesises evidence from 17 major studies and five stakeholder consultations to map how capacity is currently assessed, what these approaches capture, and where critical blind spots persist. We find that existing assessments rely on heterogeneous definitions, static surveys, and proprietary or incomplete datasets, offering limited visibility into platform-specific capabilities, input bottlenecks, surge potential, and real-world timelines for scaling production. COVID-19 exposed these weaknesses: uncertain capacity estimates, unanticipated raw-material constraints, and limited insight into platform flexibility hindered coordinated global response. Our review highlights major methodological gaps—including a lack of standardised metrics, limited predictive modelling, and uneven transparency—that impede comparability and decision-making. We propose an integrated framework emphasising three priorities: (1) establishing shared, platform-specific metrics for capacity and surge readiness; (2) building a brokered, confidentiality-protected data system for aggregating global manufacturing information; and (3) shifting from static capacity counts toward scenario-based analysis that reflects supply-chain fragilities, regulatory processes, and workforce readiness. Strengthening these foundations is essential to move from fragmented visibility to actionable, resilient global manufacturing preparedness.

## What We Know (and Don't Know) About Global Vaccine Manufacturing Capacity

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## Key messages

1. Global vaccine manufacturing capacity remains poorly defined and inconsistently measured. Existing assessments use incompatible definitions, uneven data sources, and varying levels of granularity, leaving policymakers without a clear or comparable picture of where capacity exists, how it operates, or what it can realistically deliver in a crisis.
2. COVID-19 exposed deep information gaps—especially around platform readiness, input bottlenecks, and surge potential—that complicated real-world decisions.
3. A major limitation of current approaches is that they focus on static inventories rather than how fast systems can adapt and scale. Assessments rarely capture switching timelines, supply-chain dependencies, regulatory steps, or workforce constraints—all central to understanding how manufacturing behaves under pandemic conditions.
4. Manufacturing resilience depends on a balanced system: one that supports economies of scale while reducing the risks of over-concentration. No country can be self-sufficient across all platforms and inputs; regional interdependence—combined with strategic specialisation—offers greater robustness than isolated national investments.
5. Surge capacity should be actively maintained between crises. Facilities need routine production, trained staff, and stable supply chains if they are to scale up rapidly during an emergency; dormant or mothballed lines cannot respond at speed. New incentives are needed in order to fund this greater resilience.
6. Moving from fragmented visibility to coordinated preparedness requires shared metrics, targeted data collection, scenario-based assessments, and governance that links data to institutions with financing power. These elements together can shift the global system from descriptive mapping to actionable planning, aligning investment, manufacturing strategy, and pandemic preparedness.

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## Introduction

Knowing where vaccines can be manufactured, on which platforms, and at what scale is fundamental to pandemic preparedness. Yet the global system still lacks a clear and consistent view of vaccine manufacturing capacity. Estimates come from a mixture of surveys, one-off landscape studies, self-reported figures, and donor-driven assessments—each using different definitions, assumptions, and levels of granularity. As a result, the global community does not have a coherent answer to a seemingly basic question: what manufacturing capacity actually exists, and how might it be mobilised in the next pandemic?

Globalisation can also lead to an increasingly opaque supply chain operation, as it becomes difficult for purchasers and regulators to observe processes happening on the other side of the world (Foster et al., 2021). Whilst these systems garner little public attention when they work, the poor understanding of them leaves the world vulnerable to both supply and demand shocks.

COVID-19 exposed this gap clearly. As countries scrambled to expand supply, it became apparent that information on production capacity, platform readiness, input bottlenecks, and surge potential was limited, inconsistent, or simply unavailable. These blind spots made it harder to understand what the manufacturing system could realistically deliver, where constraints were likely to arise, and which facilities or regions might be able to scale faster (Hay et al., 2025). In short, decision-makers lacked visibility into several operational questions that would have been useful to answer before the crisis arrived. We believe that having this information would have improved our vaccination response to COVID-19 and made it easier to plan. We recognise that the lack of data was not the primary reason for the slow and unequal rollout of vaccination plan. However, a lack of information about manufacturing and timelines made it more difficult to plan or challenge unequal allocation decisions in real time, which probably increased inequality (Hussmann et al., 2021). Low- and middle-income countries also tended to have much less good access to the data that did exist, which further disadvantaged these countries.

This paper seeks to understand what information would it have been realistic—and valuable—to know before COVID-19, and do we have that knowledge now? Our focus is specifically on vaccine manufacturing capacity rather than the wider pharmaceutical supply chain, and on the types of data and analytical approaches that could meaningfully support emergency planning. We examine existing global and regional assessments to understand how capacity is currently measured, what these approaches capture, and where important gaps remain. We complement this with insights from expert consultations to identify which aspects of manufacturing readiness matter most for rapid response: platform-specific capabilities, bottlenecks in inputs and equipment, surge potential, and the time required to scale production.

The sections that follow map how vaccine manufacturing capacity is currently understood, identify the persistent blind spots, and consider how future research and policy efforts can better align data collection with the needs of funders, manufacturers, and global health actors preparing for the next pandemic.

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## How capacity blind spots undermined pandemic response

The COVID-19 pandemic demonstrated that limited visibility into global vaccine manufacturing capacity can complicate both planning and production. Policymakers and technical agencies entered the crisis without a clear sense of where vaccines could be manufactured, which platforms existing facilities were capable of running, or how much output was realistically achievable. This made operational decision-making more difficult and introduced avoidable ambiguity into projections, investment choices, and coordination efforts (Hay et al., 2025; So & Woo, 2020).

Several types of information would have been particularly valuable to have in place before COVID-19. The first is facility-level capacity, disaggregated by platform and by production stage. Knowing how much mRNA, viral-vector, or protein-subunit capacity existed—as well as the split between drug-substance and fill-finish—would have offered a clearer picture of where rapid scale-up was feasible. Closely related is information on platform flexibility: which sites could plausibly switch platforms, how long tech-transfer would take, and whether regulatory prerequisites were in place. These factors determine how quickly a manufacturing network can adapt when a new pathogen emerges (CEPI, 2020).

Equally important is visibility into the supply of inputs and equipment. Many of the most constraining bottlenecks during COVID-19 originated upstream in areas such as lipids, adjuvants, filters, or single-use bioreactor bags. Without information on the availability and scalability of these components, it is difficult to distinguish between facilities that are constrained by physical capacity and those that are constrained by the materials needed to run that capacity. Finally, fill-finish throughput—the availability of vials, stoppers, packaging lines, and cold-chain equipment—plays a central role in determining how many finished doses can actually reach distribution channels, regardless of antigen availability (Feddema et al., 2023; IFPMA, 2021).

In a pandemic, each of these categories of information is used to answer core operational questions: how much vaccine can realistically be produced; which facilities could scale fastest; where bottlenecks are likely to emerge; and how manufacturing efforts should be sequenced to match platform-specific capabilities with emerging vaccine candidates. Without this visibility, it becomes harder to generate reliable production forecasts, to target support where it would be most effective, and to coordinate production across geographies.

The absence of this information during COVID-19 created three broad types of constraints. First, uncertainty about true production capacity led to wide variation in dose forecasts and repeated revisions as assumptions about utilisation or input availability proved optimistic. Second, because upstream bottlenecks were poorly mapped, constraints on raw materials or equipment were often identified only once they had already caused delays, limiting the ability to mitigate them proactively.

Third, surge capacity planning was challenged by incomplete understanding of tech-transfer timelines, platform readiness, and regulatory pathways—factors that shape how quickly new vaccines can move from development to large-scale production (CEPI et al., 2021).

Looking forward to potential future pandemics, these information gaps highlight the kinds of visibility that would make manufacturing responses more coordinated and realistic. The difficulties experienced during COVID-19—whether around platform capabilities, input availability, flexibility, or final-stage throughput—underscore which aspects of capacity matter most when speed and scale are essential. Reflecting on these gaps is primarily useful as a way to help us understand what data and insight will be necessary to respond more effectively to the next. The analysis that follows examines progress in data collection since 2020 and how current assessments address these questions and where important uncertainties persist.

### **BOX 1. Vaccine manufacturing process**

Vaccines are produced through a series of tightly controlled steps that turn a biological starting material into a finished dose that can be given safely to people. After a candidate vaccine has passed pre-clinical testing and large phase 1–3 trials and been licensed by regulators, the challenge shifts from development to manufacturing at scale. In the upstream part of the process, manufacturers receive and qualify dozens to hundreds of raw materials, then generate the antigen in bioreactors, eggs, or cell-culture systems. Depending on the product, this may involve growing whole pathogens (for inactivated or live-attenuated vaccines), expressing recombinant proteins, or producing genetic constructs such as mRNA. The antigen is then harvested from the culture, isolated from the growth medium, and purified and—in many cases—inactivated, with each step run under strict good-manufacturing-practice (GMP) requirements (Gomez et al., 2013; WHO, 2025b).

The downstream process takes this purified bulk and turns it into a finished dose. Antigen is formulated with other components such as stabilisers, adjuvants, and preservatives, then transferred to aseptic fill-and-finish, where vaccine is filled into vials or pre-filled syringes, sealed, labelled, and packaged. Extensive in-process controls and end-product testing (safety, potency, sterility, and stability) are applied at multiple stages; quality control and lot release can account for a large share of total production time, and end-to-end manufacturing can take 12–36 months for complex multivalent products. After release, finished product enters the cold chain, where maintaining recommended temperatures (typically 2–8 °C, with some products requiring frozen or ultra-cold storage) is essential for preserving potency during storage and shipment (Vaccine Europe, 2016).

While these upstream and downstream unit operations are common to most vaccines, how they are implemented depends on the underlying platform (see Table 1). Egg-based whole-virus

vaccines, recombinant protein vaccines, viral-vector vaccines, and nucleic-acid platforms all rely on different biological substrates, equipment, inputs, biosafety requirements, and (for some products) cold-chain profiles. As a result, capacity in one platform (for example, egg-based influenza) is not automatically interchangeable with capacity in another (such as mRNA), even if headline dose numbers appear similar.<sup>1</sup>

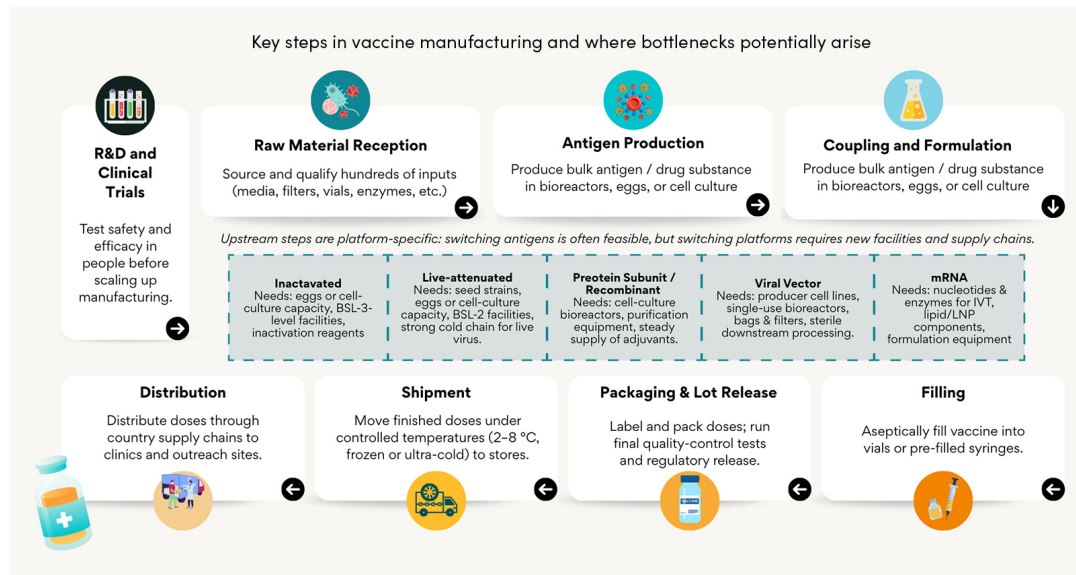
Establishing these manufacturing capabilities is highly capital-intensive, often requiring investments ranging from US\$50 million to over US\$700 million, depending on the platform and scale. Furthermore, constructing and validating a new facility is a lengthy process to reach commercial licensure due to stringent regulatory requirements for facility qualification. For example, Pfizer took five years and US\$ 600 million to build a manufacturing site in the US (Plotkin et al., 2017). Therefore, the choice of platform is critical to determine the equipment and raw materials needed and how quickly production can be scaled during a crisis. Capacity is just not only counting how many vials a factory can fill, but also about three interlinked dimensions: speed, flexibility, and where bottlenecks are likely to emerge. The vaccine platform determines all three (Sabet-Azad et al., 2025).

**TABLE 1. Platform-specific manufacturing mechanism<sup>1</sup>**

Platform Type	Mechanism	Examples	Manufacturing Key Feature
<b>mRNA (nucleic acid)</b>	Delivers an mRNA sequence in lipid nanoparticles so host cells transiently produce the viral antigen.	Pfizer–BioNTech and Moderna COVID-19 vaccines.	Cell-free/enzymatic
<b>Viral vector</b>	Uses a harmless carrier virus (e.g. adenovirus) to deliver the genetic code of the target antigen.	AstraZeneca and J&J COVID-19 vaccines; some Ebola vaccines.	Cell-based
<b>Protein subunit/recombinant</b>	Produces and purifies a specific viral protein (e.g. spike), often given with an adjuvant.	Novavax COVID-19, hepatitis B, HPV.	Cell-based with complex purification
<b>Inactivated (whole-virus)</b>	Uses whole virus grown in eggs or cell culture, then chemically inactivated so it can no longer cause disease.	Many inactivated influenza vaccines, inactivated polio vaccine (IPV), some COVID-19 vaccines (e.g. Sinovac).	Pathogen-based, higher biosafety
<b>Live-attenuated (whole-virus)</b>	Uses a weakened form of the virus that can replicate and induce immunity but rarely causes disease.	Measles, mumps, rubella (MMR), oral polio vaccine (OPV), some influenza vaccines.	Pathogen-based, lower biosafety than inactivated

<sup>1</sup> These five groups cover the main platforms with substantial current manufacturing capacity. Other platforms—such as DNA vaccines and newer delivery technologies—are emerging but are not covered in detail here.

**FIGURE 1. Vaccine manufacturing process**



## Mapping how global vaccine manufacturing capacity is measured

### Search strategy and inclusion criteria

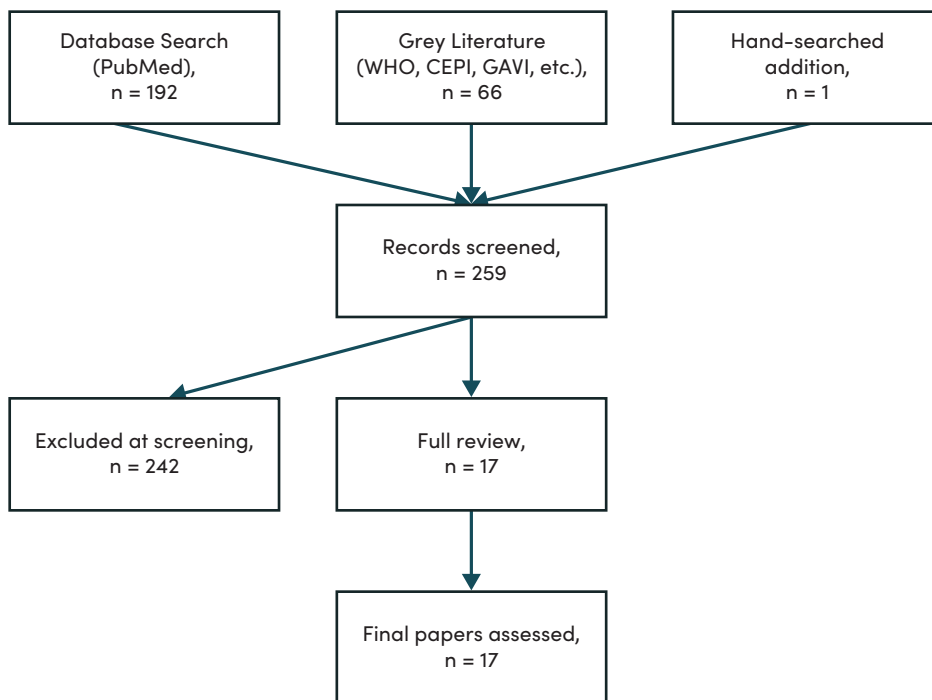
This review systematically analysed how global vaccine manufacturing capacity is measured and tracked in existing studies, with a particular focus on methods to assess readiness, surge capacity, and bottlenecks. We began with a broad search strategy combining key terms related to vaccine manufacturing, geographical scope, and emergency response.

We conducted a structured search combining academic database queries and targeted exploration of grey literature from key international organizations, including WHO, CEPI, GAVI, UNICEF, World Bank, and industry reports. This approach was essential given that many insights into manufacturing capacity exist outside academic literature, particularly in organizational assessments and policy documents. From an initial pool of 192 academic papers and 66 grey literature publications, we applied inclusion criteria focusing on relevance to global or regional capacity tracking, clarity of methodology, and forward-looking implications for pandemic preparedness. This process yielded 17 highly relevant studies that form the core of our analysis.

The selected studies represent diverse geographical focuses, assessment methodologies, and technical approaches, providing a comprehensive view of how manufacturing capacity is currently

measured and monitored (see Figure 1). We acknowledge that there are likely other relevant papers that fall outside the search criteria from this literature review. Detailed methodology, including search terms and screening steps, is provided in Appendix A.

**FIGURE 2. Literature screening and selection process**



## Categorising papers by type of methodology used

The following section categorizes key studies on vaccine manufacturing capacity by the methodologies used, allowing a systematic comparison across the literature. Table 1 summarizes the methodological approaches (Survey, Interview, Cost Modeling, Data Analysis, Predictive Modeling) used in each study, indicating clearly with “YES” when a particular method is employed and “NO” when it is not. It also indicates whether studies focus specifically on vaccine platforms or cover broader geographic scopes (global or regional). Additionally, the table highlights whether each study substantially addresses critical thematic areas, such as Supply Chain Bottlenecks, Equity & Access, and Pandemic Preparedness. The final column identifies the primary data sources utilized by each study (see Table 2).

### Semi-structured consultations

We then complemented the literature review with semi-structured consultations with five stakeholders: a global normative agency, a regional vaccine-manufacturing coordination initiative,

a product-development and preparedness funder, a global public-private partnership working on access to vaccines, and an implementation NGO working with ministries of health.

All interviewees were sent a two-page document summarising the findings from our literature review prior to the call, and reminded of the results during a five-minute presentation at the start of the call, in order to validate these results.

As agreed with participants in advance, the interviews were conducted on a confidential, non-attributable basis. As such, we present only anonymised insights that informed our interpretation and policy recommendations, without naming individual participants. Interviews are numbered one to five based on which interview the comments came from. Four of the five interviews were recorded and transcribed by Microsoft Teams and Zoom. Based on respondent preferences, interview two was not recorded, but extensive notes were taken during the call.

**TABLE 2. Current assessment approaches in global vaccine manufacturing capacity literature**

No	Title	Authors	Survey	Interview	Case Study	Data Analysis	Predictive Modeling	Primary Data	Global/Regional	Data Sources
1	Building Greater Resilience in Vaccine Manufacturing	(Cuddihy et al., 2022)	NO	YES	YES	YES	YES	NO	Global	WHO MI4A data, Our World in Data, CEPI reports, industry insights
2	CEPI 100 Days Mission Report 2022	(CEPI, 2022)	NO	YES	YES	YES	YES	NO	Global	WHO, CEPI, McKinsey analysis, regulatory agencies, vaccine developers
3	CEPI VMC Regional Global Survey 2021	(CEPI, 2021b)	YES	NO	NO	YES	NO	YES	Global	Survey responses from manufacturers in Africa, SE Asia, Latin America, Middle East
4	Expanding Emergency Vaccine Manufacturing Capacity in Latin America and the Caribbean	(Guzman et al., 2022)	NO	NO	YES	YES	NO	NO	Regional – Latin America & Caribbean	WHO, PAHO, WTO-IMF Vaccine Trade Tracker, Airfinity Reports
5	African Vaccine Manufacturing Ecosystem: Supply Landscape and Expansion Plans	(CHAI, 2022)	NO	NO	YES	YES	NO	NO	Regional – Focused on Africa	WHO, Africa CDC, Gavi, national regulatory bodies, manufacturer announcements
6	Upscaling Vaccine Manufacturing Capacity: Key Bottlenecks and Lessons Learned	(Feddema et al., 2023)	NO	YES	NO	YES	NO	YES	Global	WHO, industry reports, interviews with manufacturers and policymakers
7	Market Shaping: Strategic Considerations for a Healthy Vaccine Marketplace	(Gavi, 2011)	NO	NO	YES	YES	NO	NO	Global	WHO, UNICEF, GAVI procurement records, McKinsey reports
8	Expression of Interest for Supply of COVID-19 Vaccines	(UNICEF, 2020)	YES	NO	NO	YES	NO	YES	Global	Manufacturer-reported supply estimates, COVAX, WHO
9	Vaccine Markets: Prioritizing and Scaling up Towards Equitable Access	(UNICEF, 2023)	NO	NO	YES	YES	NO	NO	Global	WHO, UNICEF procurement records, Gavi, PAHO, manufacturers

(Continued)

**TABLE 2. (Continued)**

No	Title	Authors	Survey	Interview	Case Study	Data Analysis	Predictive Modeling	Primary Data	Global/Regional	Data Sources
10	Expanding the Capacity to Produce Vaccines in Africa: Enablers and Barriers	(Martin et al., 2023)	NO	NO	YES	YES	NO	NO	Regional – Africa	WHO, Africa CDC, USP internal reports, Gavi, national regulatory agencies
11	The COVID-19 Vaccine Production Club: Will Value Chains Temper Nationalism?	(Evenett et al., 2021)	NO	NO	YES	YES	NO	NO	Global	WHO, UN COMTRADE, Orbis firm-level trade data, WTO-IMF Vaccine Trade Tracker
12	ASEAN Regional Vaccine Manufacturing and Development: Regional Synthesis Report	(Mutasa et al., 2023)	NO	YES	YES	YES	YES	NO	Regional – South East Asia	WHO, ASEAN Secretariat, CEPI, World Bank, regional government agencies, IMF-WTO vaccine trade tracker
13	Scaling Up African Vaccine Manufacturing Capacity: Perspectives from Industry	(Andrew Rodriguez et al., 2023)	YES	YES	YES	YES	YES	YES	Regional – Africa	WHO, Africa CDC, Gavi, Biovac, Boston Consulting Group (BCG) analysis, national regulatory agencies
14	Global Vaccine Market Report 2023	(WHO, 2025a)	NO	NO	YES	YES	NO	NO	Global	WHO MI4A, UNICEF procurement data, PAHO Revolving Fund, vaccine manufacturers’ sales data
15	COVID-19 Vaccine Development and Rollout in Historical Perspective	(Amanda Glassman et al., 2022)	NO	NO	YES	YES	NO	NO	Global	WHO MI4A, UNICEF, Our World in Data, national vaccination databases
16	WHO Global Influenza Vaccine Production Capacity – 2025 Update	(Taaffe et al., 2025)	YES	NO	NO	YES	YES	YES	Global	WHO survey, internal WHO yield assumptions, MI4A, GVM
17	Vaccine Almanac	(Linksbridge, 2024)	NO	NO	NO	YES	YES	NO	Global	Gates Foundation, Gavi, PAHO, PATH, UNICEF, U.S. CDC, WHO, CHAI and other partners.

This systematic classification reveals that surveys and data analysis are the most commonly used methodologies, whereas predictive modeling and comprehensive cost modeling are notably less frequent. The table further illustrates that many studies focus on global or regional capacities but are often limited in their use of multiple methodologies simultaneously. Additionally, while pandemic preparedness receives relatively consistent coverage, issues like equity, access, and detailed supply chain analysis tend to be addressed unevenly, highlighting significant gaps and opportunities for future research. See Box 2 for more details on the trade-offs of each approach.

## **BOX 2. Trade-offs of Approaches to Capturing Manufacturing Capacity**

### **SURVEYS:**

Surveys are frequently used to assess manufacturing capacity, but have several limitations. They depend heavily on identifying the correct respondents, meaning key experts or organizations may be inadvertently excluded. Respondents may also have commercial incentives to inflate their reported capacities to attract prospective clients (as factories operating near capacity could be seen as less reliable), leading to inaccurate data. Non-response bias is another significant issue, with larger firms more likely to reply, skewing results toward higher-capacity producers. Surveys typically provide static, retrospective data, which poorly capture dynamic operational realities during crises. Additionally, operational constraints such as actual utilization rates or downtime are rarely reported, making the capacity estimates misleading.

### **INTERVIEWS:**

Interviews share similar weaknesses to surveys but tend to amplify these issues due to their smaller sample sizes and higher resource demands. The risk of significant selection bias increases if informants are not representative or sufficiently diverse. Furthermore, their qualitative nature can limit comparability and generalizability across different manufacturing contexts (Creswell & Poth, 2024).

### **CASE STUDIES:**

Case studies offer valuable insights into specific scenarios or methodologies but inherently lack comprehensive coverage. Findings from case studies are difficult to generalize broadly due to their context-specific conditions, limiting their effectiveness for informing global preparedness policy (Eisenhardt & Graebner, 2007).

### **DATA ANALYSIS:**

Data analysis approaches depend heavily on existing datasets, which often suffer from being outdated, incomplete, or inconsistent. Such analyses rarely reflect real-time operational constraints and variations. Even sources that provide more dynamic data, like Airfinity, restrict access due to proprietary concerns, further limiting transparency and replicability.

### **PREDICTIVE MODELLING:**

Predictive modelling is critical for preparedness planning but is seldom performed comprehensively. When conducted, these models often use static or overly optimistic assumptions and fail to integrate real-world disruptions such as raw material shortages, regulatory delays, or geopolitical issues, limiting their practical utility. Additionally, limited transparency in methodologies and assumptions makes validation challenging.

### **PRIMARY DATA COLLECTION:**

Primary data collection methods depend significantly on the specific data points collected and methodologies used. To date, primary data efforts generally suffer from similar issues encountered in broader data analyses—such as incomplete, inconsistent, or outdated information—resulting from limitations in data collection methods and proprietary constraints. Thus, the quality and comprehensiveness of primary data collection efforts remain inconsistent and often insufficient for effective preparedness planning.

## **Assessment framework**

To provide a more nuanced evaluation of how each study addresses critical aspects of vaccine manufacturing, we developed a comprehensive assessment system across three key topical focus areas with three sub-components derived from documented COVID-19 bottlenecks:

- i. **Supply-chain readiness:** inputs, equipment, and fill-finish for supply-chain readiness.
- ii. **Pandemic preparedness:** surge, platform adaptability, and timelines for preparedness.
- iii. **Equity and access:** geography, affordability, and allocation.

For each study, we reviewed whether these elements were not mentioned at all, mentioned only briefly, analysed with some data/examples, or covered in depth. Rather than reporting numeric scores, we summarise overall coverage for each topical area using an **ordinal classification**:

- **Limited:** only mentions the topic or covers one sub-component superficially.
- **Moderate:** addresses several sub-components with some data or analysis.
- **Extensive:** provides detailed, data-driven analysis across most or all sub-components.

The underlying rubric and detailed per-sub-component assessments are provided in Appendix A. Table 3 below presents the resulting classification for all 17 studies across the three topical areas.

**TABLE 3. Assessment summary of 17 studies on vaccine manufacturing capacity topical areas**

No	Author, Year	Supply Chain Bottlenecks	Pandemic Preparedness	Equity & Access
1	(Cuddihy et al., 2022)	Moderate	Moderate	Limited
2	(CEPI, 2022)	Moderate	Extensive	Moderate
3	(CEPI, 2021b)	Limited	Moderate	Moderate
4	(Guzman et al., 2022)	Moderate	Moderate	Moderate
5	(CHAI, 2022)	Moderate	Moderate	Extensive
6	(Feddemma et al., 2023)	Moderate	Moderate	Limited
7	(Gavi, 2011)	Limited	Limited	Extensive
8	(UNICEF, 2020)	Limited	Extensive	Moderate
9	(UNICEF, 2023)	Moderate	Moderate	Moderate
10	(Martin et al., 2023)	Moderate	Moderate	Moderate
11	(Evenett et al., 2021)	Moderate	Moderate	Moderate
12	(Mutasa et al., 2023)	Limited	Limited	Moderate
13	(Andrew Rodriguez et al., 2023)	Moderate	Limited	Extensive
14	(WHO, 2025a)	Limited	Limited	Extensive
15	(Amanda Glassman et al., 2022)	Moderate	Moderate	Extensive
16	(Taaffe et al., 2025)	Limited	Limited	Moderate
17	(Linksbridge, 2024)	Moderate	Moderate	Limited

Assessment across the 17 studies shows wide variation in how comprehensively vaccine manufacturing capacity is assessed. Only a few reports—most notably the WHO Global Influenza Capacity report, WHO MI4A, and UNICEF Supply Division—consistently cover almost all subcomponents of supply chain bottlenecks, pandemic preparedness, and equity and access. Many others mention these dimensions but fall short on depth, particularly around production infrastructure, affordability, or response timelines. Predictably, pandemic surge and fill-finish receive more attention than upstream inputs or platform adaptability. While geographic disparities are frequently noted, structured analysis of pricing or allocation remains limited.

## Current understanding of global vaccine manufacturing capacity

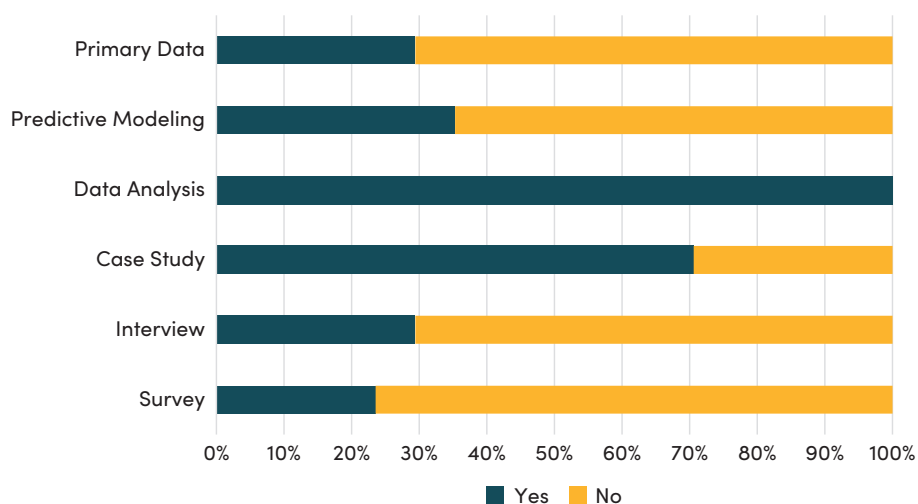
### Common patterns in methodology

Our systematic review of 17 key studies reveals how global vaccine manufacturing capacity is currently understood and measured (see Figure 3). From the reviewed works, vaccine manufacturing capacity is tracked through a patchwork of global surveys, manufacturer self-reporting, and donor-led initiatives, each with its own scope and limitations.

A fundamental challenge then emerges: **the absence of a standardized framework for measuring vaccine manufacturing capacity**. Unlike clinical trials or other industrial domains—which operate under globally harmonized protocols—there is no international agreement that defines what data on manufacturing capacity must be collected, how often, or in what format. While some studies report annual production volume, this figure is inconsistently defined and rarely reflects actual output. Even when cited, it often refers to theoretical or maximum installed capacity, with little disclosure on utilization rates, downtime, or product-type constraints. The result is a fragmented landscape that makes it difficult to compare capabilities across regions and platforms or to align investments with true gaps in global readiness. It is also supported by the stakeholder consultation, which stated:

*“There are so many different methodologies that are going into all these different surveys, um, and questionnaires, and so it’s really hard to compare between regions, or compare within a region, because you’re comparing apples and oranges.” Interview five*

**FIGURE 3. Methodologies across 17 key studies**



### Types of data sources used

Most existing studies rely on point-in-time assessments that provide static snapshots of manufacturing capacity, an approach misaligned with the dynamic nature of pharmaceutical production technologies. The COVID-19 pandemic illustrated how rapidly manufacturing capabilities can evolve, yet current assessment methods remain predominantly retrospective, offering limited predictive insights into potential surge capacities or technological adaptabilities.

The most prominent data source is WHO’s Market Information for Access (MI4A)<sup>2</sup>, alongside UNICEF’s Supply Division<sup>3</sup>, both of which collect information on production volumes, platforms, and geographic spread through confidential manufacturer surveys. On the other hand, Airfinity—a health analytics company that gained prominence during COVID-19—claims to provide real-time facility-level estimates by tracking public announcements, regulatory filings, and delivery data.<sup>4</sup> Despite its methodological advantages, Airfinity’s data remains behind substantial paywalls, limiting access to many stakeholders and perpetuating information asymmetries in global vaccine planning.

**TABLE 4. Global vaccine manufacturing capacity datasets**

Dataset	Owner	What They Track	Data Points	Access Level
WHO Market Information to Vaccines (MI4A)	WHO	Manufacturer name, location, vaccine platform, production volumes, capacity estimates	Production volumes, platforms, manufacturer-level data	Public access, underlying survey data confidential
UNICEF Immunization Market Dashboard	UNICEF Supply Division	Vaccine types procured, quantities ordered, delivery details by country	Procurement records, delivery details	Public access
CEPI Vaccine Manufacturing Tracker	CEPI	Survey results on manufacturing capacity, regional availability, and scale-up plans	Capacity tracking, survey responses, manufacturing plans	Limited public access
Gavi Vaccine Market Dashboard	Gavi	Vaccine purchase agreements, quantities procured, delivery timelines	Purchase orders, delivery timelines	Restricted
COVAX Data Brief and Internal Reports	COVAX	Supply and demand estimates, coverage projections, internal planning assumptions	Supply estimates and coverage projections	Restricted, public access to aggregated report
PAHO Revolving Fund	PAHO	Pricing data, vaccine volumes procured, delivery schedules across PAHO member states	Pooled procurement pricing and quantities	Restricted, Public access to prices yearly
Africa Vaccine Manufacturing Mapping	Africa CDC, CHAI, PATH	Regulatory approvals, manufacturer-reported production figures, regional readiness	Manufacturer reports, regulatory approvals	Restricted, public access to aggregated report

(Continued)

- 2 <https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a> WHO’s MI4A collects data through manufacturer surveys, focusing on vaccine pricing, volumes, and market dynamics primarily for routine immunization programs.
- 3 <https://www.unicef.org/supply/> UNICEF’s Supply Division monitors production capacity through procurement relationships and voluntary manufacturer reporting, publishing market updates that inform global allocation decisions.
- 4 <https://www.airfinity.com/> Airfinity gathers health and life science data, including government information, academic research, real-time “global listening” technology, and commercial partnerships.

**TABLE 4. (Continued)**

Dataset	Owner	What They Track	Data Points	Access Level
Airfinity One ID and Biorisk	Airfinity	Vaccine manufacturing trends, forecasts, and production capacity by manufacturer and region	Facility-level estimates, announcements, delivery tracking	Proprietary (paid)
Global Vaccine Market Model (GVMM)	Linksbridge SPC	Country-level vaccine demand, pricing, and procurement forecasts	Demand volumes by vaccine and year, price per dose, Gavi co-financing phase, coverage targets, procurement timelines	Proprietary (paid), public access to aggregated report
WTO-IMF Vaccine Trade Tracker	WTO & IMF	Cross-border trade volumes and values of vaccines by country	Trade volumes and values of vaccines across borders	Public

### *Analytic approaches and frameworks*

Current approaches to analysing global vaccine manufacturing capacity are often misaligned with the information needed to support a timely and effective pandemic response. While all 17 reviewed studies incorporated some form of data analysis, the majority relied on manufacturer one-time surveys (14/17), which could possibly introduce systematic distortions, particularly when manufacturers may have incentives to overstate or underreport capacities for strategic reasons (Goodman et al., 2021).

Case studies, though valuable for contextual insights, often lack generalizability to broader manufacturing ecosystems and may not capture evolving technological landscapes. The underutilization of comprehensive cost analysis frameworks further inhibits understanding of economic sustainability and scale-up feasibility. These methodological imbalances collectively hamper the development of robust, forward-looking assessments that could effectively inform pandemic preparedness policies and investment decisions. More information on this is available in Box 2.

### *Use of predictive modelling*

Despite the critical importance of scenario-based planning in pandemic preparedness, predictive modelling remains rare across global vaccine manufacturing studies. Only a handful of reports, including WHO's and CEPI's, offer structured modeling of surge conditions. These exercises typically simulate best- and moderate-case outputs, incorporating assumptions on facility readiness, platform types, and dose timelines. While useful, they often lack transparency in methods, omit demand-side constraints, and rely on static input assumptions without stress-testing for supply shocks or geopolitical disruptions.

*“CEPI does lots of different levels of modelling in terms of what the supply chain is and how rapidly you can produce things ... but they don’t really track capacity.”*

Interview one

Most other assessments fall short of predictive rigor. Some white papers, institutional reports, and donor-funded diagnostics tend to default to manufacturer-reported capacities or historical procurement volumes. These are often backward-looking with minimal disaggregation by platform or geography, and almost no visibility into how production would respond dynamically in a crisis. Critically, no study integrates real-time variables—such as raw material bottlenecks, platform-switching constraints, or labour shortages—into its modelling. This reflects not only data fragmentation but also a lack of institutional investment in building replicable, future-facing analytical tools. Without predictive modelling that incorporates these dimensions, global preparedness plans risk being reactive and blind to emerging threats.

WHO leverages internal modelling to generate forward-looking demand forecasts for specific antigens, but this approach has not yet been widely extended to pandemic surge capacity projections across platforms.

### ***Data gaps, transparency, and replicability***

Commercial sensitivities and competitive dynamics in the pharmaceutical industry further complicate comprehensive capacity assessments. Limited transparency, driven by proprietary concerns among manufacturers, significantly restricts data sharing and impedes holistic analysis (Pagliusi et al., 2020). Few of the studies reviewed disclosed sufficient methodological detail to allow replication or independent validation. This lack of transparency reduces the comparability and policy utility of the findings and makes it difficult for donors, governments, or global institutions to use the results for planning or investment decisions.

A key limitation cited by stakeholder consultations is the trade-off between transparency and maintaining supplier confidentiality. While a global agency emphasizes the need for more transparency—aligned with recent calls under the Pandemic Accord—they stressed the importance of *“finding the right broker to do this ... and the right methodology,”* to have a trusted intermediary who can collect sensitive capacity data, anonymize or aggregate it appropriately, and share it in ways that support preparedness without compromising competitive interests.

By illuminating these methodological gaps, our review emphasizes the necessity of developing more robust, dynamic, and holistic frameworks for understanding global vaccine manufacturing capacity. Future research must prioritize standardized, transparent, and granular approaches that can capture the complex, evolving landscape of vaccine production technologies and capabilities.

## Thematic findings: Global manufacturing capacity landscape

### *Supply chain and production bottlenecks*

#### *1. Raw materials & inputs*

Most studies acknowledge that input shortages constrained vaccine production, but few offer meaningful analysis of raw material readiness. While the WHO 2025 Influenza report flags overreliance on egg-based inputs and notes that only four manufacturers had access to critical adjuvants like AS03 and MF59, such details are rare. One study identified filters, stoppers, and vials as key chokepoints (Feddema et al., 2023), yet most literature stops short of quantifying risk or mapping suppliers. The Linksbridge Almanac, CEPI, and Gavi reports largely omit upstream supply tracking. Across the landscape, raw material constraints remain more assumed, projected than assessed in detail—an evidence gap that leaves pandemic preparedness exposed.

Consultations reinforced that visibility is weakest upstream where production depends on hundreds of qualified inputs (e.g., filters, single-use bioreactor bags, stoppers, vials, adjuvants, LNPs). Practitioners highlighted hundreds of components that must be available and qualified, and emphasized the need for practical “bottleneck flags” over static capacity lists. These indicators would surface emerging constraints early and are more decision-useful for surge planning than inventories of facilities alone.

“There are too many inputs—200 to 300 components—and they’re really difficult to track or manage. Fill-finish is often assumed sufficient, but in practice it can be a constraint.” Interview two

#### *2. Production equipment*

While input shortages drew some attention, production equipment received even less scrutiny. Very few studies examine production equipment in any depth, despite its centrality to manufacturing readiness. Most reports refer vaguely to “infrastructure needs” or “facility upgrades” without specifying equipment types or bottlenecks. Feddema et al. mention single-use bioreactors and filtration systems as constraints, but do not quantify global availability or throughput. As we were told in interview two “Gaps persist in understanding what equipment is scalable or interchangeable,” which can make surge capacity hard. The WHO 2025 Influenza report notes fill-finish as a pressure point but gives limited attention to upstream manufacturing hardware like fermenters or cleanroom systems. Linksbridge provides site-level platform information but not technical capacity or equipment readiness. Overall, visibility into core production infrastructure—what exists, where, and how scalable it is—remains notably absent across the literature.

### *3. Fill-finish & distribution*

Fill-finish capacity is more frequently discussed than other supply chain nodes, but detailed analysis remains limited. Several assessments cite it as a major bottleneck during COVID-19, particularly due to shortages in vials, stoppers, and cold chain infrastructure. CEPI's global survey found that 25% of manufacturers faced potential fill-finish constraints, and regional gaps were especially pronounced in low- and middle-income countries. While some sources distinguish between bulk antigen producers and fill-finish-only sites, few quantify throughput or assess whether current facilities can pivot across vaccine platforms. Without clearer visibility into capacity and distribution logistics, fill-finish remains a partially diagnosed risk in global manufacturing readiness.

## *Resilience and future preparedness*

### *1. Surge capacity*

Despite widespread emphasis on surge capacity as a core element of pandemic preparedness, most existing analyses stop short of quantifying it. While several efforts reference the concept, few define clear metrics or simulate scenarios under which routine vaccine manufacturing could pivot to emergency response. One of the few published estimates of global surge manufacturing capacity comes from Sparrow et al. (2021), who assessed the production potential for pandemic influenza vaccines in 2019. They estimated global surge capacity at 8.26 billion doses in a best-case scenario, and 4.13 billion doses in a more moderate one (Sparrow et al., 2021). These projections assume optimal financing, unrestricted access to raw materials, and functional coordination.

Even among more data-rich assessments, surge capacity is often inferred from self-reported expansion plans or procurement contracts, with little alignment to actual lead times for scaling inputs, modifying platforms, or validating new production runs. No standardized metric exists to define or benchmark surge, and few tools can stress-test the system under plausible threat conditions. As a result, surge remains more of a conceptual goal than an operationally measurable parameter.

Stakeholders also consistently argued that “surge capacity” is often treated as a single number when, in practice, it hinges on fill-finish speeds, upstream inputs, workforce, and regulatory steps; several advised shifting from headline dose counts to measures of response time and ecosystem readiness. A global market actor noted that average vs. maximum reported supply could be used as a (limited) proxy for surge today, but does not capture platform switching or speed.

### *2. Platform adaptability*

While many assessments note the distribution of vaccine production across platform types—such as mRNA, viral vector, and inactivated vaccines—very few evaluate the ability of manufacturers to

switch platforms or adjust formulations in response to new pathogens. Platform adaptability remains more implied than analysed, with limited visibility into the technical, regulatory, or infrastructure constraints that shape real-world flexibility. This is despite it being recognised that after COVID-19 that greater ease in repurposing manufacturing of vaccine types could greatly improve outputs in a future pandemic (Feddemma et al., 2023; McElwee & Newall, 2024).

Several reports acknowledge structural barriers to adaptability, including the limited uptake of novel platforms in low- and middle-income countries, gaps in tech transfer, and regulatory misalignment. Yet no study provides systematic data on how quickly production lines can be retooled, nor the proportion of vaccine manufacturing that can be quickly adapted.

It also aligns with the consultations with stakeholders which cautioned that platform switching is rarely rapid or simple due to infrastructure needs, regulatory processes, and lengthy tech transfer timelines.

“Platform switching is not easy. It involves infrastructure changes, regulatory hurdles, and tech transfer timelines.” Interview one

### 3. Response timeline

During COVID-19, it took 326 days from when the virus was genomically sequenced until it received an emergency use authorisation from a stringent regulator (Saville et al., 2022). CEPI wants to build a system so that by the next pandemic, there will be vaccines with emergency use authorisation within 100 days of sequencing, and that large-scale manufacturing that utilises global manufacturing capacity will have started by this date too (CEPI, 2021a). This is a realistic yet ambitious target, that it’s estimated would have saved 4.8 million deaths in LMICs during COVID-19 (Barnsley et al., 2024).

It is not clear from the literature how quickly production of new vaccines can be scaled up using existing infrastructure: This is a key question that will need to be answered in more detail before we know whether the 100-day target can be met.

## Equity and access

### 1. Geographic distribution

Geographic distribution was one of the most consistently addressed dimensions across the studies reviewed (9/17 studies high-scored in this subcategory), with many reports offering disaggregated analyses or regional mappings. This body of work tends to focus on the disparity between high-income countries and the rest of the world, often with a particularly strong emphasis on Africa, which accounts for just 1% of global manufacturing (CHAI, 2022). Published data is usually aggregated at the regional level rather than the national level. Given that the national level is where

most health decisions are taken, this lack of granularity means that the information is not as useful as it could be.

More generally, papers tend to focus on distribution of manufacturing infrastructure, rather than whether there is a clear blueprint to ensure widespread access to vaccines across the world. It is not realistic to place a manufacturing plant in every country (and nobody advocates for this), which means in practice, there will be many countries in the world that rely on imports during the next pandemic. This suggests research should go further than simply looking at the regions where vaccines are manufactured, to examine whether the manufacturing country is likely to limit exports, where binding distribution plans have or could be put in place. When asked about this question, one interviewee raised the importance of diversifying supply chains across many countries, so that more countries have leverage in discussions over where to allocate vaccines, whilst also trying to keep facilities large enough to benefit from economies of scale.

*“Thinking about inputs in such a way where they’re not all in one country makes a lot of sense. You get the best of both worlds, possibly, in having the large facilities, but also having the leverage, so countries have to trade”* Interview one

Regional actors urged planning for interdependence—such as distributing inputs (vials, filters, LNPs) and different manufacturing steps across countries—to reduce the risk of export restrictions and vaccine nationalism in a crisis.

## 2. Affordability

Affordability is one of the least developed areas across the literature reviewed. A few reports note the persistence of tiered pricing structures, with evidence that some upper-middle-income countries pay more per dose than high-income countries for select vaccines. Others point to donor dependency and procurement fragmentation as major risks to long-term financial sustainability for LMICs. Yet few studies offer comparative cost data, and even fewer analyse the pricing mechanisms that shape manufacturing incentives.

Affordability is tightly connected to the manufacturing landscape itself. While many aspects of vaccine production are not directly driven by market price, production constraints can create temporary or structural market power, allowing manufacturers with scarce capacity—or control over key inputs—to command higher prices. Similarly, the cost of scaling up surge capacity, from installing new equipment to expanding fill–finish lines, can significantly influence long-term price trajectories if these investments if we rely on technology that is expensive to scale up. Finally, the underlying cost structure of different platforms (e.g., mRNA versus protein subunit) affects the price and by extension impacts which technologies are viable for LMIC manufacturers.

Despite these linkages, discussions of affordability often remain anecdotal or aspirational, lacking quantitative analysis on margins, procurement terms, or unit economics. As a result, one of the most decisive levers for equitable access—price—is among the least interrogated in the vaccine manufacturing capacity agenda.

### 3. Allocation

Several studies reference COVAX's allocation framework, which proceeded in two stages. In Phase 1, countries received doses proportional to population with an initial 3% coverage benchmark to vaccinate health and social-care workers, then continued allocations up to 20% of each country's population. In Phase 2, allocations shifted toward a weighted approach that considered epidemiologic risk and vulnerability as supply improved (WHO, 2020).

Yet few papers assess how these frameworks function in practice, particularly in relation to timeliness or equity. Critiques highlight donor-driven distribution, slow disbursement, and lack of transparency in matching supply to epidemiological risk. Regulatory delays, such as lags in WHO prequalification or national licensure, are acknowledged as access barriers, especially for newer platforms like mRNA, but rarely quantified.

More importantly for manufacturing capacity, existing literature seldom considers how the characteristics of individual production sites shape allocation in the first place. Allocation is not determined by epidemiological criteria alone; it is influenced by who owns the plant. A profit-maximising manufacturer may be more likely to favour high-income countries than one with philanthropic goals. The commercial relationships it maintains, the countries that have more leverage, for example, from having contributed funding or supplied critical inputs. A manufacturing site may implicitly favour long-standing commercial partners, countries that host upstream suppliers, or those that co-financed the platform or facility. These dynamics mean that manufacturing capacity itself is a determinant of who gets vaccines, when, and under what terms, not just a neutral source feeding into global allocation mechanisms.

Given that in any future pandemic where we are relying on vaccines, there is likely to be a period where demand for vaccines is far greater than supply, it would be good if assessments of global manufacturing capacity took greater consideration of where early vaccines might go.

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## How we expect research to progress

Interviews and consultations with relevant stakeholders confirmed that many of the most pressing knowledge gaps in vaccine manufacturing capacity remain unresolved. Current efforts are often patchworks, with each organization approaching the issue through its own lens, focusing on different parts of the supply chain according to its specific goals and responsibilities. While there

is momentum in several ongoing initiatives, progress will depend on bridging data fragmentation, aligning methodologies, and creating incentives for sustained participation from manufacturers and governments.

In response, several ongoing initiatives are working to close these gaps, offering complementary approaches that, if better aligned, could improve global manufacturing readiness. Several initiatives underway could help close these gaps:

- **WHO** is conducting a global market landscape study that maps manufacturing capacity from drug substance through fill-finish, alongside procurement patterns, platform use, and regional dependencies. By leveraging its Mi4A dataset—which covers 170–180 countries annually—WHO can triangulate confidential manufacturer and country-level data to estimate surge capacity.
- **CEPI** and the **Regional Vaccine Manufacturing Collaborative (RVMC)** are developing tools to measure platform fungibility and regional resilience. RVMC is also creating a Progress Scorecard to track sustainable capacity across LMIC manufacturing hubs.
- **CHAI** is carrying out regional, facility-level analyses to improve visibility on operational capacity, bottlenecks, and the economics of sustaining production between pandemics.

Interviews also highlighted two persistent barriers that cut across regions and stakeholders: (1) data confidentiality and lack of incentives to report. Manufacturers and some governments remain hesitant to share detailed capacity figures due to commercial sensitivity, political considerations, and uncertainty over how the data will be used. (2) Uneven reporting in LMICs, where monitoring is often donor-driven and irregular. Without clear benefits for contributors, such as improved demand forecasts, pooled procurement opportunities, or access to financing, reporting remains patchy. Some experience shows that even with a trusted, neutral platform, coverage can be inconsistent, while an organization noted that the absence of systematic, ground-level reporting obscures the true bottlenecks in areas like fill-finish or input availability, limiting the ability to model surge capacity with accuracy.

There is broad support for establishing a standardized, global framework to measure surge capacity—one that integrates infrastructure, inputs, workforce, and regulatory readiness rather than relying solely on volume metrics. A streamlined, incentive-aligned system could enhance both country and manufacturer participation, particularly if measurement tools are tied to financing mechanisms and regulatory processes. Regional institutions mentioned several times that they could play a central role in ensuring data collection aligns with local priorities while contributing to global visibility.

Open questions remain over who should coordinate such a global framework, how frequently data should be collected, and which indicators most accurately reflect real-world readiness. More research is also needed to understand how quickly new production can be scaled using existing infrastructure, and how to sustain pandemic-response capacity in peacetime without creating idle, politically vulnerable facilities.

In short, while the next few years will likely see more systematic mapping of vaccine manufacturing capacity, the greatest progress will come from moving beyond static inventories toward real-time, stress-tested systems that can model how platforms, supply chains, and regulatory pathways would perform under actual pandemic conditions.

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## Challenges to sustaining surge capacity

Maintaining meaningful surge capacity in the periods *between* major outbreaks is one of the most persistent structural challenges in global vaccine preparedness. Interviews consistently underscored that “surge” is often misunderstood: it is not a fixed pool of idle facilities waiting to be switched on, but the ability of a living manufacturing ecosystem—facilities, people, input suppliers, regulators—to expand output rapidly in the face of new demand. As a respondent in interview one explained, dedicated pandemic plants are not a practical solution: *“If you build that capacity, it will sit there idle ... it takes longer to set something up from scratch, or that’s been sitting mothballed, than it does to scale something already running”*. Without continuous use and revenue, facilities deteriorate, staff disperse, and quality systems degrade. Surge capacity, in practice, requires globally distributed multi-use infrastructure that remains commercially viable in peacetime.

Yet achieving this baseline activity is difficult. Manufacturing remains heavily demand-driven, and interviewees repeatedly noted the absence of predictable, long-term demand for many platforms or product types. Interviewee two highlighted that many surge assumptions used in modelling are “overly simplified,” failing to reflect the real constraints that emerge from fill-finish throughput, the speed of packaging lines, and the availability of 200–300 specialised inputs. In their view, surge is not a single number but a moving target shaped by upstream and downstream bottlenecks as much as by bioreactor volume.

A second challenge lies in platform adaptability and tech transfer. As was noted in interviews two and three, switching platforms is often assumed to be straightforward when in reality it involves infrastructure modifications, specialised workforce skills, regulatory approvals, and lengthy technology-transfer processes—none of which can simply be “stored” in standby mode. These elements must be maintained continuously to remain viable, further raising the cost of keeping surge options warm.

The economic sustainability problem is perhaps the most acute. Participants in interview one were explicit that maintaining idle or single-use pandemic capacity is financially impossible without a diversified commercial base, noting capital costs “in the hundreds of millions of dollars” and higher unit costs for low-volume production runs.

Taken together, these insights point to a clear conclusion: surge capacity cannot be preserved as dormant infrastructure. It must be embedded within sustainable, multi-platform, globally distributed manufacturing ecosystems, supported by reliable demand signals, routine production,

and investment in workforce, regulatory agility, and supply-chain robustness. Without these foundations, the world risks repeating the scramble of early 2020—entering the next crisis with impressive facilities that are limited by our capacity to scale.

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## Critical knowledge gaps and what it means for future research and policy

### Toward a shared understanding of capacity

“Manufacturing capacity” appears throughout vaccine policy discussions without consistent definition—a practical problem that hinders pandemic planning. Across the reviewed literature, authors use the term to mean production volume, surge capability, fill-finish operations, or platform adaptability without explaining their assumptions. Most studies report theoretical maximum output rather than realistic production levels, which typically run 40–60% lower due to maintenance, changeovers, and yield variations. Units also vary: some studies count doses, others vials, and still others population coverage, making cross-study comparison nearly impossible.

Moving forward requires agreement on what capacity means and how to measure it, with clear distinctions between production stages, platform types, and surge readiness. Governments and international organizations should invest in monitoring systems that continuously track capacity and bottlenecks rather than relying on periodic snapshots. Such improvements would enhance forecasting accuracy, resource allocation, and response time during emergencies—modest investments that could significantly strengthen pandemic preparedness.

### What current efforts still fail to capture

Current tracking systems provide only fragmented snapshots of manufacturing capacity without capturing how systems perform under stress. WHO MI4A offers retrospective data while platforms like Airfinity with more dynamic capabilities remain behind paywalls. Few studies model production under pandemic conditions, and those that do rely on optimistic assumptions. Missing from most assessments are critical elements like platform switching capabilities, regulatory coordination, cold-chain requirements, and workforce mobilization—factors that significantly affected COVID-19 vaccine rollout.

Future work must stress-test capacity rather than simply mapping it. This means modeling disruption scenarios such as input shortages, regulatory barriers, or concurrent demand spikes across multiple regions. Strategic approaches for securing critical components like lipids, adjuvants, and bioreactor bags deserve particular attention, as these proved to be significant bottlenecks during the pandemic. Without these improvements, even sophisticated tracking systems will provide limited value during actual emergencies.

## Risks of inaction for future pandemics

The world entered COVID-19 without shared infrastructure to measure or manage global vaccine manufacturing capacity, leading to predictable failures. COVAX's repeated downward supply revisions, stock-outs across 68 countries, and allocation weren't primarily scientific failures but information and coordination failures. Production estimates routinely exceeded actual output by 30–50%, while capacity was concentrated in a handful of countries that prioritized domestic needs over global equity.

These patterns will likely worsen without intervention. Increasing trade barriers, intellectual property disputes, and vaccine nationalism create a more challenging landscape for coordinating future responses. While regional manufacturing initiatives offer potential solutions, the risk of isolated capacity blocks rather than strengthening global resilience should be mitigated. Manufacturing infrastructure built during emergencies proves difficult to maintain during “peacetime” without sustainable financing mechanisms and regular utilization. Without investing in transparent tracking systems and coordinated response frameworks now, the next pandemic will trigger another uncoordinated, inequitable, and inefficient struggle for vaccines—at potentially devastating human cost.

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## Policy recommendations

The evidence reviewed in this paper—and the insights from stakeholders—suggests three overarching priorities for improving global vaccine manufacturing readiness. These recommendations focus on building systems that are decision-relevant, financially sustainable, and capable of supporting rapid scale-up in a future pandemic.

### 1. Establish a shared, minimum set of metrics for manufacturing capacity and surge readiness

Across the literature and consultations, the most consistent gap is the absence of a coherent and comparable definition of “capacity.” Developing a shared minimum set of metrics—co-designed by regional bodies, manufacturers, and a neutral global convener—would enable different organisations to provide data in compatible formats without imposing a single methodology. These core metrics would allow for greater visibility while respecting different institutional mandates. At a minimum, they should include:

- Platform-specific drug-substance capacity and utilisation
- Fill-finish throughput, including line speed and shift patterns
- Availability of key inputs and equipment (e.g., LNPs, adjuvants, filters, vials)
- Platform switching timelines, tech-transfer requirements, and regulatory readiness
- Realistic estimates of routine versus surge output

To be effective, this effort will require agreement on where the metric-setting function is housed and how it is governed. This function could be anchored in a strengthened WHO mechanism; led by a consortium of regional vaccine manufacturing initiatives; managed by a technical partnership involving CEPI, UNICEF, and development banks; or overseen by a new light-touch coordinating entity created specifically for manufacturing visibility. Each model has advantages, and the appropriate choice will ultimately be a political choice.

## **2. Publish an aggregated, brokered dashboard**

To make manufacturing information genuinely decision-useful, data will need to be aggregated, triangulated, and translated into high-level insights that governments and global institutions can rely on. A brokered dashboard—hosted by a trusted entity or consortium—could combine manufacturer-reported capacity, country procurement records, and supply-chain indicators into a single, regularly updated view. Crucially, this should operate under clearly defined confidentiality rules that protect commercially sensitive information and allow only aggregated insights to be shared. Different institutional arrangements are possible: the function could sit within WHO; be managed jointly by CEPI, UNICEF, and development banks; or be run by a specialised neutral data trust. Whatever model is chosen, the emphasis should be on ensuring that participants trust the governance and that data feeds into real planning and investment decisions.

## **3. Set clear, platform-specific capacity targets and use them to guide monitoring and investment**

A forward-looking manufacturing strategy requires not only mapping existing capacity but defining what the world *needs* across key platforms and regions. Setting explicit, platform-specific capacity targets—such as the volumes required for a 100-day response, the desired mix across mRNA, viral-vector, protein-subunit and other platforms, and the regional distribution needed for resilience—provides a strategic anchor for monitoring and investment. These targets turn data collection from a descriptive exercise (“what do we have?”) into a preparedness tool (“are we where we need to be?”). Clear goals also help align funding, industrial policy, and technology-transfer partnerships across institutions, ensuring that investments move the global system toward a coherent and sufficiently diversified manufacturing base.

## **4. Shift monitoring from static capacity counts to scenario-based simulations**

Static inventories cannot capture the dynamics of how manufacturing systems behave under pressure. Monitoring should evolve toward scenario-based approaches that simulate how quickly production could scale in different circumstances and where delays are most likely to occur. This includes modelling time-to-scale under a range of assumptions about input availability, bioreactor and fill-finish equipment constraints, regulatory review timelines, and workforce mobilisation. Scenario-based analysis would allow global and regional actors to identify both platform-specific

strengths and systemic weaknesses, making preparedness plans more realistic and targeted. These could play a role similar to stress tests in the banking sector.

## 5. Design for regional interdependence

No country can realistically be self-sufficient across all vaccine inputs, platforms, and production stages, and attempting to do so would be both inefficient and economically unsustainable. Some degree of concentration is unavoidable—and often desirable—because certain steps, such as large-scale bioreactor operations or specialised input production, benefit significantly from economies of scale. However, COVID-19 demonstrated that when too much capacity or too many critical inputs are concentrated in a small number of geographies, the entire global system becomes vulnerable to export controls, supply-chain disruptions, domestic political pressures, alongside a greater risk from natural disaster.

Preparedness strategies should therefore aim for *regional interdependence*: a deliberate distribution of critical functions—such as API production, adjuvants, vials and stoppers, and fill-finish—across multiple countries in a region, while still allowing centres of excellence to operate at efficient scale. This model preserves the cost and productivity advantages of specialised manufacturing hubs but avoids the fragility that comes from over-concentration. Interdependence also creates practical incentives for cooperation: when countries rely on each other for inputs or downstream steps, they are more likely to maintain open channels during crises.

Achieving this balance will require coordination across industrial policy, trade measures, and regulatory alignment. But a system built on shared capacity rather than isolated national investments is more resilient, more politically stable, and better able to scale rapidly during a pandemic.

## 6. Keep capacity alive between crises through pooled procurement

Rapid scale-up is essential in any pandemic, but it is only possible if manufacturing capacity is already active, staffed, and maintained before the crisis begins. Dormant facilities cannot expand output quickly: they face delays in re-qualifying equipment, rehiring or retraining staff, re-establishing supply chains, and meeting regulatory requirements. Warm, routinely used capacity, by contrast, can pivot and scale up far faster.

To preserve this surge potential, governments and global partners should support mechanisms that keep critical manufacturing lines viable during non-emergency periods. Options include pooled procurement for routine vaccines and biologics, advance purchase commitments that provide baseline demand for products made on pandemic-relevant platforms, and support for dual-use facilities that manufacture routine products in peacetime but can switch rapidly in an emergency. However, sustaining this capacity will require deliberate work to **create the incentives** for firms to maintain and use this additional capability. Manufacturers face real opportunity costs when reserving space or running lines that could otherwise be allocated to more profitable products, and without predictable demand or financial support, they have limited reason to keep surge-relevant capacity warm.

Effective mechanisms could therefore include guaranteed minimum purchase volumes, contracting models that reward surge-readiness, and partnerships with development banks or global health financiers to offset the costs of maintaining these lines. By ensuring firms are incentivised to keep capacity active rather than idle, these measures make rapid scale-up feasible when it is most needed and reduce the need for costly reactivation or rebuilding when the next crisis emerges.

**FIGURE 4. Policy recommendation**

## Policy recommendations for improving vaccine manufacturing capacity

-  **1 Adopt a common measurement set** for vaccine manufacturing capacity and surge readiness (definitions, minimum data fields, and reporting schedule), co-designed by regional bodies and a neutral convener.
-  **2 Publish an aggregated, brokered dashboard** that triangulates country procurement and manufacturer supply, while protecting sensitive data with agreed rules for confidentiality.
-  **3 Set clear, platform-specific capacity targets** for manufacturing vaccines that can be used to guide monitoring and investment.
-  **4 Shift monitoring** from static capacity counts to scenario-based simulations, including time-to-scale scenarios that explicitly model inputs, equipment, regulatory steps, and workforce.
-  **5 Design for regional interdependence**, distributing critical inputs and steps across countries to reduce hoarding and enable mutual leverage in crises.
-  **6 Keep capacity alive** between crises, use pooled procurement, advance purchase commitments for routine products, and allowances for dual-use manufacturing to keep lines warm and viable.

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## Conclusion and next step

The COVID-19 response wasn't just a race to develop vaccines—it was a journey to *produce* them. Yet governments and global agencies lacked answers to basic questions: How many doses could actually be made? Where were bottlenecks forming? This paper diagnoses why those questions often went unanswered, tracing the problem to three failures: (1) lacking a shared framework to define, measure, and compare capacity across platforms, geographies, and time, (2) treating manufacturing

as static when pandemics demand dynamic tracking, and (3) fragmented data governance, leaving decision-makers without timely, usable country-level analysis.

Looking ahead, efforts to strengthen pandemic preparedness must move beyond ad hoc diagnostics. This includes building standardized, forward-looking systems for assessing capacity; investing in real-time, transparent data infrastructure; and developing cross-platform benchmarks that reflect readiness, not just volume. As funders, manufacturers, and policymakers chart the next phase of preparedness, ensuring visibility into how, where, and how fast vaccines can be made will be essential to avoid repeating the blind spots of the past.

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## Appendices

### Appendix A. Detailed methodology for literature review and assessment

#### A1. Search strategy

We conducted a structured literature review to assess how global vaccine manufacturing capacity is measured, tracked, and evaluated across different studies. The search combined:

- Academic database: PubMed.
- Grey literature from key institutions: WHO (MI4A & market reports), UNICEF Supply Division, PAHO Revolving Fund, Gavi, CEPI/RVMC, World Bank/ASEAN, CHAI, Linksbridge/GVMM, Airfinity briefs, industry associations.
- Hand-searching: reference list and stakeholder suggestions.

The search terms were grouped into three categories:

1. Manufacturing capacity (“vaccine manufacturing capacity”, “biomanufacturing”, “vaccine production”, “drug production”).
2. Geographic scope (e.g., “global”, “regional”, “Africa”, “Latin America”).
3. Emergency preparedness (“pandemic”, “emergency response”, “surge capacity”, “stockpiling”, “scale-up”).

Search terms:

("vaccine manufacturing capacity" OR "biomanufacturing" OR "vaccine production" OR "drug production") with geographic terms (global, regional, or continent-specific) and emergency-related terms ("pandemic" OR "emergencies" OR "surge capacity" OR "stockpiling" OR "scale-up production"), yielding 192 initial results.

We screened 259 documents in total (192 academic papers and 66 grey literature publications, plus 1 hand-searched), narrowing down to 17 studies that met our inclusion criteria.

#### A2. Inclusion Criteria

Studies were included if they met the following:

- Addressed vaccine manufacturing capacity and supply chain readiness either globally or regionally.
- Contained implications for pandemic preparedness (surge, platform, timeline) or equity (geography/affordability/allocation).
- Presented sufficient methodological clarity (data sources or approach described).

We excluded:

- Studies focused exclusively on R&D or clinical trials.
- Commentary pieces without empirical data or methods.

### **A3. Assessment Framework**

For each study, we recorded: citation; scope (global/region); product/platform focus; methods used (survey, interview, case study, data analysis, predictive modeling, primary data); data sources; and coverage of the three topical areas and their sub-components.

Each study was assessed across three topical areas:

#### **1. Supply Chain Readiness**

We evaluate coverage of: (1) Raw Materials & Inputs – assessment of critical components like cell lines, adjuvants, lipids, and chemical reagents; (2) Production Equipment – analysis of bioreactors, filtration systems, and specialized manufacturing infrastructure; and (3) Fill-Finish & Distribution – examination of vial production, stoppers, cold chain requirements, and logistics networks.

#### **2. Pandemic Preparedness**

We consider: (1) Surge Capacity – the ability to rapidly scale production volume during emergencies; (2) Platform Adaptability – flexibility to switch between vaccine types or adjust formulations for new pathogens; and (3) Response Timeline – speed of manufacturing ramp-up from pathogen identification to mass production.

#### **3. Equity and Access**

We evaluate coverage of: (1) Geographic Distribution – track whether there are access challenges in any region, and examines supply allocation patterns; (2) Affordability – cost structures, pricing tiers, and financial sustainability considerations; and (3) Allocation – track whether the vaccine is registered to be sold across the world and sufficient regulatory approval.

For each sub-component, reviewers classified coverage using an ordinal scale:

- Not mentioned – no reference to the topic;
- Limited – brief mention or very high-level treatment only;
- Moderate – several aspects discussed with some data or examples;
- Extensive – detailed, data-driven analysis of most or all aspects.

We then derived an overall rating for each topical area (supply-chain readiness, pandemic preparedness, equity and access) by looking across its three sub-components. If most

sub-components were rated Limited, the topical area was classified as Limited; if coverage was mixed, it was classified as Moderate; and if most sub-components were Extensive, it was classified as Extensive. Table A1 summarises the framework, and Tables A1 present the resulting classifications by study.

#### ***A4. Review Process***

A primary reviewer assessed all studies; a second reviewer independently checked assessments and rationales; disagreements were resolved by consensus.

#### ***A5. Limitations***

This review relies primarily on publicly available and grey literature where key underlying survey microdata and proprietary datasets are not fully accessible or reproducible. Our assessment approach, while guided by a structured rubric and reviewed by two readers, necessarily involves judgment and may retain some subjectivity. In addition, inconsistent terminology across studies—particularly around core concepts such as “capacity” and “surge”—limits direct comparability and requires cautious interpretation of cross-study differences.

## A6. Assessment Table

**TABLE A1. Detailed assessment by study and sub-component**

Authors	Supply Chain Bottlenecks				Pandemic Preparedness				Equity & Access			
	Raw Inputs	Equipment	Fill-Finish	Overall	Surge Capacity	Platform Adaptability	Response Timeline	Overall	Geography	Affordability	Allocation	Overall
(Cuddihy et al., 2022)	low	low	medium	Moderate	medium	low	medium	Moderate	low	no	no	Limited
(CEPI, 2022)	low	low	medium	Moderate	medium	medium	high	Extensive	medium	low	low	Moderate
(CEPI, 2021b)	no	low	medium	Limited	low	medium	low	Moderate	high	no	low	Moderate
(Guzman et al., 2022)	low	low	medium	Moderate	medium	medium	low	Moderate	medium	low	medium	Moderate
(CHAI, 2022)	low	low	medium	Moderate	medium	medium	low	Moderate	high	medium	low	Extensive
(Feddema et al., 2023)	medium	medium	medium	Moderate	medium	low	low	Moderate	low	no	medium	Limited
(Gavi, 2011)	no	low	low	Limited	low	no	low	Limited	medium	high	medium	Extensive
(UNICEF, 2020)	no	low	medium	Limited	high	medium	high	Extensive	medium	low	medium	Moderate
(UNICEF, 2023)	low	low	medium	Moderate	medium	low	medium	Moderate	medium	medium	medium	Moderate
(Martin et al., 2023)	medium	medium	medium	Moderate	medium	medium	low	Moderate	high	medium	low	Moderate
(Evenett et al., 2021)	high	low	low	Moderate	medium	low	low	Moderate	high	low	medium	Moderate
(Evenett et al., 2021)	low	low	low	Limited	low	low	low	Limited	medium	low	low	Moderate
(Rodriguez et al., 2023)	low	medium	medium	Moderate	low	low	no	Limited	high	medium	medium	Extensive
(WHO, 2025a)	low	low	low	Limited	low	low	no	Limited	high	high	medium	Extensive
(Taaffe et al., 2025)	low	low	medium	Moderate	medium	low	high	Moderate	high	medium	medium	Extensive
(Linkesbridge, 2024)	no	low	medium	Limited	no	low	no	Limited	medium	medium	medium	Moderate

Note: The table below summarizes the results, offering a snapshot of how 17 studies assessed across this framework and highlighting where gaps in depth and coverage remain.

## Appendix B. Detailed methodology for stakeholder consultations

**Consultation approach.** We conducted semi-structured interviews (Apr–September 2025) with five stakeholders spanning global market analytics, regional manufacturing coordination, and implementation partners. Interviews followed a common guide on (i) definitions/metrics; (ii) data sources and confidentiality; (iii) surge/readiness and platform agility; (iv) supply-chain inputs/equipment; and (v) policy levers for peacetime sustainability.

**Analysis.** Notes were coded against our rubric (supply-chain readiness; surge & platform agility; equity & access) and used to refine our assessment interpretation and recommendations. We report only anonymized, non-attributable insights; any direct quotes are paraphrased to protect confidentiality.