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VACCINE INSIGHTS

SPOTLIGHT

Vaccine manufacturing: downstream and supply chain

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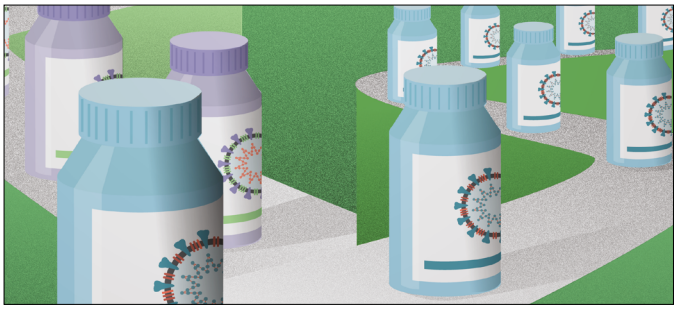

VACCINE INSIGHTS

VACCINE MANUFACTURING: DOWNSTREAM PROCESSING AND SUPPLY CHAIN

SPOTLIGHT

EXPERT INSIGHT

Building manufacturing efficiency in early process development: challenges and opportunities

Yan-ping Yang and Tony D'Amore

Manufacturing efficiency is a major investment focus in the vaccine and biopharmaceutical industry, as reducing costs and improving scalability are critical for long-term success. While building robust upstream and downstream processes early can enhance long-term manufacturability, it may delay initial clinical entry, thus creating a strategic tension between speed to clinic and manufacturing efficiency. This article explores how emerging tools and approaches, such as artificial intelligence, automation, single-use systems, and standardized platform technologies, can help bridge this gap. Application of quality by design, which is a systematic, risk-based framework that integrates process understanding, critical quality attributes, and control strategies into early development, may serve as a key enabler in supporting more efficient tech transfer, flexible scale-up, and regulatory alignment. As regulatory agencies increasingly emphasize the early demonstration of process robustness, platform consistency, and lifecycle management planning, these integrated strategies may collectively provide a pathway to accelerate development without compromising long-term manufacturing success.

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In the vaccine and biopharmaceutical industry, manufacturing efficiency plays a critical role not only in operations but also in determining a company's financial sustainability, competitive position, product pricing and long-term viability. As bio-manufacturing becomes more complex and capital-intensive, the ability to reduce production costs and increase profitability is a strategic imperative.

Although it is well recognized that manufacturing decisions made during early development stages have a profound impact on the success of late-stage commercialization, prioritizing manufacturing efficiency early in the product lifecycle remains a challenge in the vaccine industry. This tension stems from the intense pressure to rapidly progress vaccine candidates into clinical trials, especially during public

health emergencies or under significant competitive environments.

As a result, companies often face a strategic dilemma: prioritize short-term clinical milestones or invest in manufacturing efficiency that may delay early outputs but may streamline commercialization and reduce the total lifecycle cost. In this article, we will discuss the application of tools and technologies during early-stage development that may offer opportunities for balancing short-term milestones with long-term production readiness.

THE DILEMMA

The dilemma of speed to clinic vs manufacturing efficiency is a strategic challenge in vaccine and biopharmaceutical development [1]. In early phase development, the primary objective is to demonstrate safety and immunogenicity in humans with an intense pressure to reach clinical trials as quickly as possible. This urgency often leads teams to make *ad hoc* or short-term process decisions, such as using non-scalable equipment, selecting materials based on immediate availability, rather than long-term supply, or bypassing robust design practices. While these shortcuts may accelerate early milestones, they can cause major challenges later, including inefficient scale-up, process redesigns, regulatory delays, increased costs, and longer time to commercial readiness, ultimately jeopardizing the product's success and company's sustainability. On the other hand, focusing too early on scalable, robust manufacturing can delay clinical milestones and weaken the company's competitive edge.

The ability to strike the right balance between the two requires a well-thought strategy, careful planning, and cross-functional collaboration (e.g., between R&D, manufacturing, quality and regulatory, etc.) that bridges clinical urgency with commercial foresight. It involves aligning scientific innovation with scalable process design, incorporating risk management frameworks, and applying platform-based and digital solutions to ensure flexibility without compromising future manufacturing robustness.

OPPORTUNITIES EXPLORED

The recent innovations and technology advancement in vaccine development offers great opportunities to the long-standing challenge of balancing speed to clinic with manufacturing efficiency. These technologies may offer scalable, flexible, and rapid production platforms that could minimize trade-offs between development speed and manufacturing viability.

Table 1 summarizes some of the tools and technologies that may benefit both speed to clinic and manufacturing efficiency, plus some foreseen regulatory advantages.

UPFRONT MANUFACTURABILITY ASSESSMENT IN EARLY VACCINE DEVELOPMENT

While the primary goal during early-stage vaccine development is to achieve rapid entry into clinical trials and demonstrate proof of concept, this urgency does not need to be at the expense of long-term manufacturing considerations. In fact, evaluating manufacturability early on (before lab-scale execution) is highly valuable and cost effective. This can be done through a structured, paper-based exercise, leveraging prior knowledge, platform experience, and cross-functional expertise [2].

By involving experts from process development, manufacturing, engineering, quality assurance, and regulatory affairs, teams can identify:

- Potential risks (e.g., yield bottlenecks or impurity profiles)

TABLE 1

Opportunities offered by innovations and technology advancement.

Tools/technologies	Benefits to		Regulatory advantages
	Speed to clinic	Manufacturing efficiency	
Design for scalability: upfront manufacturability assessment	Avoid delays from process redesign during scale-up production of clinical materials	Ensures smoother tech transfer, cost-effective and efficient commercialization	Ensures process comparability, simplifies scale-up validation and regulatory review
Platform technologies (e.g., mRNA, viral vectors, etc.)	Rapid vaccine design and shortened development timelines	Reusable, scalable processes across multiple products	Enables the use of platform data and prior knowledge for faster approval
Single-use system and flexible manufacturing	Quick setup and changeover, reduces significant upfront capital investment; rapid facility deployment and adaptability	Lower cleaning and validation costs, improved batch turnaround; multi-product capability, scalable at lower capital expenditure	Reduces validation complexity, supports flexible cGMP compliance; facilitates faster facility approval with modular design principles
Integrated and digital solutions (e.g., data management and PAT)	Real-time data for faster development decisions; enhances process understanding, accelerates troubleshooting and process optimization	Improves yields, reduces deviations, and simplifies compliance; enhances process consistency and quality during scale-up	Enhanced data integrity. Ensures traceability, enables digital batch records, supports real-time release; supports QbD, electronic records, and improved compliance oversight
Artificial intelligence (AI)	Antigen prediction, faster trial design and monitoring, early risk assessment	Process optimization, predictive quality control, smart automation	Streamline regulatory submissions by providing robust, data-driven justifications, ultimately accelerating regulatory review and approval

- Scalability challenges (e.g., mixing, filtration, or shear sensitivity)
- Raw material constraints
- Equipment compatibility and facility fit
- Regulatory and compliance implications

These early assessments, based on historical data, platform benchmarks, and experts' input, will allow development teams to identify red flags, prioritize development experiments, and make more informed design choices. This proactive approach will help reduce rework, minimize delays in scale-up, and support a smoother path to commercialization, while controlling costs.

In short, even in a speed-driven environment, upfront manufacturability assessments provide a strategic advantage, aligning early development goal with long-term manufacturing success.

PLATFORM TECHNOLOGIES

Although the concept of platform-based product development has been established for many years [3] in industries such as automotive and electronics, its application in vaccine development has gained significant traction only recently, especially during the COVID-19 pandemic [4–6]. Traditionally, each vaccine was developed with a customized process, leading to long timelines and high costs [7]. Platform technology-based approaches, such as using established cell lines, viral vectors, or mRNA delivery systems, etc. are now being embraced to streamline development, enhance scalability, and reduce regulatory burden. This approach enables industry to leverage prior process knowledge and established technical competencies, reuse core components such as raw materials and equipment, and accelerate the path from discovery to commercialization. As a result,

platform-based strategies are becoming a cornerstone of modern vaccine innovation and pandemic preparedness. Some examples include:

- CHO-based cell culture or *Escherichia coli*-based microbial expression systems for recombinant protein and subunit vaccines: widely used, scalable, and regulatory-friendly platforms
- Viral vector platforms (e.g., adenovirus, lentivirus, AAV): allow standardized upstream and downstream processes for gene-based vaccines
- Membrane-based separation technologies which separate molecules based on size, charge, or affinity, are applied across both upstream and downstream processes, increasing efficiency, scalability, and ability to enhance product purity and recovery
- mRNA-LNP delivery systems: use templated processes for mRNA synthesis and lipid nanoparticle formulation, accelerating scale-up

While the platform technology-based approach in vaccine development (i.e., using standardized technologies, materials, and processes across multiple products, etc.) may offer efficiency and speed, it also presents evolving regulatory expectations. Authorities would expect developers to demonstrate robust knowledge of the platform's performance, establish a consistent control strategy, and justify any data bridging between products. While some validation and documentation can be leveraged, full comparability must be supported by risk assessments and data. Some key challenges may include defining platform boundaries, managing post-approval changes, and navigating the different global regulatory requirements. Therefore, proactive engagement with regulators, and clear lifecycle management strategies are essential to successfully implementing a platform-based model.

SINGLE-USE SYSTEMS & FLEXIBLE MANUFACTURING

Single-use systems (SUS) and flexible manufacturing platforms have revolutionized the way vaccines are developed and produced, offering key advantages in agility, speed, scalability, cost-efficiency, and contamination control, all essential for modern upstream and downstream processes (Table 2) [8,9]. supporting both rapid clinical advancement and long-term commercial viability (Table 3) [10–14]. Figure 1 presents an example of applying SUS in a completely closed system for vaccine manufacturing [15].

In early development, SUS components, such as disposable bioreactors, tubing sets, and filtration units enable rapid process setup, reduced cleaning validation

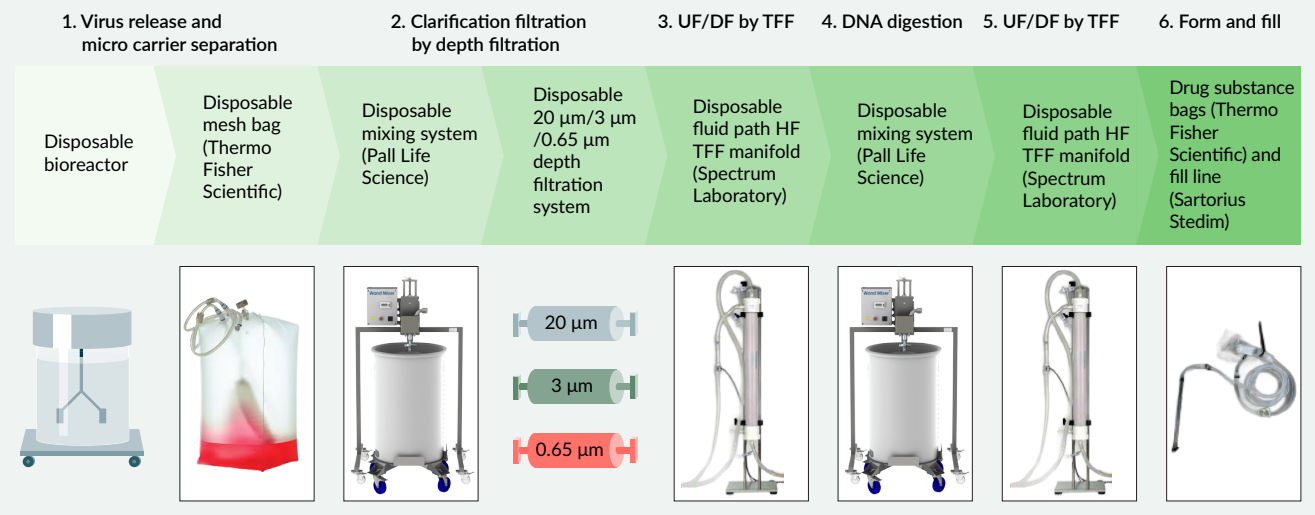
TABLE 2

Some examples of single-use systems in vaccine production [8,9].

Process stage	SUS technologies	Key advantages
Upstream (e.g., cell culture, fermentation)	Single-use stirred-tank bioreactors (2–2000 L); disposable sensors (pH, DO, cell density); pre-sterilized mixing bags and feed lines	No need for cleaning/sterilization (CIP/SIP); lower water/energy consumption; reduced cross-contamination risk; faster tech transfer and scalability
Downstream (e.g., purification, formulation)	Single-use membrane chromatography columns; disposable tangential flow filtration modules; closed, single-use filling systems	Faster changeovers, less validation; improved yield and reduced contamination; flexibility for diverse vaccine platforms (e.g. viral, protein, mRNA)

FIGURE 1

A completely closed system from manufacturing to formulation with single-use technologies [15].



DF: diafiltration. HF: hollow fiber. TFF: tangential-flow filtration. UF: ultrafiltration.

requirements, and minimized risk of cross-contamination. This accelerates timelines for proof-of-concept studies and clinical trial material production.

As the product progresses toward commercialization, these same technologies provide seamless scalability and facility adaptability, supporting faster scale-up, reduced capital investment, and easier technology transfer. Flexible manufacturing setups are often built around modular, plug-and-play systems allowing

TABLE 3

Single-use system and flexible manufacturing benefit both early development and commercial viability [10–14].

	Benefits	
	Early development	Commercial manufacturing
Speed and agility	Rapid setup and turnaround time; quick delivery of clinical trial materials	Faster changeovers; responsive to market demand fluctuation
Scalability	Supports small-scale, parallel development; modular scale-up paths	Seamless scale-up using pre-validated, standardized components
Cost efficiency	Lower capital investment: reduced need for clean-in-place (CIP)/sterilize-in-place (SIP)	Decreased operating costs; reduced utility usage and cleaning validation
Flexibility	Enables development of multiple vaccine modalities simultaneously	Adaptable for different products or production volumes in the same facility
Risk reduction	Minimizes cross-contamination risk; fewer cleaning validations	Improves batch integrity and compliance with multi-product operations
Tech transfer and standardization	Simplifies process transfer due to consistent platforms	Harmonized global operations and ease of regulatory filings
Regulatory and compliance	Accelerates early engagement with regulators via platform familiarity	Easier to validate and maintain consistent quality for licensure

manufacturers to pivot between vaccine modalities (e.g., mRNA, viral vector, recombinant protein, etc.) and respond to fluctuating demand with greater efficiency.

By standardizing equipment and workflows across development and manufacturing, SUS platforms can help streamline regulatory approval, simplify process validation, and improve supply chain flexibility. This integration across the lifecycle ultimately supports both speed to clinic and long-term manufacturing efficiency, bridging a critical gap in modern vaccine strategy.

INTEGRATED & DIGITAL SOLUTIONS

Integrated and digital solutions play an important role in modern vaccine and biopharmaceutical development by enhancing data collection and management, increasing process visibility and control, across development stages. The comprehensive process knowledge generated during development is a critical foundation for scale-up and future commercial manufacturing, facilitating smoother tech transfer, regulatory filing, and continued process verification (CPV). These digital capabilities not only support speed to clinic but also promote long-term manufacturing efficiency, quality, and compliance [16].

Some key digital tools include:

- Electronic lab notebooks (ELNs) and Laboratory Information Management Systems (LIMS) to centralize experimental data and ensure traceability [17]
- Process analytical technology (PAT) for in-line, real-time monitoring and control of critical process parameters
- Manufacturing execution systems (MES) that link development and production data for end-to-end traceability
- Advanced analytics, including artificial intelligence (AI) and machine learning, to model process trends, identify variability, and optimize conditions proactively

Some examples of integrated and digital solutions used to improve speed to clinic and/or manufacturing efficiency in vaccine and biologics development are shown in Table 4 [18–21].

In summary, PAT enables real-time monitoring and control of critical process parameters, reducing reliance on end-product testing and minimizing batch failures. Over time, this leads to faster decision-making, fewer deviations, and more consistent output.

MES can streamline operations by digitizing workflows, automating documentation, and accelerating batch review and release. This reduces manual effort, shortens cycle times, and supports efficient scale-up and tech transfer.

Together, PAT and MES may contribute to long-term time savings by enabling a more agile, automated, and data-driven manufacturing environment.

ARTIFICIAL INTELLIGENCE

Although AI is part of the integrated and digital solutions to vaccine development, it also deserves special mention due to its transformative capabilities across the entire development and manufacturing continuum from early-stage antigen discovery and clinical trial design to predictive process modeling, and commercial production optimization. AI accelerates decision-making, reduces experimental burden, enhances process robustness, and enables proactive quality control, ultimately improving both speed to clinic and long-term manufacturing efficiency. AI has attracted significant attention across the life sciences industry. In the context of vaccine development, AI is no longer just a futuristic concept but a practical tool

TABLE 4

Examples of integrated and digital solutions used in vaccine and biopharmaceutical development.

Technology	Example application	Organization/use case
Process analytical technology	Real-time monitoring using Raman spectroscopy for critical parameters (e.g., glucose, cell density)	CHO cell culture process monitoring in biomanufacturing [18]
Machine learning	Machine learning to enhance cell culture bioprocess development	AstraZeneca R&D project [19]
Manufacturing execution systems	Linking global production data for rapid scale-up of vaccine production	Pfizer's COVID-19 vaccine production [20]
	Digital batch record automation and real-time production traceability	GSK smart manufacturing facilities [21]

TABLE 5

Examples of AI applications in vaccine development.

Application area	AI use case
Antigen discovery	AI used to predict vaccine candidates using protein structure and genomic data [22]
Vaccine design	AI-assisted mRNA vaccine design and optimization [23]
Clinical trials	Machine learning to assess the effects of vaccination on the fatality rate of the COVID-19 pandemic [24]
Clinical trials	AI- assisted COVID-19 vaccine clinical trial data review [25]
Smart manufacturing	AI-driven predictive maintenance and process control (Sanofi's digital manufacturing transformation) [26]

delivering real impact. From accelerating antigen discovery and streamlining clinical trial design to enabling predictive analytics in manufacturing, AI technologies are reshaping how vaccines are developed, tested, and produced (Table 5) [22–26].

At the discovery stage, AI-driven computational modeling helped identify optimal antigen targets and predict immunogenic responses, significantly reducing the timeline from genome sequencing to candidate selection [27]. During clinical development, AI tools were used to optimize trial protocols, identify patient cohorts, monitor safety signals, and accelerated data analysis, enhancing the speed and success rate of trials.

On the vaccine process development side, however, its application remains relatively underexplored and AI's integration into upstream and downstream processes is still developing. Potential uses include optimizing cell culture conditions, predicting yield based on raw material variability, automating process control using pattern recognition, and supporting continuous bioprocessing through real-time decision-making. Tools such as AI-enhanced PAT, digital twins, and machine learning algorithms are beginning to show promise in identifying process anomalies, predicting deviations before they impact product quality, and improving batch consistency in biopharmaceutical manufacturing [28–30]. These advancements will not only improve the overall manufacturing efficiency but also align with regulatory expectations for enhanced process understanding and control. AI is proving to be a valuable enabler of both speed to clinic and long-term manufacturing efficiency, and its role will continue to expand as digital maturity grows across the vaccine industry.

QUALITY BY DESIGN

Quality by Design (QbD) is a systematic, science- and risk-based approach to pharmaceutical development that was first introduced by the FDA in 2004 [31] and further supported by the International Council for Harmonization (ICH), notably through ICH guidelines Q8 (R2), Q9, Q10, and Q11 [32]. Its core principle is that quality should be built into a product from the very beginning, rather than tested into it at the end.

While the benefits of QbD are well recognized, its application in early development is often perceived as time consuming and resource intensive. In fast-paced vaccine programs, where speed to clinic is a high priority, teams may hesitate to invest in comprehensive risk assessments, experimental designs, and control strategy development upfront. However, the FDA's concept of QbD presents a forward-looking framework that can help developers to achieve high product quality, regulatory compliance, and long-term manufacturing efficiency. By shifting from reactive quality control to proactive process design, QbD may bridge the gap between rapid early-phase development and robust commercial readiness. It embeds scientific understanding, risk management, and process control into development activities, reducing the likelihood of costly redesigns or regulatory hurdles later on. When combined with enabling technologies such as AI, automation, and modular platforms, QbD may serve as a powerful strategic tool to support agile, scalable, and globally deployable vaccine manufacturing

CONCLUSION

The long-standing dilemma between accelerating speed to clinic and ensuring long-term manufacturing efficiency has become increasingly complex in today's competitive and high-stakes vaccine landscape. However, recent technological advancements and integrated approaches offer a path forward that doesn't need to compromise one for the other. The adoption of single-use systems, standardized platform technologies, and digital tools such as AI, PAT, and advanced analytics enable faster, more flexible development processes while building a strong foundation for scalable, cost-effective, and compliant manufacturing. In addition, application of QbD, a systematic, risk-based framework endorsed by regulators, may offer a strategic advantage in aligning early development with long-term manufacturing goals. By emphasizing process understanding, control, and continuous improvement; defining critical quality attributes and control strategies early in development, QbD can support both product quality and manufacturing agility.

By embedding considerations of manufacturability, scalability, and data integration into early development strategies, organizations can minimize late-stage redesigns and regulatory delays. This proactive mindset, supported by paper-based manufacturability assessments, modular design, and smart process automation, will allow for agile development without sacrificing quality or commercial readiness. Nevertheless, challenges remain, including the need to meet global regulatory expectations, manage the evolving nature of platform technologies, and sustain clear, modular documentation throughout the product lifecycle.

Ultimately, the right combination of innovation, cross-functional alignment, and strategic foresight will empower vaccine developers to not only bring products to clinic faster but also ensure they are manufacturable, sustainable, and globally deployable at scale.

REFERENCES

1. Hotha K. Fast-to-clinic, fast-to-market in biotech innovation: optimizing chemistry manufacturing & controls (cmc) excellence for clinical and commercial success. *Adv. Chem. Eng. Sci*. 2024; 14, 155.
2. Brower KP, Patil RA, Walther JL, *et al*. Manufacturability assessment: a tool for effective and transparent decision-making and efficient process development. *Bioprocess International* Dec 17, 2020. https://www.bioprocessintl.com/risk-management/manufacturability-assessment-a-tool-for-effective-and-transparent-decision-making-and-efficient-process-development.
3. Zhai XF, Sriram RD. (2005) Platform-Based Product Design and Development: Knowledge Support Strategy and Implementation. In: *Intelligent Knowledge-Based Systems* (Editor: Leondes CT). 2005; Springer, 3–35.
4. Hume HKC, Lua LHL. Platform technologies for modern vaccine manufacturing. *Vaccine* 2017; 35, 4480–4485.
5. Ghattas M, Dwivedi G, Lavertu M, Alameh MG. Vaccine technologies and platforms for infectious diseases: current progress, challenges, and opportunities. *Vaccines* 2021; 9, 1490.
6. Li XJ, Jin S, Guo S, *et al*. Platform technology in global vaccine regulation: development, applications, and regulatory strategies with insights from China. *Vaccines 2024, 12, 1436.*
7. Plotkin S, Robinson JM, Cunningham G, Iqbal R, Larsen S. The complexity and cost of vaccine manufacturing—an overview. *Vaccine* 2017; 35, 4064–4071.
8. Tischler D. Upstream processing with single-use systems. *Single Use Support* Dec 20, 2022. https://www.susupport.com/knowledge/manufacturing-processes/bioprocessing/upstream-processing-with-single-use-systems.
9. Challener CA. Benefiting from single-use tech downstream. *BioPharm Int.* 2024; 37, 8–13.
10. Millipore Sigma. Flexible manufacturing of vaccines. 2021. https://www.sigmaaldrich.com/deepweb/assets/sigmaaldrich/marketing/global/documents/195/026/flex-manufacturing-br5360en-ms.pdf.
11. Fuchs A. How single-use technologies improve vaccine production. *Single Use Support* Sep 26, 2024. https://www.susupport.com/knowledge/biopharmaceutical-products/vaccines/vaccine-manufacturing#single-use-technologies.
12. Hederman J. Single-use systems: the future of biopharmaceutical processing. *Medical Design Brief* Feb 1, 2022. https://www.medicaldesignbriefs.com/component/content/article/40742-single-use-systems-the-future-of-biopharmaceutical-processing.
13. Bhatkhande S. Single-use bioprocessing technologies enabling more rapid vaccines production. *American Pharmaceutical Review* Apr 1, 2023. https://www.americanpharmaceuticalreview.com/Featured-Articles/596309-Single-Use-Bioprocessing-Technologies-Enabling-More-Rapid-Vaccines-Production/.
14. Deni I. Embracing single-use innovations in a post-COVID era. *Pharma Manufacturing* Sep 5, 2024. https://www.pharmamanufacturing.com/production/unit-operations/article/55136462/embracing-single-use-innovations-in-a-post-covid-era.
15. D'Amore T, Yang Y-P. Advances and challenges in vaccine development and manufacture. *BioProcess International* Sep 21, 2019. https://www.bioprocessintl.com/vaccines/advances-and-challenges-in-vaccine-development-and-manufacture.
16. Tran M. Digital transformation of vaccine manufacturing. DCVMN International and Merck workshop. Dec 7, 2023. https://dcvmn.org/wp-content/uploads/2023/11/Digital-Transformation-of-Vaccine-Manufacturing.pdf.
17. Wilson O. How to choose the right electronic lab notebook for your biotech company? *Scispot* Aug 17, 2024. https://www.scispot.com/blog/how-to-choose-the-right-eln-for-your-biotech-company-wip#:~:text=The%20Role%20of%20an%20Electronic,staple%20in%20progressive%20biotech%20labs.

18. Classen J, Langer M, Jockwer A, Traenkle J. Raman spectrometric PAT models: successful transfer from minibioreactors to larger-scale, stirred-tank bioreactors. *Bioprocess International* Sep 28, 2022. https://www.bioprocessintl.com/pat/raman-spectrometric-pat-models-successful-transfer-from-minibioreactors-to-larger-scale-stirred-tank-bioreactors.
19. Loning M, Ballinger T, Bucholc M, *et al*. AstraZeneca machine learning for enhanced understanding of cell culture bioprocess development: Data Study Group final report. Aug 2019. https://www.researchgate.net/publication/337009790_Data_Study_Group_Final_Report_AstraZeneca_Machine_learning_for_enhanced_understanding_of_cell_culture_bioprocess_development.
20. Pfizer. Expanding COVID-19 manufacturing efforts to increase global vaccine access: 2021 annual review. 2021. https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2021/story/expanding-covid-manufacturing-efforts.
21. GSK. Robots, AI, and machine learning: how smart manufacturing is getting medicines and vaccines from factories to patients faster. Jan 22, 2024. https://www.gsk.com/en-gb/behind-the-science-magazine/smart-manufacturing-factories-uppermerion-medicines.
22. Callaway E. DeepMind's AI predicts structures for a vast trove of proteins. *Nature* Jul 22, 2021. https://www.nature.com/articles/d41586-021-02025-4.
23. Dolgin E. 'Remarkable' AI tool designs mRNA vaccines that are more potent and stable. *Nature* May 2, 2023. https://www.nature.com/articles/d41586-023-01487-y.
24. Magazzino C, Mele M, Coccia M. A machine learning algorithm to analyse the effects of vaccination on COVID-19 mortality. *Epidemiol. Infect.* 2022;150, e168.
25. Pfizer. mRNA and artificial intelligence for advanced vaccine innovation. 2025. https://www.pfizer.com/news/articles/how_a_novel_incubation_sandbox_helped_speed_up_data_analysis_in_pfizer_s_covid_19_vaccine_trial.
26. O'Callaghan B. AI goes industrial. *Sanofi* Jun 19, 2023. https://www.sanofi.com/en/magazine/our-science/ai-goes-industrial.
27. Olawade DB, Teke J, Fapohunda O, *et al.* Leveraging artificial intelligence in vaccine development: a narrative review. *J. Microbiol. Meth. 2024; 224,* 106998.
28. Manzano T, Whitford W. AI-enabled digital twins in biopharmaceutical manufacturing. *Bioprocess International* Aug 17, 2023. https://www.bioprocessintl.com/sponsored-content/ai-enabled-digital-twins-in-biopharmaceutical-manufacturing.
29. Campolongo G. Intelligent manufacturing: how smart-PAT and GenAI can transform biopharmaceutical manufacturing. *Pharma's Almanac* May 30, 2024. https://www.pharmasalmanac.com/articles/title-intelligent-manufacturing-how-smart-pat-and-genai-can-transform-biopharmaceutical-manufacturing.
30. Synapse. What role does AI play in optimizing biopharmaceutical manufacturing processes? *Synapse* Mar 20, 2025. https://synapse.patsnap.com/article/what-role-does-ai-play-in-optimizing-biopharmaceutical-manufacturing-processes.
31. Winkle HN, Nasr MM. (2011) FDA perspectives: understanding challenges to quality by design. *Pharm. Tech.* 2011; 35, 9.
32. ICH Quality Guidelines. https://www.ich.org/page/quality-guidelines.

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AUTHORSHIP & CONFLICT OF INTEREST

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VACCINE INSIGHTS

VACCINE MANUFACTURING: DOWNSTREAM PROCESSING AND SUPPLY CHAIN

SPOTLIGHT

COMMENTARY

Vaccine wastage through a new lens: improving estimates through analytics

Laila A Akhlaghi and Wendy Prosser

Wastage rates of vaccines are an inevitable part of immunization supply chains. With the increasing cost of vaccines and resource constraints, however, minimizing wastage has become a critical priority for immunization programs globally, perhaps at the risk of coverage. Reported or calculated wastage rates using only health service delivery data are often inaccurate and, when aggregated from different levels of the supply chain, lose their nuance and the ability to provide true insight. In a unique approach, our analysis, which utilizes a combination of service delivery and supply chain data from two districts in Mozambique to calculate wastage rates, proves both feasible and applicable. This illustrative analysis show wastage rates at the district level are comparable to global standards, yet markedly different, at times with a wide range, when disaggregated at the facility level. This analysis also shows the link between lower volumes of monthly administration and higher wastage rates. With improved data and information systems now available, immunization programs have the opportunity to calculate accurate and tailored wastage rates, using them to identify sites requiring strengthening of service provision, program implementation, or reporting quality data, and thereby improving the accuracy of forecasts and re-supply decisions for the facility level. We take this opportunity also to suggest an update to the language used for vaccine 'wastage rate' as it no longer reflects the nuanced realities of vaccine management and inadvertently casts a negative light on essential operational processes and can hinder the provision of immunization services.

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BACKGROUND

Some loss of product is an inherent aspect of any supply chain. In the context of immunization programs, this loss is categorized into two primary forms: closed-vial wastage and open-vial wastage. Closed-vial wastage typically stems from suboptimal vaccine storage and handling practices, leading to issues such as expired

doses, broken vials, or exposure to extreme temperatures (heat or freezing). Conversely, open-vial wastage occurs when multi-dose vials are opened for administration but are not fully utilized within the stipulated timeframe, necessitating the discard of remaining doses. Wastage can be influenced by vial size, catchment population size, demand, and inventory management and handling practices.

Historically, a certain degree of vaccine loss has been tolerated. However, with the advent of higher-cost vaccines and increasing resource constraints faced by governments and donor organizations, a renewed emphasis on minimizing wastage has become a critical priority for immunization programs globally. That said, this increased focus on wastage should be considered when weighing the consequences for service delivery and the program's ability to reach all eligible people. This heightened awareness underscores the need for accurate wastage calculation methodologies and the strategic design of supply chains and programs aimed at substantially reducing vaccine wastage, while increasing coverage.

The accurate measurement and effective management of vaccine wastage rates present a significant conundrum for immunization programs, influenced by a multitude of interconnected factors. A key consideration is the willingness of health workers to open multi-dose vials, which often involves a delicate trade-off between minimizing potential wastage and maximizing vaccine coverage [1]. Data on wastage are typically reported by health facilities via service delivery reports or determined, based on the number of vials opened rather than the actual doses discarded. The difficulty and disincentives to reporting accurate wastage data result in the reporting of questionable data. Moreover, as these figures are aggregated through various levels of the health system, the granular details and specific drivers of wastage at the facility level become obscured, hindering the identification of sites that require targeted interventions. Meanwhile, supply chain or transactional data is reported separately, sometimes by different staff, and is typically not considered when reviewing wastages.

Large-scale studies are occasionally undertaken to provide more accurate assessments of wastage [2,3]; however, these are labor-intensive, time-consuming, inherently expensive, and a one-time snapshot that do not allow for ongoing quality control monitoring. Crucially, even comprehensive studies often struggle to capture the significant geographic and operational differences in wastage rates that can exist within a single country, making it difficult to develop applicable solutions.

Additionally, planning tools such as the **Vaccine Wastage Rate Calculator** have been created to provide an easy way to calculate wastage rates per session size, yet true data about session size is not readily available. As such, users are required to estimate probable session sizes to calculate wastage, beginning the process with an error introduced by this assumption.

The World Health Organization (WHO) provides global standards for acceptable wastage rates differentiated by vial size and vaccine type (e.g., lyophilized vs liquid) [4]. However, it is important to recognize that these global standards were established at a time when the requisite facility-level data for achieving true insight and a comprehensive understanding of wastage rates were not yet available or of poor-quality. The global standards served a purpose at the time, yet with the evolution of data systems and the quality of facility-level data now available in some settings, wastage rates can be calculated to serve tailored benchmarks and can reflect the reality of different geographies and health facilities. As the barriers to calculating tailored benchmarks fall, so does the rationale for a one-size-fits-all model.

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ALTERNATIVE DETERMINATION OF WASTAGE RATES

As an illustrative analysis to build the case, we examined how existing data can be queried in a different way to better understand how to calculate tailored wastage rates reflecting local realities. We took data from all health facilities (a total of 36) in two Mozambican districts as a case study, integrating data from the logistics management information system (LMIS) and the health management information system (HMIS). The objective of this analysis was to better understand the feasibility of calculating wastage rates tailored to the facility and district levels and determine how that can be incorporated into more accurate re-supply calculations for facility-level vaccine distribution.

Stock data on the number of vaccines at the beginning of the month, doses received during the month, and stock balances at the end of the month from the LMIS at the facility level were used to calculate the total vaccines consumed each month. This was compared to doses administered that were reported through HMIS. What was consumed but not reported as an administered dose was calculated to be wastage. What is unique about this approach is the comparison to the transactional data reported in the logistics system, as conventional facility-level reporting of open vial and wastage rate through the HMIS are typically of questionable accuracy.

The analysis did not distinguish between closed-vial or open-vial wastage. The logistics system in Mozambique, much like in many countries, does not easily allow for reporting of losses and adjustments to record closed-vial wastage in the system. If losses and adjustments were part of reporting forms and used by staff, the closed-vial wastage rate could be calculated using the losses and adjustments field, and the wastage rates identified in this analysis would be representative of open-vial wastage only.

Additionally, since consumption data has historically not been collected, calculated, or reported as an indicator, nor compared to HMIS data, the quality of both systems has stagnated. There has been little feedback to healthcare providers to fully account for where doses are going, and consequently, countries have not had quality data to use for alternative forecasting methods (i.e., consumption-based methods).

BETTER UNDERSTANDING OF WASTAGE RATES

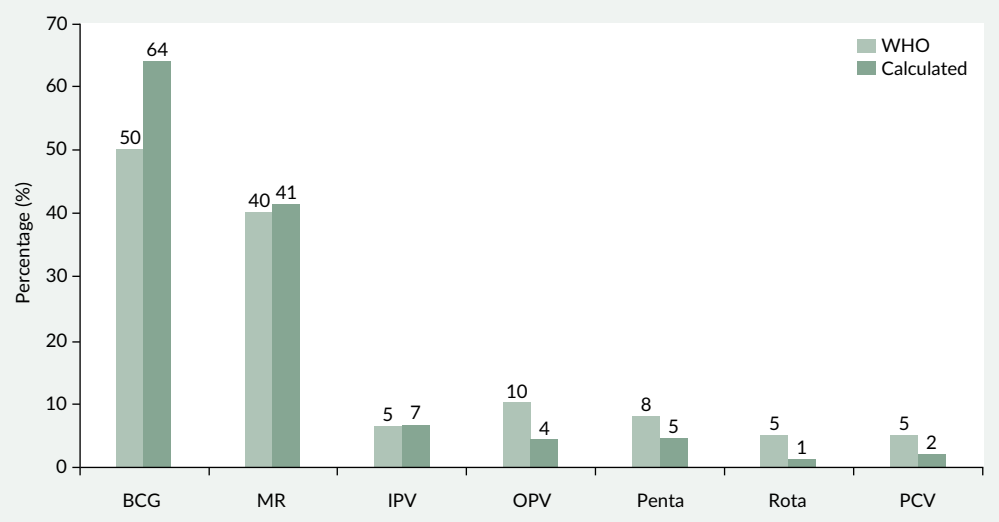
The results of this illustrative analysis for district-level wastage rates averaged across facilities were somewhat comparable to the WHO global standards with BCG as the significant exception (Figure 1). We acknowledge that there may be data quality issues with the data used in this analysis that contributed to the differences seen from the WHO standards.

Particularly compelling insights came from reviewing the results of the facility-level wastage rates, indicating a large range of wastage rates across vaccines. For example, Figure 2 shows particularly high variability for the two lyophilized vaccines, BCG and MR, with BCG wastage rates spanning from 40–85%, and MR spanning from 8–68%. Each dot represents a different facility and month, demonstrating variability and local realities, and/or quality of reported data.

Session size, specifically the number of children attending a facility for vaccine services, is a key factor influencing wastage rates, especially for lyophilized vaccines (BCG and MR). Figure 3 compares the wastage rate to the doses administered of that vaccine at the facility per month as a proxy for session size, since session size is not a readily available indicator. Logically, facilities that have a lower volume of doses administered in a month (likely linked to smaller facilities or population targets) will have higher wastage rates, particularly

FIGURE 1

District-level wastage rates for seven vaccines.



for BCG and MR. The outcomes (Figure 3) are similar to those identified previously in studies showing this relationship with the birth cohort of the catchment area and the session frequency [5]. These findings suggest that further research with a larger volume of data and across multiple countries would be beneficial to determine if the same relationship previously reported also exists with doses administered.

Additionally, an acceptable range (confidence interval) unique to service provision and the type of sites providing immunization services in a country could be identified. Outliers, far from the trend line and its confidence interval in either direction, can be used to uniquely identify facilities requiring follow-up or training on reporting to information systems, or retraining on vaccine administration and service provision.

NEW DATA-DRIVEN APPROACHES

Managing vaccine wastage is at an opportune moment for transformation, driven by the availability of data in electronic information systems and the willingness to use this data to mature processes [6]. Global standards of wastage rates provided useful, if imperfect, measures, but these benchmarks no longer reflect current opportunities. The results of this illustrative analysis, and three other country analyses underway, demonstrate that there is an opportunity to revise the approach to calculating wastage rates where such data exists. Preference is for facility-level measures, but where this is not possible, sub-national-level measures may be useful as a start.

As we explore this approach in three countries, where the data quality is thought to be strong, similar wastage rate patterns (to those represented in Figure 3) have emerged with fewer outliers that need to be reviewed through supervision or data quality checks. Initial analysis in settings where data quality is highly questioned provided no patterns, calling into question the quality of the data and the readiness for the system to apply such analysis.

With available data and the drive for efficiency, immunization programs have an opportunity to refine methods for calculating vaccine re-supply decisions to the facility level with more accurate and tailored wastage rates and further insight into true consumption. Consumption-based

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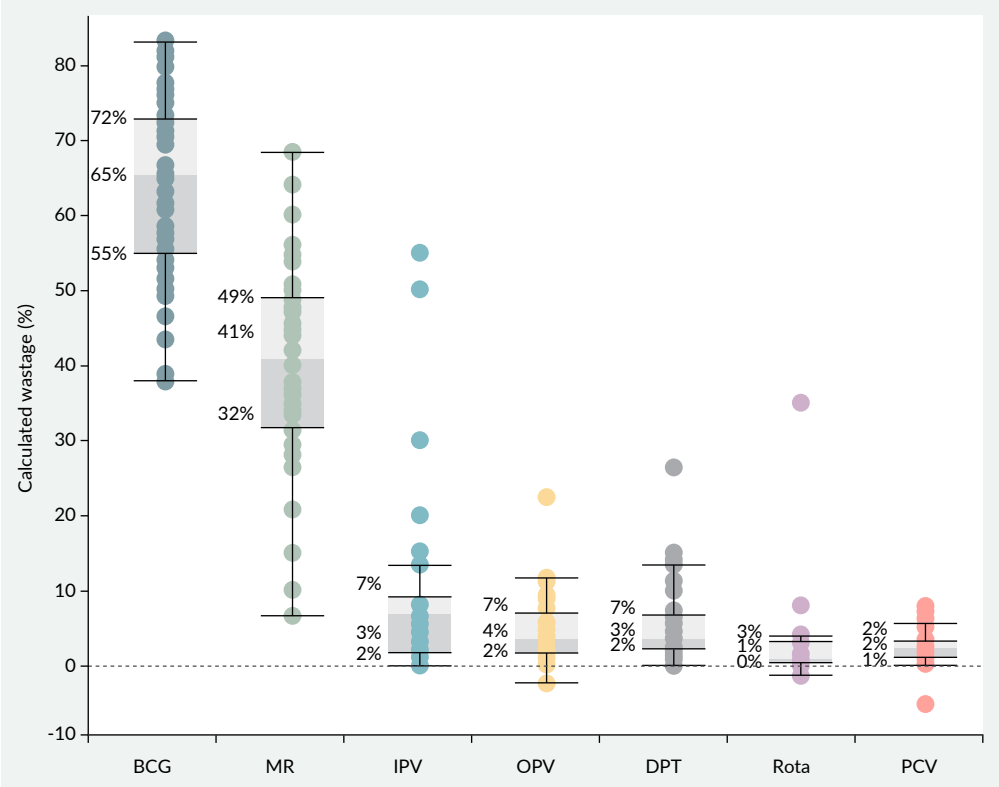
FIGURE 2

Range and median of facility-level wastage rate.



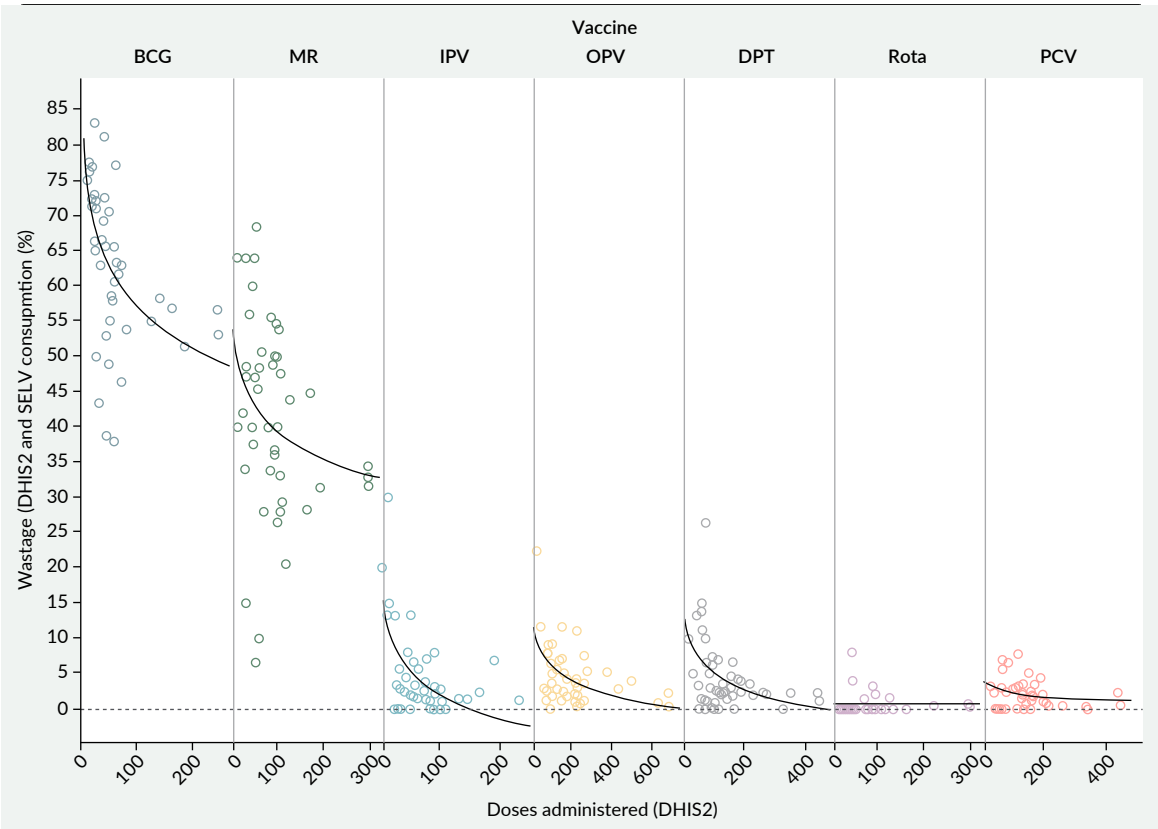
BCG and MR have the largest range. Each dot represents a health facility's calculated wastage rate for 1 month.

forecasts and resupply calculations can add to a more accurate projection of vaccine needs by considering actual utilization patterns for planning rather than relying solely on population estimates. We acknowledge wastage rate cannot be based on a single metric and decisions must also consider upstream factors such as vial size and supply chain design, as well as downstream issues like demand creation activities, routine versus campaign or new vaccine introduction efforts, the size of the catchment population, and policies governing the use of open vials, as examples.

One concern often raised is that the data quality is not strong enough to calculate wastage, undermining confidence in its reliability for informing supply chain decisions. While this concern regarding data quality is evident in the Mozambican data presented here with some outliers, practical experience demonstrates that the consistent use and continuous review of data inherently leads to quality improvements as specific concerns are addressed through routine analysis and application [7–9]. Although not the sole solution to increasing the quality of data, using indicators like the wastage rate discussed here, will lead to data quality improvements. Since our proposed wastage rate is calculated using both logistics and service data, outliers identified may be a result of inaccurate reporting of either or both data. Follow-up of outliers would identify a real or perceived wastage and improve reporting behavior and quality of reported data. Additionally, integrated data systems can facilitate enhanced quality control checks through data entry and reporting, enable

FIGURE 3

Results of wastage rate compared to doses administered as a proxy for session size.



timely resolution of data quality issues and flag prioritization of supportive supervision, such as when doses reported to be consumed are higher than were available in inventory, or when wastage rates are calculated to be gains rather than losses. Our other country analyses have begun to demonstrate these advantages.

DRIVING FOR CHANGE

The current terminology of 'vaccine wastage rate' no longer accurately reflects the nuanced realities of vaccine management and inadvertently casts a negative light on essential operational processes. The term 'wastage' implies an avoidable loss, leading to misinterpretations and discouraging transparent reporting of necessary vaccine use. High wastage is often and inadvertently attributed to the health worker by supervisors and in literature and guidance, defining open vial wastage as 'attributable to immunization workers' practices and discarding of unused doses from…multi-dose vials' [4]. In settings where client flow is unpredictable, strict adherence to minimizing open-vial wastage can inadvertently lead to missed opportunities for vaccination, coming at the cost of coverage.

Wastage is an inevitable part of an immunization program and should be accounted for and factored into supply planning using a tailored estimate. The current global emphasis on reducing wastage provides a disservice to health workers when they have to decide between a vaccination or reporting higher wastage rates, when they are not in control of when a caregiver will walk into the waiting room next for service. Using wastage rates unique to the site's past performance of doses administered,

re-supply decisions can ensure a health worker has all the vaccines necessary to guarantee that all children are vaccinated and no opportunities to vaccinate are lost.

In reality, a significant portion of what is currently categorized as 'wastage' includes critical elements like vaccine doses remaining in multi-dose vials after the required doses have been administered to ensure high coverage. The use of the word wastage obscures the important distinction between truly avoidable losses due to supply chain mismanagement (such as expiries or long exposure to heat or cold) and unavoidable losses that are inherent to the optimal delivery of vaccination services.

To foster a more accurate and constructive dialogue around vaccine management, we must evolve our lexicon. We propose replacing 'wastage rate' with terms that better capture the operational realities, such as 'operational loss rate', 'utilization rate', or 'use balance'. This shift allows for a clearer differentiation between a 'standard operational loss' (which accounts for the unavoidable amount remaining in multi-dose vials) and truly avoidable losses. Furthermore, adopting concepts like 'acceptable loss' or 'tailored standard loss' can enable facilities to monitor their vaccine handling against a more realistic and context-specific benchmark to ensure all eligible children receive their vaccines. This updated language will encourage more transparent reporting, facilitate estimates of tailored operational losses for improved supply planning, and ultimately support the more effective and equitable distribution of life-saving vaccines.

By calculating and identifying appropriate and acceptable operational loss rates (or utilization rates) tailored to each facility and its catchment area, we can improve data quality and service provision, optimize resupply quantities, add to the criteria used to determine where new vaccines are introduced, effectively shift blame away from health workers, and ultimately reach greater numbers of children vaccinated.

SUMMARY

By using available data to calculate and identify appropriate and acceptable wastage rate tailored to each facility and its catchment area, we can improve data quality and service provision, optimize resupply quantities, add to the criteria used to determine where new vaccines are introduced, effectively shift blame away from health workers, and ultimately reach greater numbers of children vaccinated.

REFERENCES

1. Krudwig K, Mvundura M, Lambo K, *et al.* The effects of switching from 10- to 5-dose vials of MR vaccine on vaccination coverage and wastage: a mixed-method study in Zambia. *Vaccine* 2020; 38, 5905–5913.
2. Mvundura M, Lambo K, Krudwig K, *et al.* Vaccine wastage in Ghana, Mozambique, and Pakistan: an assessment of wastage rates for four vaccines and the context, causes, drivers, and knowledge, attitudes and practices for vaccine wastage. *Vaccine* 2023; 41, 4158–4169.
3. Lambo K, Krudwig K, Mvundura M, *et al.* Minimizing vaccine wastage in Nigeria: a national assessment of vaccine wastage rates and potential determinants. *Vaccines* 2024;12, 900.
4. World Health Organization. Revising global indicative wastage rates: a WHO initiative for better planning and forecasting of vaccine supply needs. Apr 8, 2019. https://www.who.int/docs/default-source/immunization/tools/revising-wastage-concept-note.pdf.

5. Colrain P, Chang Blanc D, Grundy J, Kone S. The binomial nature of immunization session size distributions and the implications for vaccine wastage. *Vaccine* 2020; 38, 3807–3813.

6. Lazarus JV, Abdool Karim SS, van Selm L, *et al.* COVID-19 vaccine wastage in the midst of vaccine inequity: causes, types and practical steps. *BMJ Glob. Health* 2022; 7, e009010.

7. Nutley T, Reynolds HW. Improving the use of health data for health system strengthening. *Glob. Health Action* 2013; 6, 20001.

8. Vomberg A, Nambisan S, Lyytinen K, *et al.* The cold-start problem in nascent AI strategy: kickstarting data network effects. *J. Bus. Res.* 2023; 168, 114236.

9. Loshin D. *The Practitioner's Guide to Data Quality Improvement*. 2010; Elsevier.

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VACCINE INSIGHTS

SPOTLIGHT

Building sustainable, forward-looking immunization programs: lessons from Rwanda

VIEWPOINT

"Rwanda's immunization system demonstrates the importance of integrating vaccination into broader healthcare systems and embracing innovative technologies..."

In recent years, immunization efforts in Rwanda have shifted from a primarily reactive approach to a proactive one, driven by the integration of vaccination into broader healthcare systems, an open-door policy to innovative technologies, last-mile delivery initiatives, and strong political support. The country is moving away from vertical, isolated programs toward horizontal, integrated interventions to strengthen immunization services. Having worked in public health for the past decade and in my current role as Program Manager for Immunization at Clinton Health Access Initiative Rwanda, I have been fortunate to observe this evolution—not only in Rwanda, but across the region. In this article I will highlight some of the key factors that I believe contribute to successful vaccine delivery, including the critical last mile.

On August 5, 2025, **Charlotte Barker**, Editor, *Vaccine Insights*, spoke to **Hyacinthe Mushumbamwiza**, Senior Program Manager, Clinton Health Access Initiative about Rwanda's evolving immunization strategies. This article has been written based on that interview.

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LINKING VACCINATION WITH BROADER HEALTH SERVICES

It is important to acknowledge that immunization is not a standalone service but rather a core part of a broader healthcare system. The integration of immunization services into wider healthcare systems in Rwanda has allowed for sharing resources, staying connected to other essential services, and reaching communities more easily, improving access and coverage.

In Rwanda, most services are delivered at the primary healthcare (PHC) level, including immunization, so that those who seek vaccination services do not have to travel long distances to access them and ensure equitable access.

Furthermore, by staying aligned with broader healthcare developments, immunization benefits from shared investments in other services, ensuring it continues to receive support and resources. The country's plan for healthcare to 2028 is to continue to prioritize PHC—more than 95% of patients are expected to be treated at the PHC level, and immunization will be a key part of these services, benefiting from the momentum.

EMBRACING INNOVATION IN VACCINE DELIVERY: DIGITIZATION & AI/ML

When investing in immunization, it is crucial to embrace new technologies, especially those that allow vaccine developers and public health professionals to better understand the communities being served and make informed, data-driven decisions.

In Rwanda, the immunization field has become increasingly digitally focused, with greater emphasis on data use, decision-making, and adaptability through tools such as analytics, artificial intelligence (AI), and machine learning (ML).

For example, the country uses a digital Vaccine Logistics Management Information System to manage supply chain logistics information from the central warehouse down to the service delivery level. This system has been tremendously useful for planning supplies and providing real-time visibility of stock levels. This ensures that when it is time to plan for procurement, especially since vaccines are imported, decision-makers can be proactive and informed if they notice unusual demand, which might trigger early procurement. Moving from a paper-based system to a fully digital one leads to improved data utilization, cost savings, and faster decision-making.

Furthermore, Rwanda is exploring AI/ML for improving and optimizing the supply chain by predicting demand, which helps minimize wastage and reduce costs by avoiding unnecessary supplies as well as for cold chain management. The AI models use data from different sources—civil registration, vital statistics, as well as maternal and child health services—to predict and plan vaccine demand, rather than relying on retrospective monthly data for forecasting and distribution.

LAST-MILE VACCINE DELIVERY: OPPORTUNITIES & CHALLENGES

Rwanda's Expanded Program on Immunization is working to ensure that vaccination services are available at the individual level by strengthening the supply chain, embedding training for the health workforce, and ensuring all necessary precautions and resources are in place.

More specifically, the Ministry of Health is now working to improve PHC by improving the number and capacity of health posts. A few years ago, last-mile delivery services were mainly happening at the health center level. With the increased number of health posts as part of country priority to strengthen PHC, immunization services are using this opportunity to bring immunization to that level.

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Rwanda has also adopted drones to deliver cost-effective and timely healthcare services, including vaccines. For example, drones can quickly deliver what is needed daily to health posts, helping to minimize costs and wastage rates compared with larger, less frequent deliveries by road. Drones can be useful even at larger facilities—for example, if a family arrives unexpectedly at a health center requesting a vaccine that is out of stock, it could be delivered within minutes by a drone, meaning no one is sent home without getting vaccinated.

There are still challenges that must be addressed for effective last-mile delivery. First, costs must be kept within tight budgets, and wastage avoided. Micro-planning and scheduling for immunization days must be carefully managed—not only to reduce wasted vaccine doses but also to ensure efficient use.

There are always operational costs attached to last-mile delivery. As last mile delivery is expanded, there is a need for additional investment, since more immunization sites are required. Plus, if new technologies are incorporated, it is important to ensure that the cold chain does not consume too much energy and become prohibitively expensive. Finally, it is important to ensure essential physical and technological infrastructure, building a capable and skilled health workforce are in place to accommodate these technologies and innovations.

FROM VISION TO ACTION: POLITICAL SUPPORT FOR IMMUNIZATION

Another factor in improving vaccination rates and successful delivery is high-level political support. One of the reasons why Rwanda is known for its rapid response to outbreaks and pandemics is that leadership recognize the value of immunization, and there is a shared understanding that immunization is a key pillar in disease prevention. For example, HPV immunization is at the heart of Rwanda's current cervical cancer elimination strategy.

Active participation and streamlined communication also help address vaccine hesitancy, which is relatively minimal in Rwanda.

SUMMARY

Countries around the world are strengthening immunization programs through a variety of strategies, and all can learn from each other. Rwanda's immunization system demonstrates the importance of integrating vaccination into broader healthcare systems and embracing innovative technologies such as digital tracking, AI/ML, and drones for last-mile delivery. The country's proactive, data-driven approach balances efficiency with equity, addressing challenges in supply chain management and vaccine wastage.

BIOGRAPHY

Hyacinthe Mushumbamwiza is a seasoned public health professional with over 9 years of experience leading health systems strengthening initiatives in Rwanda and across East and Southern Africa. Currently serving as Senior Program Manager at the Clinton Health Access Initiative, he oversees portfolios on oxygen systems, immunization, and climate and health, supporting the Ministry of Health in designing and implementing sustainable strategies. Hyacinthe has played a pivotal role in developing Rwanda's first National Oxygen Strategy and integrating oxygen access into maternal, newborn, child health, and primary healthcare services regionally through UNICEF. His expertise spans health systems program design, digitalization, financing and resource mobilization, policy development, monitoring

and evaluation, and multi-stakeholder engagement, with a proven record of managing large teams and complex projects. In addition to his programmatic leadership, Hyacinthe is a member of UNAIDS' Monitoring Technical Advisory Group (MTAG), where he contributes to strengthening global monitoring frameworks and improving the quality of HIV program data. He holds an MSc in Public Health for Development from the London School of Hygiene and Tropical Medicine, London, UK and a BSc in Pharmacy from the University of Rwanda, Kigali, Rwanda.

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VACCINE INSIGHTS

VACCINE CLINICAL UPDATE

Science that serves: building sustainable vaccine clinical research capacity in Malawi and the UK

INTERVIEW

"The fundamental insight is that research capacity cannot be built through external expertise alone."

Charlotte Barker (Editor, *Vaccine Insights*) speaks to **Stephen Gordon** (Professor of Respiratory Medicine, University of Edinburgh) about his 25 years researching vaccine immune responses and controlled human infection models in Malawi. The discussion covers the unique immunological advantages of high-endemic settings, progress in tuberculosis challenge model development, and sustainable approaches to building research capacity in resource-limited settings.

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Q What was your path to clinical vaccine research?

SG Having lived in Africa as a child, I had always wanted to return. After completing my medical degree, my wife (also a doctor) and I spent 6 months working in southern Zambia at the height of the AIDS pandemic in 1993. The sheer scale of unmet medical need we saw convinced us both that the solutions lay in research-driven approaches to global health challenges. This led me to become a specialist in respiratory medicine, with a focus on infectious diseases in resource-limited settings.

I joined the newly established Wellcome clinical research program (later to become Malawi Liverpool Wellcome Program, MLW) in Malawi in 1997 as one of four founding clinical fellows. Over subsequent decades, MLW has seen remarkable institutional growth, from that initial team of four to nearly 1,000 staff by 2022, when I concluded my tenure as director.

Q How have your research interests evolved and what are the common threads?

SG Over the years, my research interests have evolved from occupational lung disease in UK factory workers [1], to HIV-associated respiratory infections [2,3], and later to controlled human infection models (CHIMs) for vaccine development [4,5]. This progression reflects a consistent philosophy of asking not just 'what is happening in the lung?' but also 'what can be done about it?'.

Early pulmonary vaccination studies, including our failed inhaled pneumococcal vaccine trials [6] in the early 2000s, revealed the complexity of lung immune responses. These challenges drove the development of CHIMs as more effective tools for understanding respiratory pathogen interactions and vaccine efficacy [7].

My current focus encompasses pneumococcal disease and tuberculosis CHIMs, with an emphasis on translating findings into interventions that address the most pressing respiratory health challenges in global health settings.

A common thread throughout my research has been understanding respiratory host–environment interactions and translating those insights into actionable interventions.

Our work on household air pollution [8] and improved cook stoves in Malawi [9] demonstrated that even substantial environmental exposures to lung toxins do not necessarily increase susceptibility to infection. This paradox was also apparent when studying the impact of HIV infection on lung health in Malawi, where we discovered that the lung maintains remarkable resilience, even in immunocompromised populations [10]. Significant disease progression and tissue damage must occur before respiratory defense mechanisms become compromised.

These discoveries led to a fundamental insight: the lung has evolved sophisticated regulatory mechanisms that prevent excessive immune responses to routine environmental challenges. This principle became evident when we attempted pulmonary vaccination approaches. While systemic immunization generated measurable antibody responses in both serum and bronchoalveolar lavage fluid, direct pulmonary delivery produced only systemic antibody production with no local enhancement. The lung's measured immune response system, designed to avoid overreaction to environmental exposures, also dampened responses to our vaccination approach [6].

These insights collectively demonstrated that traditional vaccination approaches fail to harness the lung's natural capacity for protective immunity. Since natural pathogen exposure can generate long-lasting protection, and the respiratory tract clearly possesses sophisticated immune capabilities, we needed controlled experimental systems to understand what constitutes effective pulmonary immune activation. This scientific rationale drove the development of CHIMs as tools for dissecting respiratory pathogen interactions and informing next-generation vaccine strategies.

"The persistence of type 3 pneumococcus in Malawi provides an ideal testing scenario that cannot be replicated elsewhere."

Q Why is it important to conduct CHIMs in high-endemic settings like Malawi?

SG Most importantly, conducting CHIMs in high-endemic settings tests interventions in the immunological context where they will ultimately be deployed. Vaccine efficacy data from low-endemic populations may not translate to high-burden regions due to fundamental differences in baseline immunity. CHIMs ensure that promising interventions are evaluated under realistic immunological conditions rather than the artificial low-exposure environments of high-resource settings.

High-endemic populations provide unique immunological landscapes that cannot be replicated in low-endemic settings, offering critical insights for vaccine development in the regions where interventions are most needed [11].

Malawians experience continuous exposure to diverse bacterial pathogens, including tuberculosis, which results in complex pre-existing immune profiles—markedly different from populations who encounter primarily seasonal respiratory viruses. These differential exposure patterns generate distinct immunological signatures that directly influence vaccine efficacy and post-vaccination protection.

Paradoxically, extensive prior pathogen exposure in high-endemic populations often reduces vaccine effectiveness—a phenomenon that is clearly demonstrated in our pneumococcal research. Despite conjugate vaccine rollout, type 3 pneumococcus carriage has remained highly prevalent in Malawi due to high rates of prior pathogen exposure [12].

The persistence of type 3 pneumococcus in Malawi provides an ideal testing scenario that cannot be replicated elsewhere. This strain demonstrates substantial antimicrobial resistance and lacks an existing preventive vaccine. The pathogen poses significant clinical threats while remaining amenable to safe experimental modeling in a population with established community support for research participation.

Our UK Research and Innovation-funded protein vaccine trial leverages this unique opportunity by comparing protein vaccine to conjugate vaccine and placebo in a type 3 human challenge model. This study addresses locally critical questions that could potentially alter vaccination practice if the protein vaccine demonstrates superior efficacy against this resistant strain.

Q You have also worked on the development of TB CHIMs. What progress has been made and what are the key hurdles?

SG TB presents a unique immunological paradox that makes CHIM development both essential and exceptionally challenging [13]. Through mechanisms we do not fully understand, most infected individuals never develop active disease, and current vaccines show geographic efficacy patterns that suggest fundamental gaps in our knowledge of protective immunity.

"The ultimate goal is not simply to develop safe TB challenge models, but to understand what constitutes protective immunity against mycobacterial infection."

The critical breakthrough has been recognizing that we cannot simply apply conventional CHIM approaches to TB. Wild-type TB poses unacceptable safety risks due to unpredictable latency and reactivation potential. This constraint has driven the development of innovative models using safer mycobacterial surrogates that can provide immunological insights while maintaining participant safety.

Our current approach focuses on skin-based BCG models as the most scientifically tractable starting point. BCG offers several advantages: an established safety profile from billions of administrations, demonstrated protective efficacy in certain populations, and compatibility with skin delivery that permits recovery of both organisms and immune cells for detailed analysis. The skin site allows controlled inoculation, precise monitoring, and complete tissue sampling, capabilities impossible with pulmonary delivery.

Critics correctly note that intradermal BCG represents an imperfect model for pulmonary TB infection. However, this criticism misses the strategic value of establishing proof-of-principle for controlled mycobacterial challenge methodology. Skin macrophages and trafficking lymphocytes may provide translatable insights into TB immunity, while the experimental framework allows us to develop safety protocols and immunological readouts essential for progression to more complex models.

Parallel development of genetically modified *Mycobacterium tuberculosis* with engineered kill switches represents the next evolution toward more representative challenge strains. These approaches maintain greater sequence homology to wild-type TB while incorporating safety mechanisms that address concerns about pathogen persistence.

The ultimate goal is not simply to develop safe TB challenge models, but to understand what constitutes protective immunity against mycobacterial infection. Current vaccine failures suggest we lack fundamental knowledge about the immune responses that prevent disease progression. CHIMs provide the only experimental system capable of dissecting these mechanisms in humans, making this challenging development pathway essential for advancing TB vaccine science.

Q How does your new position at Edinburgh fit with your ongoing work in Malawi?

SG My Edinburgh appointment provides access to advanced analytical capabilities that can address fundamental questions about population-specific immune responses—questions that cannot be easily answered in resource-limited settings. This represents a strategic approach to leveraging high-resource laboratory infrastructure for globally relevant research questions.

The critical scientific opportunity lies in understanding why vaccine responses differ so dramatically between populations. Our previous pneumococcal research demonstrates that identical vaccines generate markedly different efficacy profiles in UK versus Malawi populations, yet we lack mechanistic understanding of these differences. Edinburgh's

advanced analytical platforms—particularly single-cell transcriptomics and high-dimensional immunoglobulin functional assays—can dissect these population-specific immunological signatures at unprecedented resolution.

Several specific research questions exemplify this approach. We are investigating how pre-existing bacterial exposure shapes innate immune cell programming and whether these differences explain differential vaccine responsiveness. Additional work examines whether mucosal immunity patterns in high-endemic populations could inform improved vaccine delivery strategies for temperate climates.

This model extends beyond simply analyzing Malawi-derived samples in UK laboratories. In equitable north-south partnerships, UK-based researchers gain access to unique immunological questions that cannot be addressed in low-endemic populations, while African scientists gain access to analytical capabilities that enhance their research programs [14]. This bidirectional scientific exchange ensures that both institutions benefit from complementary expertise and infrastructure.

Ultimately, this approach addresses a critical gap in global health research: understanding how interventions developed in high-resource settings must be modified for effectiveness in high-burden regions. By combining Malawi's unique population immunology with Edinburgh's analytical sophistication, I hope we can develop vaccines and interventions that are effective across diverse immunological landscapes.

Q What are the most important considerations for building sustainable research capacity in resource-limited settings?

SG Sustainable research capacity requires integration of clinical training with research methodology, rather than treating them as competing pathways. Traditional models that force young clinicians to choose between specialist training and research careers ultimately limit both clinical expertise and scientific innovation in regions where both are desperately needed.

The Clinical Research Excellence and Training Open Resource (CREATOR) initiative at MLW addresses this challenge through deliberate architectural and programmatic design that facilitates natural progression from clinical questions to research investigation. CREATOR establishes research infrastructure within clinical settings, enabling practitioners to develop and maintain clinical specialist skills while also building and refining research expertise. The concept recognizes that the most impactful research emerges when clinicians who understand local disease patterns have access to the tools, training and collaboration necessary to investigate their clinical observations systematically.

The fundamental insight is that research capacity cannot be built through external expertise alone. Malawian physician-scientists in training address regionally relevant questions that external researchers cannot conceptualize or execute in a contextually nuanced manner. Trainees in my team work on bacterial lysates, protein vaccines, and TB-CHIM development—their interest and motivation emerge from direct clinical experience with local disease patterns, combined with sophisticated research training.

The impact extends to systemic transformation. With 200 postgraduates across 20 research groups engaging with integrated clinical–research training in Malawi, CREATOR has the capacity to allow the entire healthcare ecosystem to develop enhanced analytical capabilities. This will, I think, create sustainable scientific infrastructure that persists

beyond external funding cycles, representing genuine institutional capacity-building at regional scale.

REFERENCES

1. Gordon SB, Curran AD, Turley A, *et al.* Glass bottle workers exposed to low-dose irritant fumes cough but do not wheeze. *Am. J. Respir. Crit. Care Med.* 1997; 156, 206–210.
2. Gordon SB, Chaponda M, Walsh AL, *et al.* Pneumococcal disease in HIV-infected Malawian adults: acute mortality and long-term survival. *AIDS* 2002; 16, 1409–1417.
3. Gordon SB, Walsh AL, Chaponda M, *et al.* Bacterial meningitis in Malawian adults: pneumococcal disease is common, severe, and seasonal. *Clin. Infect. Dis.* 2000; 31, 53–57.
4. Collins AM, Wright AD, Mitsi E, *et al.* First human challenge testing of a pneumococcal vaccine. Double-blind randomized controlled trial. *Am. J. Respir. Crit. Care Med.* 2015; 192, 853–858.
5. Dula D, Morton B, Chikaonda T, *et al.* Effect of 13-valent pneumococcal conjugate vaccine on experimental carriage of *Streptococcus pneumoniae* serotype 6B in Blantyre, Malawi: a randomised controlled trial and controlled human infection study. *Lancet Microbe* 2023; 4, e683–e691.
6. Gordon SB, Malamba R, Mthunthama N, *et al.* Inhaled delivery of 23-valent pneumococcal polysaccharide vaccine does not result in enhanced pulmonary mucosal immunoglobulin responses. *Vaccine* 2008; 26, 5400–5406.
7. Pollard AJ, Savulescu J, Oxford J, *et al.* Human microbial challenge: the ultimate animal model. *Lancet Infect. Dis.* 2012; 12, 903–905.
8. Gordon SB, Bruce NG, Grigg J, *et al.* Respiratory risks from household air pollution in low and middle income countries. *Lancet Respir. Med.* 2014; 2, 823–860.
9. Mortimer K, Ndamala CB, Naunje AW, *et al.* A cleaner burning biomass-fuelled cookstove intervention to prevent pneumonia in children under 5 years old in rural Malawi (the Cooking and Pneumonia Study): a cluster randomised controlled trial. *Lancet* 2017; 389, 167–175.
10. Rylance J, Fullerton DG, Scriven J, *et al.* Household air pollution causes dose-dependent inflammation and altered phagocytosis in human macrophages. *Am. J. of Respir. Cell Mol. Biol.* 2015; 52, 584–593.
11. Galafa B, Chikaonda T, Kudowa E, *et al.* Natural carriage of *Streptococcus pneumoniae* is associated with increased experimental pneumococcal carriage but reduced conjugate vaccine efficacy in a human challenge model. *J. Infect. Dis* 2025; 231, 334–343.
12. Swarthout TD, Fronterre C, Lourenco J, *et al.* High residual carriage of vaccine-serotype *Streptococcus pneumoniae* after introduction of pneumococcal conjugate vaccine in Malawi. *Nat. Commun.* 2020; 11, 2222.
13. Gordon SB, Sichone S, Chirwa AE, *et al.* Practical considerations for a TB controlled human infection model (TB-CHIM); the case for TB-CHIM in Africa, a systematic review of the literature and report of 2 workshop discussions in UK and Malawi. *Wellcome Open Res.* 2023; 8, 71.
14. Hodson DZ, Etoundi YM, Parikh S, Boum Y, 2nd. Striving towards true equity in global health: a checklist for bilateral research partnerships. *PLOS Glob. Public Health* 2023; 3, e0001418.

BIOGRAPHY

Stephen Gordon has conducted clinical and translational research in the UK and Africa since 1993; his research in pulmonary disease in Malawi began in 1997. His initial research focus was on HIV-associated lung macrophage functional defects, specifically against pneumonia. He subsequently expanded his interest to include the effect of household air pollution on pulmonary defense including a landmark cook stove intervention trial published in *Lancet*. His current research focuses on defense against respiratory infection using a pneumococcal challenge model. This model was developed in Liverpool, UK, transferred to Malawi, and is now being used to explain the relative lack of herd immunity following pneumococcal conjugate vaccine implementation in Malawi. New studies focus on more resistant serotypes, populations at risk including people living with HIV, and new immunomodulatory agents as well as new vaccines. Future projects include TB human challenge studies to bring forward vaccine discovery in Malawi. As Director of the Malawi Liverpool Wellcome program (2015–2022), Stephen led with a vision of 'research to benefit health and training the next generation of researchers'. He was known for developing research groups and a training program that nurtured trainees from postgraduate to professor level. Prior to that, he developed the Pan African Thoracic Society research training program, which has resulted in a network of respiratory research across Africa. During the COVID times in Malawi, he and others brought an oxygen plant to Queen Elizabeth Central Hospital, saving many lives at the time and in the future. Currently Stephen leads the CREATOR (Clinical Research Excellence and Training Open Resource) program, a £10 million project and building aiming to change the paradigm of clinical specialist and research training in Africa by combining these in-country in Malawi. Stephen is now Professor of Global Respiratory Medicine at the University of Edinburgh, and Director of Experimental Medicine at the Infection Innovation Consortium in the Liverpool School of Tropical Medicine (**iiCON**). His work focuses on translational clinical research and capacity building to realize global health impact.

Stephen Gordon, Professor of Respiratory Medicine, University of Edinburgh, Edinburgh, UK

AUTHORSHIP & CONFLICT OF INTEREST

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EVENT PREVIEW

World Vaccine Congress Europe 2025

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As part of our ongoing coverage of key events in the vaccines space, *Vaccine Insights* presents a preview of World Vaccine Congress Europe 2025, taking place on October 13–16, in Amsterdam, the Netherlands. The conference will showcase the latest advances, technologies, and collaborative opportunities in the global vaccine industry. Readers of *Vaccine Insights* can claim a 20% discount on delegate tickets (details at the end of the article).

RESEARCH & DEVELOPMENT

Innovation in vaccine platforms is a central theme. Jeffrey Almond (University of Oxford) will chair a pre-congress workshop on Platform Technlogies, which will include a panel on next-generation modalities, including self-amplifying RNA, circular RNA, and peptide-based vaccines, with insights from Robbert van der Most (Vaxxcellence), George Dakwar (CureVac), Joanna Rejiman (Novo Nordisk Foundation Initiative for Vaccines and Immunity) and Rajeshwari Adhiseshan (Bill & Melinda Gates Foundation).

In the main program, Mark Howarth (University of Cambridge) will define and discuss immunofocusing in the Immune Profiling track, while Matt Higgins (University of Oxford) will address computational approaches immunofocusing and antigen design in the Pre-Clinical Development session.

CLINICAL DEVELOPMENT

Sessions on clinical development span trial design, regulatory strategy, and real-world evidence. Walter Straus (Moderna) opens the Vaccine Safety pre-congress workshop, featuring contributors including Ofer Levy (Harvard), Marco Cavaleri (EMA), and Emilie Karafillakis (Vaccine Confidence Project).

AI-driven safety monitoring will be discussed by Miriam Sturkenboom (Vac4EU), while the Clinical Trials track will feature Ingrid de Visser-Kamerling (CHDR) on CHIM models, William Smith (AMR Clinical) on recruitment, and Christine Dalhke (CEPI) on correlates of protection.

In the Partnerships & Access track, Kundai Chinyenze (IAVI), Maria Elena

Bottazzi (Baylor College), Moy Bracken (Access to Medicines Foundation) and Dakshina Reddy (Bill & Melinda Gates Foundation) will explore strengthening local clinical trial partnerships.

PANDEMIC PREPAREDNESS & PUBLIC HEALTH THREATS

The Biothreats & Disease X pre-congress workshop, led by Joris Vandeputte (VacciM), will feature Swati Gupta (IAVI) and Ruben Rizzi (BioNTech) on pandemic-ready vaccine profiles.

A keynote panel moderated by Bassam Hallis (UKHSA) will bring together experts such as Wolfgang Phillip (European Commission), Ivo Classen (EMA), Robb Butler (WHO), Nikki Romanik (Brown University), and Yap Boum (Africa CDC) to discuss global health threats and response strategies.

The Emerging & Infectious Diseases track will include talks from Jerald Sadoff (Centivax) on MERS-CoV, Bart Haagmans (Erasmus MC) on Merbecoviruses, and Kashmira Date (Pfizer) on diagnostics and surveillance.

A dedicated track on the pressing issue of antimicrobial resistance, chaired by Jan Poolman, will highlight vaccine development for drug-resistant infections. A keynote panel on vaccines & AMR will feature experts such as Timothy Cooke (Omniose), Ed Buurman (CARB-X), Charlie Weller (Wellcome), Rino Rappuoli (Scalvo Association), Morwenna Carrington (UK Health Security) and Jamie Findlow (Pfizer) discuss how commitment can be turned into practical action.

MANUFACTURING & SUPPLY CHAINS

Martinus Cappelle (J&J) will chair a session on innovative manufacturing technologies, including VLP automation and RSV stabilization. Zoltán Kis (University of Sheffield) will present RNAbox, a continuous RNA production platform.

The Supply & Logistics session will feature presentations on end-to-end vaccine supply chains, with contributions from from Giovanna Riggall (Unimed), Jack Moss (UKHSA), And Christopher Green (University of Birmingham).

SPECIAL POPULATIONS

In this session, Geert Leroux Roels (University of Ghent) and Kristen Maertens (University of Antwerp) will examine gender-based reactogenicity and maternal immunization. Elsewhere, Chelsea McLean (J&J Innovative Medicine) will share insights about immunogenicity in pregnancy gained from J&J's Ebola vaccine trial.

The closing keynote, moderated by Britt van de Ven (HollandBio), features Jerome Kim (IVI), Jennifer Moisi (Pfizer), Jane Barratt (International Federation on Ageing), and Melanie Saville (PATH) debating the future of adult vaccines.

Readers of *Vaccine Insights* can claim a **20% discount** on delegate tickets—just use the code **VI20**! You can find out more about the event here.

To learn about other events coming up in your field, you can find our online Events Calendars here.

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EVENT PREVIEW

Vaccine World Asia Congress 2025—South East Asia

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Vaccine World Asia Congress 2025—South East Asia will take place on November 5–6, 2025 at the Amari Bangkok, Thailand. The congress aims to bring together leading scientists, policymakers, and industry stakeholders to address Southeast Asia's most urgent vaccine challenges—from platform innovation to equitable distribution.

POLICY & REGIONAL COLLABORATION

The congress will address multiple topics including examining how political and economic instability may affect immunization programs across Southeast Asia. Nakorn Premsri (National Vaccine Institute, Thailand) will lead a session on ASEAN Vaccine Security and Self-Reliance, focusing on regional manufacturing, supply chain resilience, and sustainable vaccine access.

A leadership panel chaired by Nizam Uddin Ahmed (Synesis Health) will explore cross-border collaboration, equitable access, and budgetary strategies for vaccine rollout. Panelists will include Dr Mohd Azlan bin Zaharudin (Ministry of Science, Technology & Innovation, Malaysia) Luigi Bonfatti (RVMC, Norway) and Fitriana Rahmawati (PT Biofarma, Indonesia).

DISCOVERY & PRECLINICAL DEVELOPMENT

The agenda will feature cutting-edge research in malaria, leptospirosis, and Nipah virus vaccines. Takafumi Tsuboi (Ehime University) will present on wheat germ cell-free systems for malaria vaccine candidate discovery. Kanitha Patarakul (Chula Vaccine Research Center) and Jetsumon Sattabongkot (Mahidol Vivax Research Unit) will discuss mRNA platforms for leptospirosis and *Plasmodium vivax*, respectively. Pei Yin Lim (Hilleman Laboratories) will share preclinical data on a circular RNA vaccine candidate for Nipah virus.

CLINICAL TRIALS & REAL-WORLD DATA

A panel on clinical trial infrastructure in Southeast Asia will address adaptive

designs, population diversity, and regulatory harmonization. Edwin Simjaya (PT Kalbe Farma) will highlight cybersecurity risks in digital trials, while sessions on adaptive and decentralized trial models will explore innovations in trial speed, retention, and data quality.

MANUFACTURING & FORMULATION

Vipul Doshi (Zydus Lifesciences) will lead a session on scaling vaccine production from lab to commercial scale, with emphasis on quality control and tech transfer. A panel featuring Prashant Chawla (Biological E Limited) will discuss formulation innovations, including adjuvant technologies and stability optimization.

NEXT-GENERATION VACCINE PLATFORMS & DELIVERY MECHANISMS

This program will include a special session by Amaran Biotech covering the topic Building the Future on a Solid Foundation: How Superior Adjuvants AB-801 Accelerate Vaccine Commercialization. Other speakers include Petro Terblanche (Afrigen Biologics) on mRNA vaccine development in LMICs, Waranyoo Phoolcharoen (Baiya Phytopharm) on plant-based biomanufacturing, and Seyed Reza Banihashemi (Razi Institute) on respiratory vaccine delivery systems, including aerosol and nanoparticle technologies.

ENSURING ACCESS

Sessions will explore adult immunization, vaccine hesitancy, and coverage in underserved populations. Nirutti Pradubyati (Pfizer) will present on preventive vaccines for non-infectious diseases, including cancer and diabetes. A panel on vaccine safety funding will address public trust and political influences, while Badarulhisam Abdul Rahman (Pharmaniaga) will discuss Halal vaccine development.

Distribution sessions will cover cold chain risks, last-mile delivery, and supply chain resilience, with insights from Sebastian Chua (Supply Chain Asia).

The congress will conclude with a panel on equitable vaccine distribution during outbreaks, reflecting on lessons from COVID-19 and future strategies for global health preparedness.

Readers of *Vaccine Insights* can claim a **15% discount** on delegate tickets—just reach out to rima.karan@imapac.com! You can find out more about the event here.

To learn about other events coming up in your field, you can find our online Events Calendars here.

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VACCINE INSIGHTS

VACCINE CLINICAL UPDATE
EVENT PREVIEW

Biologics CDMO Europe 2025

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As part of our ongoing coverage of key gatherings in life sciences, BioInsights presents a preview of Biologics CDMO Europe 2025. Scheduled for November 19–20, 2025, in Munich, Germany, this summit will unite up to 300 senior manufacturing and external supply-chain experts from across Europe. Focusing on agile, tech-enabled biologics manufacturing, regulatory alignment, and strategic CDMO partnerships, the agenda features off-the-record case studies, executive roundtables, and deep-dive sessions.

OUTSOURCING STRATEGY AND CDMO PARTNER EVALUATION

A strategic panel including Suyamburam Sathasivam (Associate Vice President, SUN PHARMA), Ulrich Rümenapp (Head of Launch Preparation and Coordination, Bayer), and Daniel Hurni (Former Director of Manufacturing Network Strategy and Business Intelligence, Bristol Myers Squibb) will discuss outsourcing trends toward 2030. Additionally, Christopher Pawlak (External manufacturing Lead, Bayer) will outline practical tools for CDMO partner evaluation, while Andreas Schaaf (Managing Director/CSO, Eleva) will highlight innovations in biomanufacturing technologies. Key sessions will also explore risk allocation in CDMO agreements and resilient partnership models, setting a collaborative tone for navigating Europe's evolving biologics landscape.

TECH TRANSFER AND GLOBAL REGULATORY HARMONIZATION

The summit will also focus on tech transfer and regulatory compliance for advanced therapies. Christian Simon (Head of Technical Transfer External Manufacturing, Sanofi) will explore how AI-driven predictive maintenance can reduce downtime and improve equipment performance. Jenny Prange (CTO, Muvon Therapeutics) will present strategies for navigating tech transfer in regenerative therapies. Furthermore, a panel on global regulatory harmonization will follow, featuring Pavan Beleyur Narayanaswamy (Head of CMC and Regulatory Affairs, AATec Medical) and Eoin McGrath (Executive Director, ICCBBA).

COST OPTIMIZATION AND EVOLVING CONTRACT MODELS

Ulrich Rümenapp (Head of Launch Preparation and Coordination, Bayer) will address strategic approaches to outsourcing CMC development and manufacturing, including IP protection and building effective CDMO partnerships. Giulio Cavalli (Principal Lead, External Manufacturing, Johnson & Johnson Innovative Medicine) will share best practices for managing cross-border tech transfers in a globalized production landscape. The summit will also include a panel discussion on the evolution of contract models in biomanufacturing, featuring Ralf Huss (Managing Director, Biom Biotech Cluster) and Chris Baldwin (Vice President, Manufacturing and Supply, Resolution Therapeutics), who will explore shifting trends and collaborative opportunities in outsourcing agreements.

Biologics CDMO Europe 2025 will convene key stakeholders from across the biologics manufacturing landscape to address the most pressing challenges and innovations shaping the industry, from evaluating CDMO capabilities and optimizing outsourcing strategies to simplifying tech transfer and scaling single-use technologies.

As a reader of the BioInsights journals, you're entitled to a **15% discount** on delegate tickets—just use the code **CDMO-Insights**! You can find out more about the Biologics CDMO Europe 2025 events here.

To learn about other events coming up in your field, you can find our online Events Calendars here:

Vaccine Insights, *Nucleic Acid Insights*, *Bioconjugation Insights*, and *Cell & Gene Therapy Insights*

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