Country COVID-19 Vaccine Post Introduction Evaluations (cPIE)

Cross-country review of findings

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THE TASK FORCE FOR GLOBAL HEALTH

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

Acknowledgements

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THE TASK FORCE FOR GLOBAL HEALTH

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

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Acronyms

AEFI	Adverse Event Following Immunization
AESI	Adverse Events of Special Interest
BeSD	Behavioral and Social Determinants
CCE	Cold Chain Equipment
CDC	Centers for Disease Control and Prevention
CHW	Community Health Worker
COVID-19	Coronavirus Disease
cPIE	COVID-19 Vaccine Post Introduction Evaluation
DP	Development Partner
eIR	electronic Immunization Register
eLMIS	electronic Logistic Management Information System
EUA	Emergency Use Authorization
EUL	Emergency Use Listing
EVM	Effective Vaccine Management
HF	Health Facility
HR	Human Resources
HW	Health Worker
IPC	Infection Prevention Control
IT	Information Technology
KAP	Knowledge, Attitudes, and Practices
LMIC	Low- and Middle-Income Countries
MMGH	MM Global Health Consulting GmbH
MoH	Ministry of Health
mRNA	Messenger Ribonucleic Acid
NDVP	National Deployment and Vaccination Plan for COVID-19
NGO	Non-Governmental Organization
NIP	National Immunization Program
NITAG	National Immunization Technical Advisory Group
NRA	National Regulatory Authority
PHC	Primary Health Care
PIE	Post Introduction Evaluation
PPE	Personal Protective Equipment
QR	Quick Response
RCCE	Risk Communication and Community Engagement
SMS	Short Message Service
SOP	Standard Operating Procedures
SRA	Stringent Regulatory Authority
TFGH	Task Force for Global Health
UCC	Ultra-Cold Chain
UNICEF	United Nations Children's Fund
US	United States
USAID	The United States Agency for International Development
VIRAT	COVID-19 Vaccine Introduction Readiness Assessment Tool
VPD	Vaccine Preventable Disease
WHO	World Health Organization

Executive Summary

This report provides anonymized findings from COVID-19 Vaccine Post Introduction Evaluations (cPIEs) conducted in 20 low- and middle-income countries from November 2021 to April 2023. (See Annex A for a full list of countries.) The evaluations were commissioned by the respective Ministries of Health and conducted by in-country teams with the support of national and international partners.

The COVID-19 pandemic challenged the world to rapidly develop, approve, and introduce safe and effective vaccines within a constantly evolving environment constrained by movement restrictions, and in areas often already overwhelmed and desperate for socio-economic stability. The initially limited supply of vaccines had to be introduced to adult populations that were not usually targeted for vaccination in many countries. The rapid pace of vaccine development and deployment raised concerns about their safety and effectiveness.[1] Whilst most countries have tremendous experience introducing new vaccines in their childhood vaccination programs, the adult vaccination context provided challenges which had to be overcome quickly and creatively, by numerous stakeholders working together.

Following the introduction of any new vaccine, countries typically undertake a Post Introduction Evaluation (PIE) using a standard World Health Organization (WHO) evaluation tool.[2] This evaluation serves to assess the impact of the vaccine on the country's immunization program and to identify problems that need correction as vaccination progresses. The evaluation supports in-country learning, as well as providing lessons for other countries for future vaccine introductions.

The PIE tool was tailored for COVID-19 vaccination for this evaluation.[3] Countries then conducted these evaluations six to eighteen months after initiating COVID-19 vaccination. The cPIEs were structured around the nine chapters of the COVID-19 National Deployment Planning and Vaccination Plans (NDVPs), namely: regulatory preparedness; planning and coordination; service delivery; costing and funding; supply chain and waste management; human resource management and training; vaccine demand; vaccine safety; and monitoring and evaluation.[3]

The purpose of this report is to document learnings on the achievements, challenges and lessons learnt during the COVID-19 vaccine introduction and roll-out from the sample of 20 countries. The report is structured around key research questions defined under each of the NDVP evaluation areas and reflects the main queries from senior Ministry of Health (MoH) staff raised during the cPIE preparation and debriefing sessions in the various countries. These research questions therefore illustrate some of the key concerns faced by countries, and include considerations for future pandemic vaccine use, as well as the need for health system strengthening and integration of COVID-19 activities.

Methodology

All cPIEs were country-led and performed at all levels of the health system. A purposive sampling strategy was used to provide a rapid, but representative picture of the immunization service delivery situation in the country. Using standardized primary data collection forms and survey tools based on the WHO COVID-19 vaccine post-introduction evaluation guide, data collection covered the nine thematic areas aligned with the chapters of the NDVP.[3,4] A debriefing presentation and a final summary report was provided to the senior country leadership following primary data collection and analysis.

This cross-country report explores the quantitative data collected from 16 countries and the qualitative data collected from all 20 sample countries. Country data reports were selected based on their willingness to share their information for inclusion in this anonymized summary of findings. Quantitative datasets were compiled, checked for errors, and merged into one database per administrative level for analysis. Descriptive analysis included frequencies, proportions, histograms, and cross-tabulations. In cases where detailed electronic datasets had not been shared, national data were extracted from national debriefing presentations and final reports. A qualitative content analysis was conducted on the cPIE reports. The analysis was both inductive and deductive and centered around key research questions defined per NDVP thematic area.

Findings

Key learnings from the cPIE evaluations are summarized below:

Regulatory preparedness: Strengthened regulatory procedures and reliance on other mechanisms shortened traditionally lengthy regulatory approval timelines. Whilst regulatory procedures were enhanced in many countries, some of the new processes may only apply to the COVID-19 vaccine and not be further leveraged for other vaccines and drugs. Most countries still relied on the WHO Emergency Use Listing (EUL) and Emergency Use Authorization (EUA) from Stringent Regulatory Authorities (SRAs). Countries identified the need to further consolidate regulatory functions, noted limited laboratory capacity, and acknowledged challenges in obtaining regulatory approvals and import permits for vaccines. Countries also saw this as an opportunity to expand the revised legislative frameworks to include vaccines beyond COVID-19.

Planning and coordination: Coordination was key, as was flexibility in adapting plans to meet evolving needs. Strong oversight and multisectoral involvement were essential for effective implementation, within and between each level of the health system. The various government ministries, development partners, and private sectors needed to be closely coordinated. Whilst planning was critical for coordinating the multiple stakeholders, and to identify populations and allocate resources, given the ad hoc nature of vaccine supply and the evolving disease, flexibility in adapting plans in response to the evolving situation was key to success.

Service delivery: There was a strong focus on bringing the vaccine to the clients. Innovative, and flexible vaccination campaigns in churches, mosques, markets, work offices, venues of convenience for adults, and even in homes, made it more convenient for target populations to access services without adversely affecting their livelihoods, and reach hard-to-reach and neglected populations. Different service delivery strategies and sites were required at different stages of the pandemic and for different population groups. These needed to be monitored and budgeted for.

Costing and funding: Complex costing and budgeting exercises and lengthy disbursement processes may have impacted service delivery activities. Estimating the financial needs for vaccine roll-out was complex and countries lacked the capacity to cost and develop a budget for the COVID-19 vaccination response, particularly at the sub-national level. Many countries also lacked the financial resources to cover all the operational costs from domestic resources. Resources

were thus raised from bilateral and multilateral partners, and the private sector. However, despite the availability of funds at the national level, timely distribution to the sub-national levels created challenges leading to delayed payment of salaries and incentives and out-of-pocket expenses for health workers. A contingency plan and budget for future public health emergencies should be considered by countries.

Supply chain and waste management: Careful planning of vaccines, related supplies and cold chain equipment ensured products were available at the right time, in the right place, and in the right condition. Despite initial global shortages of COVID-19 vaccines and related supplies, countries did not report significant stock-outs. Substantial investments were made in increasing cold chain capacity, including refrigerated vehicles and ultra-cold chain (UCC) capacity. However, some cold chain capacity challenges at health facility levels remained, often due to the ad-hoc arrival of vaccine shipments. Safe disposal of the large amounts of healthcare waste generated by the vaccination response posed a challenge for most countries. Several countries outsourced waste disposal to the private sector, but there were examples of sub-optimal waste disposal practices.

Human resource management and training: Taking care of health workers and community health workers (CHWs) was a priority. Health workers needed to be amongst the first to receive information to effectively build trust and communicate with their clients and patients. In addition, they required regularly updated information on changes to policy and practice guidelines. Feedback loops on programmatic challenges in implementation were required to enable optimization of policies and strategies. To protect and motivate health workers and CHWs, incentives (including non-monetary ones) were provided, and actions were taken to ensure health workers' well-being and to reduce burnout. Infection Prevention and Control (IPC) measures and Personal Protective Equipment (PPE) were prioritized within allocated budgets, and mechanisms were put in place to rapidly increase the workforce in response to surges in the number of cases. Whilst virtual training had its benefits, it was often insufficient and health workers required additional on-site training, supportive supervision, and updated Standard Operating Procedures (SOPs) to guide service delivery.

Vaccine acceptance and demand generation: Investments in vaccine demand generation paid dividends. Adult vaccination required tailored strategies, trusted messengers, and consistent and understandable messages delivered in a variety of ways to different communities to ensure optimal uptake. CHWs, community leaders and volunteers were critical in generating demand and were at the forefront of allaying concerns. Countries developed and implemented a range of risk communication and community engagement (RCCE) strategies. In an evolving environment with conflicting information disseminated through mainstream and social media, it was important to get ahead of misinformation, rumors, and myths. Measures were therefore put in place to respond to misinformation with evidence-informed messages delivered through a variety of trusted sources.

Vaccine safety: Vaccine safety and monitoring of adverse events following immunization (AEFI) required strengthening. The number and variety of COVID-19 vaccines, including those using innovative technologies, proved a challenge for vaccine safety monitoring. Efforts were made to bolster global, regional, and national safety surveillance systems. Vaccinators had to be sufficiently trained and equipped to monitor possible AEFI. AEFI committees and causality assessment processes were strengthened, and where possible, surveillance mechanisms improved.

Monitoring and evaluation: Ensuring access to, and control over, data for analysis and action was critical for success. Disaggregated data was a necessity for COVID-19 vaccination. Health workers needed support and tools to easily collect, report and use data. A variety of electronic data management tools were developed and countries with adequate electricity, internet connectivity, hardware, and a trained workforce saw the benefits of these tools. New electronic systems were particularly useful in environments where similar systems were already in place before the pandemic, and/or if they were interoperable with other electronic databases. Some immediate benefits of individualized data systems included scheduling vaccination appointments, sending reminders for follow-up doses, defaulter tracking, issuing electronic vaccine certificates, and assisting in microplanning. However, countries that introduced new electronic tools without a sufficient enabling

environment often placed undue pressure on the already overburdened workforce, resulting in dual electronic and paper-based reporting systems, reducing data quality, and negatively impacting service delivery.

Routine immunization and integration with primary health care (PHC) services: The COVID-19 vaccination response saw significant shifts in program implementation and investments in the vaccine roll-out. During the later stages of the pandemic, many countries reviewed their policies, activities, strategies, and investments to support routine immunization and integration with other PHC services.

Conclusions

Countries used the cPIE findings to inform recommendations to improve the continued delivery of COVID-19 vaccines, to increase coverage among certain target groups, to improve strategies for the completion of primary series and booster vaccination, and to assess the impact of COVID-19 vaccination on routine immunization and other PHC services. cPIE findings also provided lessons to strengthen health systems and improve the countries' readiness for responding to future pandemics.

This report presents a global perspective, acknowledging strengths and challenges that, while unique to certain countries, were cross-cutting across regions. Strong coordination and communication, within all levels of the health system, and across all government ministries and public and private stakeholders, is vital to support a coherent and comprehensive pandemic response. There is a need to refine and simplify the budgeting and costing processes related to vaccine procurement and distribution and improve disbursement processes to sub-national levels. Future priority investments should be explored e.g., for electronic information management systems, appropriate cold chain equipment and enhanced supportive supervision and training. An appropriately resourced health workforce, supported by governments, partners, non-governmental organizations (NGOs), and the private sector, can generate demand and deliver services rapidly across a range of geographical and socio-economic environments. Risk communication and social behavior change activities need to be consistent, honest, and clear – staying ahead of misinformation, and providing opportunities for community and political leaders to advocate for vaccines. Reporting and managing AEFI needs further strengthening, as does waste management and the delicate dilemma of donated vaccines. Without exception, the COVID-19 pandemic highlighted weaknesses in health systems across the globe and shone a light on opportunities for improved global coordination and communication mechanisms.


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VACCINATION
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Summary of recommendations

Regulatory preparedness	• Expand legal frameworks that were used for expediting use of COVID-19 vaccines to include other vaccines. • Improve coordination between NRA and NIP, specifically for vaccine safety monitoring.
Planning and coordination	• Provide timely global guidance, including provision of vaccine specific recommendations. • Leverage established coordination structures and strengthen broader healthcare delivery, including with development partners and the private sector.
Service delivery	• Improve microplanning processes to ensure target populations are well-defined and appropriately served. • Acknowledge vital role of health workers, community health workers and volunteers in vaccine roll-out. Consider appropriate incentives to sustain their motivation.
Costing and funding	• Analyze expenditures incurred to better estimate costs for pandemic response. • Establish contingency plans for rapid resource mobilization.
Supply chain and waste management	• Improve forecasting, allocation and vaccine stock management. mechanisms for real time visibility on stock levels at all levels to enable redistribution to reduce closed vial wastage.
Human resource management and training	• Develop training, recruitment, and surge capacity plans to monitor and ensure staff wellbeing. • Ensure early information sharing with health workers with sufficient detail for them to be able to respond to queries from their public.
Acceptance and demand generation	• Appropriately fund vaccine acceptance and demand activities at the service delivery levels. • Enhance mechanisms to stay ahead of misinformation and rumors. • Incorporate social listening and promptly make available targeted messages to respond to misinformation.
Vaccine safety	• Enhance health worker capacity to identify, manage and report AEFI. • Ensure proper feedback of results of AEFI investigations to local levels.
Monitoring and evaluation	• Harmonize electronic tools for vaccination with those for other health programs and civil registration and vital statistics systems (wherever possible). • Leverage tools developed for COVID-19 vaccination for routine immunization and other primary health care services.

Introduction

The COVID-19 pandemic challenged the world to develop an effective vaccine much faster than ever before. These vaccines then had to be quickly and safely disseminated and introduced across the globe amidst movement restrictions and constantly evolving and overwhelmed environments. A number of challenges had to be overcome quickly, with creativity, and through the close collaboration of a number of stakeholders. These included the initial limited vaccine supply, vaccination of adult populations not usually targeted for vaccination in many countries, and concerns about the safety and efficacy of the vaccines given their rapid development.[1]

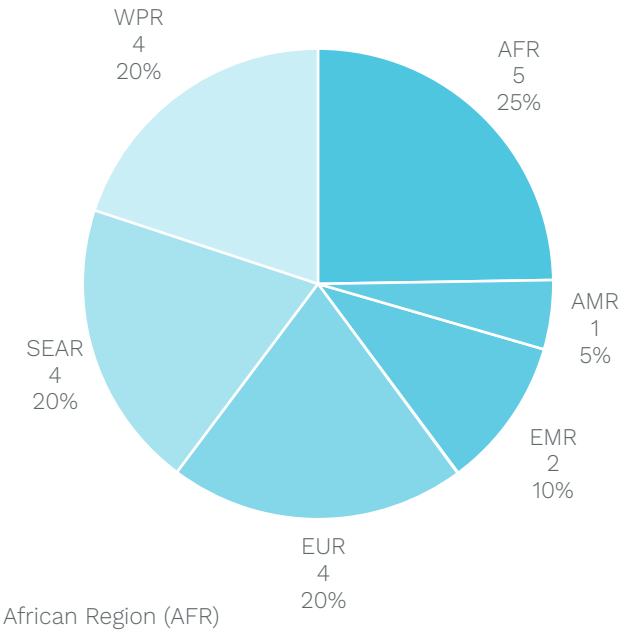
A COVID-19 vaccine Post Introduction Evaluation Tool,[3] based on the WHO New Vaccine Post-Introduction Tool [2,3] and the Influenza Vaccine Post-Introduction Evaluation Tool[5], was developed to assess the COVID-19 vaccination program. The tool was organized into thematic areas aligned with the COVID-19 NDVPs.

The cPIE provides a systematic method to assess the impact of the vaccine on a country's immunization program. Specifically, it is used to highlight deployment and vaccination activities that went well and should be maintained; identify problems needing corrective action; highlight lessons learned from COVID-19 vaccine deployment to strengthen a country's overall national immunization program (NIP) and health services; inform recommendations to improve the continued roll-out of COVID-19 and other vaccines across the life-course; and provide lessons learned for COVID-19 and future pandemic vaccine deployments.

This report provides a summary of cPIE findings from 20 low- and middle-income countries, namely, Albania, Armenia, Barbados, Benin, Cote d'Ivoire, Ghana, India, Indonesia, Kenya, Lao Peoples Democratic Republic (Lao PDR), Lebanon, Mali, Maldives, Mongolia, Nepal, the Philippines, Tajikistan, Thailand, Tunisia, and Uzbekistan. The selected reports include countries from all six WHO regions: Africa (5), Europe (4), South-East Asia (4), Western Pacific (4), Eastern Mediterranean (2) and the Americas (1) (see figure 1). Annex A provides the full list of countries included in the qualitative and quantitative analyses and the time periods between first vaccine use and the conducting of the cPIE

The report documents the findings on the achievements, challenges and lessons learnt during the COVID-19 vaccine introduction and roll-out activities.[6] It is structured around key research questions for each of the thematic areas. It further reflects some of the main queries raised by senior MoH staff during cPIE preparatory and debriefing sessions in the various countries, as documented in the cPIE debriefing presentations. These questions are thus illustrative of some of the key issues and concerns faced by countries, and include considerations for future pandemic vaccine introductions, as well as the need for health system strengthening and integration of COVID-19 vaccination activities into routine healthcare delivery. The key research questions relevant to each thematic area are outlined at the beginning of the respective chapters. A full list of research questions is available in Annex B.

Figure 1: Geographical spread of countries analyzed in the report findings (n = 20)



Methodology

cPIE methods and tools

cPIE implementation

cPIE implementation was country-led with the support of national and international partners. cPIEs were performed at all levels of the health system i.e., central/national, regional/provincial, district, and health facility levels. Site visits were an important component of the cPIEs and included observation of vaccination sessions, when applicable, and review of vaccine storage facilities.

A purposive sampling strategy was adopted in each country to provide a rapid, but representative picture of the immunization service delivery situation. The number and selection of regions, districts, and health facilities included in the sample depended on the size of the country, the heterogeneity of the health systems, and the performance of the vaccination programs. Criteria for site selection included, the types of sites offering vaccination (fixed or mobile), the priority population(s) served (including sociodemographic groups particularly at risk), predicted or estimated performance based on prior immunization coverage rates or other appropriate metrics, estimated COVID-19 disease burden, size of the catchment population, and urban, peri-urban or rural location.

Data collection

Standardized primary data collection forms and survey tools were based on the WHO COVID-19 vaccine post-introduction evaluation guide.[3] Guidance tools for comprehensive stakeholder interviews (including the survey tools used), observation of vaccination sessions, and review of cold chain and storage facilities were adapted for each country context.

Interviews were conducted with the person(s) most involved in COVID-19 vaccination services at the health office or health facility and with health workers and vaccine recipients who were purposefully chosen by cPIE teams during the site visit.

Data collection covered nine thematic areas aligned with the chapters of the respective COVID-19 NDVPs.[4] These areas included regulatory preparedness; planning and coordination; service delivery; costing and funding; supply chain and waste management; human resource management and training; vaccine demand; vaccine safety; and monitoring and evaluation.[3] Survey tools were translated (if needed) before data collection.

Data were usually recorded electronically using tablets programmed with country-adapted questionnaires using Open Data Kit software. Electronic questionnaire data were aggregated in a cloud or server-based data management platform in the country. In some cases, data were collected on paper forms and entered into electronic databases immediately following data collection.

cPIE data analysis

Data sources

Quantitative data from 16 countries and qualitative data from 20 countries were shared by country ministries of health with WHO, US Centers for Disease Control and Prevention (CDC), Task Force for Global Health (TFGH), and MMGH Consulting (MMGH), with permission for inclusion in an anonymized global summary of findings. Datasets did not contain any personally identifiable information. Quantitative datasets were compiled, checked for errors, and merged into one database per administrative level for analysis. In cases where detailed electronic datasets had not been shared, national data were extracted from national debriefing presentations and final reports. Given the lack of granular data, these countries are not included in sub-national, health facility or priority group analyses.

The qualitative findings are reflective of the national cPIE reports and / or debriefing presentations provided to the senior MoH officials from the 20 countries.

Data analysis

Quantitative analysis Country-level analyses were performed locally in line with the guidance provided, and generally included WHO recommended key indicators. Quantitative data were summarized and descriptively analyzed. Aggregated cPIE data from health facilities and health worker and vaccine recipient interviews were imported into Power BI software to summarize data and explore patterns and distributions. Descriptive analysis included frequencies, proportions, histograms, and cross-tabulations. Interactive dashboard views were developed to allow dynamic filtering and stratification by country. Missing data and responses indicating "not applicable" were excluded from the analysis for each variable of interest. The total number of responses included in each analysis is indicated in the description of the findings.

Qualitative analysis A qualitative content analysis of cPIE reports was conducted. All reports were imported into the MAXQDA® software - a qualitative data management and analysis software program that facilitates the coding, analysis, and retrieval of qualitative data. The DeepL® program was used to translate cPIE reports from other languages (e.g., French) into English. The initial code system was defined by the NDVP chapters and the related pre-defined research questions. Further inputs to the code system were made by the research team composed of US CDC, TFGH and MMGH team members, all of whom had led or participated in cPIEs. The code system was then adjusted based on the qualitative review, making the analysis both deductive and inductive. A summary code system is provided as Annex C.

A single coder was responsible for the coding and analysis of the cPIE reports. The project team met regularly to discuss emergent ideas, the application of the code system, and emerging findings. Auto-coding was used as an additional coding strategy in parallel with human coding, to ensure that key terms were accounted for in the final coded data set. The analysis focused on the main body of each cPIE report. Annexes were excluded, but referred to for clarification of issues reported in the main body of the reports.

Funding source

Funding and technical support for the implementation of the cPIEs were provided by the national governments of the respective countries and supported by global immunization partners including the WHO, the US CDC, and the TFGH. Countries included in this analysis were either supported by these organizations in their cPIE implementation, and/or agreed to disseminate their cPIE findings through the sharing of quantitative datasets and/or final cPIE reports and presentations.

Ethical considerations

cPIEs evaluated the process and outcomes of COVID-19 vaccination programs in different countries. No personal data on human subjects were collected and care has been taken to anonymize any country data in this report.

Findings

Regulatory preparedness

Background

All vaccines require regulatory authorization by designated national bodies before they can be deployed and used within a country. In an outbreak or pandemic situation caused by a novel pathogen, procedures need to be in place to provide emergency use authorization to ensure the timely deployment of vaccines to respond to the pandemic, while minimizing any potential risk to vaccine recipients. The multiplicity of COVID-19 vaccines available through various sources, developed in unprecedented short timelines, with some using novel platforms, e.g., nucleic acid vaccines and viral vector vaccines, posed a regulatory challenge for all countries. Many vaccine regulatory bodies lacked the capacity to conduct the required assessments. While some had existing emergency procedures that were activated, others needed to establish legislation and procedures to enable the use of emergency procedures.

Regulatory reliance on the WHO EUL or an EUA provided by SRAs such as the European Medicines Agency (EMA) or the United States Federal Regulatory Agency (US FDA) enabled many low- and middle-income countries (LMICs) to overcome such challenges. However, in the vaccine supply-constrained situation during the peak of the pandemic, countries were forced to make decisions on the use of vaccines that neither had a WHO EUL nor an EUA from an SRA. Often, such vaccines were available through bilateral donations.

While data on the safety of the vaccine were required for WHO EUL and EUA, they were insufficient to identify the rarer AEFI. These data needed to be collected during the implementation phase. Countries required robust reporting processes for monitoring AEFI and for assessing causal pathways to determine whether these were linked to the vaccines. This required the strengthening and expansion of countries' expert committees to monitor AEFI and conduct causality assessments and the close collaboration between the national regulatory authorities (NRAs) that have the responsibility for pharmacovigilance and the NIPs that often have the responsibility for monitoring and reporting AEFI.

Key research questions

What were the lessons or facilitators for expediting regulatory approval?

While most countries reported having an NRA, a few noted that the regulatory functions were distributed among several different agencies and that there was a need to consolidate these functions within a single agency.

All countries strengthened their regulatory procedures to facilitate the timely approval for the importing and use of COVID-19 vaccines for emergency use. Many established or strengthened legislation or established legal frameworks for the use of vaccines during emergencies. Sometimes these were done through Executive Orders that only applied to COVID-19 vaccines. The need for formalizing this and for expanding the legal or legislative basis to cover other vaccines was noted in a few cPIE reports.

Regulatory reliance on WHO EUL and EUA from SRAs was established or expanded during the pandemic. A few cPIEs referred to the use of the WHO Good Regulatory Practices and Good Reliance Practices to inform national policies and practices.[7] This included reliance on the lot release certificates from the country of manufacture and the waiver for laboratory testing in the recipient countries. However, several countries also noted the lack of local laboratory capacity for testing of vaccines and the need to strengthen this capacity for lot release of vaccines or when severe AEFI were reported.

Overall, four of 14 countries (29%) reported barriers and/or delays in obtaining the regulatory approvals or import permits required for the COVID-19 vaccine(s) at the national level.

How did NRAs manage the licensing of vaccines that did not have WHO EUL?

Most countries authorized the use of more than one COVID-19 vaccine product, with a few countries reporting authorizing up to eight vaccines. Six countries reported that they issued EUA to vaccines before they had received WHO EUL. Although two countries reported this as a challenge, not all countries provided details on the provisions or processes applied for authorizing these vaccines.

Several countries had the following provisions for vaccines that were authorized to be imported: (i) they had to be manufactured in compliance with Good Manufacturing Practices (GMP); (ii) they were in use in the country of manufacture or other countries; (iii) they were authorized by the NRA of the manufacturing country; and (iv) there were certifying statements that the previous three clauses were met. In other countries, the NRA collected additional evidence on vaccine efficacy and safety and data on the use of the vaccine in other countries to issue authorization.

The vaccines without WHO EUL whose use was most often reported were those manufactured by Gamaleya and Sinopharm. In one country these vaccines were only authorized for use in adults 18 to 64 years of age without any comorbidities.

What was the role of the NRAs in monitoring vaccine safety?

Most countries reported pharmacovigilance as one of the functions of their NRAs, and several reported being part of the WHO International Programme for Drug Monitoring. However, a lack of integration or collaboration between the NRA and the NIP in conducting safety monitoring was reported in several countries. While the detection and reporting of AEFI was often the responsibility of the NIPs, who also often managed the national AEFI committees, the NRAs oversaw reporting AEFI through VigiBase, the WHO's global drug safety data repository. In one country, the NRA focused on pharmacovigilance for medicines while the NIP took the lead in monitoring vaccine safety. Several country reports recommended the need to improve collaboration between the NRA and NIP with respect to vaccine safety monitoring.

Recommendations

Regulatory functions should be consolidated within a single agency, e.g., an NRA. However, improved coordination between the NRA and NIP in monitoring vaccine safety is required. Countries should consider expanding, or formalizing, the legal frameworks that were used for expediting the importing and use of COVID-19 vaccines to include other vaccines.

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Planning and coordination

Background

Addressing the public health threat posed by the COVID-19 pandemic required unprecedented political leadership and intricate coordination involving multiple sectors and partners. Effective pandemic response and vaccine distribution relied heavily on robust coordination structures within national health ministries and collaboration across diverse sectors. Planning for the rollout of COVID-19 vaccines proved challenging, given the persistent uncertainties surrounding vaccine availability, performance characteristics, handling requirements, shipment timelines, and volumes for each shipment. As new information surfaced, health ministries and National Immunization Technical Advisory Groups (NITAGs) or equivalent bodies had to adapt national vaccination policies, schedules, and strategies in response to the evolving situation. These decisions were vital in aiding vaccination programs to make informed decisions regarding the use of specific vaccine products and prioritizing high-risk groups.

Data on vaccine use was rapidly emerging during the pandemic, though initially this was often unstructured and incomplete. National planning efforts required engagement with sub-national levels to conduct feasibility assessments and complementary planning exercises. In turn, sub-national entities relied on information from the national level for developing local microplans, identifying target populations within their communities, and devising optimal strategies for reaching them. At the global level, guidance on developing NDVPs and carrying out simulation exercises played a pivotal role in assisting countries in formulating comprehensive plans and testing their feasibility.[6]

Key research questions

How did coordination work at the national level (task forces, committees) and between the national, regional, district, and service delivery levels? Was there intersectoral coordination?

The need for coordination to address the COVID-19 pandemic was unparalleled. In every country, multiple task forces, emergency operations centers, and coordinating committees were established, involving a diverse range of stakeholders - extending beyond the MoH - and often coordinated by the offices of Presidents or Prime Ministers. The level of intersectoral collaboration required was substantial, and the vaccine roll-out had to account for the varying governance structures of each country. While parts of the COVID-19 response could build upon existing task forces and committees, all countries needed to implement additional coordination mechanisms. All reporting countries (n=12) had a fully functional NITAG which provided guidance and support on COVID-19 vaccine introduction to the respective MoH.

Overall countries described experiences of good delineation of roles and responsibilities, good leadership and coordination between stakeholders, and flexible and creative strategic planning. This extended to good adherence to policies, strategies and guidelines, and recalibration of macro and microplans as per the guidance in the NDVP. In some instances, daily planning and coordination meetings at the district, regional and national levels took place to work through challenges. In other countries weekly implementation plans were developed by the COVID-19 Vaccination Programme Coordinators and provided to senior nurses to communicate to health facility staff. Regular meetings on vaccine demand generation and communications were generally effective for discussing how messages would be developed and disseminated.

Some countries, however, described challenges with inadequate communication and coordination between the national, regional, and district levels. This was particularly evident in data sharing between the levels and the different coordinating bodies. There was a need for more clearly defined responsibilities of the different government departments, and improved coordination between external stakeholders and national and subnational advisory groups. Countries with decentralized health systems noted that strong central and regional coordination could benefit services that are the responsibility of the local governments. However, local government planning did allow for the necessary flexibility in service delivery at the health facility level (when resources were available).

How did the coordination work between the different levels?

Were NDVPs useful?

Were external development partners intimately involved?

How was prioritization of target groups done?

How were vaccination schedules developed?

Some inconsistent experiences with microplanning were reported. In some instances, microplanning was considered strong at the provincial and health facility levels with precise planning and direct lines of communication and supervision between the national, provincial and health facility levels. Other country reports noted that microplans at the health facility level needed to be periodically updated and further developed for specific high-risk areas or target groups.

In response to some of the planning and coordination challenges, some countries proposed to transition from delivering vaccines through a campaign approach to the mainstreamed delivery of vaccination at designated health facilities and vaccination posts. Microplans were updated accordingly and communicated to stakeholders. In some instances, this was also an opportunity to update the seasonal influenza multi-year plan. Improvements to inter-sectoral collaboration, beyond the MoH (including e.g., Ministries of Finance, Education, Family / Women), to enable more comprehensive planning and budgeting were considered important.

Were NDVPs useful?

In many instances, NDVPs served as a framework to guide vaccine delivery at the different health system levels and formed the basis of subsequent planning, costing, and budgeting of the COVID-19 vaccination roll-out. Planning was sometimes informed by baseline assessments, such as with the use of the COVID-19 Vaccine Introduction Readiness Assessment Tool (VIRAT). The arrival of different vaccines required modifications to the NDVP and the creation of new guidelines and SOPs.

The NDVP was widely used to outline planning and coordination mechanisms, define the roles and responsibilities of key stakeholders, guide the prioritization and distribution of human, financial and medical resources, define priority target groups, map out vaccine delivery strategies, establish vaccination teams' compositions, and guide the monitoring and evaluation activities.

Were external development partners intimately involved?

The critical contributions of partners were acknowledged by many countries. Partnerships were leveraged to provide technical and financial assistance, to develop

strategic and planning documents (including funding proposals) and communication campaigns, to conduct surveys on behavioral and social determinants (BeSD) of demand, to develop and host health worker training, to assist in vaccination efforts, and to support monitoring and supervision to allow for mid-course corrective actions. Whilst some countries acknowledged that the actual vaccination effort rested entirely with the MoH, with limited involvement from the private sector, NGOs, or other government sectors, other countries relied heavily on the engagement of other stakeholders for the vaccine roll-out. As a result, some countries faced the challenge (particularly initially) of poor coordination and unclear roles and responsibilities between the public, private, NGO and other volunteer staff, sometimes leading to duplication of activities, poor resource allocation, and inadequate planning processes.

Towards the end of the acute pandemic phase, calls were made to maintain the momentum and interest from partners who came to support COVID-19 activities and to transition this support to strengthening the systems for routine immunization.

How was the prioritization of target groups done?

There was inconsistent use of the WHO Strategic Advisory Group of Experts on Immunization (SAGE) prioritization roadmap: some countries aligned their initial priority groups with the roadmap, whilst others noted that further adoptions were required.

Similarly, inconsistent planning and preparation practices in some countries impacted on the identification and vaccination of priority target groups. In the initial phase of limited vaccine supply, countries had to screen and prioritize even within target groups. Some countries had positive experiences with pre-registration and checks of eligibility for vaccination, including the use of registration forms at health facility level. Often, however, such pre-registration was done by only a small proportion of clients. Most countries indicated they had some Information about priority groups at sub-national levels. In fact, 74% (57 of 77) of health facilities reported having population estimates available for priority target groups–including health workers - in the facility's catchment area.

Some countries did benefit from previous influenza planning experiences by reverting to pre-defined microplans and identifying priority groups (particularly older population age groups) to inform COVID-19 target population prioritization.

How were vaccination schedules developed (including booster doses)?

There were challenges with the implementation of vaccination schedules due to limited and varying vaccine supply in the initial months. The use of multiple donated vaccines complicated the situation and undermined the application of established vaccination schedules as the arrival of each new vaccine required modifications to guidelines and SOPs. Furthermore, the use of short-dated vaccines sometimes needed to be prioritized.

Even if the official policy was to deliver a homologous primary series, limited vaccine availability often led to the use of different (heterologous) vaccines. Booster doses were sometimes administered using inactivated vaccines, even if vector-based or mRNA vaccines had been used in the primary series, deviating from WHO recommendations or national guidance.

Despite these challenges, countries developed vaccination schedules appropriate to specific target groups e.g., the elderly and people living with disabilities. These were often provided as single-dose vaccines during community or household visits. Countries also used single-dose vaccines to reduce dropouts and for remote communities. Vaccines were also pre-allocated to certain target groups e.g., Astra Zeneca and Sinopharm vaccines to health workers, the elderly, and persons with comorbidities. Conversely, other countries insisted that vaccination sites should only handle one type of vaccine product at a time to avoid programmatic errors in vaccine administration. This was specifically important when administering the temperature-sensitive Pfizer vaccine.

Vaccination schedules were also impacted by evolving preferences. Initially, with limited supplies, beneficiaries only expressed a few preferences, however, this changed over time. For example, the single-dose Johnson & Johnson vaccine became a popular choice for migrant workers due to its global acceptance. Some vaccines were considered by certain communities to have fewer

side effects (e.g., Sinopharm), while others (e.g., Astra Zeneca and mRNA vaccines) were considered to have a higher rate of side effects. The Pfizer vaccine was thought to be one of the most effective vaccines in many areas. Such changing preferences created challenges for the availability of vaccines and impacted adherence to vaccination schedules.

Overall, there was limited uptake of booster doses due to the reduced perception of risk during the later stages of the pandemic, uncertainty amongst health workers on eligibility criteria for booster doses, and no mandatory booster requirements (particularly for travel).

NITAGs in many countries provided updated national guidance on schedules, including booster doses.

Recommendations

The need for timely global-level guidance to facilitate improved planning and coordination is critical, including the provision of vaccine-specific recommendations. There is also a need to improve country-level and sub-national coordination. The lessons from the COVID-19 vaccination response should be used to improve planning and preparedness for future pandemics and emergency response as well as for strengthening health and immunization planning. Some of the coordination structures and processes used for the COVID-19 vaccination response could be sustained or leveraged to improve coordination within the wider health sector, and across other sectors, to strengthen healthcare delivery. Collaborations established with development partners and the private sector should be sustained and further leveraged for routine primary health care delivery, planning and coordination.

Service delivery

Background

To ensure widespread COVID-19 vaccination across different priority target groups, countries employed diverse approaches in the delivery of vaccination services. The most common approach involved administering vaccines at fixed sites, either at health posts well-known to communities or at dedicated COVID-19 vaccination centers that were easily identifiable. While many countries utilized their existing routine immunization sites for COVID-19 vaccination, additional mass vaccination sites (exclusive to COVID-19 vaccinations) were established to accommodate the large-scale vaccination effort and the differing eligibility criteria between COVID-19 and routine immunization.

Recognizing the challenges faced by some individuals in accessing fixed sites, such as those residing in geographically remote areas or with limited mobility, outreach and mobile delivery services were provided to ensure equitable vaccine administration. Some countries also conducted highly publicized vaccination campaigns over a short duration, particularly during the later stages of the pandemic, to enhance vaccination coverage or to use vaccines that were approaching their expiration dates.

To broaden the reach to non-traditional target groups, especially those with co-morbidities who often sought healthcare from private providers, engagement with private healthcare establishments was actively encouraged in many countries. Throughout the pandemic, vaccination sites had to implement rigorous IPC measures, which added to the intricacy of administering vaccines on a large scale.[6]

Key research questions

How much of the vaccine delivery took place at fixed sites and how much was done through new mass vaccination (in special sites)?

In the evaluated countries, a combination of delivery strategies and vaccination sites were used, although vaccine deployment strategies were heavily dependent on the supply of vaccines.

In some cases, the COVID-19 vaccination programs started at central special locations but were later transitioned to primary health care facilities and other vaccination points. Health facilities and general practitioner offices were repurposed, and additional mass vaccination sites quickly established to deliver the volume and rate of COVID-19 vaccinations needed

while maintaining IPC measures. The increase in fixed vaccination sites drove coverage during periods of restricted movement, while mobile health posts and outreach facilitated incremental coverage increases by improving access to vaccination.

Vaccination at fixed sites was either integrated into routine health services or separate from other services in order to prevent nosocomial transmission. Other fixed site delivery strategies included vaccination at home (including in long-term facilities and remote communities), at work sites (e.g., schools and universities) and at private clinics.

In response to the weakening demand in the later stages of the pandemic, service delivery strategies evolved. While fixed facilities were used as successful platforms for vaccine delivery in the early stages, outreach efforts were intensified once demand had waned.[3] Seventy nine percent of health facilities (170 of 215) indicated that outreach sessions were conducted to reach priority groups.

Mobile vaccination was performed sometimes by using specialized buses and mobile teams. Mass vaccination sites included stadiums, drive-in cinemas, and other public spaces. The use of additional community-based sites (e.g., churches, temples, and markets) also assisted in increasing convenient access to immunization services.

Mass vaccination campaigns were implemented that leveraged experiences from other supplementary immunization campaigns (SIAs), such as those against measles, rubella, and polio. These included national vaccination days and "focus months" with targeted efforts to target specific priority groups. Early communication on campaign dates improved the planning, coordination, and implementation of these campaigns. Some countries considered conducting final mass campaigns to increase the uptake of booster doses to allow for increased protection, as well as to reduce large amounts of unused vaccine stock.[4]

Countries acknowledged limitations in the initial lack of vaccination sites, or delivery at vaccination sites that were inappropriate (e.g., under trees), and made arrangements to improve services e.g., by providing tarpaulin coverings, and chairs and tables at sites, or by providing larger spaces. Initial challenges included poorly established registration procedures aligned with the prioritization of the target groups. Other challenges during the vaccine deployment phase included, over-crowding of vaccination sites, disorganized patient flows from registration to observation, poor communication to the public on spacing out and scheduling visits, and a lack of trained health workers to administer vaccines. There were also challenges vaccinating individuals without identity cards in places where this was a requirement. In some places, during the later stages of the vaccination response, health workers were sometimes discouraged to open multidose vials for less than a specified number of people.

What special strategies were used to reach priority or vulnerable populations?

Programs tried to prioritize and accommodate high priority target groups by adjusting and extending opening

Where did vaccinations take place?

What special strategies were used to reach priority or vulnerable populations?

Was COVID-19 vaccination integrated into clinical settings or other vaccination settings?

Were private providers engaged? If so, how?

hours, or by offering transport or extra seating, flexible session times for those working a shift system, and special 'booths' for women. Community leaders and officials engaged with migrant and seasonal workers were involved in communicating dates and times of special vaccination sessions for these populations.

Subsidized transportation was used to increase access to service delivery sites. Mobile units (including auto rickshaws) were used to serve special target groups who were not mobile, such as residents of long-term care facilities, and homes for the elderly.

Other strategies to reach remote and vulnerable communities included offering vaccinations at places of work, at construction camps and transportation hubs, in prisons, and at points of entry in border regions. Health teams also provided drive-through vaccination services, while mobile teams were leveraged for patient follow-up post-vaccination.

Some countries relayed positive experiences of home visits, including the opportunity for providing additional education on COVID-19. However, there were instances where door-to-door visits may have resulted in sub-optimal coverage because human resources were deployed to areas where door-to-door vaccine delivery was not warranted but requested by local politicians.

Was COVID-19 vaccination integrated into clinical settings and other vaccination settings?
There were different levels of integration of COVID-19 vaccination into existing health service delivery settings to minimize exposure of healthy individuals coming to receive vaccination to COVID-19 cases attending health facilities. Additional temporary vaccination sites were often designated for COVID-19 vaccination, including in campaign approaches, while health facilities were exclusively used for routine immunization. Most health facilities (66%, 106 of 161) reported organizing COVID-19 vaccine-specific vaccination sessions. However, a high proportion of facilities (63%, 42 of 67) also indicated that there were plans to further integrate COVID-19 vaccination into routine immunization or other primary health care services.

Case study: A multi-stakeholder vaccination team

Vaccination teams included: security agent(s) to check the beneficiaries' registration status and, where applicable, identity cards; trained vaccinators; and support staff to manage the crowd, assist vaccinators, ensure a 15 minute wait time following vaccination, and to provide communication, information, and education, etc.

Were private providers engaged? If so, how?
Most of the sub-national level respondents (67%) (61 of 91) reported participation from agencies and organizations beyond the MoH to support vaccine administration for certain priority groups or in certain settings. These included various community, government, and international agencies, such as the police and firefighters, the Ministry of Defense / Army, the Red Cross, WHO, UNICEF, USAID, and a variety of religious organizations.

Were defaulters tracked? If so, how?

Were beneficiaries satisfied with the services and why?

Did health workers follow COVID-19 instructions and SOPs?

Was there sufficient personal protective equipment?

Were community health workers involved in the COVID-19 vaccination effort?

Some private health service providers supported vaccine administration, and, in some places, community pharmacies were allowed to administer COVID-19 vaccines. Volunteers were also sometimes used for record-keeping and registration and tracking of defaulters. In some instances, health management information systems included data from private vaccination providers.

Case study: Poor campaign delivery

Short notice for campaign preparations, in part due to delays in securing funds and late arrival of vaccines, resulted in delays in planning at the district and facility levels and ultimately poor social mobilization and low uptake.

Were defaulters tracked? If so, how?

Intensified communications were undertaken to mobilize uptake in places where coverage was low, including SMS reminders for booster shots.

Fifty-six percent of health facility respondents (84 of 151) reported having a system to follow up on defaulters (i.e., persons who did not return for second doses, where indicated). This defaulter tracking was acknowledged as a major achievement in many countries. There were positive examples of using electronic immunization registries to identify unvaccinated eligible individuals, or defaulters, and send SMS reminders. Several countries were able to negotiate private sector support for free SMS messaging. Other defaulter tracking mechanisms included the use of phone calls, in-person contact (e.g., through CHWs), through family members (particularly in rural areas), through collaboration with community leaders, and the constant updating of available electronic systems to successfully identify and track defaulters. However, defaulter tracking was not consistently undertaken across countries.

Were beneficiaries satisfied with the services and why?

Some beneficiaries reported very high satisfaction with the COVID-19 vaccination services delivered, knew what vaccines they had received, and understood the benefits of vaccination. When asked if the process to register for COVID-19 vaccine was difficult or easy, 86% (199 of 231) of vaccine recipients interviewed indicated that the process was easy. They reported quick turn-around times from the time of being registered to post-vaccination observation (93% of respondents (94 of 101) felt that the waiting time was not too long). However, in some settings, beneficiaries reported having struggled with long waiting times, over-crowding, and disorganized patient flow for registration to observation, particularly in the early days of the vaccination drive.

Did health workers follow COVID-19 instructions and SOPs?

Challenges emerged when cascading COVID-19-related information, directives, and plans to lower levels. The use of SOPs at sub-national vaccine delivery sites and storage facilities was often inconsistent. While this was often due to geographical and technical capacity reasons, there were also difficulties in the uptake of innovations at facility levels e.g., the use of electronic tools. At the same time, guidance had to be adapted and changed regularly to new situations given changes in the supply of vaccines and their scheduling as new scientific information became available. Because of these challenges health workers were, in some instances, confused and/or mistrustful of the government's messaging on issues such as vaccine effectiveness or safety.

Case study: Local action plans resulted in increased coverage

Local action plans included 'search and immunize' strategies for people who had missed a vaccine dose. Household visits were done to identify and vaccinate people living with disabilities and the elderly and provide them – if possible - with a single dose vaccine.

Was there sufficient personal protective equipment?

There was mixed access to PPE with some countries reporting adequate supplies including masks, gloves, and hand sanitation supplies, while others had shortages. Seventy-three per cent of respondents at health facilities (52 out of 71) indicated that they had not run out of PPE since vaccination began. In many countries, concerns were raised regarding IPC measures that were not

consistently observed e.g., wearing of masks, physical distancing, and the availability of proper hand-washing facilities.

Case study: "Camp outs" resulted in improved access for hard-to-reach communities

To reach isolated populations, vaccination teams travelled by boat and stayed on islands for several days vaccinating willing persons. Health workers 'camped out' at various locations to ensure access to vaccination services. This strategy proved to be successful in reaching hard-to-reach areas.

Were CHWs involved in the COVID-19 vaccination effort?

CHWs were considered integral to the COVID-19 vaccination effort. Their activities included demand generation and social mobilization, including door-to-door outreach, or recording of phone numbers for follow-up. They also assisted with managing vaccination sites (e.g., crowd control), ensuring the predefined waiting time for clients following vaccination, data entry for coverage validation, following up with defaulters, and supporting community-based surveillance. There was consensus across most countries that CHWs should be further supported through incentives and additional training to foster their important role in service delivery, and in generating acceptance and demand for vaccines.

Recommendations

Whilst a variety of service delivery strategies were adopted to facilitate the uptake of COVID-19 vaccines, hard-to-reach and vulnerable populations should remain a priority when designing service delivery strategies and planning outreach activities. Similarly, improved microplanning processes are necessary to ensure target populations are well-defined and service delivery strategies appropriately implemented.

The role of the health workers, community health workers, and other volunteers in the roll-out of the vaccine was vital. Appropriate monetary and non-monetary incentives should be considered to sustain motivation and improve performance. These workers must be fully equipped to undertake their functions. This includes being appropriately trained, and appropriately, and timeously informed of changes and updates. This extends to the expectation on health workers to use electronic tools without the necessary enabling environment e.g., access to the internet, electricity, or hardware for data entry.

There are opportunities to strengthen defaulter tracking mechanisms and demand generation activities; particularly as corrective action is required to increase the declining routine immunization coverage rates in most countries.

SMS reminders and electronic vaccine certificates impacted vaccine uptake

"Little did we know that the last-minute addition of the communications module (which sent SMS reminders and provided digital vaccination certificates) would drive acceptance. The messages sent through the system were a big positive contributing factor. Also, you can imagine the hassle of going to a facility to get a vaccination certificate. Now people can get the certificate from where they are. Now, we can't even think of the system being shut down."

Costing and funding

Background

The timely availability of funds at national, sub-national and service delivery levels was critical to managing the massive vaccine roll-out on the scale that was required for responding to the COVID-19 pandemic.

To ensure adequate funding, countries needed to estimate their financial needs for the vaccine roll-out. This was not an easy task since the operational costs for delivering vaccines at the scale required, and to those not normally targeted for vaccination, were not easily available. In addition, many countries did not have accurate estimates of the number of people they needed to vaccinate and over what period, based on prioritization. Few immunization programs could undertake a complex costing exercise within the short time frame available to complete the task. While costing tools were developed to assist with estimating costs, these tools were complex to use, and significant support was required for many LMICs to complete the costing exercise and develop budgets and applications for financial support.

Many countries lacked the financial resources to cover all their operational costs from domestic resources. This required applications for grants or loans from external agencies, which were complex and sometimes lengthy processes that led to delays in accessing funds to roll out vaccination. Even when funds became available at the national level, weak financial management systems in many LMICs led to delays in the distribution of funds, especially to lower levels, affecting the quality of the vaccine roll-out.

Key research questions

Was there a costing and budgeting exercise? How was it done? Was it used?

Some countries embarked on a formal costing and budgeting assessment at the start of the COVID-19 pandemic. The COVID-19 Vaccine Introduction and Deployment Costing (CVIC) Tool was sometimes used, with partners often providing the needed technical support for its application. In one country, health care organizations coordinated to maintain daily records of income and expenses of vaccines. Costing and budgeting were supported by digital tools, including the vaccine logistics management information system (LMIS), to facilitate real-time monitoring of vaccine supplies and support provincial and district health centers to produce expense reports.

In many places the cost estimates for the different activities at the national and sub-national levels were inadequate. Overall analyses proved difficult as the visibility of costs was often very limited. Countries identified the need to further improve financial management capacities at the sub-national levels.

Case study: Challenging budgetary processes

Challenges were reported with the bottom-up budgeting process because, a) districts tended to base their budgets on their experience with routine immunization programming which was not suitable for costing COVID-19 response activities; and b) budgets from lower levels often did not have enough detail to allow for the release of funding.

The processes for review of funding requests and their approval by funding agencies were reportedly complex and included multiple steps. These also often required budgets to be submitted well in advance of need, which was not always possible at the height of the pandemic. Countermeasures were implemented, such as dropping some of the required steps, but the release of funds was still delayed at times. This necessitated health workers sometimes using their own personal resources, for example, to deliver vaccines to remote communities.

Health facility and district level staff were also reported to have limited capacity for budget planning and financial management. Requests from districts and provinces were often submitted with insufficient detail and justification, resulting in the need for multiple revisions to budget requests. Even after national funds were released to provincial level there were also subsequent additional delays at lower administrative levels.

How much of the funding came from development partners vs. from the domestic budget? / Were domestic/local funding options explored (e.g., private sector)? / Did the response engage new partners and donors? In what areas? Is there potential for them to engage in routine immunization?

A variety of funding mechanisms were available to countries, including domestic public funding, donations, multilateral funding (e.g., from the World Bank), and bilateral funding from both within and external to, the COVID-19 Vaccines Global Access (COVAX) Facility. All but two countries benefited from financial support from external donors, while in three countries the COVID-19 response was primarily funded from government sources.

Private sector donations were leveraged for, amongst others, the transportation of vaccine supplies, sending of free SMS messages to track defaulters, providing additional vaccination sites, purchasing cold chain equipment (CCE), or refreshments or incentives for vaccinators. There were also private donations of injection materials, cotton swabs, and disinfectant.

Was there a shortage of funding at any time?

Of 16 country responses, 10 (63%) reported some financial constraints and/or delays of funding for COVID-19 vaccination services at the national level. These resulted in human resource limitations, reductions in the number of sites, and delays to service delivery and demand generation activities. Interestingly, a majority (72%) of sub-national respondents (78 of 109) reported no financial constraints to vaccine deployment activities. Where sub-national financial constraints were reported (in 28% of countries - 31 of 109), these affected the installation of additional vaccination sites, health worker salaries, the transportation and storage of vaccines, demand generation and communication activities, AEFI reporting, and other operations.

In some instances, vaccinators used personal funds to fund urgent activities or mobilized funds from local partners. At times, reliance on external donor support led to issues in HR management given that necessary additional staff could only be employed on short-term contracts.

Was there a costing and budgeting exercise? How was it done? Was it used?

Where was the funding sourced?

Was there a shortage of funding at any time?

Was there a seamless mechanism for the timely release of funds to the lower levels?

Was there a seamless mechanism for the timely release of funds to the lower levels?

Challenges in the timely release of funds to lower health service levels were noted. These related to irregular salary payments and delayed or missing incentive payments for volunteers. Local processes for the review of funding requests and their approvals were often complex and included multiple steps, including the requirement for budgets to be submitted well in advance which was difficult in the pandemic context. While the processes were adjusted, limited planning and financial management capacity at the sub-national level sometimes impeded the flow of funds, both from national to provincial and from provincial to lower administrative levels. Countries were working on refining the funding processes to streamline and shorten the fund release time.

Recommendations

There is a need to refine and simplify budgeting and costing tools, considering the sometimes-limited country capacity to estimate costs and develop specific budgets. Costing tools used at the national levels should be accompanied by simpler and more appropriate tools for use at the sub-national levels. Funding approval and disbursement processes, from national to sub-national levels, should be made more efficient and timelier.

Expenditure incurred during the current pandemic should be carefully analyzed and used to estimate the costs of responding to future pandemics and establishing contingency plans for rapid resource mobilization.

Supply chain and waste management

Background

Immunization programs had well-established mechanisms in place for procuring and managing vaccines. However, these mechanisms needed to be adapted to effectively handle the diverse COVID-19 vaccine products with varying storage requirements, that demanded swift deployment. Notably, certain COVID-19 vaccines necessitated ultra-cold storage at temperatures as low as -70°C. Additionally, many vaccines initially authorized for emergency use had shelf lives of less than three months, which demanded meticulous stock management to ensure they were used before expiration. Countries also used multiple vaccine products simultaneously, necessitating the availability of the appropriate products at each vaccination site to complete the primary vaccination series and administer booster doses.

Effective stock management was of utmost importance, particularly during the initial phases when supplies were limited, to guarantee equitable distribution of vaccines for the highest priority groups. The extensive scale of vaccination efforts resulted in substantial quantities of healthcare waste, which required safe management and disposal. This included not only waste from injections, but also PPE used by health workers at vaccination sites.[6]

Key research questions

Were there specific problems (beyond the initial global shortage of supplies) that hindered vaccine supply allocation within the country?

Initially there were shortages of both COVID-19 and routine vaccines, as well as vaccine-related supplies e.g., syringes/injection devices. Five of 13 countries (38%) reported at least one COVID-19 vaccine shortage for any population or priority group since vaccination began, with shortages impacting all eligible populations, including children (aged 12-17). Overall, countries did not report significant stock-outs of COVID-19 vaccines or related supplies and only a few health facilities (21%, 50 of 236) reported vaccine stock-outs in the last six months. However, certain vaccines were not always available, or there was insufficient stock of recommended vaccines for boosters.

Most countries noted that some provinces experienced a shortage of vaccines at some stage during vaccine roll-out. On the other hand, in some instances, there was a surplus of supplies as some donations were ad hoc and partly not fit for purpose. It was difficult to plan when donated vaccines were supplied in small quantities, infrequently, close to expiry, or without sufficient advance notice.

The timely in-country distribution of vaccine injection and safety supplies, e.g., syringes and safety boxes, to provincial and health facility levels was not considered a problem in most countries. Some places did however experience challenges with syringes and safety boxes not being bundled with vaccines. About a quarter (27%) of health facilities (19 of 71) reported shortages of IPC supplies (masks, gloves, hand sanitizer, etc.) for use during vaccination sessions.

Was the cold chain sufficient and well-maintained? Was It upgraded?

There was significant investment made in the upgrading of cold chain storage capacity and cold chain equipment, including refrigerated vehicles. Some of these investments were particularly targeted to the UCC requirements of the Pfizer mRNA vaccine. Similarly, some health facilities reported not having sufficient -20°C storage capacity for Gamaleya vaccines. While health workers found ways to keep these vaccines frozen, the lack of freezer capacity was sometimes a challenge. A proportion of health facilities (36%, 77 of 211) reported having obtained new cold chain equipment for the introduction of COVID-19 vaccines, and most (82%, 191 out of 234) reported having adequate cold chain capacity.

Five (36%) of 14 countries reported problems with cold chain management of COVID-19 vaccines. These problems included power outages, generator malfunctions, limited and/or poor refrigerators, an inability to monitor vaccine temperature during transport, and insufficient staff for cold chain management.

Most sub-national level respondents (81%, 68 of 84) reported appropriate cold chain management. Some challenges were noted regarding insufficient storage capacity at health facility level, insufficient maintenance of cold chain equipment at district and health facility level, insufficient temperature monitoring, and disruptions to power supply. Where cold chain space was a challenge, particularly at the beginning of the vaccine roll-out, sub-contracts with private companies were, in some circumstances, established for both storage and transportation. Additional cold chain investments were required in some countries for UCC, back-up generators, and cold carriers. In general, cold chain equipment was considered clean, well maintained, and functional.

Were there specific problems which hindered supply allocation within the country?

Was the cold chain sufficient and well-maintained?

Was vaccine distribution to the lower levels satisfactory?

How was the huge amount of additional injection waste handled?

How was short shelf life handled?

Most (61%, 97 of 159) health facilities reported tracking vaccine wastage. Some countries experienced wastage due to temperature excursions. In some instances, the frequency of monitoring of UCC sites decreased due to staff shortages, also leading to wastages. Challenges regarding the processes for cold chain monitoring and reporting between private and public facilities were also noted. Respondents acknowledged the need for updated SOPs for temperature monitoring and training on CCE operations and maintenance, as well as for a simple way of calculating open and closed vial wastage. Toward the end of the pandemic, in 2023, parts of the upgraded CCE (particularly the UCC equipment) were standing idle in central medical stores without a clear plan for shifting it to other health or research institutions.

Was vaccine distribution to lower levels satisfactory?
Many countries had positive experiences with vaccine stock management at both provincial and facility levels with direct lines of communication and supervision between national, provincial, and health facility levels. The planning and distribution of vaccines at the national level was often flexible, with vaccines redeployed to new areas as demand decreased in some priority groups; this assisted in ensuring vaccines were largely used before expiration.

Less than half (44%) of sub-national level respondents (37 of 85) reported seamless COVID-19 vaccination distribution and transport. In some instances, distributing vaccines from district-level stores to health facilities was challenging because of difficult terrain (e.g., mountainous regions) or other delivery problems, including the non-availability of refrigerated trucks. This was exacerbated when vaccines arrived with little warning (because of vaccines being donated from a variety of sources).

Overall, however, 84% of health facilities (140 of 163) reported continuous distribution of COVID-19 vaccines. There were no reports of substantial COVID-19 vaccine stock-outs beyond the initial phase, although specific vaccines weren't always available. Stock-outs of routine vaccines were however reported due to 'competition for space' with COVID-19 vaccines and challenges in distribution from national vaccine stores. Supply of mRNA vaccines to the lower levels was naturally limited and more strictly controlled according to actual consumption because of their UCC requirements and the non-availability of UCC equipment at sub-national levels.

Case study: Lack of clarity on waste management

An unprecedented amount of immunization waste was generated at all vaccination sites nationwide. Waste generated from used PPEs were disposed in a local waste disposal site, while waste from COVID-19 vaccinations were buried after autoclaving. However, implementation of the ministerial order (on waste management) varied in provinces and districts depending on their infrastructure and resources. Regarding COVID-19 vaccines, it was not clear how to organize the redistribution and re-collection process of the unused vaccines, even though regulations had been put in place on how to use and dispose vaccine vials.

How was the huge amount of additional injection waste handled – including expired vaccines? Was waste disposal safe and well managed?
Countries did not report making major changes to waste management systems for the introduction of COVID-19 vaccine. Waste management was frequently outsourced, in some instances already prior to the pandemic. Private waste management companies often collected vaccine vials, syringes, and other materials and managed the disposal process. However, in some countries such arrangements did not work well at the district level and health workers resorted to burning or burying waste locally, sometimes after autoclaving. At times medical waste was mixed with municipal waste and dumped in landfill sites, rivers, or forest areas. Alternatively, health facilities brought injection waste (safety boxes) to district or provincial hospitals where incinerators were largely available. Some PPE waste was disposed in local waste disposal sites. Attempts were made to reduce the extra burden on disposal facilities by considering reusable PPE where possible. Implementation of these practices varied widely based on available resources and infrastructure.

During outreach activities, attempts were made to reduce the risk to communities, and health care waste was taken back to the health facility to be disposed of along with other hazardous waste.

There was a challenge with the disposal of expired vaccines due to insufficient monitoring of vaccine expiry dates at some health facilities.

In many countries, injection waste management guidance is being reviewed in view of environmental concerns, with incinerators being phased out. Countries are developing updated guidance on waste management and the development of sustainable solutions for appropriate waste management at all levels.

Case study: A reverse logistics system for used vials supports the vaccine roll-out

A reverse logistics system was in place at all levels for used vials. Empty vials were collected at delivery points and sent to provinces and regions. Vials were separated by product brand, counted, and stored in plastic containers, to be collected by sub-contracted companies for final transport, auditing, and destruction.

How was short shelf life handled (e.g., was there a system to redistribute vaccines that were close to expiry, conduct campaigns to move vaccines, communication efforts, etc.)?

In most countries, there was no clarity or official policy recommendations for the use of vaccines nearing expiration, vaccine redistribution, and recollection of unused vaccines.

For some donated vaccines, the short shelf life required fast turn-around times, making some sub-national levels hesitant to accept these doses near expiry as this complicated management and coordination efforts. Many countries needed to prioritize the use of vaccines with short shelf lives. This sometimes resulted in different vaccines being administered to an individual as first or subsequent doses.

A later shelf-life extension granted to Pfizer vaccines led to confusion in some countries due to a lack of regulatory approval for the off-label use of such vaccines.

Some countries did develop policies and regulations to guide the redistribution of unused vaccines or to include them in existing or new eLMIS to assist in monitoring and preventing their expiry. Several countries were able to regularly track vaccine expiration using such reporting systems. In some specific cases, vaccines could thus be quickly redeployed based on demand. At the local level in many countries, however, details of how to organize such redistribution processes remained unclear and closed vial wastage due to vaccine expirations was still unacceptably high. Overall, 35% (34 of 96) of health facilities reported having vaccines expire within the last six months.

Case study: Many short-dated vaccines impacted on vaccine schedules

The vaccination strategy initially prioritized the use of vaccines with the shortest shelf life to avoid their expiry. This also meant that the vaccine being distributed may not have been the same as the vaccine received in earlier doses. Additionally, there was insufficient stock of recommended vaccines for heterologous boosters, i.e., vector-based (Astra Zeneca) and mRNA vaccines (Pfizer) at the health facility level.

Case study: Sharing / borrowing vaccines improved programme implementation

Coordination extended to sharing and borrowing vaccines between districts and even provinces. This enabled supplies to be available in areas where demand was greatest and likely promoted higher coverage and lower wastage. Staff at sub-district health facilities were empowered to initiate this sharing without needing approval from the provincial level; this reduced the time needed to acquire vaccines.

Recommendations

Improved forecasting, allocation and stock management mechanisms are required to have real time visibility on vaccine stock levels at all levels and redistribute doses to reduce closed vial wastage.

The cost-benefit and programmatic challenges for deploying donated vaccines should be carefully considered as countries struggled with challenges surrounding near-to-expiry / expired donated vaccines.

Further investments in CCE should be thoroughly considered and CCE maintenance plans developed and budgeted for. CCE procurement should follow a meticulous cold chain sizing exercise. Countries may also consider conducting targeted Effective Vaccine Management (EVM) assessments to guide refresher training and further investments. Specific investments into eLMIS should also be considered to allow for more effective vaccine stock management.

Human resource management and training

Background

Countries faced the need to mobilize a substantial workforce for vaccination efforts, right at the time when health systems were burdened with caring for individuals afflicted with severe COVID-19. The entire process of handling vaccines and the increased public awareness surrounding COVID-19 vaccination necessitated the recruitment of diverse cadres and skill sets among immunization staff. In addition to estimating and securing the surge capacity, governments had to ensure adequate training for health workers and establish supervisory networks in advance of vaccine administration. Countries provided key learnings on how to better identify, train, and supervise frontline health workers, including initiatives related to motivation, remuneration, education, and sustainability. These activities need to be carefully reviewed and refined in preparation for a future pandemic response.[6]

Key research questions

Were there sufficient human resources for the task at hand? Did additional staff need to be recruited? Were staff re-allocated?

Most countries were concerned about inadequate numbers of trained and available staff at the national level to support the pandemic response. Likewise, at the sub-national level 34% of respondents (30 of 89) reported a shortage of health workers. At the vaccine delivery level, on the other hand, most health facilities (86%, 184 of 213) reported sufficiently trained vaccinators with at least one staff member having participated in COVID-19 vaccine training (91%, 89 of 98). Staff shortages were addressed by task shifting and training other staff, enlisting volunteer vaccinators (e.g., medical students), or mobilizing retired staff. About one-third (30%) of health facilities (69 of 232) had to hire additional health workers to deliver COVID-19 vaccines.

Some counties conducted a human resource needs assessment to identify optimal ways to manage staff workload. Countries developed public health surge staffing plans, including rosters, alongside supervision plans for surge staff. This was often accompanied by a review of staff allocations based on the requirements for the pandemic response, routine immunization, and PHC activities. In addition, in some countries, the possibility of allowing licensed allied health care professionals to administer vaccines (including auxiliary health care professionals, e.g., pharmacists) was explored, while other countries specified that COVID-19 vaccines could only be administered by authorized doctors, and that midwives and nurses were only allowed to vaccinate under their supervision.

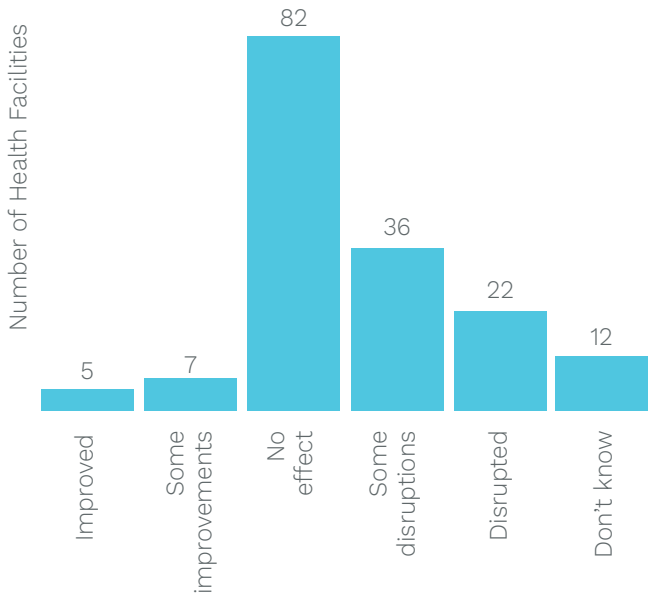
In cases of a shortfall of health workers to deliver vaccines, surge staff were also often deployed from other departments within and outside of the health sector to supplement the vaccination program. Additional staff included retired nurses and doctors, health workers from neighboring countries, nursing assistants, environmental health officers, medical record clerks, university students, clinical service providers, nursing students, volunteers, and general workers. Additional training and supervision, sometimes including internship programs, were required for these resources, particularly if they had not had previous experience in vaccine delivery.

Concerns regarding the sustainability and affordability of the financial resources needed to pay for the additional health workers were noted, and countries later began considering repurposing staff to support other areas, including in the education and sanitation sectors.

Were routine health services disrupted due to task shifting?

Nearly half (43%, 70 of 164) of health facilities reported an impact (some level of disruption or improvement) from the COVID-19 vaccination program on existing immunization programs (see figure 2). The negative impact of pulling staff from their daily roles in routine immunization and preventative health care to focus on COVID-19 vaccine roll-out was acknowledged. Countries therefore started to shift any excess health workers to focus more broadly on the integration of COVID-19 vaccination into other PHC services.

Figure 2: Health facilities indication of whether existing immunization programs were affected by COVID-19 vaccination programs



How and when were human resources trained (virtual, in-person)? How was continual training managed when new vaccines were deployed, and because of staff turnover?

Training was provided using a variety of modalities, including train-the-trainer sessions, cascade training, virtual, in-person, and blended learning. Of the health

Were there sufficient human resources for the task at hand?

Were routine health services disrupted due to task shifting?

How and when were human resources trained?

Was vaccinator knowledge adequate? Were there any gap areas?

Was supervision done well and regularly?

Are there any lessons on managing health worker fatigue, burn-out, and retention?

workers interviewed who had received training, 67% (128 of 191) had received in-person training, 11% (21 of 191) had received virtual training, and 22% (42 of 191) had received blended (in-person and virtual) training. Even in countries with continuous and frequent training, knowledge gaps and training needs continued to be identified.

Some countries developed a training needs assessment, or training plan, identifying the job categories that needed further training, developing, or adapting training materials, and identifying appropriate stakeholders to conduct the training.

In some instances, newly hired staff at vaccination sites received virtual training before or during the COVID-19 vaccine roll-out. Often, however, virtual training had a lower level of engagement than in-person training. Health workers stated that during virtual training internet connectivity was often poor, it was difficult for queries to be adequately responded to, that sessions were often too short, and that hands-on training was missing, but still required. Suggestions were made to conduct virtual training in smaller groups, to allow for in-depth discussions, supplemented with videos and job aids. To mitigate these shortcomings, countries conducted post-training evaluations to assess the level of health worker understanding and, where needed, institutionalized refresher training including offline/hands-on training for staff.

Case Study: Countries that had already made long-term investments in health human resources were better equipped to respond to the pandemic

The long-term investment in staffing health-care delivery and the public health system paid off during the COVID-19 pandemic. Baseline staffing for health at service delivery level was good, and while COVID-19 stressed the system requiring workers to work overtime, the level of staffing was generally sufficient to meet demand. This was especially true at service delivery level where designated vaccinators were needed for administering vaccines. Other nurses and clinical service providers, nursing students, and retired health workers were drafted to support the vaccine roll-out, but these served as screeners and provided other ancillary support.

Countries further enhanced training opportunities by facilitating active knowledge sharing at the district level, supporting health workers from different health facilities to meet up to learn from each other. Countries also conducted tailored training for various health worker groups, facilitating knowledge transfer from senior to junior health workers, including succession planning. Internship programs were established as a form of training for provincial staff. Training curricula for nurses were updated and offered continuously, and comprehensive / updated training resources were made available for the onboarding of new staff.

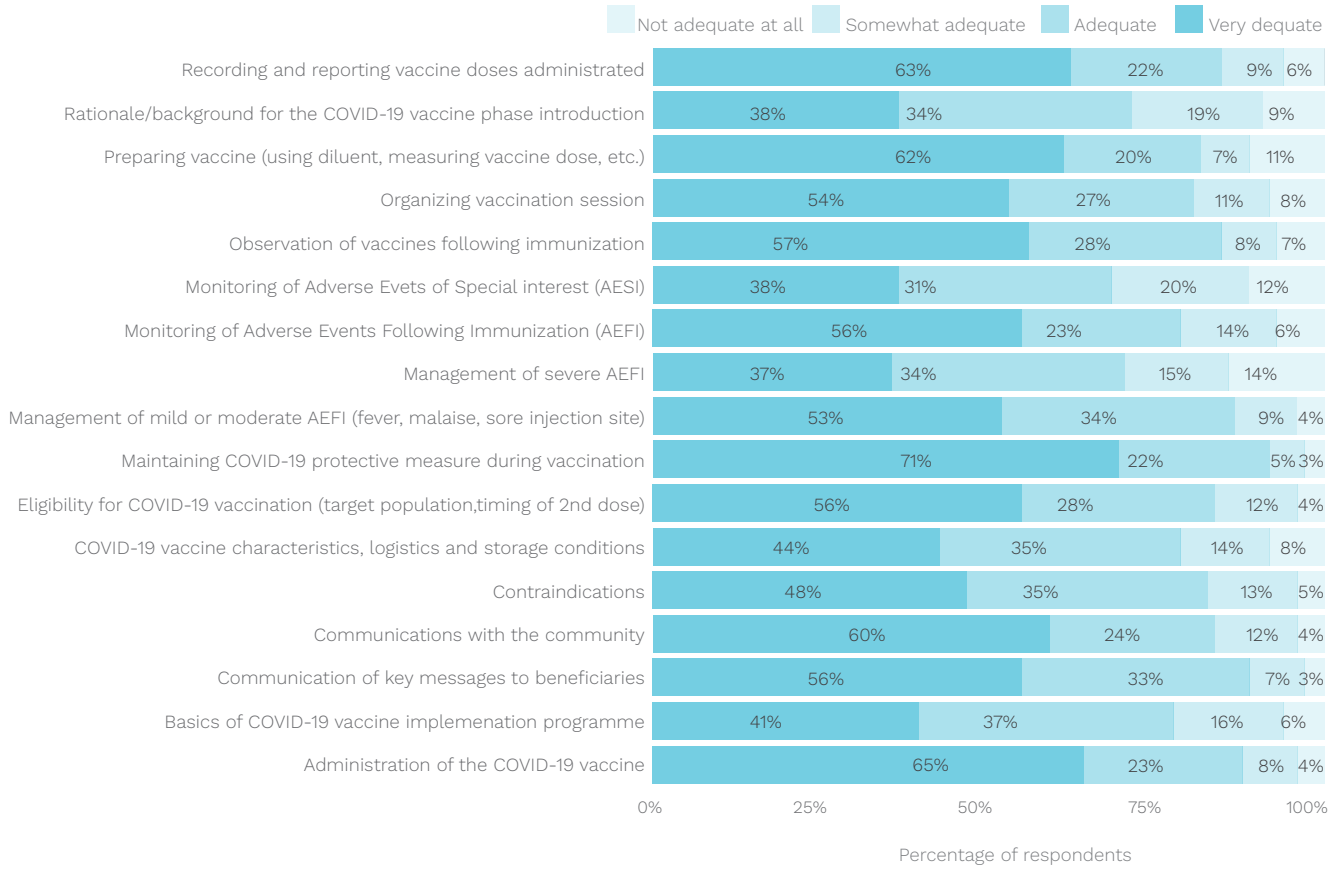
Was vaccinator knowledge adequate? Were there any gap areas?

Among health workers interviewed, 91% (129 of 142) indicated they felt confident in their ability to communicate with clients/patients to address their questions and concerns about COVID-19 vaccines. When asked how adequate they felt their knowledge was in various topic areas, health workers indicated strong knowledge in the areas of maintaining COVID-19 protective measures (93% adequate), communicating key messages to beneficiaries (89% adequate), administering COVID-19 vaccines (88% adequate) and the management of mild and moderate AEFI (87% adequate) (see figure 3). Monitoring of adverse events of special interest (AESI) and management of severe AEFI were the areas of least adequate knowledge, with 69% and 71% of health workers indicating they did have adequate knowledge, respectively. Health worker knowledge gaps were evident across all countries.

Other knowledge gaps included the vaccine administration process (e.g., who is responsible for vaccine administration), data management and reporting (including the use of individual, disaggregated data to identify gaps and to prioritize target groups) and in the use of electronic tools, (e.g., some health facility staff were unsure of electronic data entry and thus first record vaccinations in paper, and later enter into the electronic system, creating inefficiencies, additional work and room for error).

Specific training was provided, or requested, for the Pfizer vaccine where logisticians and vaccinators, at all levels of the health system, needed to be trained on the specific UCC storage and handling requirements.

Figure 3: Self-reported health worker knowledge in COVID-19 vaccine program areas



Countries also trained health workers not directly involved in the COVID-19 vaccine administration on communications approaches, thus equipping them to educate their patients on COVID-19 vaccination, particularly amongst priority groups.

In many instances, job aides for specific product handling, or as a quick resource for vaccination teams and cold chain focal points were made available.

Was supervision done well and regularly?

Ninety-five per cent of health facilities (190 of 200) reported receiving supervisory visits specifically for COVID-19 vaccination. Many countries, however, also noted highly variable supervision services. Some countries acknowledged that prior investments in training and supervision, particularly on vaccination monitoring, resulted in better program performance, including more complete registration and minimal drop-out rates.

Supervision was provided via several channels, including face-to-face, through text messages, phone calls, and emails. Face-to-face supervision was naturally limited due to movement restrictions. Supportive supervision provided before and during the vaccine roll-out was considered helpful, and in some places, it was shown to have significantly improved health worker performance and motivation. On the other hand, the often-large number of inspections and visits from multiple government agencies and authorities to assess the progress of the vaccine deployment also placed an undue burden on the day-to-day operations of vaccination activities.

Countries updated their supervision plans (including for surge staff), partly integrated these into other supportive supervision activities, and worked on increasing the frequency and overall strengthening of supportive supervision activities.

Are there any lessons on managing health worker fatigue, burn-out, and retention?

Staff burnout and fatigue were noted as major challenges to service delivery. Countries were mostly aware of these

challenges and initiated motivational strategies (e.g., financial incentives, awards, friendly competitions, and acknowledgements from political figures and community leaders), and logistical support (e.g., the provision of transportation and/or food). Supervisory oversight was also increased.

Health worker fatigue was addressed by recruiting additional staff, and by ensuring regular working hours to the extent possible. To relieve health workers of the additional efforts of transferring paper-based records to electronic systems, electronic tools (e.g., for sending automatic reminders) were rapidly implemented, and additional staff dedicated to data entry hired. In some instances, the coadministration of COVID-19 vaccines with influenza vaccines for overlapping target groups also helped to lighten vaccinators' workload.

Case study: Well-planned training and supervision positively impacted health worker performance and motivation

To monitor the quality of the training (particularly at service delivery level), several mechanisms were used: pre- and post-training knowledge, attitudes, and practices (KAP) tests were administered; and the use of short videos to ensure that the quality of the content was maintained across different levels of training. Supportive supervision activities were used to monitor COVID-19 vaccination and were intensified for the first two months after introduction. It was shown that supervision significantly improved health worker performance and motivation.

Recommendations

Training, recruitment, and surge capacity plans should be developed, as well as incentive packages and mechanisms to monitor and ensure staff wellbeing. Supportive supervision should also be adequately budgeted for, with the provision to increase the frequency and quality of supervision when needed.

Training modalities and tools should be carefully revisited, acknowledging that virtual training may have limitations and may need to be accompanied by on-the-job training and supervision. Cross-learning opportunities should also be encouraged, both within a country and across borders.

Vaccine acceptance and demand generation

Background

The introduction and rapid expansion of COVID-19 vaccination brought unique communication and vaccine confidence challenges. The unprecedented speed of vaccine development, the emergency use authorization granted by regulatory agencies instead of full market authorization, and the existence of various vaccine products, some of which utilized novel platforms, raised concerns for many individuals. Numerous communities felt vulnerable, and mistrust of governments was prevalent in certain settings. Vaccine effectiveness and safety worries were exacerbated by the spread of misinformation and disinformation through social media channels.

The constantly evolving nature of the pandemic and the continuous influx of new data necessitated frequent adjustments in vaccination strategies and schedules. The focus shifted between achieving high population coverage with vaccines and prioritizing the prevention of severe outcomes in selected high-risk populations. These shifts in strategies and priorities often led to confusion among the public, posed challenges in communications, and may have further eroded trust in public health institutions.[6]

Key research questions

Was there sufficient political support, and high-level advocacy, for creating demand?

Most countries (14 of 15) developed national plans to generate acceptance and demand for COVID-19 vaccines. Such plans were also available in the majority (75%) of countries at the sub-national level (66 of 88). Over half (55%) of health facilities (40 of 73) reported having a plan to generate acceptance and demand for COVID-19 vaccine and most (70%, 49 of 191) had relevant activities in place. Most commonly reported activities included conducting community engagement and home visits and developing educational materials. Several countries identified implementing specific activities, such as branded mask giveaways or advocacy at professional association meetings. National strategies and activities in demand generation included RCCE strategies (10 countries knowledge, attitudes, and practices (KAP) surveys (7 countries), and implementation of WHO's BeSD assessment (5 countries).

There were numerous examples of leadership involvement from the highest level, including the President's office or Prime Minister's office, to enable the mobilization of adequate resources and bargaining power. Frequent (in some cases daily) and consistent messages from top political figures contributed to building vaccine acceptance. Whole-of-government and whole-of-society approaches were established to ensure multi-sectoral collaborations and effective approaches to demand generation. Similarly, leveraging trusted voices, such as religious and community leaders, scientists, business, and government officials (including parliamentarians), and celebrities assisted in generating demand; particularly later when it waned. Specific advocacy activities were developed to target these role models, and in some instances, they were amongst the first to be vaccinated, promoting the perception that vaccines were safe.

How did demand change over time? What were the reasons for this change?

Largely, demand for vaccines was extremely high in the early days of the vaccine roll-out and declined over time as risk perception declined. Vaccine mandates, particularly for travel, increased initial uptake, but not for booster doses, which were largely not mandated for travel. Vaccine preferences also changed over time. While initially no such preferences were stated, later there was a preference for single dose globally used vaccines (to allow for immediate travel abroad, particularly for work). Preferences for specific vaccines also changed as additional information became available, sometimes resulting in challenges in the availability of vaccines in certain locations.

Were any priority groups particularly hesitant?

The evaluations provided examples of hesitancy in vaccinating children and pregnant or breastfeeding women. The reasons for not wanting to vaccinate children, despite the parents being vaccinated, included the perception that children were less at risk for severe COVID-19 disease, balanced against the risk of AEFI.

Was there sufficient political support, and high-level advocacy, for creating demand?

How did demand change over time? What were the reasons for this change?

Were any priority groups particularly hesitant?

Was social listening done? Which rumours were mostly prevalent?

Did hesitancy 'spill over' into routine immunization?

Were there good lessons or approaches to responding to hesitancy/rumours?

Was there sufficient capacity and expertise to track and respond to hesitancy?

Hesitancy among pregnant and breastfeeding women centered around fears of adverse effects on the fetus or infant, and/or a negative impact on fertility. Other hesitant groups were inhabitants of geographical areas where misinformation was dominant, and among certain religious groups. Vaccine hesitancy was also sometimes found among older adults and persons with underlying medical conditions who were concerned about vaccine contraindications and had a lower risk perception due to largely staying at home. Vaccine hesitancy for booster doses was noted as a challenge in most countries given the waning risk perception during the 'Omicron period'.

Was social listening done? Which rumors were most prevalent?

Social listening was undertaken in most countries (64% at both national and sub-national level). Several large surveys e.g., KAP assessments and BeSD assessments provided a broader understanding of barriers to COVID-19 vaccination. It was evident in many countries that demand issues were mostly context-specific and that gaps remained in understanding and generating data on local reasons for non-vaccination. This lack of local insights hindered the tailoring of strategies with context-specific solutions and was compounded by the limited capacity and availability of trained human resources at sub-national levels to respond to these concerns.

A variety of rumors persisted across countries, including, among others, that vaccines had many side effects, were unsafe, or weakened the immune system. There were concerns regarding the speed of development and lack of proper market authorization of vaccines, and some Muslim populations were concerned about the vaccines not being halal. Rumors spread about risks around fertility / impotency; hair loss; paralysis; that certain blood types would not tolerate vaccination; that COVID-19 vaccination caused disease; that it was a way of reducing the population; and that vaccine recipients would die within two years. A relatively ubiquitous rumor was that COVID-19 vaccines contained microchips to track personal movements.

Did hesitancy 'spill over' into routine immunization?

Whilst data is limited, it appears that no such spill-over occurred in most countries, and that confidence in other vaccines remained about the same. In specific situations, the overall high trust in the effectiveness and

safety of COVID-19 vaccines may have resulted in an increased trust in other vaccines, including the influenza vaccine. Similarly, in some health facilities, clients coming to receive COVID-19 vaccines also asked about influenza and other vaccines, and vice versa. Intensive communications about COVID-19 vaccines may therefore have assisted the public in better understanding the overall value and safety of vaccines.

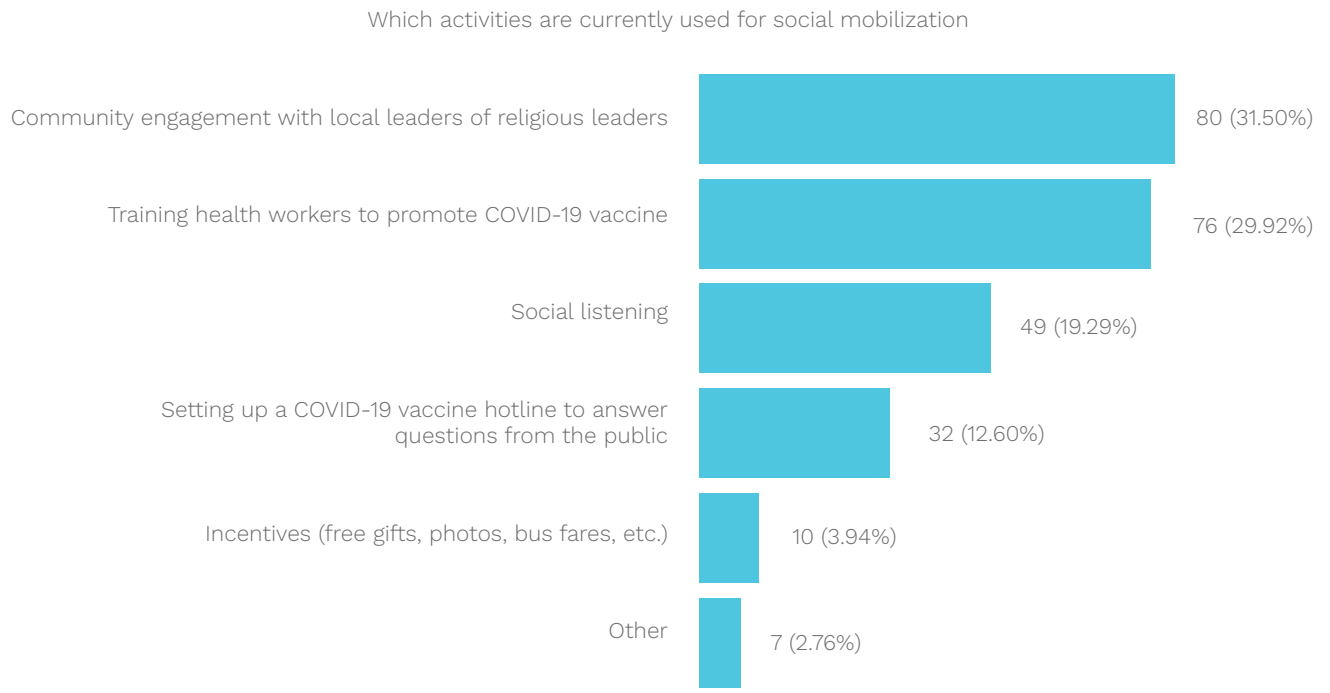
Were there good lessons or approaches to responding to hesitancy/rumors?

Door-to-door and community outreach enabled vaccinators and CHWs to speak with individuals, building confidence in vaccines and addressing questions to minimize hesitancy. These interactions extended to other community venues, including marketplaces, workplaces, schools, universities, and other healthcare visits (including those for routine vaccines). Developing targeted messages for key stakeholders assisted in addressing some hesitancy, as well as using community leaders, and the media, to immediately address misinformation or false reports. National hotlines were made available for the public to call and ask questions about COVID-19 and other issues. Targeted in-depth training was also provided in some countries to journalists and key community members to provide them with facts and figures and the skills to better communicate these.

Was there sufficient capacity and expertise to track and respond to hesitancy?

Health authorities used a variety of strategies to increase uptake, including developing communication materials, producing videos to support vaccination and combat specific misinformation, providing personal testimonials, and leading by example. Health facility staff noted community engagement activities, health worker training to promote acceptance, social listening, hotlines, and incentives as activities used for social mobilization (see figure 4).

Figure 4: Activities health facilities reported using for social mobilization for COVID-19 vaccination.



There was unanimous understanding that health workers were important in shaping community confidence in vaccines and that they needed to be convinced of the safety and efficacy of the vaccines and trained on appropriate strategies to generate demand and respond to queries. In situations in which health workers were not confident about the vaccines, this may have negatively impacted the public's trust in, and demand for, the vaccines. Sometimes, the lack of specific training materials could also have resulted in health workers

being unable to respond to vaccine-related community concerns.

In some countries, the spread of misinformation and 'fake news' were not immediately and adequately addressed, while some of the educational materials used for mobilization and education came late in the pandemic period; this could have slowed awareness creation activities. Given the often reactive (rather than proactive) communication approaches, important information sometimes reached the public before it was disseminated to the health workers, which may have been a source of confusion. Similarly, in some countries, there was a lack of coordination amongst different communication units resulting in disjointed or siloed responses. In some instances, the process to approve messages took a long time and was not adaptive. Often there were also insufficient financial and human resources to respond to vaccine hesitancy, particularly given the need to provide continuous information updates to communities.

Case study: CHWs played a critical role in generating demand

The importance of CHWs in the creation of vaccine demand and getting shots in arms cannot be overstated. As one provincial health officer stated, CHWs were "where the magic happened." Some of their key contributions included the creation or updating of master lists for their respective communities, conducting individual follow-up to help drive uptake of first, second, and booster doses, and to better understand any hesitancy within a particular location; and to conduct active surveillance for AEFI by checking in with each individual in the days following their vaccination.

Countries outlined ways to improve the capacity of frontline health workers in actively responding to vaccine hesitancy through several actions. This included the development of a health staff communication strategy that outlined how communications should be done, what information would be communicated, and to whom this communication should be provided. Country examples of activities in this area include, providing communication bulletins, developing written question and answer (Q&As) materials and improved education materials on COVID-19 vaccines, and offering clear messaging around the benefits of the vaccines. Countries continued efforts to keep the public regularly informed of the vaccination progress. Targeted demand strategies for specific population groups were developed, including for health workers, and RCCE strategies were updated to respond to the changing population and epidemiology needs. In some areas, additional funds were provided at local levels for social mobilization and responding to vaccine hesitancy.

Recommendations

Consistent, accurate, and timely communication is key to a strong vaccine uptake. Information sharing with health workers should be done timeously (ideally before the public) and with sufficient detail for them to be able to respond to queries from their clients. Health workers and CHWs should be appropriately supported to strengthen their interpersonal communication skills and provided up-to-date information to engage with their communities.

Whilst strong political and community leadership, alongside a variety of RCCE and social behavior change (SBC) mechanisms to generate demand are vital, it is just as important for countries to establish mechanisms to stay ahead of misinformation and vaccine rumors. Social listening should be incorporated into communication activities, and targeted messages and materials should be available to respond to any misinformation.

Vaccine acceptance and demand activities should be appropriately funded – particularly at the health facility level – to ensure health workers have the resources they need to inform their communities. Attention should be paid to ensure that messages are reaching hard-to-reach and vulnerable groups, including persons living with disabilities.

Vaccine safety

Background

The vaccine safety monitoring of COVID-19 vaccines was a unique challenge. The availability of several different COVID-19 vaccines brought many complexities, especially as some of them utilized technology platforms not previously used or licensed. Further, vaccines were targeting a novel pathogen, characterized by numerous unknown and evolving factors, within diverse settings with varying capacities to identify, report, investigate, and ascertain the causality of AEFI, and respond adequately to safety concerns. Efforts were made to bolster global, regional, and national safety surveillance efforts and ensure vaccinators were sufficiently trained and equipped to administer vaccines safely, and respond to any possible AEFI, with the support of national and/or sub-national AEFI committees.

Key research questions

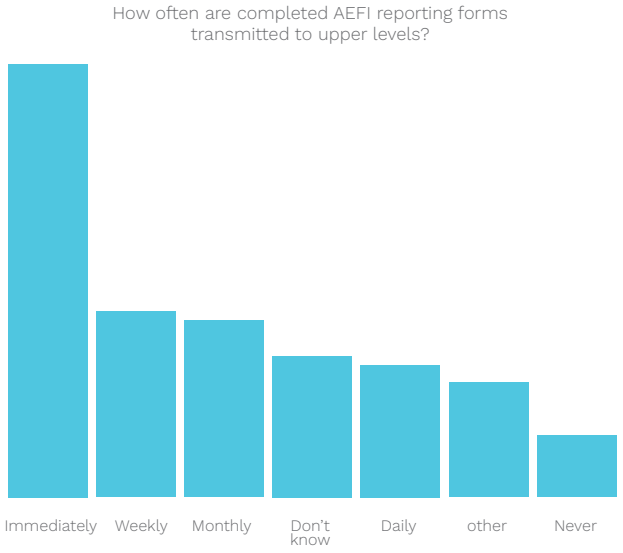
Were expected numbers of AEFI reported? Were AEFI managed properly?

All countries reported having vaccine safety guidelines for the identification, notification, and management of AEFI, and almost all (92%, 67 of 73) health facility respondents felt that sufficient guidance had been provided to adequately respond to and report an AEFI.

Seventy percent of health facilities (156 of 222) indicated they had reported an AEFI for COVID-19 vaccines in the last year or since COVID-19 vaccination began. At the sub-national level across countries, less than a third (29%) of health facilities (59 of 202) indicated having reported a severe AEFI associated with COVID-19 vaccination in the last year. Countries mentioned numerous challenges in monitoring and reporting of AEFIs, including insufficient coordination, lack of AEFI reporting and monitoring systems, use of multiple reporting platforms, limited expertise, and knowledge of staff in recognizing AEFI symptoms, limited use of standard reporting forms, and limited IT infrastructure. Despite several investments in improving vaccine safety surveillance, including training of health workers, developing AEFI guidelines, and establishment of advisory committees, gaps remained. This may have resulted in substantial underreporting of AEFI in some countries, whereas the AEFI reporting rate was in the expected range in others.

Thirty four percent of health facilities (49 of 141) indicated that completed AEFI reports were transmitted to upper levels immediately after they occurred (see figure 5). Different digital pharmacovigilance reporting systems were used to report AEFIs in real time from health facilities. Manual reporting systems complemented this by submitting paper based AEFI reporting forms to the higher health system levels. AEFI reporting was done through both passive and active surveillance. Some countries set up online portals for reporting adverse events or created additional mechanisms to report these via a hotline for vaccine recipients. Several countries also ensured that private practitioners were included in the pharmacovigilance processes.

Figure 5: Health facilities reporting on how often AEFI reporting forms were sent to higher levels of the health system



Investigations of reported AEFI were nevertheless often delayed due to human resource limitations and difficulty accessing specialists for the causality assessment.

Were expected numbers of AEFI reported? Were AEFI managed properly?

Were AEFI committees instituted at the national and sub-national level? Were the committee members well-trained?

Was causality assessment done properly?

Was the MoH prepared to communicate about AEFIs? Was any sort of risk communication done?

Was there any monitoring for AESI?

Case study: Positive aspects in the vaccination safety and AEFI monitoring system

AEFI systems were robust and worked well for reporting and following up serious AEFI. There was good patient monitoring for the observation period following vaccination. Knowledge about high-risk groups was good in all health workers interviewed. Correct vaccine administration techniques were observed. Doctors and nurses were able to correctly describe the process for managing and reporting AEFI. Lower-level staff knew how to refer AEFI. Having medical doctors on-site made nurses more comfortable in managing potential serious adverse events. Clinics were well stocked with AEFI emergency kits for managing a serious AEFI if needed. AEFI technical committees worked with specialists to conduct investigations. The online AEFI reporting system worked well once established.

Were AEFI committees instituted at the national and sub-national levels? Were the committee members well-trained?

Ten of 11 countries reported having a national AEFI committee or vaccine safety committee to guide the safety aspects of COVID-19 vaccine use. Of these countries, six (60%) reported having established a new AEFI committee specifically for COVID-19 vaccines, with others leveraging existing AEFI committees.

AEFI committees were largely established at the national level, with varied establishment at regional, provincial and district levels. Most countries acknowledged that further training was required for AEFI committees, as well as improved coordination and collaboration between AEFI committees and other medical specialists. Nevertheless, national and regional AEFI committees were considered a strength of the COVID-19 response, including the strong collaboration with medical societies and surveillance units. Vaccine Safety Guidelines and notification systems used for influenza vaccine in adult populations, along with the relevant causality assessment protocols, were often used for COVID-19 vaccination, minimizing the need to develop new materials amidst an intense vaccination campaign.

Was the causality assessment done properly?
Experiences of undertaking causality assessments were mixed. In some instances, a causality assessment committee was in place, or causality assessment was part of the responsibilities of the AEFI committee. The causality assessment process functioned well in some countries, but poorly functional in others, where a lack of clear SOPs at the sub-national level, an inability to complete the investigations on time, and non-cooperation of clients due to religious and cultural reasons, amongst others, were some of the challenges faced. Surveillance Medical Officers supported the causality assessment in many locations. Many countries supported training on AEFI causality assessments and worked on improving the communication of findings of the investigations, including immediate feedback to the reporting health workers and patients.

Was the MoH prepared to communicate about AEFIs? Was any sort of risk communication done?
Overall, risk communication strategies were improved in many countries. A risk / crisis communication plan was available in some countries. However, there was a need to develop sub-national plans and/or capacity, including the need for health workers to have more information on vaccine contraindications as part of their training and education, and ensuring that it was aligned with the most current WHO recommendations. Some health facility staff were unaware of the number of AEFIs reported at their respective levels, as limited official data was fed back from the national level. This lack of feedback could have contributed to concerns about transparency and ultimately to community mistrust of the vaccine program. Whilst in some countries there was a national crisis communication plan and the use of trusted experts for vaccine safety messaging, in others there remained the need for transparent public dissemination of vaccine safety reports to enhance trust in health services and vaccines.

Was there any monitoring for AESI?
Surveillance of AESI was implemented to some extent in countries, with some AESI reported through passive surveillance systems. Of eight countries responding, five reported that they were conducting AESI monitoring. Here, recommended AESI data collection tools were used along with the electronic tools for data collection, collation, transmission, and processing.

Other countries noted that sentinel AESI surveillance should be established alongside incentives for AEFI/AESI reporting at all levels of the immunization program. The requirement for additional training for AESI committees was noted.

Case study: Electronic toolsassisted in self-reporting AEFI

A self-report electronic system was set up for citizens to voluntarily report AEFI without delay, in addition to the active efforts by the health workers to record AEFI. This passive surveillance system was useful for monitoring trends over time.

Recommendations

Strong coordination between stakeholders, especially the NRA and NIP is critical for the establishment and use of vaccine safety and AEFI procedures. Health workers and vaccine recipients should have different options of mechanisms to report AEFI (e.g., paper-based forms, online forms, hotlines).

Vaccine safety guidelines and notification systems used for other adult vaccines can and should be leveraged, minimizing the need to develop new materials.

Knowledge gaps amongst health workers regarding what AEFI need to be reported, and how, need to be filled; and a mechanism to provide feedback to health facilities / health workers on the results of investigations, including the number and types of AEFI reported at national levels, should be put in place.

Monitoring and evaluation

Background

The presence of robust monitoring systems is crucial for assessing the progress and effectiveness of any health program and for identifying operational gaps. The extensive scale and rapid pace of the COVID-19 vaccine rollout necessitated the swift expansion and adaptation of data systems to monitor implementation and inform operational planning. Existing immunization monitoring systems had to be adjusted to track COVID-19 vaccine uptake among specific target groups, such as health workers, older adults, and individuals with co-morbidities, who were not traditionally part of routine immunization programs in many countries.

In response to this demand for data, many countries undertook unprecedented efforts to strengthen their data systems and enable real-time monitoring of COVID-19 vaccination. Countries chose to establish new data systems or enhance existing ones to provide timely and more detailed information. Innovative digital applications were implemented to facilitate pre-registration, prioritize target groups, schedule vaccination appointments, send reminders for follow-up doses, and issue digital certificates with bar or Quick Response (QR) codes. While these advancements presented new opportunities and additional resources, countries also faced unprecedented challenges in the process.

Key research questions

Did the electronic tools developed for COVID-19 'survive'? Were these tools useful? Was there an eLMIS for COVID-19 vaccine management?

Countries were at different stages of development of their national digital health systems, set up to enable the collection and synchronization of clinical, administrative, and financial data.

Multiple electronic tools were used in the COVID-19 response, including tools used for registration and reporting of COVID-19 vaccines; electronic immunization registries (eIR), that included tracking and SMS reminder tools for vaccination appointments; online booking systems; tools for the creation of vaccination certificates; and AEFI reporting tools. In some instances, these tools were linked to other registries e.g., primary care physician registries and infectious disease surveillance systems. Often, these electronic tools were accompanied by paper-based recording systems.

Across countries, over half of health facilities (60%, 86 of 143) used new electronic systems specifically developed for COVID-19 vaccination reporting. In some instances, the systems required the procurement of new hardware and modems for use at vaccination sites and to accommodate mobile-based vaccination. In many instances, the newly designed tools were well received, and it was recommended they be leveraged for other activities, including routine immunization.

Summary vaccination reports generated by the electronic reporting systems were acknowledged for providing significant decision-making support to the COVID-19 response. In some countries, however, data were not readily available for immediate decision-making or program implementation at the lower levels (e.g., for estimating coverage or identifying and following up defaulters). Eighty-three percent of health facilities (153 of 185) across countries reported data on COVID-19 vaccination in real-time during the vaccination session or at the end of each vaccination session, while most other health facilities reported daily (11%, 20 of 185).

Case study: A well-functioning eIR can improve program monitoring and may impact coverage

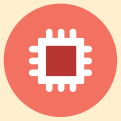
The eIR enabled real-time tracking of vaccine administration and coverage which was critical for monitoring and evaluating the roll-out of the COVID-19 vaccines nationally and sub-nationally. The eIR allowed health officials to estimate vaccine coverage by age, vaccine type, and number of doses. The system also enabled the identification of dropouts and hard-to-reach populations. Additionally, the eIR provided the ability to print vaccination certificates which were important for travel purposes and to access certain services.

About half of health facilities (48%, 89 of 184) reported experiencing challenges related to reporting and recording systems. A primary challenge related to the duplication of work because of multiple electronic tools, and multiple reporting mechanisms, leading to inconsistent numbers across databases. Many health facilities (62%, 133 of 213) reported using a mixed (electronic and paper-based) reporting system to report to higher administrative levels. Other reporting challenges included the lack of internet access, insufficient skilled personnel, and lack of IT equipment. To respond to these challenges, makeshift reporting methods were implemented in many countries, including health facilities sending photographs of paper registries via messaging apps as part of daily reporting procedures. Countries acknowledged that some of the 'innovations' were slow to be adopted at the local level – including the use of eIR.

Many countries worked on harmonizing existing health information systems (including removing parallel paper processes) and improving their interoperability with civil registration and vital statistics (CRVS) systems or AEFI reporting mechanisms. Countries also worked to improve data sharing between different stakeholders by providing support to private doctors for entering data into electronic tools and increasing tool uptake by providing training and equipment. Strengthened data quality controls were also implemented.

LMIS were used in all countries. Use of these systems for national COVID-19 vaccine stock planning was initially slow, but became increasingly relevant over time, allowing national warehouses to plan for the appropriate distribution of vaccines to the lower levels. In countries with an eLMIS, this was not consistently available across the vaccine stores and did not always allow for a real-time view of vaccine stock. Countries were exploring the adoption of cohesive eLMIS to be used across all levels, for both COVID-19 and routine vaccines. At the same time, there were attempts to develop eLMIS integrated with the national digital health information systems to ensure effective stock management across the entire health sector.

Good practices in rolling out electronic immunization tools (eIR or eLMIS) to lower levels to note included intensive 'hand holding' during the implementation



Did the electronic tools developed for COVID-19 'survive'?

Was there a vaccine registration and certification system?

How did countries manage the intense amount of data entry at service delivery level?

Are there any lessons that can be carried over to routine immunization programs on the use of electronic tools?

Did COVID-19 surveillance help to strengthen Vaccine Preventable Diseases (VPD) surveillance?

phases, particularly at provincial and local government levels, monthly refresher training, adequate funding, and sufficient partner support. Efforts were made to ensure the use of standard data capture forms, and to facilitate improved reporting during outreach and mobile health services.

Case study – Investments in training and supervision on monitoring resulted in higher performance

Investment in training and supervision on monitoring resulted in higher performance, including more complete and correct registration and minimal drop out. Front-line health workers were in close communication with immediate supervisors and district and regional officials as needed. Through whatever mechanisms appropriate to the context, including messaging apps where needed, they reported daily, and frequent supervision was provided with specific feedback.

Was there a vaccine registration and certification system? Was it available to all – or mainly to travelers?

Electronic vaccine registration systems existed, often alongside paper records. Vaccination certificates were often made available through an electronic system, often including a QR code for ease of verification. In some instances, vaccine recipients received paper vaccination certificates at the time of vaccination but were also able to access the certificates through an electronic reporting system. The issuing of digital certificates was thought to have improved vaccine acceptance in some countries. Other countries acknowledged challenges because of a lack of standardized national vaccination cards and certificates, resulting in a variety of local makeshift vaccination cards and certificates in circulation.

How did countries manage the intense amount of data entry at the service delivery level? Did they have adequate staff to meet the needs of timely data capturing and reporting?

In managing the intensive data reporting tasks, frontline health workers were often in close communication with supervisors and district and regional officials.

Countries acknowledged problems in data capture and data availability for decision-making. Limitations in the number of personnel and the necessary skills for data entry were evident, specifically in transferring paper-based reports to electronic databases. In some places health facilities had dedicated data clerks, relieving clinical health workers of the burden of data entry.

Are there any lessons that can be carried over to routine immunization on the use of electronic tools?

The electronic tools developed for the COVID-19 response were considered assets to be further developed and integrated into routine immunization. In some countries, there was a recognized need to integrate electronic reporting tools at the policy level, alongside a dedicated unit for digital solutions. Upgrading of equipment, instituting regular reporting practices, and a change in management approach were considered necessary for the successful implementation of such tools beyond COVID-19 vaccination efforts.

Did COVID-19 surveillance help to strengthen VPD surveillance? Were existing surveillance platforms leveraged to support the COVID-19 response? Were surveillance forms recording vaccination status? Were these used for any vaccine effectiveness studies?

Overall, there was a stated need to update COVID-19 case investigation forms to include vaccination status, and to ensure that this data is tracked systematically. Countries acknowledged the need for SOPs and guidelines for collecting, recording, and analyzing this data, as well as sustaining and establishing routines around surveillance procedures. While surveillance activities were very active at the beginning of the pandemic, under-reporting was noted in many places as the pandemic progressed. Vaccination status of COVID-19 cases was not routinely recorded in surveillance systems.

COVID-19 case surveillance systems were often built on existing influenza-like (ILI) and severe accurate respiratory infection (SARI) sentinel surveillance structures. Countries acknowledged the need to integrate COVID-19 surveillance with ongoing acute respiratory disease surveillance.

Seven (of 16) countries had conducted or were planning to conduct vaccine effectiveness studies or vaccine impact assessments using routinely recorded data on

vaccination status of hospitalized cases. Results of such studies were, however, not yet available.

Recommendations

Additional capacity building is required to upskill health workers on data quality and data use.

Where electronic tools exist, it is essential to ensure the enabling environment exists for their adoption e.g., consistent, and reliable electricity and internet access, and availability of hardware to enter, view and analyze data. Ideally, these electronic tools should be harmonized with electronic monitoring tools used for other health programs.

Tools developed for COVID-19 should be leveraged for routine immunization and other primary health care services to improve efficiency. These tools can be used for defaulter tracking, sending targeted communication messages, appointment reminders, and to provide vaccine certificates. Parallel and dual reporting, using both electronic and paper-based tools should be avoided to reduce the burden on health workers. Case investigation forms should be updated to include vaccination status to facilitate surveillance activities.

Conclusions

The findings from the cPIEs conducted in this convenience sample of 20 countries indicate a wide variability in COVID-19 vaccination preparedness, implementation, and acceptance in different settings.

All countries reported the presence of a NITAG and highlighted strong planning and coordination mechanisms. Despite the financial constraints and supply chain challenges noted by some countries, robust participation from organizations beyond the MoH and broad use of a variety of delivery services and sites proved beneficial in reaching priority target groups with COVID-19 vaccines. Training and supervision of the workforce was a priority; and the role of the health workers in encouraging vaccine uptake was fundamental, with most health workers themselves having received the COVID-19 vaccine. All responding countries in the analysis had developed detailed plans to generate acceptance and demand for COVID-19 vaccines.

These findings underscore the complexities involved in global immunization efforts against COVID-19, emphasizing the need for continued focus on integrated and well-coordinated planning, regulatory preparedness, adequate resource allocation, service delivery optimization, human resource management, training and supervision, excellent demand generation, stringent pharmacovigilance and enhanced monitoring and evaluation efforts.

Limitations

This analysis had several limitations. Firstly, the findings of this study may lack generalizability beyond the countries included in the analysis. While efforts were made to select evaluations from diverse settings, the specific characteristics and context of these countries did not fully represent the global landscape. Secondly, the completeness and quality of the data used in the evaluations may be varied. The reliance on data collected by different persons, countries, and organizations introduced the possibility of inconsistencies, missing data, and variations in data quality. Questionnaires were translated into other languages in some countries, which may have impacted the understanding of questions by respondents.

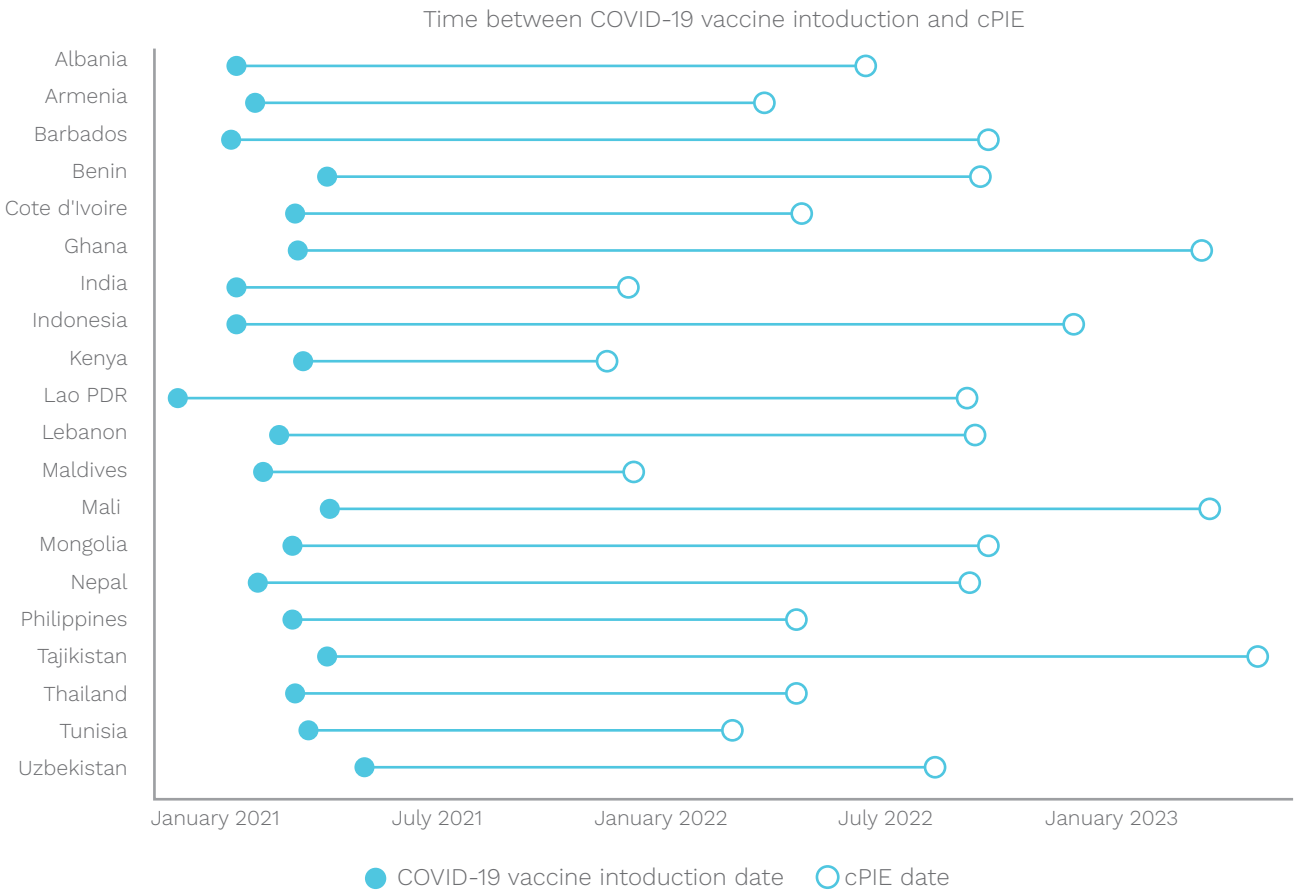
Recall bias may be a further limitation. The qualitative evaluations relied on retrospective data collection, which may be subject to the participants' ability to accurately recall and report relevant information. Similarly, the qualitative analysis was partly conducted on secondary data (i.e., country cPIE reports and debriefing materials) with researchers often unable to return to country cPIE participants to clarify or validate findings. Researchers could, however, revert to leads or participants of most of the cPIEs who were able to respond to queries and provide clarifications and insights on the process of conducting the cPIE, data quality and any limitations to the findings.

Finally, the evolving nature of the pandemic has influenced policies, strategies, and implementation of COVID-19 vaccination programs over time, so that earlier and later cPIE findings (2021 - 2023) may reflect different stages of program implementation and thus provide a more diverse view of issues and findings.

Annexes

Annex A: List of countries included in analysis

Country	Time between introduction and cPIE	Qualitative	Quantitative	
			National to HF level	National level only
Albania	>1 year	√	√	
Armenia	>1 year	√	√	
Barbados	>1 year	√	√	
Benin	>1 year	√		√
Cote d'Ivoire	>1 year	√	√	
Ghana	>2 years	√	√	
India	<1 year	√		
Indonesia	>1 year	√		
Kenya	<1 year	√		
Lao PDR	>1 year	√	√	
Lebanon	>1 year	√	√	
Maldives	<1 year	√		√
Mali	>1 year	√	√	
Mongolia	>1 year	√		√
Nepal	>1 year	√	√	
Philippines	>1 year	√		√
Tajikistan	>2 years	√	√	
Thailand	>1 year	√		√
Tunisia	<1 year	√	√	
Uzbekistan	>1 year	√		√


Time between COVID-19 vaccine intoduction and cPIE
Albania
Armenia
Barbados
Benin
Cote d'Ivoire
Ghana
India
Indonesia
Kenya
Lao PDR
Lebanon
Maldives
Mali
Mongolia
Nepal
Philippines
Tajikistan
Thailand
Tunisia
Uzbekistan
January 2021
July 2021
January 2022
July 2022
January 2023
COVID-19 vaccine intoduction date
cPIE date

Annex B: Research questions by NDVP chapter

Regulatory preparedness

- What were the lessons or facilitators for expediting regulatory approval?
- How did NRAs manage the situation of having to license vaccines that did not have WHO EUL?
- What was the role of the NRAs in vaccine safety monitoring?

Planning and coordination

- How did the coordination work at the national level (task forces, committees) and between the national, regional, district, and service delivery level? Was there intersectoral coordination?
- Were NDVPs used/useful?
- Were external development partners intimately involved?
- How was prioritization of target groups done?
- How were vaccination schedules developed (including boosters)?

Service delivery

- How much fixed site delivery, and how much new mass vaccination (in special sites) was done?
- What were special strategies for reaching priority or vulnerable populations?
- Was COVID-19 vaccination integrated into clinical settings or other vaccination settings?
- Were private providers engaged? If so, how?
- Were defaulters tracked? If so, how?
- Were beneficiaries satisfied with the services and why?
- Did health workers follow COVID-19 instructions and SOPs?
- Was there sufficient personal protective equipment?
- Were CHWs involved in the COVID-19 vaccination effort?

Costing and funding

- Was there a costing and budgeting exercise? How was it done? Was it used?
- How much of the funding came from development partners vs. from the domestic budget? Were domestic/local funding options explored (e.g., private sector)? Did the response engage new partners and donors? In what areas? Is there potential for them to engage in routine immunization?
- Was there a shortage of funding at any time?
- Was there a seamless mechanism for the timely release of funds to the lower levels?

Supply chain and waste management

- Were there specific problems (beyond the initial global shortage of supplies) that hindered supply allocation within the country?
- Was the cold chain sufficient and well-maintained? Was it upgraded?
- Was vaccine distribution to the lower levels satisfactory?
- How was the huge amount of additional injection waste handled – including expired vaccines? Was waste disposal safe and well managed?
- How was short shelf life handled (e.g., was there a system to redistribute vaccines that were close to expiry, conduct campaigns to move vaccine, communication efforts, etc)?

Human resources management and training

- Were there sufficient human resources for the task at hand? Did additional staff need to be recruited? Was staff re-allocated?
- Was routine immunization/PHC service delivery disrupted due to task shifting? Are there any lessons for minimizing this?

- How and when were human resources trained (virtual, in-person)? How was continual training managed when new vaccines were deployed, and in view of staff turnover?
- Was vaccinator knowledge adequate? Were there any gap areas?
- Was supervision done well and regularly?
- Are there any lessons on managing health worker fatigue, burn-out, and retention?

Vaccine acceptance and demand generation

- Was there sufficient political support, and high-level advocacy, for creating demand?
- How did demand change over time? What were the reasons for this change?
- Was social listening done? Which rumors were mostly prevalent?
- Did hesitancy 'spill over' into routine immunization programs?
- Were there good lessons or approaches for responding to hesitancy/rumors?
- Was there sufficient capacity and expertise to track and respond to hesitancy/RCCE?

Vaccine safety

- Were expected numbers of AEFI reported? Were AEFI managed properly?
- Were AEFI committees instituted at the national and sub-national level? Were the committee members well-trained?
- Was causality assessment done properly?
- Was the MoH prepared to communicate about AEFIs? Was any sort of risk communication done?
- Was there any monitoring for AESI?

Monitoring and evaluation

- Did the electronic tools developed for COVID-19 'survive'? Were these tools useful? Was there an eLMIS for COVID-19 vaccine management?
- Was there a vaccine registration and certification system? Was it available to all – or mainly to travelers?
- How did countries manage the intense amount of data entry at service delivery level? Did they have adequate staff to meet the needs of timely entering and reporting?
- Are there any lessons that can be carried over to routine immunization on the use of electronic tools?
- Did COVID-19 surveillance help to strengthen vaccine preventable diseases (VPD) surveillance? Were existing surveillance platforms leveraged to support the COVID-19 response? Were surveillance forms recording vaccination status? Were these used for any effectiveness studies?

Annex C: Summary of code system

Code	Sub-code
Innovations	
Best practices	
Challenges	
Future pandemic response	
Routine Immunization	
Regulatory Preparedness	Authorization
	Licensed vaccines
	National Regulatory Authority
	Emergency Use Authorization (EUL)
	Indemnity & Liability
	Regulatory support, procedures, and processes
	Licensing vaccines without WHO EUL
	Expediting regulatory approval
Planning & Coordination	Policies
	Standard Operating Procedures (SoPs)
	Strategic plans & baseline assessments
	Coordination structure
	Intersectoral coordination
	Microplans
	Prioritization of target groups
	Development of vaccination schedules (including boosters)
	Emergency Operations Centre (EOC)
	NDVP
Costing & Funding	Resource mobilization
	Resource allocation
	Resource availability
	Procurement
	Utilization of funds
	Costing & budgeting
	Domestic funding
	External funding
	Disbursements
	Financial oversight & monitoring
Service Delivery	Vaccination coverage
	Infection Prevention Control
	Fixed site
	Outreach
	Mass vaccination
	Innovative approaches
	Integrated into clinical settings
	Other (vaccination settings)
	Hard-to-reach locations
	Defaulters
	Vaccine distribution to lower levels
	Satisfaction with service delivery
	Implementation of SoPs
	Mandatory vaccination
	PPE

SCM & Waste Management	Cold chain Product handling Logistics Transport Forecasting Distribution Availability Use Waste management Short-shelf life Open vial Closed vial
HR Management & Training	Private providers Supportive supervision Training Materials Incentives Salaries Capacity building HR allocation Roles and responsibilities Task shifting HW burnout/fatigue/retention
Acceptance & Demand	Political support Champions/influences Risk Communication Social listening Community engagement Demand generation Hesitancy and refusal Social behavioral data SMS reminders
Vaccine Safety	Surveillance Kits & guides Causality assessment Pharmacovigilance AEFI investigation AEFI reporting AEFI committees AEFI management AESI
Monitoring & Evaluation	Reporting Monitoring Data entry Data use Data triangulation Vaccination cards Data quality Denominator Research Electronic tools Surveillance

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