"In working with vaccines, you have the impression that you're working with gold, and that it's a protected field": A qualitative study on childhood vaccination decision-making in crisis-affected settings

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ABSTRACT

Background: The governance of childhood vaccination in crisis-affected populations presents distinctive and intricate challenges and has been criticized for being inadequate. In this study, our aim was to investigate the existing practices related to decision-making on vaccination in crisis-affected settings and develop practical suggestions for enhancing these.
Methods: We followed a qualitative research approach, conducting 31 remote semi-structured interviews with individuals involved in humanitarian vaccination efforts and stakeholders operating at global, regional, and national levels. We used a thematic approach using a mix of inductive and deductive coding to analyse the data while applying the Governance Analytical Framework (GAF).
Results: Our research indicates that decision-making in crisis-affected settings suffers from a lack of structure, documentation, and transparency. Participants highlighted the presence of diverse and conflicting agendas among different stakeholders and the insufficiency of timely, reliable data crucial for effective decision-making. As solutions, participants recommended improved coordination among stakeholders and emphasized the need for meaningful engagement of local actors.
Conclusion: The study uncovered a fragmented, disorganised and complex governance landscape of vaccination services in crisis-affected settings spanning multiple levels and involving various actors. To improve this landscape, it is crucial to intensify efforts to ensure fairness, accountability and effectiveness.

1. Introduction

In crisis-affected settings, displacement, food insecurity, insufficient water and sanitation, overcrowding and disruption of health systems are common risk factors (Close et al., 2016) that increase the susceptibility, transmissibility, and severity of vaccine-preventable diseases (VPDs) which can occur in both endemic and epidemic patterns (Lam et al., 2015; Leach and Checchi, 2022). An intervention such as vaccine provision can significantly reduce morbidity and mortality from vaccine-preventable diseases in such settings (Ngo et al., 2020). Ensuring access to quality vaccination services in crisis-affected settings is crucial for preventing the spread of infectious diseases and protecting the health of vulnerable populations, particularly children (Connolly et al., 2004; Roberts, 2020; Nelson, 2020). Although a standardized

approach to vaccine provision in humanitarian crises has been proposed, the decision on which vaccines to use, when, and how is often left to crisis-specific decision-makers (Leach and Checchi, 2022; Grais and Juan-Ginera, 2014). In most recent crises vaccines are primarily delivered on a routine basis as part of countries' Expanded Program on Immunization (EPI), with few supplementary actions taken to rapidly enhance immunity levels such as mass campaigns, for measles or polio (Leach and Checchi, 2022). The delivery of childhood vaccination services in crisis-affected settings presents unique challenges and complexities due to already weak and fragmented health systems (Close et al., 2016). Well-recognized challenges to vaccination in crisis settings include organizational bureaucracy, vaccine stock-outs, cold-chain needs and management, contextual restrictions, ethical considerations, high costs, and population movement (Leach and Checchi, 2022). The rapidly changing transmission dynamics during crises, the complex set and roles of governmental, United Nations and non-governmental actors, and the need to rapidly immunise large population groups further complicate the timely and effective delivery of vaccination services (Close et al., 2016). In addition to operational challenges, governance and decision-making around vaccination services in crisis-affected settings have been described as inadequate (Grais and Juan-Ginera, 2014). In this recent scoping review, Abdelmagid et al. indicated that governance of childhood vaccination in crisis-affected settings can be described as fragmented and multi-actor, which affects the appropriate design and performance of vaccination responses. The study also revealed limited information on access to vaccine stocks, which is considered the most influential factor in designing and planning vaccine interventions (Abdelmagid et al., 2023). Broadly, humanitarian health actors appear to lack robust governance and accountability structures and processes (Jarrett et al., 2021; Colombo and Pavignani, 2017) in addition to a lack of publicly available documents on decision-making processes (Abdelmagid et al., 2023).

In 2021, approximately 18.2 million children worldwide were classified as "zero-dose" children, i.e. had not received any routine vaccinations (United Nations Children's Fund, 2023). The percentage of children receiving three doses of diphtheria, tetanus, and pertussis (DTP3) vaccine, which serves as an indicator of immunization coverage, dropped from 86 % to 81 % between 2019 and 2021 globally. This alarming trend underscores the growing number of children exposed to VPDs (World Health Organization, 2023). The decline in vaccination coverage can be attributed to various factors, including the rising number of children living in conflict-affected and fragile areas, where access to immunisation services is often challenging (World Health Organization, 2023). Additionally, COVID-19 disruptions have significantly constrained vaccination and other humanitarian health services. Throughout 2020 and 2021, it was reported that vaccination efforts through all modalities were severely impacted as health systems became overstretched by the COVID-19 pandemic and the delivery of its vaccine (Leach and Checchi, 2022).

In this study, we aimed to explore current vaccination governance practices and formulate concrete recommendations to improve them by exploring crisis settings decision making drivers and barriers. Our objectives were to i) describe the features of decision-making around vaccination services in crisis-affected settings, ii) assess barriers and facilitators to equitable decision-making processes and iii) provide recommendations for equitable governance practices.

2. Methods

2.1. Study design and methodological approach

This is an exploratory qualitative study using remote semi-structured interviews with humanitarian vaccination actors and stakeholders at global, regional and national levels. For this study, we adopted the following definition of governance: "processes of interaction and decision-making among the actors involved in providing vaccination

services" (Hufty, 2023). We define crisis-affected settings as settings that face armed conflict, forced displacement, natural disasters or major disease outbreaks with widespread societal consequences, such as the Ebola epidemic in West Africa, 2013–2016 (Kohrt et al., 2019).

2.2. Conceptual framework

The Governance Analytical Framework (GAF) has been developed as a practical aide to investigate governance processes from non-normative stance and address the complexities of governance, particularly in challenging environments. The GAF uses a structured approach to understanding how decisions are made, who is involved, and what factors influence these processes. It consists of five coherently linked domains: problems, actors, social norms, processes, and nodal points (Hufty, 2023). We drew on the GAF to develop the interview topic guide and later perform both data collection and analysis.

2.3. Sampling and recruitment

We used a two-stage sampling process, First, we purposively drew from study team members' professional networks an initial list of 70 potential participants. Second, we snowballed from each interviewee's own suggestions adding another 31 potential interviewees. Eligible participants were governmental and non-governmental actors with experience in designing, planning, implementing, advising or funding childhood vaccination services in crisis-affected settings at global, regional and national levels.

Balancing between global, regional and national actors of potential participants, MA sent introductory emails to around 61 of them along with the study information sheet copying in a mutual acquaintance (a team member or an interviewee) to increase responsiveness.

Fourteen eligible interviewees did not reply to emails, six declined due to busy schedules, and five declined and suggested other colleagues. Emails were sent to the additional five suggested colleagues, but no response was received. MA sent consent forms and scheduled the interviews with 36 who initially agreed to participate. Five out of 36 potential participants did not respond after sending the consent form and the interviews were not scheduled. Thirty-one remote interviews were conducted.

2.4. Data collection

MA obtained electronically informed consent and conducted 31 semi-structured interviews between August 2022 and March 2023. No incentives were provided and interviews were conducted in English via the Zoom online platform and using the developed topic guide. Topics drew on the GAF framework (Hufty, 2023) and included questions about role and organization, characteristics of the decision-making processes of vaccination services in crisis-affected settings, perceived challenges and facilitators of decision-making for equitable vaccination services and lastly the COVID-19 pandemic's impact on the services. Interviews lasted 60 minutes on average. We determined data saturation when no new topics or observations arose in interviews. Interviews were audio-recorded and transcribed. We used Otter.ai to record and generate initial transcription drafts. MA listened to the interviews recordings and reviewed the quality of these drafts and revised accordingly. Otter.ai has proved excellent in capturing the American accent and thus producing a high-quality transcripts, but this was not the case for other accents which required more time to go through and edit the initial transcripts.

2.5. Analysis

In March 2023, MA, MD, NA, and NSS conducted a physical analysis workshop that was guided by the GAF and its main five domains. They independently worked on one interview transcript to test this synthesis approach and then compared their notes. This allowed them to build an

understanding of how to analyse the data best while applying the GAF.

Following this, each analyst was assigned a subset of the interviews to code using NVivo software (version 1.7.1). After that, NVivo files were compiled together to produce one file. Each analyst was assigned a group of themes from which to synthesise results and extract relevant quotations. We used the structure below for data analysis: 1-Problem (What is the problem and according to whom, How does each actor view the nature of the problem, How does the wider governance system influence the governance of vaccination in crisis settings), 2-Social norms (What are the norms or the rules of the game, How are the norms or rules established, and by whom, How are these norms perceived), 3-Processes (including any decision-making processes for vaccination in crisis settings), 4-Actors (Who are the actors, How do actors interact with each other, What influence do the actors have), 5-Nodal Points (including any spacetimes bringing actors together), 6-Barriers contributing to the problem, 7-Facilitators and solutions to the problem, and 8-Impact of COVID-19 on vaccination programs.

During the physical workshop, analysts constantly review and identify key messages for each built theme and collaboratively analyse the data using inductive and deductive coding. MA was responsible for drafting the initial results based on all analysts' work, which were subsequently and critically reviewed by MD, NA, and NSS to agree on discrepancies and ensure quality. The team found the GAF helpful in making sense of the data but less effective in presenting the findings. After writing up the results, we held two online feedback sessions using the Zoom platform with study participants. All 31 study participants were invited to join anonymously so that we could present and verify the findings. However, only eight participants in total attended both sessions. We also sent a PowerPoint document including all the findings for those who could not attend the virtual session to provide feedback, four participants shared theirs. Recommendations from study validation step were included in the findings.

2.6. Ethics

We obtained ethics approval for the study from the London School of Hygiene & Tropical Medicine (LSHTM) observational ethics committee in the UK (Ref No. 27465 /RR/28613). All participants provided informed consent. MA reassured interviewees that they could stop at any time and skip any questions in the topic guide. Anonymity was ensured by using identification codes in all transcripts and outputs, and confidentiality and privacy were secured by arranging interviews at times of the interviewees' choosing. All data were stored on secure servers at the LSHTM servers, being only accessible to the study team.

3. Findings

3.1. Interviewee characteristics

Table 1 provides the interviewees' details by institution type and the geographical distribution of where they are based.

We present the findings under three main themes: characteristics and components of decision-making processes, barriers and facilitators to equitable and successful decision-making processes, COVID-19 pandemic's impact on childhood vaccination programs.

3.2. Characteristics and components of decision-making processes

Identifying actors and their influence and determinants of the decision-making processes, in addition to listing both cross-cutting and contextual factors that influence the decision-making processes are the main subthemes included.

Decision-making processes for vaccination in crisis-affected settings were described mainly in the context of responding to emergency events (including outbreaks, epidemics and pandemics) and secondarily for delivering routine Expanded Program on Immunization (EPI) services.

Table 1
Participants' characteristics.

Participant ID Vaccination Actor (VA)	Sex	Institution type	Country
VA_01	Male	UN agency	Switzerland
VA_10	Female	UN agency	Switzerland
VA_19	Female	UN agency	Switzerland
VA_05	Male	UN agency	USA
VA_14	Male	UN agency	USA
VA_24	Male	UN agency	Somalia
VA_25	Male	UN agency	Gambia
VA_29	Male	UN agency	South Sudan
VA_07	Female	INGO	South Sudan
VA_11	Male	INGO	USA
VA_18	Female	INGO	USA
VA_12	Female	INGO	Belgium
VA_13	Female	INGO	Switzerland
VA_15	Female	INGO	UK
VA_03	Female	INGO	UK
VA_04	Male	INGO	Senegal
VA_17	Female	INGO	Ireland
VA_21	Male	INGO	Somalia
VA_08	Female	INGO	Denmark
VA_09	Female	INGO	France
VA_20	Male	INGO	France
VA_27	Male	INGO	Uganda
VA_28	Male	INGO	Kenya
VA_30	Male	Academia	Canada
VA_31	Male	Academia	UK
VA_02	Male	Academia	USA
VA_26	Male	Academia	Mexico
VA_06	Female	Bilateral donor	UK
VA_16	Female	Bilateral donor	USA
VA_22	Female	Bilateral donor	USA
VA_23	Female	Bilateral donor	USA

The decision-making processes were described as "*contextual*" and "*delicate*". Additionally, decision-making was reported as a bureaucratic process that often goes undocumented.

> *"In working with vaccines, you have the impression that you're working with gold, and that it's a protected field."* VA_12 INGO staff

> *"So decision-making on vaccination in crisis settings is very unstructured and very ad hoc and generally chaotic. And I don't mean it in a negative way. I mean, in a factual way, at least from what I can see."* VA_31 Academic

It was emphasized by some participants that decisions cannot be made unilaterally, as their organization operates as a partner of the Ministry of Health within the country.

> *"We are there as partners of the Ministry of Health, so we cannot decide anything on our own. Everything has to be negotiated with the local authorities and everything has to come from the local authorities first, so we can push but we don't have the last word, this is good in terms of sustainability but […] there might be some delays as well."* VA_07 INGO staff

Some participants mentioned the lack of accountability toward the crisis-affected population as one of the themes of decision-making processes and how it affects equity.

> *"Gates Foundation is not an organisation that has a lot of accountability […] And maybe there should be more diversity of interest in vaccination from different financers."* VA_20 INGO staff

> *"You have some WHO guidelines of which age groups to target. So I don't think just because they are humanitarian settings we need something that is different from what the standard is. And that may be part of the problem because if you assume that some vaccines are not useful in that routine, then you have basically deprived a cohort because you don't know when the conflict is going to end."* VA_14 UN agency staff

Participants reflected on how their organizations perceive and interact with decision-making processes. We accordingly inferred the main components of the decision-making process (who, what, where and how) as the framework shown in Fig. 1.

3.2.1. Identifying actors and their influence (who & what)

Participants described various actors actively involved in the decision-making processes and implementation of vaccination services in crisis-affected settings. They also pointed out actors who are omitted/not invited to the decision-making table despite their critical influence. Donors and international actors like UN agencies and international non-governmental organizations (iNGOS) mainly set the agendas of vaccination services and formulate guidelines, and are influential when it comes to in-country decision-making. The World Health Organisation (WHO) and specifically the Strategic Advisory Group of Experts on Immunization (SAGE) are considered to be the main body to formulate global guidelines and all participants reported relying mainly on the WHO guidelines either for direct implementation or as the source for formulating contextual guidelines (such as by Médecins Sans Frontières MSF, or Save the Children). International actors also play a main role in strategy setting especially when it comes to outbreak responses. Their way of working was described as collaborative.

"And in terms of what you're looking for decision-making _from the highest levels of World Health Organisation_ global priority, was frequently said and decided upon to be more important than the local priority." VA_02 Academic

"WHO plays a coordination role in many of the settings and the international NGOs who operate on ground like MSF and few others, such as IFRC or whoever operates on ground they come with their whole set of volunteers there on ground capacity." VA_05 UN agency staff

The role of national actors is mainly described as strategy setting and micro planning for both routine and emergency programming of vaccination. The national actors share a gatekeeping role with the local actors as well and they are mainly represented by the ministries of health. Participants mentioned a wide range of local actors involved in decision-making on vaccination, ranging from militias and de facto authorities to local NGOs, community health workers, frontline vaccinators and community members. Their participation in decision-making was described as mostly tokenistic or non-existent, and in some cases, they support microplanning and logistics.

"We do try to work quite closely with community organisations, CSOs [civil society organisations], religious and ethnic groups as well especially

Fig. 1. Characteristics and components of decision-making processes.

when it comes to things like mobilisation for vaccination." VA_13 INGO staff

"But more often than not, the decision-makers are generally people who hold political control over the population in areas where some of this is taking place.[…]Sometimes it is the warring factions that will control sometimes it is the military and at other times it is the public sector, in whatever shape and size it exists in those areas." VA_30 Academic

3.2.2. Determinants/norms of the decision-making processes (how & where)

Generally, participants reflected on how vaccination services are not perceived as an emergency priority in crisis-affected settings; however, a few participants mentioned how vaccination is usually understood within the context of global health security.

"It is a big debate within [name of NGO] because vaccination by its very nature is preventative health, right? It's preventing people from getting sick." VA_09 INGO staff

"EPI is patchy, shall we say? I think the reason for that most of the time EPI is obviously government organised or there are other donors like UNICEF involved." VA_08 INGO staff

Decision-making processes lack holistic or structured approaches for the designing, funding acquisition and implementation stages, which leads to siloed ineffective programming, imposed especially from the donors' side.

Due to the inconsistent implementation and decisions on EPI in crisis settings, Gavi, the Vaccine Alliance who only works through governments, is beginning to set up structures to support civil society organizations, so that routine EPI programs are implemented in a coherent and systematic way. This exclusivity of working through governments only was, however, criticised by most participants.

"How much vaccines a government gets or how much funding[…]those are decisions made by Gavi, and they [Gavi] are not necessarily sitting in the field, and rarely would they go to a humanitarian setting." VA_18 INGO staff

"I think that Gavi, the secretariat at least, is aware that it has a top-down approach that needs to change. But I think that even if the Secretariat in Gavi understands how to change the way they function, they are going to be severely restricted in terms of their ability to change by what their main donors and their main funding recipients do and design and pressure them to do." VA_31

On the other hand, decisions around outbreak responses are mostly reactive and usually top-down (from donors and international actors to national ones) where they lack transparency mechanisms or use of objective/reliable data sources.

"So it's not that all voices are equal when it comes to decision making." VA_23 Bilateral donor

"We really do not include communities, a lot of times it's a very top-down kind of response." VA_18 INGO staff

However, outbreak responses represent one of the main spacetimes where actors converge to make decisions. Designing and planning are both essential stages for successful decision-making but depend on data coming primarily from UN agencies and ministries of health, which might not be up to date or account for the displaced communities. Almost all participants mentioned how triangulation of data is often not performed. Additionally, upon design and implementation, guidelines (set mainly by WHO) are followed strictly and inflexibly, especially regarding the targeted age groups (either under 1 or under 5 years old) and types of vaccines provided in crisis-affected settings. In some examples mentioned by participants, challenging the existing policies, and using innovative ways were done to influence the processes of decision-
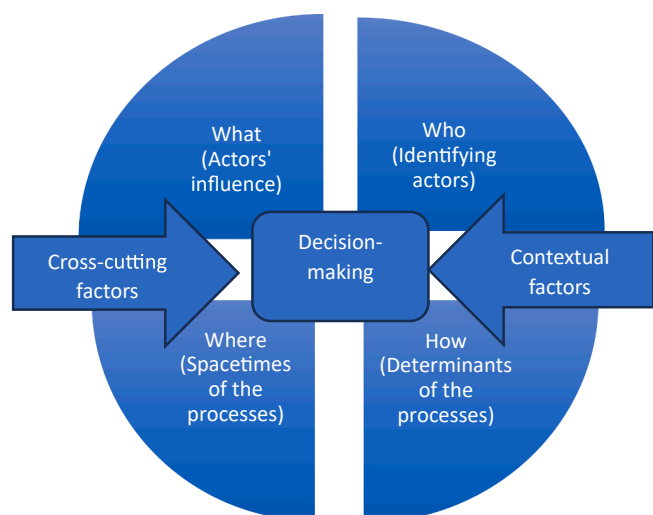
making.

> *"For example, the WHO way of estimating the size of a measles outbreak is sort of a one-size-fits-all approach[...]A lot of times MSF is kind of not well received, because they try to do things their way and innovate and not necessarily based on recommendations, but based on what they understand, based on the country, based on the contexts, based on what the community is telling them."* VA_20 INGO staff

> *"We would always want to make sure everything is consistent with WHO policies and in some humanitarian settings, this is probably less relevant. But there's also compliance with national laws and regulations that would have to be met."* VA_11 INGO staff

3.2.3. Cross-cutting factors

In addition to the above, cross-cutting factors that influence decision-making were also described by participants and grouped under four main categories:

3.2.3.1. Vaccine-specific factors. where the type of vaccine and its logistical requirements determine how decisions are made. Additionally, assessing the environmental factors that play a role in deciding which vaccines to add to the schedule and provide in a specific context and in which route. It was reported that WHO has reduced the number of vaccines recommended for crisis settings from thirteen to only seven. Even though this poses an equity issue, feasibility assessments are done based on this list.

3.2.3.2. EPI microplanning. Some activities were mentioned by participants as facilitators for better planning such as seroprevalence surveys and data extrapolation in the absence of reliable data sources. Some participants mentioned how balancing providing vaccine programs to both host and internally displaced people (IDP)/refugee communities (without interfering with the national health system) is one of the main issues they face when microplanning.

> *"We would factor that into planning and calculate that you could only vaccinate 100 that day, whereas in the easy-to-access camp you could vaccinate 500 and you would need more vaccinators."* VA_06

3.2.3.3. Monitoring progress. Some actions to monitor progress and evaluate vaccination programs were mentioned by participants especially when reported vaccination coverage would be more than 100 % in some contexts. For example; mop up campaigns are implemented to include any missing child (those need to be factored in any proposal as they involve human resources and funds), grading health zones based on outbreak risk to conduct preventative vaccine campaigns, door-to-door campaigns to register pregnant women to be followed up after delivery and leveraging birthing centres to provide vaccines to newborns.

> *"When we work on nutrition [programs], for example, everything is super survey-based. But I don't know if that is taken fully into account when doing a lot of vaccination monitoring."* VA_18 INGO staff

3.2.3.4. Coordination and collaboration. Some interviewees mentioned how health actors are sometimes left to negotiate access instead of UN agencies in some crisis settings despite the fact that staff at UN agencies are perceived to be well-trained in that. Working with partners outside the health sector was deemed essential when planning, but the vetting stage was reported as crucial before engaging with any local actor. It was indicated that humanitarian agencies that are able to provide resources and money are usually the main decision-makers. Additionally, vaccination actors rarely aim to integrate health system strengthening and resilience into vaccination programmes which is considered to be another challenge to coordination.

3.2.4. Contextual factors

The dynamic nature of crisis-affected settings, the determining circumstances and their impact on decision-making were pointed out by all interviewees. We grouped them under the following categories:

3.2.4.1. The political influence of governmental and international actors on designing and planning vaccination services. It manifests in three main areas; a) refusal or hesitancy to recognize, negotiate and or work with de facto authorities in crisis settings b) national governments' hesitancy to declare VPDs epidemics and therefore authorize reactive vaccination campaigns and c) the politically driven manipulation of population denominators:

> *"I think that granularity of numbers is hard in humanitarian settings, that information is very difficult to obtain, because of the way information may flow and governments may not be interested in knowing what the IDPs status is, and I know in places like Burma for instance, the authorities will not even let you collect that information. But in places like South Sudan, I think that government is easier to work with."* VA_16 Bilateral donor

> *"In South Sudan, what we are seeing is a very political use of this data in the sense that the denominator is changing. So if you want to demonstrate that you're doing great, you reduce the denominator. So the definition of the denominator is really politically informed."* VA_07 INGO staff

> *"So we end up kind of doing mass vaccination campaigns that are effectively replacing the routine vaccinations should be happening. A measles epidemic demonstrates debriefing vaccination failed, which demonstrates a political failure of a country where it can be very politically sensitive to even point out that there is a measles epidemic."* VA_09 INGO staff

3.2.4.2. Limited UN Security Council resolutions to provide access to and recognise de facto governance mechanisms for populations in areas not controlled by national governments. The only exception reported was the Syrian immunization group in northwest Syria.

> *"Northwest Syria is special, they're doing brilliant, because they're protected under UN Security Council mandate, northeast Syria, on the other hand, is not protected by any Security Council mandate, and it's a mess, it's just left ignored."* VA_10 UN agency staff

3.2.4.3. The short-term and unpredictable nature of humanitarian funding leads to addressing short-term priorities (i.e. a mass immunization campaign over strengthening routine services)

> *"Funding flows for in those [crisis] settings are usually shorter term, and they are coming as part of emergency appeals."* VA_11 INGO staff

> *"Our funding changes year to year. It's not constant, because it's humanitarian. And it's also short term. We don't have the ability to predict how much funding we will receive the next year to maintain a supply chain for EPI."* VA_16 Bilateral donor

3.2.4.4. Security issues that face humanitarian actors and affect the design and delivery of vaccination services and as a result affect the equity aspect of these services

> *"Given it's a difficult setting, you will not have cold chain equipment as much as you want. So you will want not to store the vaccines but to ship them whenever they're ready for implementation. You would prefer campaigns rather than using standalone services."* VA_04 INGO staff

"Many of these mobile clinics are set up very close to where the centre is. They don't really go out to the faraway villages because of insecurity." VA_30 Academic

3.3. Barriers and facilitators to equitable and successful decision-making processes

Participants were asked about barriers/challenges and facilitators/opportunities that enable or hinder decision-making processes in general and regarding reaching zero-dose children. Table 2 summarises the main barriers and corresponding facilitators. Below we provide some of the salient findings.

The barriers include a range of issues stemming from diverse and conflicting agendas and interests of various actors involved leading to a lack of cooperation.

"WHO should be doing 10 times more than is doing in terms of taking the lead competently, taking charge listening to people. Most of the time when it comes to emergencies, they're out trying to get their own money and I don't think when you say vaccination and emergencies WHO is the first thing that comes to mind." VA_02 Academic

"Basically what we hear at country level is that MoH, WHO, UNICEF, whoever holds the power within that, don't open up those meetings, for planning to partners." VA_10 UN agency staff

Decision-making is hampered by the absence of timely and reliable data and unpredictable information-sharing practices.

"You can't rely on it [available data] and all you can do is whatever is available, you say, This is what I have available." VA_05 UN agency staff

"I have no idea how accurate the data was, but it was the best that we had." VA_06 Bilateral donor

Crisis-affected settings present unique challenges, including security and access issues. Ethical concerns related to informed consent, lack of trust in governments and inadequate involvement of affected communities and local responders further complicate the decision-making processes.

"Nobody ever worries about informed consent. Everyone vaccinates and nobody ever gives people any information about what to do if there are some secondary reactions or adverse effects." VA_02 Academic

Participants proposed several solutions such as establishing better coordination by understanding each actor's strengths and weaknesses, documenting decision-making processes, utilizing innovative methods like geospatial mapping in conflict areas to identify children in need, fostering meaningful involvement of local actors beyond tokenism and providing flexible pre-positioned funding for rapid emergency responses.

"What needs to happen first is humility in the sector. Second, reestablishment and reaffirmation of what the core strength of each agency is and if there are strengths that overlap; understanding who's going to do what, and then having an overall coordinating body." VA_19 UN agency staff

"NGOs working with communities can sometimes advocate for the presence of these communities in international forums." VA_28 INGO staff

As some of the interviewees were involved in implementing vaccination services, they provided some related recommendations that could support decision-making processes.

To enhance decision-making efficiency, it was suggested to have a single entity dedicated to child health services during emergencies. This entity would encompass various services related to child survival, including immunization, rather than focusing solely on zero-dose children.

Table 2
Barriers and facilitators to equitable and successful decision-making processes related to childhood vaccination.

Barriers	Facilitators
Diverse and competing mandates, interests and capacities of vaccination actors	**Improving the relationships among international vaccine actors**
• Inflexible/unclear/bureaucratic institutional regulations/mechanisms. • Lack of desire to include/cooperate. • Politicization of decision-making. • Competing/multiple fora and partners • Poor coordination and lack of transparency about decision-making processes. • Narrow organisational mandates and areas of expertise (comfort zone). • Lack of mutual trust between partners for joint vaccination interventions. • Lack of accountability and information-sharing. • No presence of Gavi on the ground. • Restrictions on access to vaccine stocks.	• Coordinate by knowing each actor's strengths and weaknesses. • Have an effective consolidated national cluster approach. • Leverage humanitarian partnerships at the global level. • Have more clarity about institutional mandate, processes, and available, appropriate and deployable resources. • Merge development and humanitarian work • Gavi to engage with civil society organizations • Change the market monopoly on vaccines
Lack of timely and reliable data for decision-making	**Leverage different ways to obtain reliable data**
• Lack of reliable population denominators. • Lack of systematic/unified data collection systems. • Lack of skills/capacity to generate information. • Lack of documentation of decision-making. • Using only administrative data to design/vaccinate and lack of triangulation.	• Shift focus from coverage to equity to highlight vaccination gaps among zero-dose children. • Use novel and advanced methods like geospatial mapping of crisis settings. • Documentation of decision-making and having process guides. • Generation and use of timely and reliable information for early warning. • Establish and support community-based surveillance. • Improve availability and timings of enumeration and needs assessment at emergency onset.
Inadequate involvement of affected communities and or local responders	**Increase meaningful involvement of local actors beyond tokenism**
	• Involve community health workers' perspectives. • Active engagement with refugees and IDPs • Gain access to difficult-to-reach areas. • Increase local staff retention.
Contextual reality of crisis-affected settings and populations	
• Insecurity. • Humanitarian work is a band-aid and opportunistic. • Logistical and financial issues of national actors. • Weak health systems and corruption. • Vaccination hesitancy and/or fatigue. • Lack of health workforce and brain drain. • Ethical issues related to informed consent, harm reduction/ risk mitigation. • Lack of trust in governments. • Competing needs. • Population movement and geographical access. • Not involving warring factions, UN sanctions.	
Insufficient financial and R&D investment considering ambitious expectations from vaccination	**Improve funding allocation for vaccination services**

Table 2 (*continued*)

Barriers	Facilitators
• Insufficient funding (vaccine and implementation costs in particular). • Inequitable pricing of vaccines. • Vaccination is expensive in crisis settings. • Unrealistic/inappropriate vaccination performance targets and indicators. • Inappropriate vaccine formulations for crisis settings. • Shifting resources to COVID-19. • High cost of reaching the last mile (zero-dose).	• Availability of equity fund accelerator. • Improve funding dispersed in emergencies. • Having flexible pre-positioned funding for timely response to emergencies. • Better match between funding, needs assessment and service delivery.
Insufficient knowledge, evidence base and decision-support tools • Reliance on generic protocols/ready-made solutions. • No easy tools for microplanning. • Knowledge gaps about vaccine use and delivery. • Guidelines lack adaptability as they are the same for each country. • Long guidelines.	**Produce decision-support tools to enhance operational efficiency** • Availability of context-specific reference guidelines • Availability of concise, simple and practical standard operating procedures at international, national and organisational levels to improve usability. • Regular decision-making review to identify challenges and future planning. • Conduct operational research.

"I would personally favour setting up a vaccination technical working group under the Health cluster or somewhere in the humanitarian response architecture systematically for every crisis response. And this working group would need to have some sort of standing mirror group at global level that would need to be composed of vaccinologists" VA_31 Academic

Other recommendations included conducting house-to-house visits to identify zero-dose children, employing gender-balanced village teams to track these children, implementing e-vaccination cards, periodic intensification campaigns in remote areas, and improving vaccine characteristics (including the further development of heat-stable vaccines and multi-antigen vaccines) were identified as important strategies, particularly in crisis situations.

"Some research studies proved that the vaccine is stable. It doesn't need to get the cold chain or have such rigid requirements." VA_09 INGO staff

"First of all, I think we should invest more in multivalent vaccines so having more than one vaccine at a time; just take one opportunity to give more than one vaccine dose of more than one vaccine. So I think every single encounter of one person with a health structure should be an opportunity to do catch-up vaccination to check the vaccination status." VA_12 INGO staff

It was also emphasized that proper training for village teams should be provided to address religious and cultural beliefs. It was also proposed to involve communities in human-centred design processes to identify and address rumours, as well as to consider parents' knowledge and concerns (for example regarding children with disabilities). Integrating community health workers (CHWs) into the healthcare system was considered crucial.

"We need to train the community leaders as well, and that will also help us in addressing the issue of the cultural and religious beliefs." VA_27 INGO staff

Additional recommendations included adopting a "One Health" approach, establishing early warning signals of VPDs epidemics through community engagement, utilizing digitally integrated data collection systems to monitor services, adjusting vaccine waste policy and management, and addressing vaccine hesitancy and fatigue to increase service utilization and demand.

3.4. COVID-19 pandemic's impact on childhood vaccination programs

Some participants mentioned the impact of the COVID-19 pandemic on the scene of childhood vaccination even before they were asked about it. They refer to the pandemic as a big event that has changed the scene in an irreversible way providing both opportunities and barriers. Most participants reported how COVID-19 led to a drop in funding and resources for routine childhood vaccination, which negatively affected the coverage and access to routine vaccination (including EPI), and "*created more zero-dose children*". This was mainly due to prioritising COVID-19 responses including COVID-19 vaccination as per donors' policies.

"So now all decision-making processes seem focused on COVID-19 forgetting about all the rest of the immunisation for children and women[…] I'm going to receive a lot of money for COVID-19 vaccination, while I'm not seeing increasing the money available for routine EPI." VA_07 INGO staff

However, some participants mentioned the unintended positive effect where COVID-19 vaccination led to an increase investment in the cold chain.

"It's both an opportunity and a barrier. The opportunity was that there's a lot of money that went to support the cold chain." VA_12 INGO staff

4. Discussion

To our knowledge, this is the first exploratory study aimed at investigating the decision-making processes of vaccination governance in crisis-affected settings. We drew on data from diverse vaccination actors to understand how decisions around vaccination service provision in crisis settings are made. Our findings showed a fragmented and complex decision-making processes in crisis settings. The landscape surrounding implementation of vaccination services is intricate. It is characterised by the involvement of numerous actors whose interactions take place within various levels and platforms, encompassing both outbreak situations and routine EPI programmes (Jarrett et al., 2021).

An additional layer of complexity arises from an inherent imbalance, whereby global vaccine stocks are controlled by a few actors, despite the numerous implementation stakeholders. The processes are further compounded by a lack of adequate evidence-informed decision-making, stemming from challenges related to data quality and availability within crisis settings. The contextual realities of crisis-affected settings where insecurity and unpredictability of funding pose challenges to systematic and transparent decision-making processes. The overlap within the findings suggests how barriers to equitable decision-making processes, may have become the norms that determine these processes especially when it comes to contextual challenges. At the same time, poor and unstructured governance practices exacerbate these contextual challenges. Participants mentioned how applying innovative solutions has helped to manoeuvre around some of these realities such as implementing multi-antigen vaccine campaigns to overcome accessibility issues (Grais and Juan-Ginera, 2014). The COVID-19 pandemic's impact was prominent as it affected the funding and implementation of vaccination programs in crisis-affected settings (SeyedAlinaghi et al., 2022).

Vaccinations are considered crucial to protect against infectious diseases (Connolly et al., 2004), but vertical vaccination programmes are still the followed approach for vaccinating crisis-affected populations, which presents unique challenges and requires careful consideration (Nnadi et al., 2017; Megiddo et al., 2020). Integrating vaccination programs within the broader health system (Sodha and Dietz, 2015), supporting national EPI and reducing reliance on mass campaigns could yield better results.

Funding of humanitarian responses continues to be a challenge for the routine and interrupted provision of health services including childhood vaccination programs (Grais and Juan-Ginera, 2014; Leach

and Checchi, 2022; Megiddo et al., 2020). As humanitarian funding is dependent on external aid, bilateral and multilateral donors' choice of partner and footprint on the ground impacts decisions at the local level (Jarrett et al., 2021). Innovative, sustainable ways should be considered to fund the humanitarian responses, such as multi-year funding commitments and public-private partnerships, along with redistributing the power of vaccination stock monopoly.

4.1. Potential implications of findings

This study highlights the need for more efforts to reduce the imbalance among vaccination actors, redistribute the power of vaccination stock monopoly, and diversify decision-making partners by increasing representation and ensuring meaningful involvement from missing/excluded frontline actors and crisis-affected communities to participate in decision-making processes at all levels (Grais and Juan-Ginera, 2014). Documenting and publishing the decision-making processes could also ensure transparency, equity and accountability.

Dedicating a technical working group under the health cluster or a designated entity for childhood vaccination in emergencies can help channel the efforts between actors and thus facilitate the decision-making process, which was also recommended by this review (Leach and Checchi, 2022). In addition to the above, seeking more technological and vaccine innovations to address the challenges in emergencies and investing in multivalent vaccines could facilitate decision-making processes of vaccination in crisis settings (Grais and Juan-Ginera, 2014).

5. Limitations

This study findings are built on interviews with a sample of key and diverse vaccination global, regional, and national actors. One of the study limitations was the potential selection bias introduced by the study sample. While participants may not have represented the full spectrum of governance issues we believe that those who participated gave sufficient information on decision making processes in crisis settings. Future studies, especially those aiming for a more nuanced understanding of regional or national governance should include more representatives from local government officials representatives and other local actors. Another potential limitation is the diverse participant perceptions of decision-making partly shaped by institutional affiliation; each provided their own experiences and understanding of these processes based on their roles and institutions. While this might seem like a weakness, it provided the main finding of our study that no clear shared definition existed among vaccination stakeholders which reflected in weak governance practices. Further research should apply mixed methods for better understanding such as conducting observational studies of decision-making on vaccination in crisis-affected settings, analysing documented case studies from different contexts, transferring some of the best practices to other settings and assessing their impact. Further research may also consider looking at the differences if any in decision-making processes between acute and chronic crisis-affected settings.

6. Conclusion

Decision-making regarding vaccination services in crisis situations lack transparency, structure and is hindered by unclear mandates and fragmented responsibilities among the various stakeholders. Conducting observational studies of decision-making and co-designing and testing improved childhood vaccination governance models with relevant stakeholders in some crisis-affected settings are suggested recommendations to address these issues.

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CRediT authorship contribution statement

Mervat Alhaffar: Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Nada Abdelmagid:** Writing – review & editing, Methodology, Formal analysis, Conceptualization. **Maysoon Dahab:** Writing – review & editing, Formal analysis. **Barni Nor:** Writing – review & editing. **Francesco Checchi:** Writing – review & editing, Funding acquisition. **Neha S. Singh:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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