Immunisation Schedules: Negotiating the Acceptance of Change in Global Health

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I. Abstract

Immunisation schedules are central to the organisation and delivery of vaccination programmes, yet they are rarely examined as objects of analysis in their own right. While extensive research has focused on vaccine confidence and hesitancy, comparatively little attention has been paid to how people understand and respond when established immunisation programmes change. As schedules continue to evolve in response to scientific development and changes in epidemiology, understanding how such change is experienced and negotiated by parents, caregivers, and vaccine recipients is increasingly important for global health practice.

This thesis examines how changes to immunisation programmes are understood, experienced, and evaluated across diverse global health contexts. Drawing on a mixed-methods design informed by constructivist grounded theory, it integrates a systematic review of perceptions of childhood immunisation schedule change, research with caregivers in Nepal and Uganda, and a study of attitudes towards a proposed gonorrhoea vaccine programme among sexual health service users in the United Kingdom.

Immunisation schedules functioned as sociotechnical infrastructures that align actors, organise responsibilities, and stabilise expectations about timing, safety, and care. Vaccination itself was widely supported by caregivers in Nepal and Uganda, and vaccine recipients in the UK; however, the prospect of changes to established schedules consistently prompted uncertainty, questioning, and reflection, even among individuals who expressed strong confidence in vaccines more generally. The thesis develops a conceptual distinction between the acceptability of vaccines, and the acceptability of programme change, showing

that concern during periods of modification reflects engagement with disruption rather than opposition to vaccination.

At the individual level, responses to schedule change across the empirical chapters of the thesis were shaped by experiences of risk and caregiving, while trust in institutions functioned as a key mechanism for managing uncertainty. At a societal level, acceptability was structured by broader arrangements of power, governance, and civic responsibility, including expectations of state provision, regulatory legitimacy, and equitable access. By foregrounding change as an analytical moment, the thesis shows how routine delivery renders the work of immunisation invisible, while modification makes these arrangements visible and open to negotiation, revealing how acceptability is produced, contested, and sustained within the contexts examined.

The thesis concludes by reframing acceptability of immunisation schedule change as a dynamic process produced through interactions between individuals, institutions, and infrastructures over time. It argues that schedule change should be treated as a distinct phase of immunisation governance, requiring transparent justification, sustained trust, and attention to the historical, ethical, and structural conditions that shape how change is received.

II. Acknowledgements

Several years ago, I was given a piece of career advice that has stuck with me. I was told that throughout my life, I should 'collect people'. They didn't mean in some sort of transactional sense, but rather to keep a hold of those who make you, you. They said to notice those who teach you what's important, to notice those who help you find the words for things you might not yet know how to name, and those who call you out when you might be getting a little too comfortable. And to hold on to them, and to let them shape you. Over time, they said, you will become an accumulation of these encounters—of the conversations in corridors and kitchens, of travelling to new places, and of encouragement offered before you even had the thought to ask. You are made by the people you are lucky enough to meet.

This thesis, in many ways, is a record of the people I have had the pleasure to add to that collection. It carries the weight of mentors, collaborators, friends, family, and communities that have taught me more than I could ever document within a single academic text. And so, if this body of work holds any sense of purpose, it is because it is composed of the lessons I've learnt from you all. These acknowledgements are therefore less of a formality, and more a map of my gratitude, to those who I have been fortunate enough to collect, and for the many ways you have, in turn, shaped me and this work.

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Crosby, S., **Firth, C.,** Lahiri, I., Laird, K., Watson, R., & Younie, S. (2025). Communicating public health information to a global audience: An evaluation of methods to overcome barriers using a community-focused approach. *Education Sciences,* 15(2), 266. doi.org/10.1108/HE-06-2023-0066

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VI.3 Conferences and invited talks

Firth, C. (2025). *Parents' Attitudes to Changing Childhood Immunisation Schedules in Nepal.* London School of Hygiene & Tropical Medicine, London, 20 March. **(Invited Talk)**

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Firth, C. (2024). *Social Science Embedded in Clinical Trials.* Kampala, Uganda, 27 February. **(Invited Speaker)**

VI.4 Media outreach

The meningitis vaccine now sits at the centre of two health crises (2026). *The Conversation.* https://doi.org/10.64628/AB.th5xrkwmn

The UK's childhood vaccination schedule just changed — here's why that's actually reassuring (2026). *The Conversation.* https://doi.org/10.64628/AB.7jkfawtas

Featured science expert (2026) — Interviewed on a children's radio show to discuss vaccines, new vaccine schedule, and careers in vaccinology, with approximately 20,000 listeners each week. https://www.funkidslive.com/podcast/sciencequest/

Featured science expert (2025) — Interviewed by a science communicator/influencer on vaccine hesitancy and the launch of a gonorrhoea vaccine programme; videos reached over 30,000 views across TikTok and Instagram within one week.

1 Introduction

1.1 Vaccination

Vaccination has become so embedded within public health practice that its effects are often taken for granted [Pulendran and Rappuoli, 2020]. Across much of the world, routine immunisation now shapes expectations about childhood health, disease prevention, and state responsibility, contributing to substantial reductions in morbidity and mortality over the past century [Rodrigues and Plotkin, 2020]. The World Health Organization (WHO) estimates that immunisation prevents between 3.5 and 5 million deaths each year from diseases such as diphtheria, tetanus, pertussis, measles, and polio [World Health Organization, n.d]. Beyond averting a measurable number of deaths, vaccines have played a critical role in reducing disability, preventing long-term complications of infectious diseases, and limiting the social and economic disruption associated with disease outbreaks [Ozawa et al., 2016, Bloom, 2011, Shattock et al., 2024].

Despite these achievements, the success of vaccination programmes depends on more than the availability of effective vaccines alone. Sustained high coverage requires functioning health systems, reliable access to services, and public confidence in immunisation programmes [Hill et al., 2016, Bosch-Capblanch et al., 2012, Larson, 2018]. While vaccination has historically been delivered through routine schedules that are widely accepted and familiar, these schedules are not static. They are regularly reviewed and adapted in response to new scientific evidence, shifting disease epidemiology, and programmatic considerations [World Health Organization, 2020].

In recent years, increasing attention has been paid to the social dimensions of vaccination, particularly in relation to vaccine confidence and hesitancy [Black and Rappuoli, 2010] [Larson, 2018, Dubé et al., 2013]. However, many caregivers who strongly support vaccination may still hold concerns about specific aspects of immunisation programmes, including changes to established schedules [Charania et al., 2018].

1.1.1 Vaccine progress and development

Central to these evolving immunisation programmes is the development of vaccines themselves, which has progressed substantially over the past century, driven by advances in immunology, understanding of biology, and vaccine technologies [Pollard and Bijker, 2021]. Early vaccines were often developed through empirical approaches, including attenuation and inactivation, and were introduced with limited understanding of underlying immune mechanisms [Plotkin, 2011]. Nevertheless, these vaccines achieved major public health successes, most notably the global eradication of smallpox [Plotkin, 2011].

Contemporary vaccine development increasingly relies on recombinant technologies, conjugate vaccines, and platform-based approaches, such as viral vectors and mRNA, which use adaptable delivery systems that can be rapidly reconfigured to target different pathogens [Pollard and Bijker, 2021]. These innovations have expanded the range of vaccine-preventable diseases and enabled more rapid responses to emerging health threats [Pollard and Bijker, 2021]. The development and deployment of vaccines against SARS-CoV-2 within an unprecedented timeframe highlighted both the potential of modern vaccine science and the challenges associated with rapid innovation [Shahcheraghi et al., 2021].

As vaccine development has accelerated, expectations around vaccine deployment have also shifted [Bregu et al., 2011]. New vaccines are introduced more frequently, and recommendations regarding dosing, timing, and target populations may evolve as additional evidence becomes available [World Health Organization, 2014b]. Post-licensure surveillance and effectiveness studies often inform subsequent modifications to immunisation schedules, requiring health systems to remain adaptable [World Health Organization, 2014b].

Despite substantial global progress in vaccination, the benefits of immunisation have not been distributed evenly across countries or populations. While many high-income countries have achieved and sustained high levels of coverage for routine childhood vaccines, significant gaps persist in low- and middle-income country (LMIC) settings, particularly among underserved populations [Kalantari et al., 2022, Sodha and Dietz, 2015]. Fragile health systems, geographic barriers, conflict, and resource constraints continue to limit access to immunisation services in some contexts, contributing to ongoing morbidity and mortality from vaccine-preventable diseases [World Health Organization, 2020]. Even within countries with high national coverage, sub-national inequalities can result in clusters of under-immunised children, highlighting that aggregate coverage figures may mask important disparities in access and delivery [Restrepo-Méndez et al., 2016].

1.1.2 Vaccines as social objects

These persistent inequalities draw attention to the fact that vaccines do not operate solely as biomedical technologies, but are embedded within broader social, political, and institutional contexts. Although vaccines are commonly defined as biomedical interventions designed to prevent infectious disease, what a vaccine is—and what it is understood to do—varies across

settings. In this sense, they are sociotechnical objects whose meanings and effects are co-produced, meaning that scientific practice, regulatory systems, health infrastructures, and everyday social experience shape one another [Blume, 2006, Weber, 2008, Jasanoff, 2004]. While vaccines are developed and evaluated through clinical and laboratory processes, their acceptance and use are shaped by how they are embedded within institutional arrangements, historical relationships, and expectations about care, responsibility, and risk [Leach and Fairhead, 2007, Dubé et al., 2013, MacDonald, 2015].

In this sense, vaccines can acquire social and moral qualities that extend beyond their biological function. In many settings, a "good" vaccine may be understood as one that is well tested, long established, widely used, and endorsed by trusted authorities [Bedford and Elliman, 2000]. But such qualities are not inherent to the vaccine itself. As Jasanoff [2004] argues, scientific knowledge and social order are co-produced, each shaping the other, highlighting how vaccines acquire legitimacy and meaning through various regulatory, institutional, and social processes rather than through biological efficacy alone. For example, vaccines that are perceived as new, rapidly introduced, or insufficiently familiar may be regarded with greater caution, even when supported by robust scientific evidence [Organization, 2014]. These evaluations reflect socially situated judgments, rather than assessments of immunological efficacy.

Global inequalities in vaccine research, production, and regulation further shape how vaccines are perceived. Vaccines are frequently developed, tested, and manufactured in high-income settings before being introduced through international funding mechanisms or donor-supported programmes in LMICs. As a result, decisions about vaccination may be perceived as originating outside national systems. Vaccines can be interpreted through histories of

externally led trials, alongside uneven access to newer technologies, and differences in regulatory authority between countries [Wouters et al., 2021, Leach and Fairhead, 2007, Abimbola, 2019]. Such concerns can give rise to anxieties about experimentation and fairness, and whose voice counts in decisions about public health interventions [Day et al., 2024, Abimbola, 2019]. At the same time, vaccines associated with regulation or approval in high-income countries may be afforded greater legitimacy by those the vaccines are intended to help, reflecting global hierarchies in regulatory credibility and biomedical expertise [Wouters et al., 2021]. These social and moral evaluations of vaccines become particularly consequential when vaccines are incorporated into routine immunisation programmes and organised through schedules, where expectations about timing, safety, and legitimacy are translated into everyday practice [Mavundza et al., 2023, Kafadar et al., 2024, Dubé et al., 2013, Gowda et al., 2012, Black and Rappuoli, 2010].

1.2 Immunisation schedules

It is through immunisation schedules that these evaluations are operationalised within routine vaccination programmes. Immunisation schedules define the timing and sequencing of vaccines administered throughout childhood and across the life course, encompassing all stages of life from birth to older age [World Health Organization, 2020, Pollard and Bijker, 2021]. At a biological level, schedules are designed to maximise protection during periods of heightened susceptibility to infection. These considerations inform decisions about when vaccines are initiated, how doses are spaced, and whether boosters are required to sustain protection over time [World Health Organization, 2020, Pollard and Bijker, 2021].

In practice, however, immunisation schedules are shaped by a range of considerations that extend beyond immunological optimisation. Programmatic factors, including healthcare

infrastructure, workforce capacity, supply chains, and cold-chain requirements, influence how schedules are structured and delivered at scale [World Health Organization, 2014b, World Health Organization, 2020]. Decisions about co-administration, the use of combination vaccines, and the number of visits required reflect attempts to balance biological effectiveness with feasibility and sustainability within existing health systems [Organization, 2018]. For example, the use of a combined measles–mumps–rubella–varicella (MMRV) vaccine has been weighed against evidence of a slightly increased risk of febrile seizures in some age groups, with policy decisions balancing this risk against the reduced number of injections, improved uptake, and programmatic efficiency [UK Health Security Agency, 2026]. Schedules, are therefore, negotiated arrangements between scientific evidence and the practical realities of service delivery.

Over time, immunisation schedules become embedded through repeated clinic visits, age-based milestones, and standardised delivery practices. This routinisation reduces uncertainty and normalises vaccination as part of expected care, thus supporting uptake. At the same time, established expectations shape how changes are interpreted; alterations to timing or dosing disrupt familiar patterns and prompt renewed evaluation of risk and legitimacy [Larson et al., 2011, Black and Rappuoli, 2010, Gowda et al., 2012] . As such, immunisation schedules function not only as biomedical schedules, but also as points of interaction between families and health systems, where trust is enacted and reinforced through routine encounters [Larson et al., 2014].

1.2.1 Immunisation schedules as sociotechnical infrastructure

This dual role of immunisation schedules, both as biomedical instruments for optimising immune protection and as sociotechnical arrangements that organise delivery and expectations, invites a broader analytical framing of immunisation schedules. From a

sociotechnical perspective—that is, recognising that technical systems and social arrangements are mutually shaping rather than separate [Jasanoff, 2004]—immunisation schedules can be understood as infrastructures that stabilise complex systems of practice. By translating expert knowledge into standardised timetables, schedules render vaccination actionable at scale.

In doing so, they align diverse actors—policy-makers, health workers, supply systems, and caregivers—around shared expectations of timing, responsibility, and coordination. In this sense, immunisation schedules resemble what Bowker and Star [1999] describe as classificatory systems: they categorise populations by age, risk, and eligibility; they organise institutional action through standardised timing and dosing; and they embed normative assumptions about what constitutes responsible care. Like other classificatory infrastructures, schedules sit at the intersection of social organisation and technical integration, coordinating health services, supply systems, and clinical practice while simultaneously shaping expectations about who should be vaccinated, when, and under whose responsibility.

As infrastructural tools—background systems that coordinate actors and expectations—immunisation schedules operate largely out of view in everyday healthcare. They structure clinic workflows and caregivers' planning, allowing vaccination to proceed predictably without requiring active deliberation. Schedules become visible when they change, fail, or require explanation, prompting renewed attention and adjustment. Their relative invisibility is a defining feature of successful infrastructures [Bowker and Star, 1999]: schedules become taken for granted precisely because they work, embedding expert decisions into ordinary practice without requiring continual reflection or negotiation.

Immunisation schedules also act as sites where multiple forms of knowledge are standardised and reconciled, reflecting what Lampland and Star [2009] described as the role of standards in condensing heterogeneous forms of expertise into stabilised, actionable arrangements. Many forms of evidence—epidemiological evidence, clinical trial data, modelling outputs, and operational considerations—are condensed into simplified frameworks that can be implemented consistently across many settings [World Health Organization, 2025, World Health Organization, 2020]. Through this process, complex scientific and programmatic judgements are transformed into actionable guidance that structure both professional practice and caregiver behaviour. Schedules thus function as infrastructural tools, linking abstract policy decisions to concrete interactions at the point of care.

At the same time, schedules contribute to the ordering of responsibility within immunisation systems. They delineate who is expected to act, and when, by assigning roles to health services to provide vaccines, to caregivers to attend appointments, and to institutions to ensure availability and continuity. In this sense, schedules do not *just* organise the vaccines themselves, but also structure relationships of responsibility and obligation between actors within vaccination programmes, reflecting the tension Mol [2008] identified between a "logic of choice," which individualises accountability, and a "logic of care," in which responsibility is distributed. Schedules mediate between these logics: they invite caregivers to participate in timely vaccination while simultaneously embedding that participation within institutional coordination, reminder systems, and professional oversight.

1.2.2 Expanded programme of immunisation

These organising functions became particularly consequential as immunisation schedules were expanded at a global level. The global expansion and standardisation of childhood immunisation schedules is closely linked to the establishment of the World Health Organization's Expanded Programme on Immunization (EPI) in 1974. Building on infrastructure developed during the smallpox eradication campaign, the EPI aimed to ensure that all children, regardless of where they were born, had access to a core set of life-saving vaccines [World Health Organization, 2020, Pollard and Bijker, 2021]. Initially, the programme focused on six diseases: tuberculosis, diphtheria, pertussis, tetanus, poliomyelitis, and measles [Mirza et al., 2025].

Over subsequent decades, the EPI expanded considerably as new vaccines became available and global health priorities evolved. Vaccines against hepatitis B, Haemophilus influenzae type b, pneumococcal disease, rotavirus, rubella, human papillomavirus, and most recently SARS-CoV-2 have been incorporated into national immunisation programmes across many settings [Mirza et al., 2025]. As a result, while every country now operates a national immunisation programme, the composition, timing, and complexity of schedules vary according to local disease burden, resources, and policy priorities [Organization, 2014].

The impact of the EPI has been substantial. Since its introduction, global coverage of basic childhood immunisations has increased from approximately 15% to nearly 90% [Greenwood et al., 2011]. At the same time, the expansion of immunisation programmes has increased the complexity of schedules and delivery systems. The addition of new vaccines has resulted in more doses, altered visit schedules, and increased demands on health systems, caregivers, and healthcare workers [World Health Organization, 2020, Greenwood et al., 2011, Ozawa et al., 2016]. In LMICs, where health systems may already face resource constraints, these

challenges can be particularly pronounced. As immunisation programmes continue to evolve, careful consideration is required to ensure that schedule adaptations do not undermine acceptability or access.

1.2.3 Designing immunisation schedules

The design of immunisation schedules involves balancing multiple considerations, including scientific evidence, programmatic feasibility, ethical principles, and political priorities [World Health Organization, 2014b, World Health Organization, 2020]. National advisory groups—for example, the Joint Committee on Vaccination and Immunisation in the UK—play a central role in this process, drawing on data from clinical trials, epidemiological surveillance, modelling studies, and cost-effectiveness analyses to inform recommendations [World Health Organization, 2020, Pollard and Bijker, 2021].

While these technical considerations are essential, schedule design has practical implications for families and healthcare providers. Decisions regarding the timing and spacing of vaccines influence how often caregivers must attend health facilities, the number of injections administered at each visit, and how vaccination fits within broader caregiving responsibilities. Changes intended to optimise immunological protection or programme efficiency may inadvertently increase caregiver burden or generate concerns about vaccine safety and tolerability [Gowda and Dempsey, 2013]. Schedule design is further shaped by global health governance structures. International recommendations, donor funding mechanisms, and manufacturer pipelines can influence which vaccines are prioritised and how rapidly they are introduced [Zhang et al., 2025, Shearer et al., 2012, Shaum et al., 2025, Vecchio et al., 2024].

1.2.4 Changes to established immunisation schedules

These intersecting scientific, practical, and governance considerations make change an inherent feature of immunisation schedules. As scientific evidence accumulates, disease epidemiology changes, and new vaccines become available, schedules must be periodically reviewed and updated [Pollard and Bijker, 2021]. Examples of changes may include the introduction of new vaccines, adjustments to dosing intervals, modifications to the age at which vaccines are administered, or the use of combination products designed to reduce the number of injections or clinic visits required [World Health Organization, 2014b, World Health Organization, 2020]. From the perspective of health systems, schedule changes are often intended to improve coverage, reduce missed opportunities for vaccination, or increase efficiency [World Health Organization, 2020, World Health Organization, 2014b].

Immunisation schedules are also embedded within broader systems of global health governance; while this has enabled the rapid scale-up of effective interventions, it can also raise concerns about local relevance and autonomy [Blukacz et al., 2025]. For example, combining multiple antigens into a single injection may ease logistical demands and reduce the number of clinic visits required [Maman et al., 2015]. However, such changes may also prompt concerns among caregivers about safety, tolerability, or the perceived burden placed on a child's immune system [Obohwemu et al., 2022].

Importantly, established immunisation schedules tend to become familiar and trusted over time. They are embedded within routine healthcare practices and everyday expectations, serving as reference points against which new recommendations are evaluated. Changes to

these schedules can therefore represent moments of disruption. Even in settings with high baseline support for vaccination, schedule changes may generate uncertainty if not clearly explained or well understood [Gowda and Dempsey, 2013, Wagner et al., 2017]. As described by Lampland and Star [2009], such disruptions can be understood as moments through which standards are reworked, accumulating new social and interpretive layers that shape their subsequent use.

The COVID-19 pandemic highlighted these dynamics particularly clearly. Rapid vaccine development, emergency regulatory approvals, and evolving recommendations challenged established expectations about vaccination timelines and processes [Wouters et al., 2021]. While many populations demonstrated willingness to adapt, others expressed concern about the speed of change and the perceived novelty of new vaccines [Freeman et al., 2022] [Ledderer et al., 2026]. These experiences underscore the importance of understanding how schedule changes are perceived and negotiated by caregivers, rather than assuming acceptance based on prior vaccine uptake alone.

Changes to immunisation schedules can also make the social dimensions particularly visible. Moments of change reveal the work that routine hides. When schedules are stable, vaccines may recede into the background of routine care [Forster et al., 2016]. However, these changes, such as the introduction of new vaccines, alterations in timing, or the consolidation of doses, can disrupt established expectations and prompt renewed scrutiny [Gowda and Dempsey, 2013]. In this way, schedule change functions as a moment of reconfiguration, in which decisions about timing, safety, and responsibility must be explained, justified, and actively re-established in practice.

1.2.5 Recent changes to global immunisation schedules

Recent developments in global immunisation policy highlight that changes to vaccination schedules are no longer isolated or exceptional events, but a routine feature of contemporary immunisation programmes. Over the past decade, multiple new vaccines have been introduced into routine programmes across the world, while others are currently under consideration or in phased rollout, requiring ongoing adaptation of schedules across different contexts [World Health Organization, 2020].

One prominent example is the introduction of typhoid conjugate vaccines (TCVs), a newer formulation of the typhoid vaccine recommended for routine use in young children, into routine childhood immunisation programmes in several LMICs. Supported by global health agencies, TCVs have been incorporated into existing schedules in response to rising antimicrobial resistance (AMR) and persistent disease burden [Mugisha, 2025]. Their introduction has required decisions about optimal age of administration, integration with existing visit schedules, and communication with caregivers about a vaccine that differs from earlier typhoid formulations [Gharpure et al., 2024]. Similarly, the recent recommendation and rollout of malaria vaccines, including RTS,S and R21, has introduced new considerations around age targeting, dosing schedules, and programme types, often requiring additional visits or alignment with seasonal malaria transmission patterns [Seidlein, 2025].

Beyond vaccines currently being implemented, candidate vaccines for diseases such as respiratory syncytial virus (RSV), Group B streptococcal (GBS), and cytomegalovirus (CMV) are at advanced stages of development, with potential implications for maternal,

infant, and adolescent immunisation schedules [Thorn et al., 2025, Permar et al., 2025, Deng et al., 2025]. Anticipating how such vaccines might be incorporated into existing programmes underscores the importance of understanding how caregivers respond to repeated and cumulative schedule modifications over time.

Recent policy discussions have explored the use of vaccines in new populations or for new indications—that is, for different diseases or purposes than those for which they were originally licensed—such as the introduction of a gonorrhoea vaccine into sexual health programmes in the United Kingdom [Joint Committee on Vaccination and Immunisation, 2023]. Although delivered outside routine childhood schedules, such changes may unsettle established assumptions about who vaccines are intended for, what level of protection they provide, and how decisions about their use are made.

These developments show that schedule change is not a one-off policy event but an ongoing, cumulative feature of contemporary immunisation programmes. Individuals are increasingly required to interpret multiple, sometimes overlapping, changes to timing, dosing, and target groups as they encounter revised appointment schedules, new eligibility criteria, updated information materials, and altered clinical advice. While each change may be justified on scientific or programmatic grounds, the effect of successive adjustments on expectations, confidence and trust remains under-studied. Understanding perceptions of schedule change, therefore, requires examining both single interventions of schedule change and the longer cycles of adaptation through which programmes evolve.

1.3 Research gap

The preceding sections highlight that immunisation schedules are dynamic sociotechnical infrastructures, routinely subject to adaptation as vaccine science, health systems, and global policy priorities evolve. While these changes are increasingly frequent and programmatically necessary, less attention has been paid to how they are experienced and interpreted by those expected to follow revised schedules. This section identifies key gaps in existing research relating to how vaccine recipients and caregivers perceive, evaluate, and respond to changes in immunisation schedules, with particular attention to perceptions, attitudes, information needs, and acceptability.

1.3.1 Perceptions, attitudes, and acceptability of changes to immunisation schedules

Existing research on vaccination has generated substantial insight into public confidence, hesitancy, and acceptance. Foundational work by Larson and colleagues [Larson et al., 2011, Larson et al., 2014, Larson, 2018] has conceptualised vaccine confidence as a central determinant of uptake, while the SAGE Working Group on Vaccine Hesitancy, led by MacDonald [2015], formalised the definition of hesitancy as a complex and context-specific phenomenon. Subsequent contributions by Dubé et al. [2013] and Betsch et al. [2018] have further elaborated psychological and social determinants of vaccination decisions. Together, this body of work has been instrumental in identifying determinants of vaccine behaviour, including trust in institutions, perceived risks and benefits, and social influences. However, it has tended to prioritise vaccination behaviour and outcomes over how individuals interpret and respond to changes in vaccination programmes over time.

Within this literature, acceptability has become an increasingly prominent concept in the evaluation of health interventions, reflecting recognition that effectiveness depends not only

on clinical efficacy but also on how interventions are perceived and experienced by those who receive them. In the context of vaccination, acceptability has been used to explore factors shaping public and caregiver responses to immunisation, including confidence in vaccine safety, perceptions of necessity, and practical considerations such as access and convenience [Sherman et al., 2023, Abara et al., 2022b, Adhikari et al., 2022, Asmare, 2022]. For example, [Sherman et al., 2023] examine acceptance of varicella vaccination in the UK, while [Abara et al., 2022b] analysed the acceptability of gonorrhoea vaccines in men who have sex with men, and Adhikari et al. (2022a) analysed determinants of uptake for COVID-19 vaccines, with a specific focus on trust. These studies focus on the acceptability of vaccination as a concept, or of particular vaccines, rather than on how individuals interpret changes to the organisational structures through which vaccination is delivered, such as immunisation schedules.

Within immunisation research, much of the literature on acceptability is situated within broader discussions of vaccine hesitancy. This body of work has focused predominantly on decisions to vaccinate or not vaccinate, often operationalised through measures of uptake, delay, or refusal [Hansl and Paul, 2025, MacDonald, 2015]. While this literature has provided valuable insights into patterns of vaccine acceptance and refusal, it has tended to treat acceptance as a relatively stable outcome [Yaqub et al., 2014] rather than a process that may shift over time or in response to programme changes.

Comparatively little attention has been paid to how vaccine recipients and caregivers perceive and evaluate changes to immunisation schedules themselves. Few studies have examined how caregivers perceive changes in vaccine timing, spacing, or combinations, or how such changes are interpreted in relation to existing expectations about vaccination [Seidlein, 2025,

Ladhani et al., 2024]. This represents a notable gap, given that schedule modifications are a routine feature of immunisation programmes as new vaccines are introduced and recommendations evolve.

The limited evidence suggests that caregiver attitudes towards vaccination are sensitive to changes in how vaccines are delivered [Black and Rappuoli, 2010]. Studies examining parental responses to new vaccines, revised dosing schedules, or changes in administration practices indicate that even caregivers who support vaccination may express uncertainty or concern when familiar routines are altered [Shono and Kondo, 2017, Bitariho et al., 2023]. These responses are shaped not only by perceptions of safety and effectiveness but also by practical considerations, trust in decision-makers, and the adequacy of communication surrounding change [Bitariho et al., 2023]. However, such findings remain fragmented across different contexts and are rarely synthesised within a coherent framework focused on schedule change as a distinct object of analysis, marking the need for additional empirical data collection in various contexts, analysed in context of one another.

The literature has also highlighted limitations in relying solely on vaccination coverage as an indicator of programme success [Maamor et al., 2024]. High coverage may reflect strong institutionalisation of vaccination services or limited alternatives, rather than underlying confidence or understanding among caregivers [Eagan et al., 2023, Patel et al., 2023, Forster et al., 2016]. As Anderson and Creanza [2023] demonstrate, vaccine mandates constitute a salient example of this phenomenon, highlighting how high vaccination coverage can be sustained despite considerable vaccine hesitancy. As a result, coverage data may obscure latent concerns that become more visible when immunisation schedules change.

This literature suggests that while vaccination acceptability and perceptions have been widely examined, less is known about how vaccine recipients and caregivers perceive and interpret changes to the structures through which vaccination is organised, particularly immunisation schedules. These responses are shaped not only by prior orientations towards vaccination, but by how change is explained, communicated, and experienced within everyday interactions with health systems. Understanding perceptions and attitudes towards schedule change therefore requires moving beyond hesitancy and confidences based, uptake-based, or vaccine-specific accounts to examine how individuals interpret and negotiate change as it unfolds in practice.

1.4 Chapter summary

Immunisation schedules occupy a distinctive position within vaccination programmes. They are central to the delivery of protection at scale, yet they typically operate in the background of everyday healthcare, becoming embedded within routine practice and taken-for-granted expectations about how and when vaccines are delivered. When schedules remain stable, they support predictability and familiarity for vaccine recipients, caregivers and health workers alike. It is when schedules change that this infrastructure becomes visible, drawing attention to decisions, assumptions, and relationships that are ordinarily obscured by routine.

Changes to immunisation schedules are a routine and necessary feature of contemporary vaccination programmes. Advances in vaccine science, shifts in disease epidemiology, and evolving programmatic priorities necessitate that schedules be regularly reviewed and adapted, which may carry particular significance for individuals affected, precisely because they interrupt established patterns of care. Moments of change, therefore, reveal the

sociotechnical nature of immunisation schedules, bringing into view the ongoing work through which scientific evidence, health system constraints, and everyday routines are aligned.

The literature reviewed in this chapter suggests that acceptance of vaccination cannot be fully understood through measures of uptake alone, particularly in contexts where immunisation is highly institutionalised. Those who support vaccination may nonetheless express uncertainty, caution, or the need for reassurance when familiar schedules are modified. These responses reflect processes of sense-making shaped by experience, social context, and trust in health systems, rather than simple expressions of compliance or resistance. However, despite growing attention to vaccine confidence and hesitancy, comparatively little empirical work has examined how individuals understand and evaluate changes to established immunisation schedules themselves.

This thesis, therefore, focuses explicitly on immunisation schedule change as an analytical object in its own right. It examines how vaccine recipients and caregivers understand and evaluate changes to vaccination timing, dosing, and target populations, and how these interpretations are shaped through everyday encounters with health systems. In doing so, it reconceptualises acceptability not as a fixed attitude toward vaccination, but as a relational process that emerges in moments of programme change. By foregrounding schedule change, the thesis seeks to clarify how change is negotiated within evolving immunisation systems, and to illuminate the social conditions under which programme change is sustained or contested in practice.

1.5 Research aims and objectives

Building on the conceptual and empirical gaps identified above, this thesis is guided by the following research question and objectives.

1.5.1 Primary research question

What are the perceptions, attitudes, and information needs of vaccine recipients and/or their caregivers towards changes in immunisation schedules?

1.5.2 Research objectives

A. Assess acceptability and feasibility: Explore overall acceptability of hypothetical changes to immunisation schedules, including beliefs, concerns, expectations, and feasibility of implementation;

B. Analyse perceptions and attitudes: Examine the perspectives of vaccine recipients and/or their caregivers, towards existing and potential schedule changes;

C. Identify information needs: Investigate what information vaccine recipients and/or their caregivers require to understand, evaluate, and accept potential changes to schedules, and their preferred communication channels and sources.

Objective A is primarily addressed through Chapter 3 and the quantitative components of Chapters 4 and 5, which examine patterns of acceptability and feasibility. Objective B is

primarily addressed through qualitative analyses of perspectives across chapters 3,4, and 5. Objective C is addressed through a focused quantitative and qualitative exploration of information needs and communication preferences in chapters 3, 4 and 5.

1.6 Thesis overview

This thesis examines how vaccine recipients and caregivers perceive, interpret, and respond to changes in immunisation schedules. Situated at the intersection of global public health, medical sociology, and science and technology studies, the thesis approaches immunisation schedules not only as technical delivery tools, but as sociotechnical infrastructures whose stability, disruption, and reconfiguration shape everyday experiences of vaccination. By foregrounding moments of schedule change, the research seeks to illuminate aspects of vaccine acceptance that remain obscured when attention is focused solely on uptake or refusal.

The thesis is structured across seven chapters. Following this introduction, Chapter 2 outlines the theoretical and methodological framework underpinning the research. It situates the study within a constructivist epistemology and interpretivist methodological tradition, recognising that the research seeks to understand how individuals interpret, negotiate, and make sense of changes to immunisation schedules rather than exclusively measure fixed behavioural determinants. This orientation is particularly appropriate for examining processes of uncertainty, trust, and responsibility, which are shaped through social interaction and institutional context. The chapter introduces constructivist grounded theory as the overarching qualitative orientation and explains the rationale for the mixed-methods design adopted across the thesis. Reflexivity, positionality, and ethical considerations are addressed

in detail, reflecting the thesis' commitment to co-constructed knowledge and context-sensitive analysis.

Chapter 3 presents a systematic review of the existing literature on parental and vaccine recipient acceptance of changes to immunisation schedules. Drawing on both qualitative and quantitative studies of various changes to immunisation schedules, the review synthesises evidence on determinants of acceptability, including perceptions of safety, trust in institutions, social influences, and communication practices. The chapter identifies significant gaps in the literature, particularly the limited conceptualisation of schedule change as a distinct object of inquiry, and establishes the empirical and theoretical foundations for the subsequent case studies.

Chapters 4 and 5 present two empirical case studies that explore perceptions of immunisation schedule change in contrasting contexts. Chapter 4 reports findings from a mixed-methods study conducted in Nepal and Uganda, conducted between September 2024 and May 2025, examining parental perceptions and acceptability of hypothetical changes to childhood immunisation schedules. Through quantitative survey data and qualitative interviews, the chapter explores how trust, historical experience, global inequality, and caregiver burden shape responses to schedule modification, highlighting both shared and context-specific dynamics across the two settings.

Chapter 5 shifts focus to a high-income context, examining attitudes and perceptions towards a proposed gonorrhoea vaccine programme, using a repurposed MenB vaccine, among sexual health service users in the UK. The data for this Chapter was collected between April and July 2025. Although situated outside routine childhood immunisation, this case study extends

the analysis of schedule change by exploring how vaccines introduced in new populations and delivery settings are understood and evaluated. The chapter demonstrates how acceptance is shaped by trust, transparency, stigma, and programme design, and illustrates the broader relevance of schedule change beyond childhood vaccination.

Chapter 6 brings together findings from across the thesis in an overall discussion. It synthesises insights from the systematic review and empirical studies to develop a conceptual understanding of immunisation schedule change as a moment of sociotechnical reconfiguration. The chapter examines how acceptance is negotiated through processes of sense-making, conditional trust, and communication, and reflects on the implications of these findings for vaccine policy, programme design, and global health practice.

Finally, Chapter 7 concludes the thesis by summarising the key contributions of the research and outlining implications for future scholarship and policy. It reflects on the significance of treating immunisation schedules as dynamic, socially embedded infrastructures, and argues for greater attention to communication, caregiver experience, and historical context when implementing changes to vaccination programmes. The chapter closes by identifying avenues for further research on the cumulative and long-term effects of repeated schedule adaptation in an era of accelerating vaccine innovation.

2 Methodology

2.1 Introduction

This chapter outlines the theoretical and methodological foundations underpinning this research. It first situates the study within broader epistemological debates concerning how knowledge about vaccination attitudes, hesitancy, and acceptability is generated, and how these framings shape what questions are asked. It then introduces constructivist grounded theory as the overarching framework that informs the design and analysis of the thesis. Finally, it details the research design, including the mixed-methods approach, systematic review, and two empirical studies, and discusses considerations of reflexivity and ethics.

2.2 Epistemological foundation

Vaccine hesitancy has been examined through multiple theoretical lenses, each grounded in different epistemological foundations—that is, different assumptions about what counts as valid knowledge and how it should be produced - within various fields of research, including medical and social sciences. A commonly used framework in vaccine behaviour research is the Health Belief Model (HBM) [Hobani and Alhalal, 2022, Mercadante and Law, 2021, Merkelbach et al., 2023, Reindl and Catma, 2022], which is rooted in a positivist epistemology that assumes attitudes and beliefs can be measured objectively and modelled to predict behaviour.

The HBM explains health behaviours using six cognitive constructs, these are: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy, and

cues to action [Rosenstock et al., 1988]. They aim to provide a structured framework for understanding why individuals choose to vaccinate or not, and have proven useful in predicting COVID-19 vaccine hesitancy [Limbu et al., 2022], understanding the reasons why healthcare workers accept (or refuse) influenza vaccines [Silva et al., 2023], and examining parental attitudes and beliefs about childhood vaccination [Dyda et al., 2020]. However, while this model has been widely applied, it has limitations. A focus is placed on rational individual decision-making, and as such, often overlooks the social, cultural, and emotional influences that often shape health behaviours [Thompson and Harrington, 2021], exemplifying the challenges of relying solely on a positivist framework to interpret vaccine hesitancy, where decisions are frequently influenced by wider contextual factors beyond individual cognition.

2.2.1 Positivism

Positivism generally assumes that reality exists independently of human perception and can be understood through empirical observation and logical reasoning [Crotty, 1998]. This paradigm treats knowledge as objective, measurable, and discoverable, assuming that understanding of a topic arises through systematic observation and replicable experimentation. As such, it underpins much of the dominant thinking in biomedical research, particularly in the form of quantitative methodologies that strive for control, prediction, and generalisability. In line with this epistemological stance, scholars working with a positivist approach typically rely upon quantitative methods to measure and analyse observable data, aiming to discover generalised laws and principles that explain and predict phenomena [Creswell and Creswell, 2017].

In medical research, positivism has long served as the dominant epistemological paradigm. This paradigm champions the use of quantitative tools, with larger sample sizes, such as randomised controlled trials (RCTs), systematic reviews, and meta-analyses. RCTs, often regarded as the 'gold standard' of evidence-based medicine, are designed to establish causal relationships by isolating variables, eliminating bias, and minimising confounding factors. Similarly, systematic reviews and meta-analyses synthesise large bodies of empirical data to identify consistent patterns or treatment effects, offering a high level of confidence in findings that can inform public health policies and clinical guidelines.

Yet such methods may not be suited to exploring other questions arising from biomedical intervention, such as how vaccine decisions are shaped by lived experience, or how does historical trust in institutions impact intervention uptake, both of which generally lie outside the frame of quantifiable variables. This highlights a limitation of positivist models when applied to complex public health challenges that are not solely biomedical, but deeply social and relational.

In social science applications of positivism, these methodological ideals remain influential. Positivist social research is often guided by the assumption that social reality can be objectively observed and measured through the isolation of variables within standardised conditions [Cohen et al., 2018]. To achieve this, researchers may construct artificial or highly controlled environments that minimise extraneous influences. Within this framework, knowledge is considered valid when it can be generalised, replicated, and used to confirm or refine theoretical models through systematic testing [Park et al., 2020]. These methodological expectations, however, can be limiting when the phenomena under investigation are interpretive or relational, as is the case with vaccine hesitancy, where meanings attached to

vaccination are shaped by various factors, including, social context, historical experience, and discursive practices rather than variables that can easily be isolated [Bedford et al., 2018, Dubé et al., 2013, Larson, 2018, Larson et al., 2022].

Elements of positivist methodology are employed pragmatically throughout this thesis. Chapter 3 follows established systematic review procedures (e.g., PRISMA) to synthesise published evidence transparently and reproducibly, while Chapters 4 and 5 include quantitative survey components using structured instruments and Likert-scale measures to examine patterns in attitudes toward immunisation schedule change. These components draw on positivist assumptions of measurement and comparability to identify distributions and trends at scale. However, they are integrated within an interpretive framework, and their findings are brought into dialogue with qualitative data at the level of analysis rather than treated as definitive or hierarchically superior forms of knowledge.

2.2.2 Constructivism

Conversely, social science research often draws on constructivist and interpretivist epistemologies, which emphasise the role of social, cultural, and historical contexts in shaping knowledge [Crotty, 1998, Green and Thorogood, 2018]. A constructivist epistemological orientation is particularly well-suited to the social study of vaccines. Decisions about vaccination are rarely reducible to calculations of biomedical risk or rational utility. A constructivist lens treats these social dimensions as constitutive elements of the phenomenon itself [Berger and Luckmann, 1967, Bedford et al., 2018, Dubé et al., 2013, MacDonald, 2015].

Vaccine hesitancy, for example, is therefore approached as a socially situated practice grounded in meaning-making, identity, and context. Within this orientation, constructivist grounded theory provides an appropriate methodological framework, as it enables examination of how meanings are formed, negotiated, and revised over time [Charmaz, 2014]. Grounded theory attends to processes of uncertainty, ambivalence, and negotiation, allowing vaccine decision-making to be analysed as evolving and context-dependent.

Methods such as qualitative interviews, ethnography, and discourse analysis allow researchers to examine how individuals and communities perceive vaccines as a socially and culturally situated practice [Green and Thorogood, 2018]. Constructivist epistemology, therefore, challenges the foundational assumptions of positivist inquiry. Rather than viewing knowledge as something that exists independently of the knower and awaits discovery through neutral observation [Piaget et al., 1969], constructivism understands knowledge as actively produced through engagement with the world. This epistemological stance is underpinned by a relativist ontology, which holds that reality is not singular, fixed, or objective, but multiple and socially constructed. What is taken to be ‘true’ or ‘factual’ is therefore contingent upon interpretive frameworks and socio-historical context [Berger and Luckmann, 1967, Guba and Lincoln, 1994].

Within this paradigm, the researcher is not positioned as a detached or value-neutral observer, but as an active participant in the co-construction of knowledge. Research becomes an interpretive act, shaped by the interaction between the researcher and the researched, and inherently bound up with questions of power, perspective, and positionality. This requires reflexive awareness of how the researcher’s assumptions, positionality, and power shape both data generation and interpretation [Bourdieu and Nice, 1990, Finlay, 2002b].

2.2.3 Interpretivism

Like constructivism, an interpretivist approach is also particularly relevant to the social study of vaccines, as interpretivist methodologies allow the researcher to examine these meanings in context, not assuming coherence or consensus, but attending to ambivalence, contradiction, and pluralism in how vaccine decisions are made and rationalised. Interpretivism builds on the foundations of constructivism by emphasising that human experience must be understood from within, through the subjective perspectives and situated contexts of those who live it. It shares with constructivism the view that reality is not external and fixed, but multiple, fluid, and socially constructed [Schwandt, 1994]. From this perspective, the social world is constituted through interpretive acts—the ways in which people ascribe meaning to events, relationships, institutions, and practices. It therefore privileges subjective understanding, context-specific explanation, and the emic (insider) perspective over universal theories or etic (outsider-imposed) categories [Schwandt, 1994, Harris, 1976]. As such, it also challenges the assumption that social phenomena can be fully explained through standardised variables or predictive models.

The researcher, in both constructivism and interpretivism, is understood as an active participant in the knowledge production process, interpreting, filtering, and shaping meaning through their engagement with the research context, rather than as an objective instrument [Finlay, 2002b, Guba and Lincoln, 1994, Pope and Mays, 2019]. And so, reflexivity is central to interpretivist inquiry, requiring researchers to remain attentive to how their assumptions, identities, and positionality shape both the research process and the interpretation of findings [Denzin and Lincoln, 2018, Charmaz, 2014].

In this thesis, constructivism and interpretivism are not treated as competing positions, but as operating at different levels of the research process. Constructivism provides the

epistemological foundation of the study, informing how knowledge is understood. Interpretivism follows from this position methodologically, guiding how such knowledge is explored in practice. Because meanings around vaccination are understood as context-dependent and shaped by lived experience, the study employs interpretivist methods that prioritise participants' own accounts and the researcher's role in interpreting these meanings. In this sense, interpretivism reflects the practical implications of a constructivist epistemology, shaping how data are generated, analysed, and reflexively engaged with throughout the research.

2.2.4 Epistemological pluralism

No single epistemology or paradigm can exclusively support the concept of vaccine hesitancy. Yet integrating these contrasting epistemologies poses challenges, particularly in interdisciplinary research that seeks to apply social science methodologies in medical contexts.

These tensions are not easily resolved, but they offer an opportunity to develop a richer, more pluralistic understanding of health behaviour. Acknowledging that no single epistemology can capture the full complexity of vaccine decision-making, this thesis primarily adopts a constructivist stance while remaining attentive to the contributions of positivist research. It recognises that such models are valuable in producing population-level data and clinical insights, yet also that such data must be interpreted within the socio-cultural matrices through which people make decisions.

This epistemological orientation aligns with Charmaz's (2006) constructivist grounded theory approach, which assumes that both data and meaning are co-constructed between researchers and participants. It provides a philosophical foundation for the study's methodological

design, which seeks to move beyond individual-level cognitive models to incorporate broader sociocultural and institutional contexts. Constructivist grounded theory enables an inductive and iterative process in which theory emerges through deep engagement with empirical data and continuous reflection on the researcher's role within the knowledge production process.

Ultimately, this approach allows the study to investigate vaccine schedule acceptance not as a static psychological barrier or individual deficit, but as a fluid, contested, and socially embedded process These frictions between positivist, constructivist and interpretivist paradigms form the foundation for this study's methods, outlined in each chapter.

2.3 Constructivist grounded theory approach as a framework

This thesis adopts a constructivist grounded theory approach as the primary qualitative analytical framework. Grounded theory was originally developed to support the inductive generation of theory from empirical data [Glaser and Strauss, 1967]. This study draws specifically on Charmaz's [2014] constructivist approach, by treating data, analysis, and theory as interpretive products shaped through interaction between researcher and participant, embedded within specific social and institutional contexts, and developed through reflexive engagement with the researcher's own assumptions, positionality, and analytic decisions.

Analytically, constructivist grounded theory involves an iterative process in which data collection and analysis proceed concurrently. Initial coding remains close to participants' language, with constant comparison used to refine and relate emerging categories across cases and contexts [Charmaz, 2006, Charmaz, 2014]. Memo-writing about context, ones own assumptions, or emerging themes supports analytic development and provides a transparent record of theoretical and reflexive decision-making [Charmaz, 2006, Charmaz, 2014]. Sensitising concepts introduced in the following section were engaged with selectively to

enhance theoretical sensitivity, without constraining coding or predetermining analytical outcomes [Hoonaard et al., 2008].

The aim of this approach is not to produce a formal or universally generalisable theory of vaccine behaviour, nor to reconcile different forms of evidence within a single explanatory model. Rather, constructivist grounded theory provides a systematic yet flexible framework for developing theory grounded in participants' accounts, offering an analytically robust explanation of how vaccine perceptions and attitudes are produced, negotiated, and experienced within specific settings during a specific point in time [Pope and Mays, 2019]. The theoretical contribution developed through this process is conceptual rather than predictive. This qualitative framework operates alongside, rather than subsuming, other methodological approaches used in the study, reflecting the epistemological pluralism that characterises research in this area.

While constructivist grounded theory provides the overarching analytical framework for this thesis, individual empirical chapters employ thematic analysis as a practical analysis tool [Braun and Clarke, 2006]. This reflects a distinction between grounded theory as a logic of inquiry and thematic analysis as an analysis technique. Thematic analysis was used to organise and present findings in a transparent and accessible way, particularly as the empirical chapters integrate qualitative and quantitative data, address specific empirical questions, and are standalone studies in their own right. However, this does not represent a departure from a grounded theory orientation.

Coding, categorisation, and theme development were conducted iteratively, with constant comparison. Themes presented in the empirical chapters function as analytically developed categories rather than as descriptive summaries. They were refined through iterative discussion of how themes operated within broader contextual conditions, including

differences between country settings, health system environments, and historical or cultural factors shaping interpretation, consistent with grounded theory principles. Importantly, the use of thematic analysis at the chapter level reflects the structure of the thesis rather than the abandonment of inductive theory-building. While findings are presented thematically, the overall discussion (Chapter 6) integrates these themes into a conceptual account of how acceptability is produced and negotiated in the context of immunisation schedule change. So, grounded theory operates across the thesis as an analytic orientation guiding interpretation and synthesis. This approach is consistent with constructivist grounded theory's emphasis on flexibility and theoretical sensitivity, allowing analytic strategies to adapt to different datasets while maintaining cumulative conceptual development [Charmaz, 2006]. The resulting conceptual framework therefore emerges across chapters through iterative engagement with data and is displayed Chapter 6.

2.4 Theoretical orientation

This thesis recognises that understanding vaccine hesitancy requires bridging individual-level cognitive models and broader sociocultural theories. While the Health Belief Model provides a useful conceptual scaffold, it does not account for how trust, risk perception, and collective meaning-making influence vaccination decisions.

To address this, concepts such as Risk Society [Beck, 1992], infrastructure and classification systems [Bowker and Star, 1999], street-level bureaucracy [Lipsky, 2010], and literature regarding 'trust'[Gilson, 2003, Möllering, 2006] were drawn upon as sensitising concepts [Blumer, 1954], offering an initial framework to consider potential influences without constraining analysis [Hoonaard et al.]. These ideas help contextualise emerging patterns, ensuring that vaccine acceptance is understood not just as an individual behaviour but as part of broader societal and structural dynamics.

These concepts are particularly relevant to the social study of vaccines because they foreground the broader social conditions under which health-related decisions are made in late modern societies. Beck's notion of risk society [Beck, 1992] draws attention to how contemporary risks, particularly those linked to science, technology, and governance, are experienced as uncertain, contested, and subject to public debate, rather than as purely technical matters resolved by expert authority. This perspective helps sensitise the analysis to participants' expressions of doubt, mistrust, and ambivalence toward vaccines as products of wider social anxieties about expertise, responsibility, and institutional credibility.

In addition, scholarship on infrastructure and classification systems [Bowker and Star, 1999] informed attention to how immunisation schedules operate as organisational devices that stabilise categories, timing, and responsibility within routine practice. Their work sensitised the analysis to moments in which such infrastructures become visible through disruption, helping frame schedule change as a point at which normally backgrounded assumptions are rendered explicit. The concept of street-level bureaucracy [Lipsky, 2010] also provided an interpretive lens for understanding how policy is mediated in practice through frontline health workers, who act as intermediaries between institutional decision-making and everyday encounters. This perspective supported attention to discretion, translation, and implementation at the point of care. Finally, health systems scholarship on trust [Gilson, 2003] and sociological accounts of trust as processual and contingent [Möllering, 2006] sensitised the analysis to how trust is produced, maintained, and sometimes strained within relationships between caregivers, providers, and governing institutions. These frameworks supported the analytical distinction developed later in the thesis between trust and dependency.

Used in this way, the sensitising concepts do not function as explanatory frameworks imposed on the data, but as interpretive resources that help situate emerging patterns within broader societal and structural dynamics. They support an analysis that moves beyond individual-level cognition to consider how meanings are shaped at the intersection of personal experience, institutional trust, and contemporary social conditions, while remaining grounded in participants' accounts. The research questions of this thesis are thus designed to elicit participants' own interpretations of vaccine decision-making, in keeping with the study's constructivist epistemology and inductive grounded theory approach.

2.5 Research design

A mixed methodology research approach was adopted for this research study, where both qualitative and quantitative research methods were used to provide a thorough examination of the research questions. The decision to employ a mixed methods approach stems from the acknowledgement of the complementary strengths of each methodology and epistemological pluralism as discussed previously. The strengths of combining qualitative and quantitative methods surround the synergies between the two methodological foundations. Greene et al. [1989] described the key purposes of mixed methods design as being triangulation, complementarity, development, initiation, and expansion, to enhance the understanding and scope of the results.

Triangulation is employed in this thesis an interpretive sense rather than a confirmatory sense. Rather than using one method to validate the findings of another, qualitative and quantitative data are brought into dialogue at the level of interpretation [Greene, 2007], reflecting the epistemological pluralism that underpins the study. Different forms of evidence are examined in relation to one another without presuming convergence, equivalence, or methodological

hierarchy, allowing complexity and ambivalence in responses to immunisation schedule change to be retained rather than resolved. For example, survey findings indicating high overall support for vaccination are interpreted alongside qualitative accounts that reveal uncertainty about specific schedule changes, allowing acceptance and ambivalence to coexist analytically rather than being collapsed into a single metric.

Complementarity underpins the overall structure of the thesis. The quantitative components identify patterns in attitudes toward immunisation schedule change across populations in Nepal, Uganda, and the UK, while the qualitative components explore how those attitudes are shaped by trust, caregiving responsibilities, historical experience, and perceptions of institutional legitimacy. In this way, complementarity enables the thesis to examine both the distribution of responses and the processes through which they are formed.

Elements of development are evident in the iterative relationship between the quantitative and qualitative components. Insights generated through quantitative analysis informed the focus of the qualitative aspect, including the refinement of interview topic guides and follow up questions to explore issues arising from survey responses. This ensured that the qualitative component engaged directly with patterns identified in the quantitative data, while remaining open to emergent themes.

Initiation is reflected in instances where findings from the two components diverge or sit in tension. Rather than treating such divergences as methodological inconsistencies, they are used as analytic prompts that support a more critical examination of how acceptability is constructed and expressed in practice. Finally, expansion is achieved by extending the scope of the analysis beyond what could be addressed through a single method. While the quantitative component

provides breadth by identifying patterns across the study population, the qualitative component expands the analysis to incorporate social, relational, and experiential dimensions of vaccine decision-making.

Numerous scholars have utilised mixed methodologies to examine the complex interplay between vaccine perceptions and attitudes, leading to academic outputs, policy recommendations, and interventions to increase vaccine uptake [Tefera and Assefaw, 2022, Alasmari et al., 2022, Bitariho et al., 2023]. The strengths of qualitative methods lie in their ability to uncover in-depth narratives, often surrounding an individual's personal experience, meaning and perspective [Hammarberg et al., 2016].

Qualitative research heavily relies on the interpretation of data, but many researchers acknowledge the impossibility of complete objectivity, as that interpretation will always be informed by the bias of the researcher. However, the suggested alternative is that the notion of 'permeability' should be adopted instead, where the researcher's understanding of a notion develops, as the research develops. Good practice seeks to document this development of understanding within the write-up of interpretation [Stiles, 1999, Khatwani and Panhwar, 2019]. To better the practice of using qualitative methods, and to increase the rigour of the overall research, Finlay [2002a] stated that researchers should be reflexive throughout the research process to account for how their influence or bias impacts the study. Specifically, thought should be put into "personal, interpersonal, methodological, and contextual" [Olmos-Vega et al., 2023 pg. 241] issues that may arise based upon a personal bias of the researcher.

In this thesis, mixed methods are employed across three interconnected components: a systematic review and two empirical case studies conducted concurrently. These components

address different dimensions of vaccine decision-making and are brought into dialogue at the level of interpretation. While a constructivist grounded theory approach provides the overarching qualitative orientation of this thesis, the specific analytic approaches vary across chapters to remain fit-for-purpose given differing aims, data types and conventions. Chapter 3, the systematic literature review, follows Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidance and uses the Mixed Methods Appraisal Tool (MMAT) to ensure transparent, reproducible synthesis and quality appraisal of the literature; these tools are procedural and support rigorous evidence-synthesis rather than signalling an overall positivist epistemology for the thesis. Chapters 4 and 5 combine quantitative survey analysis (used to map the distribution of attitudes and information needs) with qualitative interviews. The quantitative analyses provide breadth and patterning, while the qualitative interview data are analysed using reflexive thematic analysis, drawing on Braun and Clarke [2006], an approach explicitly compatible with constructivist and interpretivist sensibilities. Constructivist grounded theory informs the overall study's inductive orientation, reflexivity, and attention to process; thematic analysis is deployed where practical, transparent identification of patterns across interview datasets best serves the research questions. Integration therefore occurs at the level of interpretation: different analytic tools were chosen because they best address the distinct empirical aims of each chapter, and findings are synthesised interpretively rather than forced into a single analytic procedure.

2.6 Reflexivity and researcher positionality

Reflexivity formed an integral part of this research, consistent with Charmaz [2014] constructivist grounded theory approach, which positions data and meaning as co-constructed between researchers and participants. My positionality as a researcher is shaped by an

interdisciplinary background that bridges global health, social science, and communication. Before commencing this DPhil, and throughout the DPhil, I worked in global health communication, leading engagement and dissemination within vaccine development programmes at the Oxford Vaccine Group. This included leading public-facing vaccine campaigns, shaping messaging around emerging trial results, facilitating media engagement, and contributing to how scientific findings were translated for policymakers and broader audiences. Through this work, I gained insight into the structures, priorities, and communicative cultures of biomedical research, while also being embedded within institutional processes that help shape how vaccines are represented in public discourse.

These experiences offered both strength and potential bias. My professional employment by a public-health institution could, if unacknowledged, incline me toward biomedical framings of vaccine decision-making. To address this, I adopted a reflexive stance throughout the research process, using memo-writing and iterative reflection to document assumptions, interpretive choices, and responses to data. This practice aligned with the constructivist principle that understanding evolves through continuous engagement with participants, collaborators, and context.

2.6.1 Collaboration with research assistants

Collaboration with research assistants (RAs) across all components of this research was central to its epistemological orientation and ethical integrity. It contributed significantly to epistemic diversity, interpretive rigour, and capacity strengthening, particularly in cross-cultural and interdisciplinary contexts. Rather than viewing RAs as logistical support, these

collaborations were conceived as sites of mutual learning, co-construction of meaning, and long-term professional development.

In the systematic review, RAs (Elizabeth O'Mahony, Niamh Hunniford, Karen Kelleher, Samantha White) and my supervisors (Samantha Vanderslott, Sam Martin) contributed to study screening, inclusion decisions, and theme verification, offering critical reflections on interpretation and helping to reduce the influence of my own assumptions. A subject-specific librarian (Matthew Henry) supported with constructing the Boolean search string. These collaborations demonstrated in practice how knowledge is co-constructed through dialogue, with multiple viewpoints generating richer interpretations than any single analyst could achieve alone.

In Nepal (Neha Kumari Das, Erina Khatri), and in Uganda (Maria Teddy Ndagire, Esther Awino, Georgina Nabaggala) were not only central to data collection and transcription, but also to early-stage analysis and contextual interpretation. In particular, the collaboration in Nepal evolved into a particularly meaningful and sustained process of capacity building and infrastructure development. I worked closely with two research teams based in distinct field sites that had no previous history of conducting social science research. Recognising the absence of qualitative research infrastructure, I led the design and delivery of tailored, in-country workshops on qualitative methods, including semi-structured interviewing, thematic coding, constructivist grounded theory, and reflexive practice, with an underlying practical element of embedding this work within a medical science context. This work was supported by a senior social science researcher in Nepal (Bipin Adhikari).

These training sessions were interactive, grounded in local research contexts, and well-received beyond my immediate research team, drawing interest from a broader set of institutional colleagues. Alongside these structured workshops, I provided ongoing mentorship to the RAs, including joint analysis, regular debrief sessions, memo-writing guidance, support with interpreting and presenting findings, and guidance in creating their own project proposals for research they would like to conduct in the future. This long-term, embedded engagement was designed to support the development of sustainable local research capacity. In doing so, I sought to challenge extractive models of global health research by fostering collaborative ownership, capacity building, and long-term relationship building.

In the UK MenB case study, the RA (Sophia Wilkinson) brought valuable expertise in vaccine communication, sexual health, and community engagement. Their contribution introduced a distinct interpretive lens that helped surface nuances I may not have otherwise recognised. Drawing on their practice-based insight enabled a richer understanding of how vaccination is experienced within everyday societal contexts. This collaboration also supported the RA's development from facilitator to researcher, a shift that involved building confidence with interpretive methods and theoretical framing. I provided training and guidance on coding, epistemological reflexivity, and the principles of thematic analysis. This experience reaffirmed and highlighted the generative potential of cross-boundary collaboration between practice and academia.

Across all three case contexts, I sought to uphold a model of equitable, developmental, and relational research. This involved recognising RAs as co-analysts, educators, and learners in their own right. Practices such as collaborative theme development, iterative feedback loops,

and transparent documentation of interpretive decisions helped ensure shared ownership and accountability throughout the research process.

2.6.2 Personal reflexivity

Finally, my position as a UK-based researcher conducting global health research from within a historically privileged institution, the University of Oxford, required sustained engagement with the structural, institutional, and epistemic asymmetries that underpin transnational research. I approached positionality as an iterative practice, shaped by my shifting roles across disciplines, institutions, and contexts, and informed by the recognition that research does not occur in a vacuum but within long-standing histories of power and knowledge production.

These considerations were particularly salient in Nepal and Uganda, where the history of foreign-led research—often biomedical in focus—has shaped what is legitimatised as knowledge. My role included facilitating recognition, both institutionally and among funders, of social science methodologies as valid and essential forms of research within global health. This required advocating for the value of qualitative approaches in environments where biomedical models have historically dominated research agendas and funding priorities.

This involved designing and delivering training in sites where social science infrastructure was still emerging, and initiating dialogues about the relevance of narrative, context, and meaning-making in public health. These experiences forced me to engage critically with the question of what counts as knowledge, and, who gets to decide. Historically, global health has privileged universalising, decontextualised, and statistically generalisable knowledge.

Within such traditions, the situated knowledge of communities, especially their histories, memories, and cultural interpretations, has frequently been dismissed as anecdotal, or outside the scope of 'evidence-based' frameworks. Yet, as this thesis demonstrates, individual voices and localised knowledge are not peripheral to understanding vaccine acceptance or immunisation behaviours.

Engaging with these perspectives required practising what has been described as 'epistemic humility': a willingness to sit with uncertainty, to acknowledge the limits of my own conceptual frameworks, and to, as a priority, make room for knowledge that is locally grounded, and at times, incommensurable with dominant public health narratives [Matthews, 2006]. It also demanded an appreciation of knowledge pluralism: the view that multiple, overlapping, and sometimes conflicting forms of knowledge can coexist, and that these tensions are not only inevitable but productive for a more inclusive and just form of inquiry [Santos, 2014].

These commitments also shaped how I understood my own role as a researcher. While earlier sections of this chapter have addressed the operational dimensions of collaboration, here I reflect on a deeper shift, from the role of disciplinary expert to that of facilitator, listener, and bridge-builder. This included redistributing interpretive authority, sharing authorship, and building sustainable research capacity in ways that challenged the extractive logics still embedded in much of global health. It also involved taking seriously the idea that research is not a neutral process, but a relational and political act, one that must be accountable to the communities it engages. I have sought to contribute not only to the understanding of vaccine acceptance, but also to the ongoing reimagining of how knowledge is produced, valued, and mobilised, and by whom, within global health research.

2.7 Ethical considerations

All work was conducted in accordance with the University of Oxford's research ethics procedures, following 'best practices' where available, and the national or institutional review requirements of partner organisations in Uganda and Nepal. Specific ethical approvals, consent processes, and data management procedures are described in detail within each empirical chapter. For the systematic review, ethical responsibility centred on transparency, accurate representation of existing studies, and mitigating potential bias in interpretation. The collaborative screening and synthesis process was designed to ensure fairness, reduce selective emphasis, and represent the breadth of perspectives within the literature.

For the empirical studies, informed consent, confidentiality, and voluntary participation were central. Participant information was provided in accessible and culturally appropriate formats, and consent was obtained in writing according to local expectations. Data were stored securely on encrypted institutional servers (in-country, for studies based in Uganda and Nepal) in compliance with GDPR and the University of Oxford's Research Data Management Policy.

In the Uganda and Nepal fieldwork, ethical engagement included equitable collaboration and capacity strengthening. Local research assistants were integral to data collection and analysis, ensuring cultural and linguistic sensitivity while enhancing local research capability and confidence. This approach reflected a commitment to ethical partnership, addressing potential

power imbalances between institutions in the Global North and South and aligning with decolonising principles in global health.

Ethical reflection was ongoing throughout the research process. Regular team discussions, debriefs, and wider meetings supported the identification and resolution of emerging ethical challenges, such as managing participant vulnerability or differing cultural norms around consent. Ethical approvals for each study, including reference numbers and country-specific procedures, are detailed in Chapters 4 and 5.

2.8 Methodological limitations

This study is subject to a number of methodological limitations. In line with a primarily constructivist and interpretivist orientation, these limitations are acknowledged reflexively as shaping the kinds of knowledge that can be produced, rather than as deficiencies to be corrected.

2.8.1 Epistemological and theoretical limitations

First, the thesis is grounded in a primarily constructivist epistemology yet employs interpretivist qualitative methods alongside quantitative approaches. As such, it does not seek to produce objective or universally generalisable claims about vaccine acceptability or immunisation schedule change [Pope and Mays, 2019]. Instead, it generates situated, context-dependent insights into how perceptions, attitudes, and information needs are constructed and negotiated within specific social, cultural, and institutional contexts.

The constructivist grounded theory developed through this research is therefore conceptual rather than predictive. The thesis offers an analytically robust account of processes and patterns of meaning-making, but does not claim to identify stable causal mechanisms or to predict behaviour across populations or settings. While sensitising concepts such as risk society and individualisation informed theoretical sensitivity, these frameworks were not tested or operationalised in a positivist sense, limiting the extent to which findings can be aligned with explanatory or predictive models commonly used in biomedical research.

2.8.2 Limitations of constructivist grounded theory

Although constructivist grounded theory provides a systematic and flexible analytical framework, it also entails specific constraints. The co-construction of data and meaning between researcher and participants means that findings are shaped by the researcher's interpretive lens, positionality, and analytic decisions [Pope and Mays, 2019]. While reflexive practices, memo-writing, and collaborative analysis were employed to enhance rigour and transparency, interpretation remains situated and partial.

Additionally, grounded theory prioritises depth of understanding over breadth. As a result, the study captures complexity, ambivalence, and contradiction in participants' accounts, but cannot claim saturation across all possible perspectives on immunisation schedule change. Some voices, for example, those of individuals with more marginal or extreme positions, or those geographically more isolated, may be underrepresented, especially where participation was influenced by trust in health systems or research institutions.

2.8.3 Mixed-methods integration and interpretive tensions

The mixed-methods design adopted in this study was intentionally pluralistic, with qualitative and quantitative components brought into dialogue at the level of interpretation rather than used to validate one another. While this approach enables a richer and more nuanced understanding of vaccine decision-making, it also limits claims of convergence or corroboration across methods.

Instances where quantitative findings suggest high levels of acceptability, while qualitative data reveal conditional, hesitant, or provisional acceptance, highlight the interpretive nature of attitudinal measures. Such divergences are analytically valuable but also mean that the study does not produce a single, unified account of acceptability. This limits the extent to which findings can be translated directly into simplified policy metrics or threshold-based decision tools.

2.8.4 Contextual and case-based limitations

The empirical components of this research are based on a systematic review and two case examples conducted in the UK, and Uganda and Nepal, each focused on specific vaccines, populations, or moments in time. These contexts are shaped by distinct health systems, histories of vaccination, political environments, and levels of institutional trust. Consequently, findings should be understood as contextually situated rather than broadly representative of vaccine recipients globally.

Furthermore, attitudes towards immunisation schedules are likely to shift over time in response to emerging diseases, policy changes, media narratives, and personal experience. The study captures perceptions at particular points in time, limiting its ability to account for longitudinal change or evolving responses to future vaccination programmes.

2.8.5 Practical and logistical constraints

Finally, practical constraints associated with conducting research across multiple countries and languages introduce additional limitations. The use of research assistants for data collection and translation, while essential for ethical and contextual engagement, introduces an additional layer of interpretation between participant and researcher. Despite training, collaborative analysis, and verification processes, some nuances of language, affect, or cultural meaning may have been lost or transformed in translation.

In addition, parts of the research relied on participants' responses to hypothetical changes in immunisation schedules. While this approach was necessary to explore perceptions of future or proposed interventions, hypothetical scenarios may not fully capture how individuals would respond in real-world contexts where decisions are shaped by immediate risk, social pressure, or practical constraints.

Overall, these limitations indicate that the findings of this study are best understood as offering conceptual, contextualised insight into vaccine decision-making and acceptability of schedule changes, rather than definitive or predictive conclusions. However, these same limitations also constitute the study's analytical strength, enabling a nuanced examination of

how acceptability and hesitancy are produced, negotiated, and held in tension within specific social and institutional contexts.

3 Parental and recipient perceptions of changes to childhood immunisation schedules: A systematic review

3.1 Introduction

This chapter examines how existing research has documented perceptions and attitudes to changes in immunisation schedules. While schedules are routinely modified as new vaccines are developed, existing vaccines are reformulated or combined, diseases in circulation change, and programme priorities change, less attention has been paid to how such changes are understood and received by vaccine recipients and caregivers. Although a substantial body of literature examines public attitudes towards vaccination, evidence relating specifically to perceptions of schedule change remains dispersed across contexts and has not previously been synthesised.

Two previous systematic reviews focus on changes to immunisation schedules. The first, conducted by Patikorn et al. [2023], examines the implementation challenges and real-world impact of 'switching' paediatric vaccines across various low-,middle-, and high income countries. In this case, 'switching' vaccines refers to substituting one vaccine for another directed at the same purpose—but differing in attributes such as antigenic profile, formulation, presentation format, or manufacturer—for example, the transition from whole-cell to acellular pertussis vaccines or from oral to inactivated poliovirus vaccines. Patikorn et al. [2023] reported that although such switches were essential to align with WHO recommendations and improve safety or supply stability, they were often accompanied by operational and communication challenges, including logistical adjustments, staff retraining, and temporary declines in public confidence. Vaccine acceptability emerged as a key

concern: both parents and healthcare professionals expressed hesitation, with some vaccine-hesitant parents delaying or refusing vaccination for their children. The authors concluded that clear communication and education about the rationale and safety of vaccine switches are vital to maintaining public trust and ensuring smooth implementation [Patikorn et al., 2023].

The second, by Hyde et al. [2012], examines the impact of new vaccine introduction on countries' immunisation and broader health systems, predominantly in high income countries. The review found that while new vaccines often strengthened system components such as surveillance, logistics, cold-chain infrastructure, and programme visibility, they could also strain existing workforce and supply capacities during implementation. Hyde et al. [2012] further highlighted the importance of advance planning, coordination, and communication with stakeholders, noting that limited engagement sometimes constrained the smooth integration of new vaccines into routine schedules

Other systematic reviews have focused on perceptions around specific vaccines or infectious diseases [Gottvall et al., 2011, Gallagher et al., 2016], outbreak programmes [Bish et al., 2011], or parental knowledge, perceptions and attitudes towards vaccination schedules generally, rather than examining perceptions in relation to changes to those schedules [Alabadi and Aldawood, 2020]. While valuable, these reviews have not addressed the broader concept of perceptions and attitudes towards changes in immunisation schedules. Accordingly, this review synthesises global evidence on how parents, caregivers, and vaccine recipients perceive and respond to changes in childhood immunisation schedules.

To address this overarching aim, the review explored three specific questions:

1. What are the perceptions and attitudes of vaccine recipients and/or their parents towards changes in childhood immunisation schedules?
2. What factors influence these attitudes among vaccine recipients and/or their parents regarding childhood immunisation?
3. What are the information needs of vaccine recipients and/or their parents concerning childhood immunisation schedules?

By addressing these dimensions, the review seeks to examine perceptions and attitudes towards schedule change, and to inform strategies for effective communication and policy design.

3.2 Methods

3.2.1 Search strategy and inclusion criteria

This systematic review was registered on the PROSPERO database (CRD42024598275) and was conducted in accordance with the PRISMA 2020 guidelines [Page et al., 2021] (Appendix 1). Peer-reviewed studies were included if they examined the perceptions or attitudes of vaccine recipients, or their parents, of changing of childhood immunisation schedules. For this review, "changes to childhood immunisation schedules" were defined as adaptations or hypothetical adaptions to a country's approved immunisation schedule for individuals under the age of 18 years.

To ensure the inclusion of only contemporary and relevant findings, the review was restricted to studies published between 2013 and 2024. This timeframe was selected to capture insights reflecting recent changes in immunisation policies, public health practices, and evolving

societal attitudes towards vaccinations. Only studies published in English were included due to the language abilities of the screening team. while this may limit global representation, it ensured accurate interpretation and analytic rigour.

Studies focusing on adult vaccinations or attitudes towards specific vaccines, without reference to an immunisation schedule amendment, were excluded. Studies that focused on non-immunisation programme vaccines, or supplementary or outbreak vaccine programmes were also excluded to maintain the focus on routine immunisations, that is, vaccines delivered as part of the nationally recommended schedule at specified ages to provide ongoing protection against common infectious diseases.

Commentaries, conference abstracts, reviews, and grey literature without primary data were excluded to ensure that findings were derived from empirical research subject to peer review and methodological transparency. This decision was intended to prioritise analytic depth across studies, while avoiding reliance on interpretive or opinion-based sources not grounded in systematically collected data, and to ensure there was enough data in the source to extract. Full criteria can be found in Table 1.

Table 1. Systematic review inclusion and exclusion criteria

Criterion	Inclusion	Exclusion
Population	Vaccine recipients aged ≤18 years and their parents or caregivers	Adults (>18 years) or studies of adult vaccination only
Focus / Exposure	A change (actual or hypothetical) to a childhood immunisation programme	Studies of vaccines or schedules without reference to a change
Programme change types	Change in vaccine product (e.g., switch from Gardasil to Gardasil 9); change in timing or interval; change in number of doses per visit; change in number of visits; change in eligibility criteria (e.g., inclusion of boys for human papillomavirus (HPV)); or other specified changes to a childhood vaccination programme	Not in the context of changing an established schedule
Outcomes	Attitudes, perceptions, knowledge, thoughts, or opinions regarding schedule changes	Clinical or epidemiological outcomes only
Publication period	2013 – 29 May 2024	Before 2013
Language	English	Non-English
Study design	Qualitative, quantitative, or mixed-methods studies reporting primary data	Reviews, conference abstract, commentaries, protocols, or modelling studies without primary data

An extensive search strategy was developed, in collaboration with a subject specialist librarian (MH), to enhance comprehensiveness and reduce bias. Searches were conducted on 29 May 2024, across six databases: MEDLINE, Embase, Global Health, Global Index Medicus, Cochrane Library, and Scopus. These databases were selected to capture a broad range of relevant medical sciences, social sciences, public health, and interdisciplinary literature. Search terms were developed using Boolean operators, truncation symbols, and synonyms to ensure both sensitivity and specificity. The full search strategy can be found in Appendix 2.

3.2.2 Screening and selection process

Following the database searches, all retrieved references were imported into Rayyan, a web-based platform for systematic review management, where duplicate records were removed. The titles and abstracts of these records were screened against the predefined inclusion and exclusion criteria.

The initial search screening was conducted by the first author (CF), with secondary screenings independently performed by KK, SW, EO, and NH. Each second reviewer screened 25% of the records to enhance reliability. Discrepancies in screening decisions were resolved through team discussions to ensure consistency and accuracy. Full-text screening was then conducted, with CF reviewing all identified articles. NH, SV, and SM independently assessed one-third of the full texts to further minimise bias and ensure consistency. Conflicts regarding inclusion decisions were resolved through collaborative discussions among the research team.

3.2.3 Data extraction and analysis

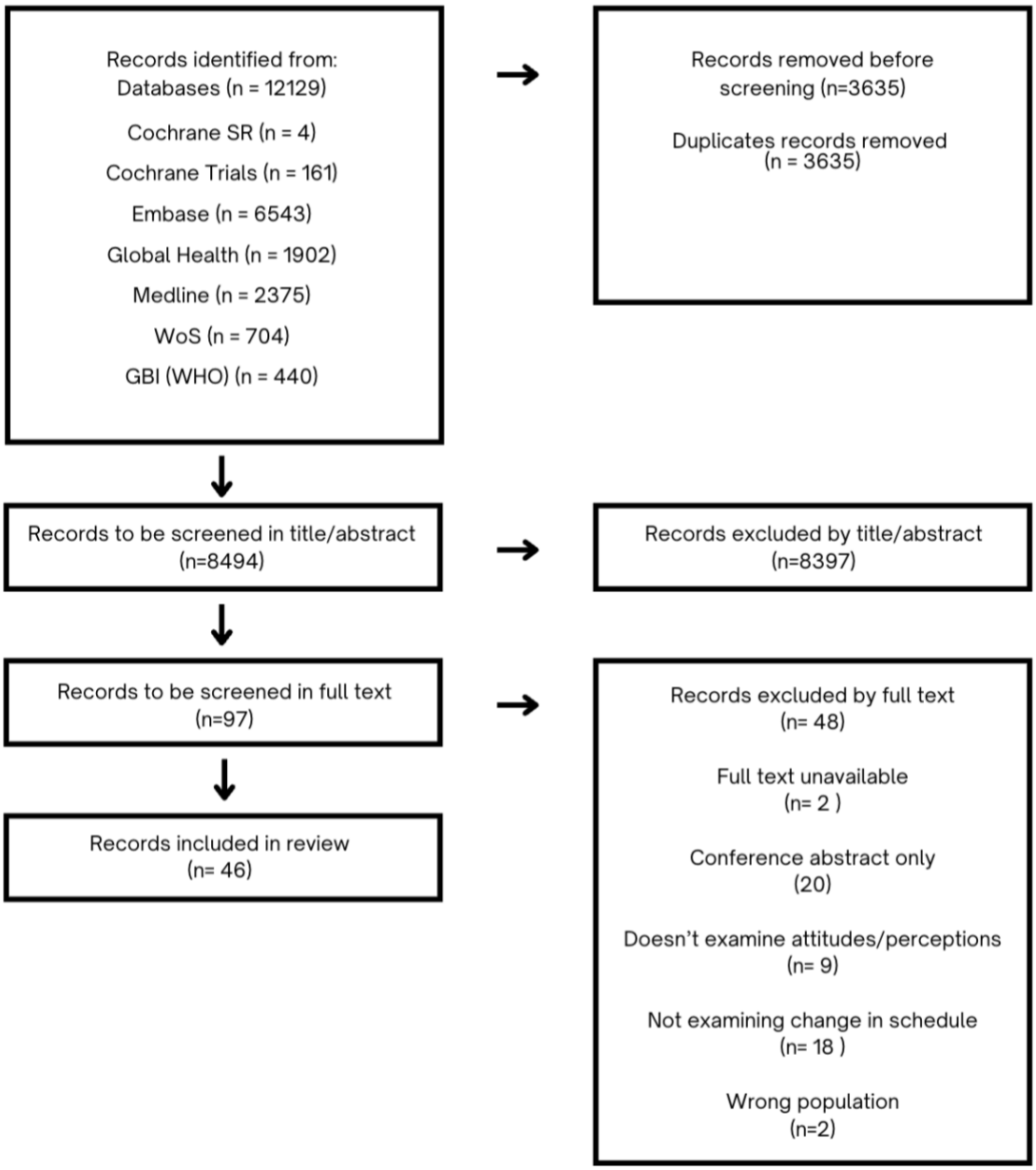
Data extraction was performed by CF and SM using a data extraction form (Appendix 3) designed to capture essential study characteristics, including design, population demographics, geographic and contextual settings, and findings related to perceptions and attitudes towards changes in immunisation schedules. To ensure the methodological rigour of the included studies, each was critically appraised using Mixed Methods Appraisal Tool (MMAT) [Hong et al., 2018]. This evaluation facilitated a systematic assessment of study quality, aiding in the identification of potential biases and enhancing the reliability of the review's findings. To ensure consistency and minimise potential bias, SV independently extracted data from a randomised sample comprising 10% of the included studies. No discrepancies were identified during this secondary extraction process, affirming the reliability and sufficiency of the extracted data.

A descriptive approach was used to summarise the characteristics and contexts of the included studies, as the diversity in study designs, populations, and outcomes precluded quantitative synthesis. Thematic synthesis was then employed to enable an in-depth, interpretive analysis of qualitative data, allowing identification of common patterns and underlying factors influencing responses to immunisation schedule changes across different settings. This involved line-by-line coding of the extracted information in Microsoft Excel to identify recurring patterns, which were subsequently grouped into broader thematic categories. Key themes were iteratively refined through discussions among the research team to ensure coherence, validity, and alignment with the review's objectives. This process allowed for a comprehensive synthesis of findings, highlighting the diverse factors influencing public attitudes towards changes in childhood immunisation schedules.

3.3 Results

The initial search yielded 12,129 references, and after deduplication, 8,494 unique records remained. After title and abstract screening, 97 references were identified as potentially eligible for inclusion. Following full-text screening, 46 studies met the eligibility criteria and were included in the final analysis.

Figure 1: PRISMA flow diagram



3.3.1 Study characteristics

The included studies reflected a wide geographic and contextual diversity. Most studies (n=46) were conducted in single-country settings, with Nigeria and Sweden the most frequently studied (n=5), followed the United States (n=4) and Uganda (n=3). The

Netherlands, Canada, China, and Tanzania were each represented in two studies. A further 16 countries were represented by one study each, including both high-income and low- and middle-income settings across multiple continents. A summary of country representation is shown in Table 2.

Table 2. Countries represented in single-country studies (n = 41)

Country or Region	Number of Studies	Study Reference
Nigeria	5	[Maduka et al., 2015, Azuogu et al., 2019, Ajayi and Emeto, 2023, Chukwuocha et al., 2018, Tagbo et al., 2014]
Sweden	5	[Grandahl et al., 2019, Oldin et al., 2019, Arnheim-Dahlström et al., 2021, Sjögren et al., 2017, Gottvall et al., 2017]
United States	4	[Santibanez et al., 2018, Kohler et al., 2023, Koskan et al., 2021, Recto et al., 2023]
Uganda	3	[Faith et al., 2020, Bongomin et al., 2024, Muhwezi et al., 2014]

Netherlands	2	[Oostdijk et al., 2021, Kaaijk et al., 2014]
Canada	2	[MacDougall et al., 2014, Humble et al., 2022]
China	2	[Yu et al., 2016, Wagner et al., 2017]
Tanzania	2	[Romore et al., 2015, Mitchell et al., 2021]
Philippines, Australia, Austria, South Africa, Mongolia, England, Greece, Denmark, Fiji, New Zealand, Kenya, Ethiopia, Japan, Ghana, The Gambia, Pakistan	1 each	[Lopez et al., 2018, Ali et al., 2022, Ojakaa et al., 2014, Idoko et al., 2016, Sherman and Nailer, 2018, Borena et al., 2016, Meñaca et al., 2014, Dalmau and Batmunkh, 2020, La Vincente et al., 2015, Souliotis et al., 2018, Shono and Kondo, 2017, Marshall et al., 2014, Kirkedal et al., 2023, Charania et al., 2018, Tabana et al., 2016, Asmare, 2022]

In addition, five studies were conducted across multiple countries, capturing cross-national variations in immunisation programme design, delivery, and public response. These studies included settings across Africa, Asia, Europe, and the Americas. Table 3 summarises the countries represented in multi-country studies.

Table 3. Multi-country studies included in the review (n = 5)

Study Region(s)	Number of Studies	Study Reference
Australia, Canada, France, Germany, Spain, Sweden, United Kingdom	1	[Bakhache et al., 2013]
Ghana, Kenya, Malawi	1	[Price et al., 2023]
Democratic Republic of the Congo, Kenya, Nigeria	1	[Lorenzetti et al., 2023]
England and Wales	1	[Waller et al., 2020]
Argentina, Malaysia, South Africa, South Korea, Spain	1	[Vielot et al., 2017]

The review identified a broad range of changes to childhood immunisation schedules across the included studies; these findings are summarised in Table 4.

Table 4. Types of childhood immunisation schedule changes identified

Type of Schedule Change	Number of Studies
Introduction of a new vaccine	27
Adjustment to eligibility criteria	7
Alteration in number of doses required	4
Combination into multi-purpose vaccine	3
Change in delivery method	2
Reintroduction of a previously discontinued vaccine	1
Alteration to timing of vaccinations	1
Substitution of vaccine type used	1

3.3.2 Quality appraisal

The methodological quality of included studies was appraised using the MMAT [Hong et al., 2018]. Overall, the quality of the 46 studies was moderate to high. Most studies met four or five of the MMAT criteria, which assess the methodological quality of qualitative, quantitative, and mixed-methods studies across core domains, including clarity of research questions, appropriateness of design and sampling, adequacy of data collection and analysis, and, for mixed-methods studies, the integration of qualitative and quantitative components. Common limitations included incomplete descriptions of sampling strategies and researcher reflexivity, reflected in several "can't tell" responses. In accordance with MMAT guidance, no studies were excluded on the basis of methodological quality; instead, these findings were used to contextualise the strength and consistency of the evidence. A full summary of MMAT ratings is provided in Appendix 3.

3.3.3 Perceptions and attitudes

Across the included studies, a range of immunisation schedule changes were examined, including the introduction of new vaccines, alteration to dose numbers or intervals, changes to eligibility criteria, and adjustments to delivery settings. Beyond these descriptive patterns, a set of recurring themes emerged that shaped how parents, caregivers, and vaccine recipients perceived such changes. These determinants were not specific to any single type of change, but their salience often varied depending on the nature of the adjustment. The following subsections outline the major factors identified across the included studies, with attention to how certain types of schedule change emphasised particular concerns or facilitated acceptance.

3.3.4 Perceptions of vaccine safety

Concerns about safety were among the most frequently reported perceptions regarding changes to the immunisation schedule. Parents and vaccine recipients often expressed apprehension about safety and potential adverse side effects, as reported across numerous studies [Vielot et al., 2017, Ali et al., 2022, Santibanez et al., 2018, Ojakaa et al., 2014, Price et al., 2023, Sherman and Nailer, 2018, Ajayi and Emeto, 2023, Yu et al., 2016, Lorenzetti et al., 2023, Borena et al., 2016, Oostdijk et al., 2021, Lopez et al., 2018, La Vincente et al., 2015, Tagbo et al., 2014, Oldin et al., 2019, Kohler et al., 2023, Arnheim-Dahlström et al., 2021, Gottvall et al., 2017, Humble et al., 2022, Kirkedal et al., 2023, Muhwezi et al., 2014, Tabana et al., 2016, Recto et al., 2023, Asmare, 2022]. Fears often stemmed from various beliefs, including the idea that multiple injections administered simultaneously might ‘overload’ or ‘overwork’ a child’s immune system [Vielot et al., 2017, Bakhache et al.,

2013], or that newer vaccines had not been sufficiently tested [Gottvall et al., 2017]. Hesitancy was typically expressed not as outright rejection but as caution, commonly characterised by a 'wait-and-see' approach, whereby individuals sought confirmation from other's experiences of no adverse events before consenting to a new vaccine [Yu et al., 2016, Lorenzetti et al., 2023], change in vaccine type [Santibanez et al., 2018], or a change in vaccine eligibility [Grandahl et al., 2019]. In a study examining the parental acceptability of a national school-based human papilloma virus (HPV) programme in Fiji [La Vincente et al., 2015], among parents who withheld consent, approximately half (23/44, 52.3%) cited concerns about HPV vaccine safety as the primary reason for non-participation. Many of the parents in this study reported hearing negative information through the media, inducing fear of the vaccine. However, such anxieties were not always absolute; in a study examining perceptions of vaccine-derived poliovirus and the introduction of a novel oral polio vaccine [Lorenzetti et al., 2023], parents in the Democratic Republic of the Congo (DRC) indicated that, despite these concerns, they would accept the new vaccine regardless, as they did not have the resources to treat a polio infection should it occur. Overall, while safety concerns were among the most consistently reported perceptions, these anxieties were not always unconditional and were often mitigated through reassurance or perceived necessity. Beyond concerns about safety, practical considerations around the number and timing of doses also shaped how caregivers and recipients perceived changes to immunisation schedules.

3.3.5 Perceptions of dosing and scheduling

Concerns about the burden of dosing and scheduling were frequently reported. Caregivers and vaccine recipients expressed apprehension about the need to attend multiple visits, as well as the experience of receiving a greater number of vaccines during a single appointment

[Idoko et al., 2016, Kaaijk et al., 2014, Wagner et al., 2017, Charania et al., 2018, Tabana et al., 2016, Yu et al., 2016, Price et al., 2023, Lopez et al., 2018, Romore et al., 2015]. Parents and vaccine recipients alike described distress when faced with an increase in the number of injections in a single visit, often linked to fear of pain, discomfort, or emotional distress [Idoko et al., 2016, Kaaijk et al., 2014, Wagner et al., 2017, Charania et al., 2018, Tabana et al., 2016, Romore et al., 2015]. However, in some cases, parents expressed greater concern about spreading injections across multiple visits. For example, in a study examining acceptance of multiple injectable vaccines in a single immunisation visit in The Gambia, approximately 70% of parents reported worry about the cumulative pain and discomfort associated with vaccines administered over several separate appointments, rather than during one appointment [Idoko et al., 2016]. In some cases, parents recommended the use of non-injectable vaccines as a way of reducing the pain associated with immunisation [Arnheim-Dahlström et al., 2021, Tabana et al., 2016, Santibanez et al., 2018, Kaaijk et al., 2014].

In one HPV dose-reduction trial in Tanzania, girls who were allocated to fewer doses reported feeling ‘lucky’, while parents similarly valued the reduction for its potential to increase population coverage, as fewer doses per person meant that vaccine supplies could be extended to more individuals [Yu et al., 2016]. However, perceptions of dosing also shaped confidence in vaccine efficacy; for example, in a study examining the four-dose schedule of the RTS,S/AS01 malaria vaccine, parents associated a higher number of doses with stronger protection, expressing greater confidence in efficacy after three doses [Price et al., 2023]. Although anxieties surrounding pain and discomfort associated with multiple injections were widespread, they were not insurmountable. Notably, reported attitudes did not always align with practices; some caregivers reported feeling comfortable with only one or two injections per visit, yet nevertheless were observed to have allowed their child to receive three [Lopez et

al., 2018]. In summary, perceptions of dosing and schedule burdens reflected a balance between concerns about pain and inconvenience, beliefs about the relationship between dose number and protection, and occasional uncertainties about scheduling requirements. While these concerns highlighted the influence of perceived burden and efficacy, willingness to accept changes was also strongly mediated by the level of trust placed in healthcare providers and institutions.

3.3.6 Trust in providers and institutions

Trust in healthcare providers consistently influenced willingness to accept changes to immunisation schedules, including the introduction of new vaccines [Price et al., 2023, Faith et al., 2020, Bakhache et al., 2013, Souliotis et al., 2018, La Vincente et al., 2015, Charania et al., 2018], introduction of multi-purpose vaccines [Vielot et al., 2017], reintroduction of a previously used vaccine [Dalmau and Batmunkh, 2020], change in eligibility criteria [Sherman and Nailer, 2018], and change in delivery method [Sjögren et al., 2017]. In an Australian study examining parental acceptance of the meningococcal B (men B) vaccine, physician recommendations were reported as pivotal, influencing 81.7% of parents to vaccinate their children [Marshall et al., 2014]. Conversely, this trust could also discourage vaccine uptake; in one US study, a parent reported being dissuaded from consenting to HPV vaccination after their paediatrician framed the vaccine as relevant only if a girl was expected to be sexually active at an early age [Kohler et al., 2023]. Similarly, mistrust of pharmaceutical companies emerged as a barrier to acceptance, with participants in one study from Argentina, Malaysia, and South Korea expressing concerns that manufacturers were driven by economic interests, that vaccines might be of inferior quality, or that populations were being used for pharmaceutical experimentation [Vielot et al., 2017].

Beyond the role of providers, trust in wider institutions also emerged as a determinant of acceptance. Caregivers expressed varying levels of confidence in the intentions of governments, industry, and scientific experts involved in vaccine development and promotion [Price et al., 2023, Mitchell et al., 2021, Kirkedal et al., 2023]. For example, in the DRC, Kenya, and Nigeria, caregivers were more likely to accept a novel oral poliovirus vaccine type 2 (nOPV2) when it was supported by either their government or international organisations, with some participants expressing the belief that authorities would act in the best interest of citizens and ensure safety [Lorenzetti et al., 2023]. Taken together, trust functioned as a double-edged factor: it facilitated acceptance where providers and institutions were regarded as credible and acting in the public interest, but it could also discourage uptake where mistrust of institutions prevailed or where trusted providers conveyed misleading or inappropriate advice. Trust, however, did not operate in isolation; vaccine decision-making was also embedded in household authority structures and broader social networks.

3.3.7 Social and household dynamics

Vaccine decision-making was rarely an individual act but embedded within wider family and community contexts. Male household authority frequently acted as a gatekeeping factor in vaccine acceptance, with paternal or spousal endorsement often being decisive in shaping outcomes [Oostdijk et al., 2021, Ali et al., 2022, Chukwuocha et al., 2018, Asmare, 2022]. In one HPV vaccination study in Pakistan, half of the respondents (50%, 24/48) identified fathers as the definitive authority, while the vaccine recipients themselves (girls aged 16-19 years) anticipated that paternal hesitation could lead to a lack of consent for them to be vaccinated [Ali et al., 2022]. Adolescents were not consistently positioned as autonomous

decision-makers within the studies reviewed. In a study of the MenACWY vaccine, their views largely mirrored parental attitudes, with most deferring to parental choices rather than engaging in independent discussion; parental scepticism or support was reflected directly in adolescents' reasoning [Oostdijk et al., 2021]. However, a contrasting perspective was reported in a study examining perceptions of HPV vaccination for 9–10-year-olds, where some mothers emphasised that adolescents should have the right to make their own decisions about their bodies [Kohler et al., 2023] to begin developing their own bodily autonomy.

Outside of the household, wider social networks also influenced attitudes, with encouragement from peers, or the presence of supportive social norms, such as the view that "we just take our children when we're told", being identified as facilitators of uptake [Price et al., 2023]. Lasting impressions of past experiences further influenced household decisions regarding vaccination; for example, families with personal connections to meningococcal disease, such as a relative who had experienced meningococcal disease, reported stronger perceptions of risk, which in turn shaped acceptance of that vaccine [Oostdijk et al., 2021]. In summary, decision-making around immunisation schedule changes was embedded within a web of social relations: in some contexts, fathers and husbands often acted as gatekeepers, adolescents largely deferred to parental authority, and household views were reinforced or challenged by peers, community norms, and personal experiences of disease, however this did vary by individual contexts. Alongside household and community influences, preferences for the physical setting of vaccine delivery further shaped acceptance and highlighted practical, safety, and record-keeping concerns.

3.3.8 Perceptions of delivery setting

Preferences for the delivery setting of childhood immunisations varied across studies, with convenience, trust, and safety emerging as central considerations [Koskan et al., 2021, Ali et al., 2022, MacDougall et al., 2014]. In one study, 42% of respondents recommended household visits as a strategy to reach marginalised girls, while 60% advocated for community-based vaccination programmes to address access barriers and build trust [Ali et al., 2022]. For some caregivers, pharmacy-based vaccination was seen as more convenient than attending primary care, due to presumptions about more flexible hours and fewer appointment requirements [Koskan et al., 2021], while others valued school-based immunisation programmes for similar convenience reasons, noting that such approaches could also reduce strain on the national health service [MacDougall et al., 2014].

Despite these advantages, concerns were reported about vaccinations delivered outside of primary care settings. In one study, 44% of respondents expressed a preference for vaccines to be administered by doctors in the presence of family [Ali et al., 2022]. Other caregivers raised doubts about the management of adverse reactions and the maintenance of accurate health records when vaccinations were provided in pharmacies or schools [Koskan et al., 2021, MacDougall et al., 2014]. School-based programmes were also critiqued for the possibility of inappropriate external influence on decision-making, as well as a few parents in one study suggesting a potential unintended consequence of reducing adult influenza uptake, as they thought some adults who usually vaccinated alongside their children might deprioritise their own vaccination if their child was immunised at school [MacDougall et al., 2014].

In some cases, knowledge gaps were also identified, with parents unaware that pharmacists could administer vaccinations, although many expressed willingness for their child to receive

pharmacist-administered vaccines if they were trained and certified [Koskan et al., 2021]. Overall, preferences for delivery settings reflected a tension between the convenience and reach offered by household, pharmacy, and school-based programmes, and concerns about safety, record-keeping, and the integrity of decision-making when vaccinations were delivered outside of primary care. Finally, across all these determinants, the role of misinformation and miscommunication was repeatedly identified as an overarching factor that could amplify anxieties, reinforce hesitancy, or undermine trust in both providers and institutions.

3.3.9 Misinformation

Misinformation and miscommunication were recurring factors shaping attitudes towards changes in immunisation schedules. Across settings, uncertainty was amplified by false or limited information, particularly where new vaccines were introduced with minimal explanation or inconsistent messaging [Price et al., 2023, Asmare, 2022, Meñaca et al., 2014, La Vincente et al., 2015, Lorenzetti et al., 2023, Kohler et al., 2023]. Some parents expressed that their search for information was triggered by a sense of novelty with the disease and/or the vaccination specifically [Oostdijk et al., 2021]. In some cases, this confusion fuelled specific rumours, which were more prevalent among caregivers whose children had only partially completed a vaccine course [Price et al., 2023]. For example, in Ethiopia, over a third of respondents (33.5%) believed that a malaria vaccine not given orally could cause paralysis [Asmare, 2022]. While in Ghana, some participants assumed that a malaria vaccine already existed, stemming from a limited understanding of specific vaccines, including perceptions that all vaccines served the same general purpose of preventing childhood illness, a lack of distinction between vaccines, injections, and other preventive measures such as

intermittent preventive treatment for malaria, and the overlap between malaria and other febrile diseases for which vaccines exist (e.g., yellow fever) [Meñaca et al., 2014].

Rumours and fears were also tied to social and media narratives. In Fiji, parents reported hearing negative information about the HPV vaccine from friends and the media, which contributed to fear about their daughters receiving it [La Vincente et al., 2015]. In the DRC and Kenya, suspicions surrounding the novel oral polio vaccine included beliefs that campaigns were intended to sterilise certain groups [Lorenzetti et al., 2023]. Such narratives reinforced mistrust and heightened anxieties about safety. Importantly, misinformation was not confined to communities or the media, but has also being documented by paediatricians themselves [Kohler et al., 2023]. Overall, misinformation and miscommunication operated across multiple levels; community, media, and even within healthcare, exploiting gaps in knowledge and inconsistent messaging, and in turn amplifying anxieties, fuelling rumours, and at times directly discouraging vaccine uptake.

In summary, responses to immunisation schedule change were shaped by interrelated clusters of factors rather than isolated determinants. These included concerns about safety and dosing; levels of trust in providers and institutions; and the influence of household, social, and informational environments, including delivery settings and the circulation of misinformation. While the relative weight of these influences varied across contexts and types of schedule change, they frequently interacted. For example, anxieties about safety were often amplified in contexts of institutional mistrust, and household authority could mediate how social norms were interpreted and enacted. These findings underscore that responses to schedule change emerge from overlapping relational and structural conditions,

and they provide the foundation for the following section on communication practices and the wider social contexts in which immunisation is negotiated.

3.3.10 Communication around changing vaccine schedules

Given the central role of perceptions and attitudes in shaping vaccine acceptance, the way in which changes to immunisation schedules are communicated emerged as a critical factor across the included studies. The following subsections examine the channels through which information was shared, the actors and institutions responsible for providing it, and the ways in which literacy, education, and social context mediated how these messages were received and acted upon.

3.3.11 Trusted information providers

Healthcare professionals were the most consistently trusted sources of vaccine information across studies, with doctors, nurses and school nurses, and other vaccinators frequently identified as central to building confidence and guiding decisions [Kohler et al., 2023, Souliotis et al., 2018, Bongomin et al., 2024, Oldin et al., 2019, La Vincente et al., 2015, Borena et al., 2016, Meñaca et al., 2014, Ajayi and Emeto, 2023, Idoko et al., 2016, Grandahl et al., 2019, Ali et al., 2022, Vielot et al., 2017, Tabana et al., 2016, Koskan et al., 2021, Tagbo et al., 2014, Arnheim-Dahlström et al., 2021, Marshall et al., 2014, Sjögren et al., 2017, Humble et al., 2022, Kirkedal et al., 2023, Wagner et al., 2017]. One study in Austria reported that parents who received vaccine information from physicians were more likely to accept HPV vaccination [Borena et al., 2016]. This confidence extended beyond respondents' own physicians to include doctors appearing on television [Dalmau and Batmunkh, 2020].

Despite this perception, some parents and caregivers reported seeking additional perspectives before making a final decision. Women in a study that examined factors likely to affect the community acceptance of a malaria vaccine in Ghana highlighted that they valued the opinions of other women who had prior experience with the vaccine [Meñaca et al., 2014] while several studies reported that respondents commonly discussed vaccination with family members [Ali et al., 2022, Idoko et al., 2016, Ajayi and Emeto, 2023, La Vincente et al., 2015, Tabana et al., 2016, Wagner et al., 2017, Arnheim-Dahlström et al., 2021].

Although people other than healthcare workers were frequently consulted, their role was often described as supportive rather than decisive. For instance, one study noted that conversations with others largely centred on the logistics of accessing vaccination and were not perceived as influencing the decision itself [Lopez et al., 2018]. Beyond families and peers, community leaders and informal networks were also engaged in providing information. In Ghana, village leaders reported using traditional communication channels such as town criers or gong beaters, but highlighted the importance of coordinating these efforts with health professionals to ensure consistent and reliable messaging as part of wider community sensitisation initiatives [Meñaca et al., 2014]. Taken together, these findings suggest that while healthcare workers remained trusted and authoritative providers of vaccine information, information rarely flowed in a single direction; instead, it was interpreted, questioned, and re-circulated within households and communities where family, peers, and social contacts were also engaged in the decision-making process by reinforcing or contextualising the guidance received from professionals.

3.3.12 Message framing

The content of vaccine messaging played a central role in shaping how parents and caregivers understood and responded to changes in immunisation schedules. Across settings, respondents emphasised the need for information that was not only accurate but also relevant to their specific concerns, with particular attention to safety, efficacy, logistics, and the rationale for new or adjusted vaccine [Santibanez et al., 2018, Price et al., 2023, Waller et al., 2020, Mitchell et al., 2021, Oostdijk et al., 2021, La Vincente et al., 2015, MacDougall et al., 2014, Kohler et al., 2023, Humble et al., 2022, Kirkedal et al., 2023, Asmare, 2022, Tabana et al., 2016]. Across studies, parents and caregivers consistently sought clear information on side effects, with some parents also requesting data on longer-term outcomes [La Vincente et al., 2015]. Further, there was a desire for communication that contextualised schedule changes, with parents in Mongolia emphasising that although the HPV vaccine is not listed in the Maternal Child Health Handbook—often referred to as 'the pink book'—it is not an entirely "new" vaccine [Dalmau and Batmunkh, 2020].

Where parents felt they lacked such information, concerns about side effects or vaccine novelty were linked to indecision [Waller et al., 2020]. Further, parents in one study in the US, comparing two types of influenza vaccines, based their decisions largely on perceived effectiveness, underscoring the need for accurate comparative data [Santibanez et al., 2018]. This extended to delivery methods of other vaccines too, with parents wanting details on the benefits of needle-free approaches, for example, a jet injector, a patch, a microneedle system, and a nasal spray [Kaaijk et al., 2014], and clear explanations about why multiple injections were required, how pain could be managed, and how dose schedules related to protection [Tabana et al., 2016]. Vaccine uptake was facilitated when parents were informed about the purpose of vaccine eligibility and the dosing schedule, while confusion on these points created barriers [Price et al., 2023].

The timing and repetition of communication were also emphasised. One study in Sweden that examined adolescent boys' perceptions of HPV vaccines suggested that information should be provided early, beginning at primary school, and reinforced at successive ages to build awareness and sustain confidence [Grandahl et al., 2019]. Taken together, these findings show that parents and caregivers did not seek general reassurance alone but specific, detailed content. Information on side effects and long-term safety, comparative efficacy and delivery methods, and clear explanations of logistics and timing were all identified as important. Messaging that combined these elements was described as most likely to address uncertainty, counter misinformation, and support acceptance of schedule changes.

3.3.13 Communication channels

Across studies, parents and community members emphasised that no single channel was sufficient for communicating changes to immunisation schedules; rather, information was most effective when delivered through multiple, complementary methods [Vielot et al., 2017, Price et al., 2023, Ali et al., 2022, Ajayi and Emeto, 2023, Grandahl et al., 2019, Meñaca et al., 2014, Dalmau and Batmunkh, 2020, Oostdijk et al., 2021, La Vincente et al., 2015, Tagbo et al., 2014, Kohler et al., 2023, Sjögren et al., 2017, Wagner et al., 2017, Charania et al., 2018, Koskan et al., 2021]. This was especially empathized in one study from Pakistan [Ali et al., 2022], where vaccine recipients aged 16-19 years explicitly recommended a multi-channel campaign, with preferences spanning household visits (67%), school or community information camps (27%), peer education (25%), announcements at religious gatherings (27%), street banners or flyers (37%), instant messaging groups (29%), and dedicated websites (15%). Mass media and broadcast methods such as radio, information vans, and street banners were also viewed as useful in extending reach within communities [Meñaca et

al., 2014]. At the same time, written resources retained a central role; pamphlets distributed to parents, particularly those accompanying appointment invitations, were widely read and regarded as reliable [Ajayi and Emeto, 2023, Kaaijk et al., 2014] . Taken together, the findings indicate that effective communication requires a layered approach. Community outreach, broadcast media, and written resources provided breadth, while interpersonal and household discussions ensured depth and relevance. Methods that combined these levels of communication were considered most likely to support awareness, address concerns, and facilitate vaccine uptake.

Overall, parent and recipient responses to changes in childhood immunisation schedules were shaped by a constellation of interrelated factors. Safety concerns, perceptions of dosing and scheduling, levels of trust in providers and institutions, household and community dynamics, delivery settings, and the circulation of misinformation all influenced decision-making in different ways across contexts. The following discussion considers the implications of these findings, situating them within the broader literature and reflecting on their significance for policy, practice, and future research.

3.4 Discussion

The findings of this review highlight the considerable diversity of childhood immunisation programmes globally, reflecting the universality of efforts to optimise vaccine delivery while tailoring strategies to local needs. The predominance of studies from a small number of countries—particularly Nigeria, Sweden, and the United States—reveals a marked geographic concentration of research, with limited representation elsewhere. Notably, Nigeria has been identified among the top five African countries contributing to vaccine research

output (alongside South Africa, Egypt, Ethiopia, and Kenya), underscoring regional hubs of activity within a broader context of limited research representation across much of the continent [Iwu-Jaja et al., 2025]. This likely reflects differences in research infrastructure, funding capacity, surveillance systems, and international collaboration networks [Shi et al., 2025, Iwu-Jaja et al., 2025], not merely interest in vaccine schedule changes.

Across these settings, schedule changes most commonly involved the introduction of new vaccines, followed by adjustments to eligibility criteria, dose number or timing, and delivery methods. This diversity highlights the multiple factors shaping national immunisation programmes, including shifting epidemiological priorities, evolving scientific evidence, and WHO guidance [World Health Organization, 2020]. The prevalence of new vaccine introductions in particular reflects the continuing expansion of childhood immunisation schedules in line with global initiatives to address emerging and re-emerging diseases [Pollard and Bijker, 2021, Burchett et al., 2011, de Melo Araújo et al., 2025].

Beyond descriptive patterns, the synthesis demonstrates that responses to immunisation schedule change were shaped by how particular modifications—such as the introduction of new vaccines (e.g., HPV, nOPV2), reductions or increases in dose number (e.g., HPV dose reduction trials; RTS,S malaria schedule), or changes in delivery setting (e.g., pharmacy- or school-based vaccination)—were interpreted in context. Caregivers frequently distinguished between general support for vaccination and concerns about how revised schedules might affect safety, pain, burden, or institutional legitimacy. Consistent with prior work on vaccine confidence [Larson et al., 2022, MacDonald et al., 2018], these responses were mediated through trust in healthcare providers and institutions. However, the review extends this literature by demonstrating that uncertainty was frequently triggered not by vaccines

themselves, but by disruption to established scheduling routines and delivery expectations. Changes to timing, eligibility, or setting required renewed explanation and justification, particularly in contexts where household authority, community norms, or past experiences of vaccination shaped interpretation. These findings reaffirm that the success of schedule changes depends not only on clinical efficacy, real-world effectiveness, or logistical capacity, but also on how changes are explained, justified, and ultimately trusted, within communities [Sommers et al., 2025, Vanderslott et al., 2024, Kafadar et al., 2024].

Concerns about vaccine safety were among the most pervasive influences on decision-making, being discussed in over half of the studies included. Apprehension about potential side effects or the perceived novelty of new vaccines was widespread but typically expressed as cautious deliberation rather than outright refusal. Many caregivers sought reassurance from trusted providers or waited for confirmation of safety within their community before consenting, reflecting a process of risk negotiation rather than resistance. This aligns with broader research showing that vaccine hesitancy is fluid and relational, shaped by trust in health authorities [Campbell et al., 2023] and the perceived transparency of communication [Wegwarth et al., 2024].

Caregivers' perceptions of dosing, scheduling, and service delivery often intersected with their sense of a programme's safety. Although multiple injections or repeated visits were frequently described as burdensome, some caregivers interpreted a greater number of doses as a sign of stronger or more lasting protection. This variation underscores previous published literature and WHO position statements that posit the acceptability of vaccination is impacted by multiple factors: how dosage, purpose, and pain are communicated [MacKenzie et al., 2021, Organization, 2015], and how clearly vaccination schedules are framed as protective

rather than onerous [Iannizzi et al., 2025], in turn, improving vaccine confidence [O'Leary et al., 2024].

Trust emerged as a central factor shaping responses to schedule changes. Confidence in healthcare providers encouraged acceptance, while mistrust of governments, pharmaceutical companies, or international organisations undermined it, echoing findings in vaccine anthropology [Enria et al., 2024]. Importantly, trust operated beyond individual encounters: vaccination decisions were embedded within household and community dynamics, where paternal authority, peer influence, and social norms often shaped final consent [Mavundza et al., 2023]. These relational dynamics show that vaccine decision-making is embedded within collective social systems rather than reducible to individual choice, echoing sociological accounts of vaccination as a socially negotiated practice [Adhikari et al., 2022, Ni et al., 2021, Vriens et al., 2023]. Trust, therefore, operates at multiple levels: in the vaccine itself, in relationships with healthcare providers, and in broader institutional arrangements, and was reinforced when healthcare workers provided clear explanations of schedule changes, when governments or international organisations were perceived as acting in the public interest, and when vaccination policies were seen to reflect community priorities rather than external imposition.

Across the included studies, misinformation often emerged where schedule changes were introduced with limited explanation or where official messaging failed to address concerns. Rumours gained traction in these informational gaps, particularly within household and peer networks. These findings suggest that communication surrounding schedule change must extend beyond one-way information provision, combining trusted healthcare providers, community intermediaries or 'champions', and clear explanations of the rationale and

implications of change [Borges do Nascimento et al., 2022, Organization, 2022, Enria et al., 2024, Iannizzi et al., 2025].

Taken together, the findings show that responses to immunisation schedule change are not determined by vaccination status or vaccine perception alone, but emerge through the interaction between the type of schedule change introduced and the social contexts in which it is interpreted. Changes that disrupted established expectations—whether through the introduction of something new, the reorganisation of dosing and timing, or alterations to delivery practices - prompted different forms of concern, but these concerns were consistently mediated by trust, understanding, and broader context. Uncertainty was present across contexts, but it manifested differently: novelty heightened attention to safety, dosing adjustments foregrounded burden and perceived effectiveness, and delivery changes drew scrutiny toward institutional oversight and convenience. Across contexts, responses to schedule change were shaped by how change was experienced within existing systems of trust and everyday practice.

This review has some limitations; It was restricted to English-language, peer-reviewed publications from 2013-2014, which may have excluded relevant evidence from earlier or non-English-speaking contexts. Considerable heterogeneity in study design and reporting precluded quantitative synthesis and limited comparison across settings. Although the thematic approach enabled an in-depth understanding of attitudes and perceptions, the review relies on what individual studies chose to report, and some determinants, such as socioeconomic status or political context, were not consistently captured or compared. Future research should examine under-represented regions, especially low-income countries and

countries in Asia, where data remain sparse, and explore how public perceptions evolve over time as new vaccines and delivery platforms are introduced.

In summary, the findings demonstrate that perceptions towards immunisation schedule changes reflects broader questions of trust, understanding, and social legitimacy. Communication that is specific to the nature of the change, whether introducing a new vaccine, altering dosing intervals, or modifying delivery settings, proved most effective when it contextualised the rationale for reform, addressed safety concerns directly, and was delivered through multiple, trusted channels. Moreover, vaccine decision-making was shown to be deeply embedded in social and household relationships, where paternal authority, peer influence, and collective norms often determined final consent. To enhance acceptance, therefore, immunisation programmes must integrate social and behavioural insights into every stage of policy design and implementation. Building and sustaining trust through transparency, dialogue, and co-creation with communities should be recognised as foundational to system resilience. As countries seek to adapt their immunisation schedules, with new vaccine development, guided in part by the WHO Immunisation Agenda 2030 [World Health Organization, 2020] and Gavi's Phase 5.0 strategy, these findings highlight that achieving confidence in schedule changes relies on a foundation of inclusive engagement that responds to the lived realities, values, and social contexts of those affected.

4 A mixed-methods study of parental perceptions and acceptability of immunisation schedule changes in Nepal and Uganda

4.1 Introduction

This chapter examines how caregivers perceive changes to childhood immunisation schedules, and how acceptable they are, in LMIC settings, Nepal and Uganda. Building on the conceptual framing developed in earlier chapters, this chapter continues to approach immunisation schedules as sociotechnical infrastructures that stabilise relationships between caregivers, health systems, and governing institutions. Schedule change is therefore treated here as an analytically interesting moment—one that brings into view assumptions about safety, authority, legitimacy, and responsibility that may otherwise remain implicit. By focusing on caregivers' anticipatory and reflective responses to potential schedule changes, this chapter contributes empirical insight into acceptability as a dynamic, relational, and context-dependent process rather than a fixed attitudinal outcome.

Data collection in both Nepal and Uganda took place alongside a clinical trial that assessed alternative childhood immunisation schedules. The 'optimising diphtheria, tetanus, and pertussis (DTwP) containing vaccine infant immunisation schedules' (OptImms) clinical trial was a randomised, five-arm, non-inferiority trial aimed to assess whether antibody levels against diphtheria, tetanus, and pertussis could be maintained while adjusting the timing and dosing of the DTwP vaccine The primary objective of the clinical trial was to identify a schedule (or schedules) that maintains early protection against pertussis prior to the booster dose and is equivalent to, or better, than the WHO's EPI schedule. Secondary objectives included optimising protection against multiple vaccine-preventable diseases, evaluating

booster timing, and assessing co-administration strategies for additional vaccines, including the concomitant administration of typhoid conjugate vaccine with Japanese encephalitis vaccine in Nepal [Kelly et al., 2023].

The five study arms were as follows: Arm 1 received DTwP vaccinations at 6, 10, and 14 weeks according to the WHO EPI schedule; Arm 2 received DTwP vaccinations at 6 and 14 weeks with a booster dose following a modified WHO EPI schedule; Arm 3 received DTwP vaccinations at 2 and 4 months with a booster dose according to the OptImms schedule; Arm 4 received DTwP vaccinations at 2, 3, and 4 months following the 2–3–4 schedule; and Arm 5 received DTwP vaccinations at 2, 4, and 6 months following the 2–4–6 schedule [Kelly et al., 2023]..

This trial context was central to selecting the study sites for this chapter, as it created a distinctive opportunity. The presence of the trial meant that caregivers were already being invited to engage with the idea of schedule changes, prior to any formal policy change or national-level implementation. This positioning enabled this chapter to examine how perceptions of immunisation schedule changes are formed in anticipation and, as a result of personal choice, enacted, rather than solely in response to policy changes. Importantly, the research presented in this chapter does not evaluate the clinical trial itself, nor does it assess trial outcomes. Instead, the trial context functions as a case through which to explore how caregivers make sense of potential changes to familiar immunisation routines, and how trust, authority, and legitimacy are negotiated at the intersection of research, policy, and everyday caregiving practice.

4.1.1 Immunisation context in Nepal

Nepal provides an instructive example of the opportunities and constraints inherent in immunisation delivery in an LMIC. Nepal's National Immunisation Programme (NIP) was established in 1977, and has expanded progressively in both antigen coverage (the diseases the vaccines aim to protect against) and geographic reach and now, in 2026, delivers vaccines against 11 vaccine-preventable diseases [Paul et al., 2022, Timsina, 2025]. Immunisation has become firmly embedded within national health policy and primary health care delivery, supported by sustained political commitment and international partnership. Over time, Nepal has achieved several major public health milestones, including the elimination of maternal and neonatal tetanus and certification as a polio-free country [World Health Organization, 2014a].

The organisation and delivery of immunisation services in Nepal have been shaped by both structural and geographic factors. Following the adoption of a federal governance structure in 2015, responsibility for health service delivery was decentralised to provincial and local governments. While this transition created opportunities for locally responsive planning and implementation, it also introduced challenges related to uneven subnational capacity. In practice, this has meant variation in staffing levels, expertise, allocation, and infrastructure across provinces and municipalities oversight [Wasti et al., 2023]. Decentralisation also requires new mechanisms of coordination between federal, provincial, and local authorities, and in some cases blurred lines of accountability for service quality and programme oversight [Wasti et al., 2023]. These governance dynamics intersect with Nepal's diverse and often challenging geography, characterised by mountainous terrain, seasonal isolation, and dispersed rural settlements, which have historically constrained physical access to health

services and necessitated labour-intensive outreach approaches for routine immunisation delivery [Hodge et al., 2015, Cao et al., 2021].

More recently, Nepal has demonstrated renewed progress in addressing persistent inequities in immunisation coverage. In 2025, all 77 districts were declared fully immunised for children under two years of age, reflecting intensified efforts to identify and vaccinate children who had previously been missed by routine services [Timsina, 2025]. This progress was achieved through a shift toward more proactive, locally coordinated delivery - combining household-level outreach with systematic follow-up of defaulters and strengthened district oversight of coverage data and accountability processes [Timsina, 2025]. Community-based delivery has been further supported by a nationwide network of Female Community Health Volunteers (FCHVs), who play a central role in caregiver engagement, and the mobilisation of immunisation services [Paul et al., 2022].

Nevertheless, high national coverage figures alone provide an incomplete assessment of immunisation system performance. WHO/UNICEF estimates of national immunization coverage suggest generally strong national coverage for key antigens in Nepal [World Health Organization, 2026a], yet such estimates may obscure important subnational variation [World Health Organization, 2026c]. Furthermore, qualitative evidence from Nepal indicates that barriers to full immunisation extend beyond issues of physical access and service availability. Interpersonal factors, including trust between caregivers and health providers, perceptions of service quality, and the responsiveness of health systems to community needs, play a critical role in shaping uptake [Paul et al., 2022]. While Nepal's experience highlights one pathway through which an LMIC has pursued high and equitable immunisation coverage, it is not representative of all settings.

4.1.2 Immunisation context in Uganda

Immunisation has also contributed significantly to reductions in child mortality in Uganda. Between 2011 and the mid-2020s, under-five mortality declined substantially, from around 90 deaths per 1000 live births to approximately 51 deaths per 1000 live births, and vaccination has been credited by national health leaders as a key driver of this change [Ministry of Health, 2024b]. Vaccination activities in Uganda commenced in 1969 following the launch by the WHO of a global six-month mass vaccination campaign against smallpox, in response to outbreaks that affected multiple regions worldwide during 1965–1966. During the late 1960s and 1970s, vaccines against poliomyelitis and tuberculosis were subsequently introduced as part of broader efforts to reduce morbidity and mortality associated with these diseases [Ministry of Health, 2024b]. However, lengthy periods of political instability and civil unrest during this time resulted in a significant decline in routine immunisation services, including the BCG vaccine that protects against tuberculosis. These challenges prompted the establishment of the Uganda National Expanded Programme on Immunization (UNEPI), which was officially launched in October 1983 [Ministry of Health, 2024b].

The creation of UNEPI responded to low routine coverage, the suboptimal potency of vaccines, inadequate managerial capacity, and insufficient community participation that was common during the earlier periods of immunisation delivery [Ministry of Health, 2024b]. The programme was designed to provide a coordinated and systematic approach to controlling and eliminating vaccine-preventable diseases in alignment with global EPI objectives. Over time, additional antigens have been incorporated into the routine schedule, reflecting

evolving public health priorities and global vaccine introductions [Ministry of Health, 2024a].

In 2024 the Government of Uganda, through the Ministry of Health and UNEPI, adopted the National Immunisation Strategy (NIS) 2024–2028 [Ministry of Health, 2024a], replacing the preceding multiyear plan. The NIS articulates a country-specific guiding framework for planning, coordination and implementation of immunisation activities over the next five years. The strategy explicitly identifies the introduction of new vaccines as a strategic objective, committing to the expansion of the national antigen package to address emerging and re-emerging vaccine-preventable diseases. The strategy emphasises that decisions regarding the introduction and rollout of additional vaccines will be guided by the National Immunisation Technical Advisory Group, with consideration given to local disease burden, cost-effectiveness, and health system readiness. This emphasis on planned vaccine introduction reflects an adaptive approach to immunisation policy, aimed at strengthening programme relevance and resilience while consolidating existing gains in coverage and equity [Ministry of Health, 2024a].

Although national coverage indicators remain relatively high for core vaccines [World Health Organization, 2026b], Uganda's immunisation programme continues to confront challenges in reaching all eligible children. The NIS situational analysis recognises that zero-dose and under-vaccinated children continue to contribute disproportionately to the pool of missed individuals; running out of stock at peripheral service delivery points and irregular service schedules, combined with incomplete data quality further undermine performance [Agaba, 2024]. Strategic priorities in the NIS [Ministry of Health, 2024a] accordingly include bolstering cold-chain logistics, improving microplanning and subnational capacity, and

enhancing community engagement to reduce inequities in access and uptake. Within this evolving programme context, the planned introduction of new vaccines represents both a continuation of Uganda's long-standing immunisation trajectory and a strategic response to emerging disease priorities.

4.1.3 Conceptual framing and chapter objectives

Rather than treating these contextual differences as background variables, this chapter approaches them as constitutive elements of how immunisation schedule changes are understood. Caregiver perspectives are situated within these distinct immunisation landscapes in order to examine how trust, authority, and legitimacy are produced through everyday interactions with health systems, as well as through collective memories of past interventions.

This chapter constitutes the first empirical examination of immunisation schedule change within the thesis and provides a foundation for the comparative synthesis developed in the overall discussion. While Chapter 3 maps how the acceptability of schedule change has been conceptualised and documented within the existing literature, this chapter contributed to this literature, adding the lived experiences of caregivers navigating potential change within routine immunisation systems in Nepal and Uganda.

Understanding how changes to immunisation schedules are perceived by parents who have recent experience of immunisation schedule changes, and which changes are most likely to be accepted, is crucial for ensuring continued vaccine acceptance and maintaining the momentum gained in recent years of high coverage rates.

The following objectives relate specifically to parents whose children were enrolled in the optimising diphtheria, tetanus, and pertussis (DTwP)-containing vaccine infant immunisation schedules (OptImms) trial, which evaluated potential modifications to routine childhood vaccine timing and dosing in Nepal and Uganda. This chapter was guided by three main objectives:

- Objective One: assess the acceptability and feasibility of changing childhood vaccine schedules amongst parents of OptImms participants,

- Objective Two: analyse perceptions and attitudes towards changing childhood vaccine schedules amongst parents of OptImms participants,

- Objective Three: identify the information needs of parents of OptImms participant regarding changes to vaccine schedules.

4.2 Methods

4.2.1 Design and setting

Data were collected using a mixed-methods approach, consisting of interviewer-administered surveys and semi-structured interviews at two urban tertiary hospitals (specialist centres that provide advanced and complex medical care beyond primary and secondary services) in Kathmandu, Nepal, and at one site in Uganda – the Medical Research Council/Uganda Virus Research Institute (MRC/UVRI) study offices located within Masaka town. The combination of quantitative and qualitative methods enabled a nuanced exploration of the perceptions

towards potential schedule changes in this specific urban context. The first site in Nepal, Patan Hospital, serves as a major teaching hospital for the Patan Academy of Health Sciences (PAHS), while the second site, the Institute of Medicine (IOM) at Tribhuvan University, is a key academic and clinical institution in Nepal. The third site, MRC/UVRI is an internationally recognised centre of excellence for research and training in Uganda. Data were collected in Nepal between September 2024 and February 2025, and in Uganda between October 2024 and May 2025.

4.2.2 Participants

The participants were a convenience sample of parents or caregivers of children who had participated in the OptImms clinical trial. This sample provided a relevant group of individuals with direct and recent interaction with the childhood immunisation schedule, ensuring that their perceptions and attitudes towards changes in these programmes were informed by real-world experiences.

4.2.3 Data collection

A mixed-methods approach was employed to gather both quantitative and qualitative data, enabling methodological triangulation [Johnson et al., 2007] whereby findings from surveys and interviews were examined in relation to one another to illuminate convergences, tensions, and complementary insights. The interviewer-administered surveys were used to collect quantitative data on participants' perceptions, attitudes, motivations, and acceptability of changes to childhood immunisation schedules. The survey for Nepal can be found in Appendix 6, and for Uganda, Appendix 12. This method was chosen for its ability to

standardise data collection, ensuring that all participants were asked the same questions in a consistent manner to generate reliable and comparable responses, particularly in a population with varying levels of literacy and education.

In Nepal, the surveys were conducted in Nepali by two research assistants (EK and ND); in Uganda, the surveys were conducted in Luganda or English by three social science research assistants (TMN, EA, GN).

Distinct but related questions were organised into four sections: (1) demographic information, (2) previous experiences with vaccine research, (3) motivations for participating in research, and (4) knowledge, attitudes, perceptions, and acceptability of changes to childhood immunisation schedules. Participants had the opportunity to provide free-text answers throughout the survey to capture a broader range of context or concerns that may influence vaccine acceptance and parental attitudes.

To complement and expand upon the survey findings, one-on-one semi-structured interviews were conducted in Nepali by EK and ND in Nepal, and in Luganda or English by TMN, EA, GN in Uganda. These interviews provided qualitative data into participants' perceptions and decision-making processes, offering in-depth context to enrich and enhance the quantitative results. Interviews were conducted until thematic saturation [Saunders et al., 2018] defined as the point at which no substantively new themes or dimensions of existing themes were identified in successive interviews. Saturation was assessed iteratively by the RAs in discussion with the whole team, through ongoing review of emerging codes and analytic memos. The interviews were recorded using external recording devices, which were then transcribed and translated verbatim into English. Each transcription and translation was cross-

checked for accuracy, with a random selection also verified by a senior social scientist, either based in Nepal (BA), or in Uganda (AS).

The semi-structured interviews followed a topic guide (Appendix 9 and 15) consisting of nine sections: (a) research recruitment, (b) initial thoughts on the OptImms clinical trial, (c) scientific justification of the research, (d) risks and safety, (e) attitudes towards vaccines, (f) knowledge of clinical trials, (g) attitudes towards changing immunisation schedules, (h) vaccine communication, and i) questions about their survey responses. The survey and interview topic guide was initially designed by CF using an inductive approach, which were then tested and refined through iterative rounds of piloting with the OptImms team.

4.2.4 Data analysis

Survey data were analysed using descriptive statistical methods in IBM SPSS Statistics (version 30.0.0.0 (171)). Descriptive analysis was employed to summarise the participants' responses, providing an overview of trends, frequencies, and patterns within the data. The results from the surveys were then integrated with the qualitative interview data to offer a comprehensive understanding of the participants' attitudes, perceptions, and motivations.

The translated interview transcripts were analysed using NVivo version 15.0, employing thematic analysis on a line-by-line basis. Each transcript was analysed twice: once by either EK or ND (Nepal), and TMN, EA, or GN (Uganda), who conducted the interview and are embedded within the local context, and once by CF, adopting an external perspective while still being immersed in the broader context. This dual approach facilitated both internal and external perspectives on the data to allow for a deep exploration of the arising themes. A

codebook was developed iteratively throughout the analysis, with the suitability of codes being reviewed and refined during periodic group meetings. All findings were discussed in-person within the group context before final agreement was reached on the codebook; emphasis was placed on the interpretation of the in-country teams, due to their personal experience and greater contextual knowledge [Bhakuni and Abimbola, 2021]. A constructivist grounded theory [Charmaz, 2014] approach was utilised to identify themes and develop an explanatory framework. The rest of this chapter presents a selection of survey data, free-text responses, and interview materials relevant to the topics of analysis, with excerpts from the transcripts used as illustrative examples.

4.2.5 Ethical considerations

Ethical approval to conduct this study was granted by Oxford Tropical Research Ethics Committee (OxTREC) (OxTREC Ref: 13-20 & 12-20), Nepal Health Research Council (NHRC) (Ref 2400) and the Institutional Review Committee – Patan Academy of Health Sciences (IRC-PAHS) (Ref: drs2002281350.A), the Uganda Virus Research ethics research and science committee (GC/12/19/12/754) and Uganda National Council for technology. All participants gave informed consent (consent forms can be found in Appendix 5, 8, 11, 14) after reading a participant information sheet (Appendix 4, 7, 10, 13).

4.3 Nepal Findings

The findings from Nepal (4.3) and Uganda (4.4) are presented sequentially to allow attention to context-specific dynamics before drawing comparative insights. The section begins with Nepal. A total of 100 participants completed the interviewer-administered survey and 33

participants completed the semi structured interview. Demographic characteristics are summarised in Table 5 and 6.

Table 5: Demographic of Nepal survey participants

Characteristic	N =100	Percentage
Age		
18-24	10	10.00%
25-34	68	68.00%
35-44	21	21.00%
Under 18	1	1.00%
Sex		
Female	80	80.00%
Male	20	20.00%
Religion		
Hinduism	79	79.00%
Buddhism	9	9.00%
Christianity	9	9.00%
Kirat	3	3.00%
Highest Level of Education		
No education	2	2.00%
Primary Education (up to class 5)	6	6.00%
Secondary Education (class 6-12)	62	62.00%
Higher than secondary	30	30.00%
Occupation		
Agriculture	1	1.00%
Business/Finance	18	18.00%

Carer for another household member	1	1.00%
Craft and related trades	2	2.00%
Education, law, social, government services	4	4.00%
Health	7	7.00%
Management	6	6.00%
Parent/homemaker	54	54.00%
Sales and services	1	1.00%
Other	6	6.00%
Total Number of Children		
One child	42	42.00%
Two children	48	48.00%
Three children	9	9.00%
Four children	1	1.00%
Distance travelled to vaccine clinic		
1-5 km (0.6-3.1 miles)	55	55.00%
6-10 km (3.7-6.2 miles)	33	33.00%
11-20 km (6.8-12.4 miles)	7	7.00%
21-30 km (13.0-18.6 miles)	3	3.00%
Less than 1 km (Less than 0.6 miles)	2	2.00%
Transport to vaccine clinic		
Motorbike	44	44.00%
Public transport	30	30.00%
Taxi	16	16.00%
Walk	9	9.00%
Car	1	1.00%

Table 6: Socio-demographic data of interview participants

Characteristic	N =33	Percentage
Age		
18-24	1	3.03%
25-34	26	78.79%
35-44	5	15.15%
Under 18	1	3.03%
Sex		
Female	30	90.91%
Male	3	9.09%
Religion		
Hinduism	26	78.79%
Buddhism	4	12.12%
Christianity	2	6.06%
Kirat	1	3.03%
Highest Level of Education		
No education	1	3.03%
Primary Education (up to class 5)	2	6.06%
Secondary Education (class 6-12)	18	54.55%
Higher than secondary	12	36.36%

4.3.1 Vaccine research acceptability and motivations

Participants' prior experiences with clinical trials and their awareness of vaccine research varied. Most participants (91/100, 91%) had never enrolled any of their children in a research study before. Similarly, 97% of participants (97/100) indicated that neither they nor anyone in their household had ever taken part in a clinical trial, with only 3% (3/100) reporting such

an experience. A slightly larger proportion (14/100) knew someone who had participated in a clinical trial, while 85% (85/100) did not, and 1% (1/100) were unsure.

74% of participants (74/100) discussed their choice to enrol their child in the OptImms clinical trial with others, with the majority (54/100, 54%) consulting only one person. Smaller groups discussed with two (15/100, 15%), three (4/100, 4%), or four people (1/100, 1%). Additionally, 24% of participants (24/100) reported that someone they spoke with had attempted to discourage them from enrolling their child in the clinical trial.

The free-text answers revealed multiple reasons behind this discouragement. A recurring theme was apprehension about whether the vaccines were newly developed and potentially untested, which fuelled fears of harmful side effects and uncertainty about the clinical trial's intentions. The unfamiliarity with the vaccine schedules used within the study also emerged as a source of discomfort, with participants highlighting confusion and reluctance to adapt to the changes. Distrust of "foreign vaccines" was another concern, reflecting scepticism toward externally developed medical interventions. Furthermore, the requirement for blood tests intensified anxieties, with participants perceiving this as an invasive and potentially distressing aspect of the study, especially amongst mothers of the survey participants. These themes underscore the interplay of perceived risks, procedural discomfort, and broader contextual mistrust in shaping decisions about participation.

Prior to participating in this study, participants self-reported varied levels of knowledge about vaccine trials. A significant proportion (36/100, 36%) had no knowledge at all, unaware of how vaccines are tested before being approved for public use. Another 36% (36/100) had limited knowledge, understanding the general concept of vaccine testing for safety but

lacking awareness of detailed processes or clinical trial participant selection criteria. A smaller group (22/100, 22%) had a basic understanding of vaccine trials, knowing that vaccines undergo extensive testing before approval, though they were unfamiliar with specific trial phases or regulatory bodies. Only 6% of participants (6/100) considered themselves very knowledgeable, possessing a deep understanding of the purpose, phases, and approval process of vaccine trials.

Table 7: Nepal OptImms trial experience

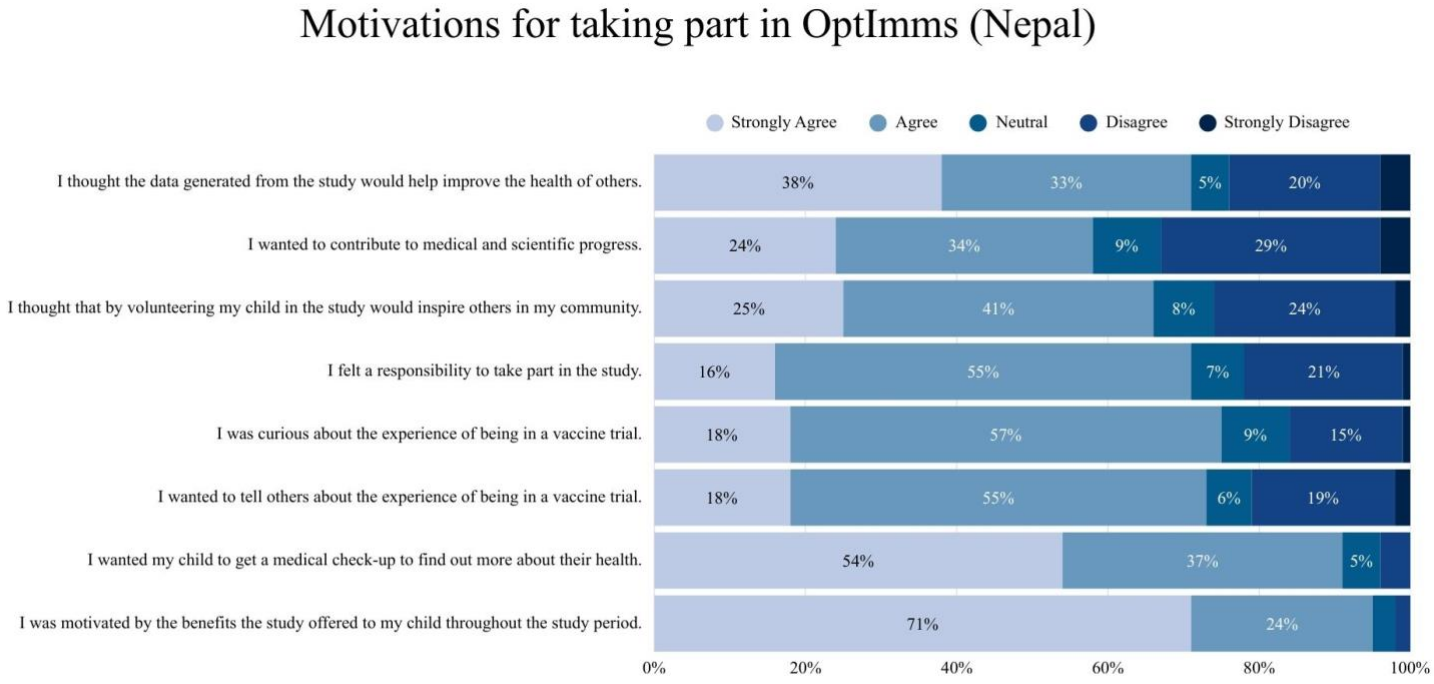
Question	N =100	Percentage
Have you ever enrolled your child (currently in OPTIMMS) or another child in research before?		
Yes	9	9.00%
No	91	91.00%
Have you, or anyone in your household, ever taken part in a clinical trial before?		
Yes	3	3.00%
No	97	97.00%
Has anyone you know ever taken part in a clinical trial before?		
Yes	14	14.00%
No	85	85.00%
Unsure	1	1.00%
Did you discuss your decision to enrol your child in this study with anyone else?		

Yes	74	74.00%
No	26	26.00%
How many people did you discuss with? *		
One	54	54.00%
Two	15	15.00%
Three	4	4.00%
Four	1	1.00%
Did anyone you discussed volunteering with try to discourage you from signing up? *		
Yes	24	24.00%
No	76	76.00%
Before this study, what was your knowledge of vaccine trials?		
Not knowledgeable at all: *I had no prior knowledge of vaccine trials. I was unaware of how vaccines are tested before being approved for public use.*	36	36.00%
Not very knowledgeable: *I had limited knowledge of vaccine trials. While I understood the general idea of testing vaccines to make sure they're safe, I may not have been aware of the detailed processes involved or the criteria for selecting participants in trials.*	36	36.00%
Somewhat knowledgeable: *I had a basic understanding of vaccine trials and why they're important. I knew that vaccines undergo lots of testing before approval, but I may not have been familiar with the specific phases of clinical trials or the regulatory bodies involved.*	22	22.00%
Very knowledgeable: *I had a deep understanding of vaccine trials, including their purpose, phases, and how they become approved for use.*	6	6.00%

* only answered by those who answered by those who answered 'yes' to discussing trial participation with others

A key motivator for participation in the OptImms clinical trial was the opportunity to access healthcare services and receive financial reimbursement. 95% of parents strongly agreed or agreed (95/100) that they were motivated by the study benefits (participants received free medical appointments where needed, additional vaccines not in the routine schedule, and travel cost reimbursements at each visit), or to get a medical check-up to find out more about their child's health (91%, 91/100). One participant noted; *"When vaccinating here, we received concessions, one thing was the treatment for my child was free for two years. And another option was we received the vaccines administered after 15 months, two vaccines, for free"* [6-27]. Interview participants underscored the importance of the research process, stating, "*It is necessary. Medicines and vaccines are always needed in the world. It should be studied"* [6-10]. Another participant articulated longer-term implications, linking the necessity of research to broader societal progress, stating: "*The children of today are the leaders of tomorrow, right! If they are made healthy from the beginning, if they are educated from the beginning, they can do something good in the future or they can contribute to the country*" [6-29]. Overall, participants' primary motivators for clinical trial participation included access to free healthcare, additional vaccines, and financial compensation, with many also recognising the broader societal value of research, suggesting strong support for vaccination, which is further examined in the following section.

Figure 2: Nepal participants motivations for taking part in OptImms



The participants showed strong support for vaccination, with 98% (98/100) considering vaccines to be very important for their child's health. A significant majority (81/100, 81%) believed that most of their close family and friends supported their decision to vaccinate their child. Notably, 97% (97/100) of participants expressed a desire for their child to receive all of the vaccines recommended in Nepal's immunisation programme. This desire partially arose as vaccination was perceived as an established norm—something that had been done for generations and should continue. One participant stated: *"If the Nepal government has issued it and everyone is getting it, then I will trust and give it" [*7-20]. However, this wasn't unanimous. Other participants recalled past adverse consequences of inadequate immunisation coverage as a reason for supporting vaccines, stating: *"Previously, some children were crippled due to a lack of vaccination. That is why it must be given now"[6-10].*

Participants largely expressed trust in the safety of vaccines, with many indicating confidence in regulatory processes and the absence of harmful substances in vaccines. One participant articulated this idea clearly, saying: *"There was no question about risk! It is a vaccine, it is not mixed with harmful things. It is given to children because it does good to them…"[6-19].* However, concerns were raised by other participants regarding the handling of vaccine safety monitoring in Nepal compared to other countries. One participant noted*: "we administered this Covishield in a rush, and we can see its effects now. In Nepal, there is nothing, the government has no policy, what do we do about it, how to compensate the people, nothing is known. There is nothing about how to put it under observation. But it is taken very seriously outside [in other countries]"* [6-20]. This statement highlights anxieties about the perceived adequacy of national regulatory frameworks and post-vaccination monitoring within Nepal.

Table 8: Nepal participant's general vaccine attitudes

Question	N =100	Percentage
How important do you think vaccines are for your child's health?		
Not at all important	1	1.00%
A little important	0	0.00%
Moderately important	1	1.00%
Very important	98	98.00%
Do you think most of your close family and friends want you to get your child vaccinated?		
Yes	81	81.00%
No	17	17.00%
N/A	2	2.00%

Nepal has a schedule of recommended vaccines for children. Do you want your child to get none of these vaccines, some of these vaccines, or all of these vaccines?		
All	97	97.00%
Some	3	3.00%
None	0	0.00%

4.3.2 Attitudes towards, and knowledge of, changing vaccine schedules

Before participating in the OptImms clinical trial, participants self-reported varying levels of knowledge about childhood vaccine schedules. A small proportion (7/100, 7%) indicated they were not knowledgeable at all, with no awareness of vaccine schedules. A larger group (39/100, 39%) described themselves as not very knowledgeable, acknowledging the need for vaccines but lacking specific knowledge about the timing or types required. Half of the participants (50/100, 50%) were somewhat knowledgeable, describing themselves as understanding that vaccines are given at specific times but were uncertain about the precise schedule. Only 4% (4/100) described themselves as very knowledgeable, with a clear understanding of when vaccines should be given and their importance.

Additionally, 31% (31/100) of participants were aware of recent changes to the national vaccination schedule, while the majority (69/100, 69%) were not. Free-text answers revealed that although there was an acknowledgement of the addition of new vaccines, there was limited knowledge about the names and details of these vaccines among respondents. However, 12% (12/100) of participants could recall the names of some. For example, the introduction of vaccines against typhoid, Japanese encephalitis, varicella, and rotavirus were discussed by some participants. Among the parents who were aware of previous changes,

their opinions of these changes were all positive, highlighting that new vaccines were important for fighting against emerging diseases and helping protect children from illnesses.

4.3.3 Acceptability of vaccine schedule changes

Parental acceptance of proposed changes to the childhood vaccine schedule varied considerably depending on the nature of the change hypothesised. The introduction of a recently approved vaccine was met with low levels of acceptance, with 35% of respondents (35/100) indicating they were likely or very likely to support this change (3% very likely, 3/100; 32% likely, 32/100). Concerns expressed in free-text responses centred on the novelty of the vaccine, with hesitancy driven by uncertainty around safety, side effects, and effectiveness. In contrast, acceptance was higher for vaccines already used in other countries, with 64% of respondents (64/100) reporting they were likely or very likely to support this change (9% very likely, 9/100; 55% likely, 55/100). In free-text responses, some participants felt that vaccines should undergo additional testing within the Nepal context to ensure compatibility with local environmental and health factors. Their described decision-making was often influenced by conversations with trusted healthcare providers, observing the experiences of others, and verifying research data. While some were open to adopting new vaccines if shown to benefit their child, others remained sceptical, fearing their use for experimental purposes or adverse effects due to contextual differences between countries.

Increasing the number of visits to the healthcare provider was a widely accepted change, with 79% of respondents (79/100) expressing support (19% very likely, 19/100; 60% likely, 60/100). Participants described their acceptance towards this change as potentially reducing the number of vaccines administered per visit, thereby minimising pain and discomfort for

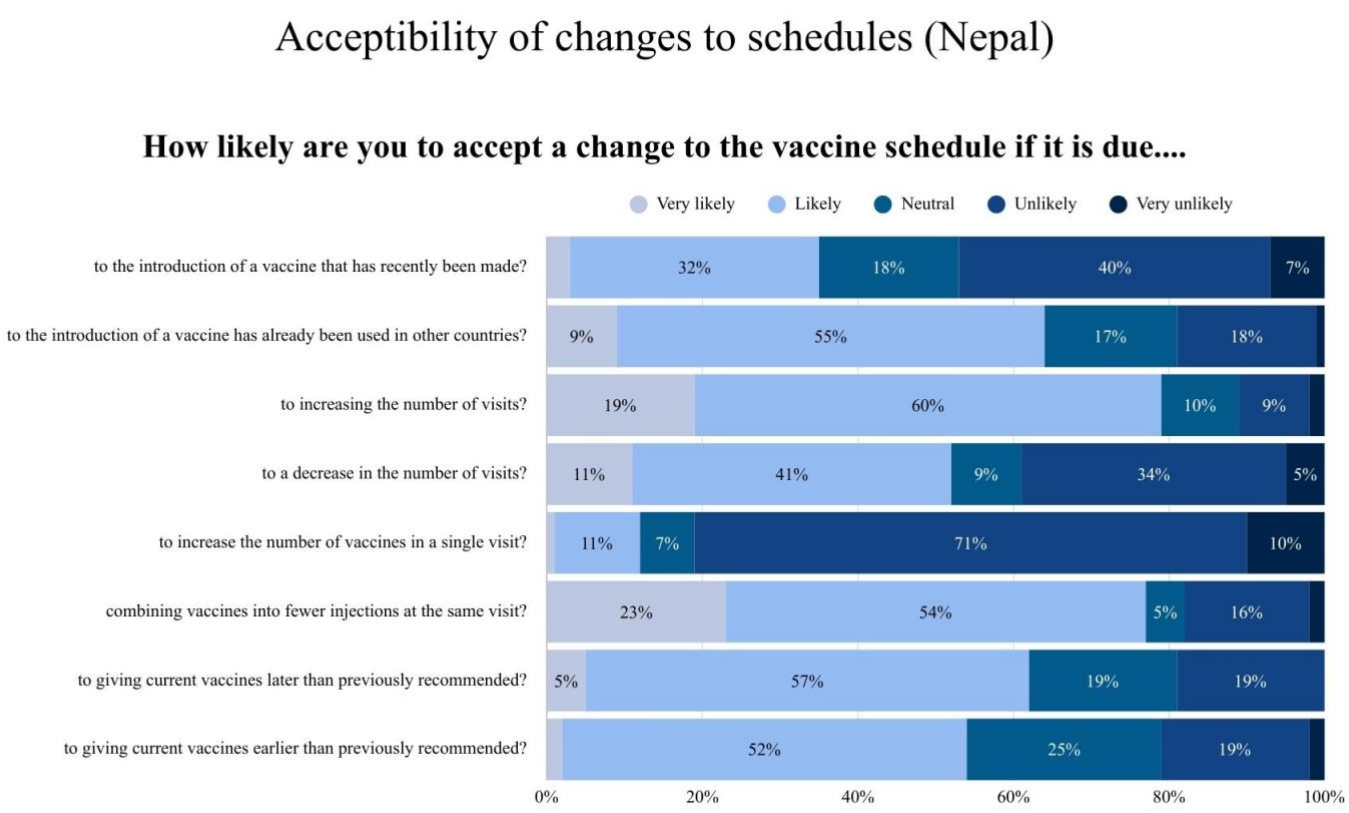
children. A decrease in the number of visits, on the other hand, received moderate levels of acceptance, with 52% of participants (52/100) likely or very likely to support the change (11% very likely, 11/100; 41% likely, 41/100). While parents described their appreciation towards the convenience and logistical benefits of fewer visits in the free text answers, concerns arose about the potential for administering more vaccines during each session, which many perceived as less tolerable for children.

Changes involving an increase in the number of vaccines administered in a single visit faced significant resistance, with 81% of respondents (81/100) reporting they were unlikely or very unlikely to accept this adjustment (71% unlikely, 71/100; 10% very unlikely, 10/100). Free-text responses highlighted concerns about the physical and emotional impact on children, with frequent mentions of pain, side effects, and perceived risks to the immune system. Combining vaccines into fewer injections at the same visit was the most accepted modification, with 77% of participants (77/100) reporting they were likely or very likely to support this change (23% very likely, 23/100; 54% likely, 54/100). Respondents valued the convenience and reduced discomfort associated with fewer injections. However, some concerns about the safety and efficacy of combined vaccines were noted, with some worried about potential cross-reactions or reduced effectiveness.

Adjustments to the timing of vaccines also revealed variability in parental acceptance. Administering vaccines later than previously recommended was more acceptable, with 62% of respondents (62/100) indicating they were likely or very likely to support this change (5% very likely, 5/100; 57% likely, 57/100). Concerns about delayed protection and increased vulnerability to diseases were prominent among those expressing reservations. In comparison, administering vaccines earlier than previously recommended was supported by a

smaller proportion of respondents, with 54% (54/100) reporting they were likely or very likely to accept this modification (2% very likely, 2/100; 52% likely, 52/100), although apprehensions about the tolerability of vaccines in younger infants and the risk of side effects were common themes in the free-text responses.

Figure 3: Nepal participant's acceptability of schedule changes



4.3.4 Perceptions of changing childhood immunisation programmes

Nepal's childhood immunisation programme is highly institutionalised and widely embedded within primary healthcare delivery, supported through longstanding government programmes, community-based outreach, and the work of FCHVs. At the same time, immunisation delivery takes place within a context shaped by geographical diversity, uneven access to

healthcare infrastructure, and ongoing adaptation of the national schedule through the introduction of new vaccines and evolving delivery strategies. These conditions formed an important backdrop to how parents interpreted proposed schedule changes throughout the semi-structured interviews, particularly in relation how well their child could tolerate the potential changes, the extent to which the parent trusted healthcare providers and systems, and whether the schedule changes were considered relevant to the Nepali context. These themes are explored in the following subsections.

4.3.4.1 Child-centred response and vaccine tolerability

Parents' perceptions of what their child's tolerance to vaccines might be, the side effects experienced, and their confidence in their child's body to cope with multiple vaccines at once played a crucial role in the acceptability of changes to childhood immunisation schedules. Many parents expressed concerns about potential side effects associated with vaccinations and how well their child's body would cope. As one parent explained:

"[Multiple] vaccines at the same [appointment] will be difficult for a child. The amount of medicine will increase; it will be difficult to take care of the child, and the child will also be at risk. It will be difficult. The child will be drowsy, sleepy, might lose appetite, and even remain sick for 2-3 days" [Participant 6-10].

To minimise child discomfort, many parents favoured strategies that reduced pain and distress during vaccinations. A recurring suggestion was to limit the number of vaccines administered in a single visit.

During the interviews, it was acknowledged by some parents that logistically, less vaccine visits could be preferable, but the comfort of the child still needed priority:
"*Yes, it will be easy for us as the vaccination will be over soon. But it causes discomfort for the baby after giving vaccines under such schedules. Due to this reason, it would be better not to do it like that, but to administer it one at a time"* [Participant 6-10].

Another parent shared their emotional response to their child receiving multiple vaccines in one visit:

"It will be difficult. Instead, I would prefer visiting 2-3 times a month or visiting weekly... Last time when she was administered two vaccines, I was sitting outside crying. I could not! Ma'am, I'm afraid" [Participant 6-37].

Many parents expressed confidence in the current schedule, viewing it as familiar and well-established, and so hypothesised changes were often thought about in comparison to this; "*If the vaccine is the same and if it works the same way, I won't mind a delay…"* [Participant 6-10]. Overall, parents' perceptions of vaccine tolerability, concerns about side effects, and a preference for pain reduction led many parents to favour fewer vaccines per visit, or other changes that reduce the discomfort faced by a child when receiving vaccines.

4.3.4.2 Trust and distrust in vaccine systems

Trust in healthcare professionals, family, and friends was a key determinant of vaccine acceptance. Doctors were frequently cited as influential figures. One participant expressed this sentiment by stating, "*I believe doctors are like a God"* [Participant 6-24]. However, trust in the healthcare worker was sometimes pragmatic or conditional, relying on institutional

affiliation and structured healthcare settings, "*If we [participant and healthcare worker] meet outside and you tell me that these kinds of services [vaccination] are available for children, I won't rush to get it"* [Participant 6-16]. In this instance, trust appears to be mediated by context; it is pragmatic in the sense that it is guided by practical considerations, and conditional in that it is granted only when certain institutional or situational criteria are met.

Many participants viewed government-led immunisation schedules as credible, reinforcing their adherence: *"Because the schedule is made by the government, the child is the leader of the future, the government should consider this and decide accordingly"* [Participant 6-20]. In contrast, private healthcare providers were viewed with suspicion, particularly due to accessibility concerns and regulatory oversight. One participant remarked: *"Private sectors are not accessible everywhere as well; such service might not be available in places other than Kathmandu, Lalitpur, Bhaktapur"* [Participant 6-10]. Concerns also emerged regarding unregulated vaccine administration from private services: "*People owning the pharmacy are also vaccinating children... even in pharmacies, they wear the doctor's set. Many people assume they are a doctor*" [Participant 6-29].

Interestingly, the acceptance of government recommendations was sometimes framed as a form of reliance, or dependence, rather than a reflection of deep confidence or trust: "*We are dependent on the government regarding this matter"* [6-10], "If the government says it must be done, then there's no other option"[Participant 7-35], and in some cases, it was evident that this dependency on the government was liable to shift onto another entity when a better option occurred:

"If the government has made a change, and the information is already available… If it's confirmed, then I will follow it. But if [there is] something else, if it seems better, then I will follow that instead" [Participant 7-35].

Another example of this is where participants' dependency switched from the government to the clinical trial team; "I feel [taking part in a clinical trial is] definitely beneficial. Compared to the vaccines provided by the Nepal government, I feel like I received a bit more, didn't I? They provide additional services, which I find very good" [Participant 7-21].

A significant theme surrounding new vaccines was a suspicion that unregulated vaccine trials may be carried out in Nepal. Some participants expressed concern that if new vaccines were introduced in Nepal, they might primarily be for testing purposes rather than for the immediate health benefits. One participant explained: *"Now we have to think about it if the foreigners discovered it there and introduced it to Nepal for testing"* [Participant *6-20].* However, not all participants shared this scepticism. Some acknowledged that vaccine development was largely driven by high-income countries and that Nepal, as a lower-income country, depended on external support for vaccines:

"Because it is rich countries or developed countries that produce vaccines. Nepal is one of the developing nations and we know that if any new disease arises, we have to seek help from developed countries" [Participant 6-10].

This perspective illustrates the tension between concerns over external influence and recognition of global health dependencies. Broadly, trust in healthcare professionals, government-led immunisation schedules, and concerns about unregulated vaccine administration influenced vaccine acceptance, with a notable tension between reliance on external support and scepticism about vaccine trials in Nepal.

4.3.4.3 Relevance of vaccines to Nepal

Parents emphasised the need for vaccine schedules to be tailored to Nepal's specific geographical, epidemiological, and health challenges. Many linked the necessity of immunisation to emerging diseases and environmental factors:

"Various new diseases are arising… to build our immune system's ability to fight against such diseases, to produce different types of medicine, to produce medicine by studying and research, I think such studies are important to be conducted" [Participant 6-10].

Environmental factors were described as a compelling reason for changes to vaccine schedules too*:*

"If the government of Nepal has issued [a vaccine] which is not available in other countries, we are ready to use it even if it is only for Nepal in order to control the diseases posed by the geography, water quality, and various things here" [Participant 6-10].

Another parent reinforced this view, stating*, "Rather than high- or low-income countries, the climate could make a difference! We have to understand whether the climate and the environment where we grow up can cause any difference"* [Participant 6-18].

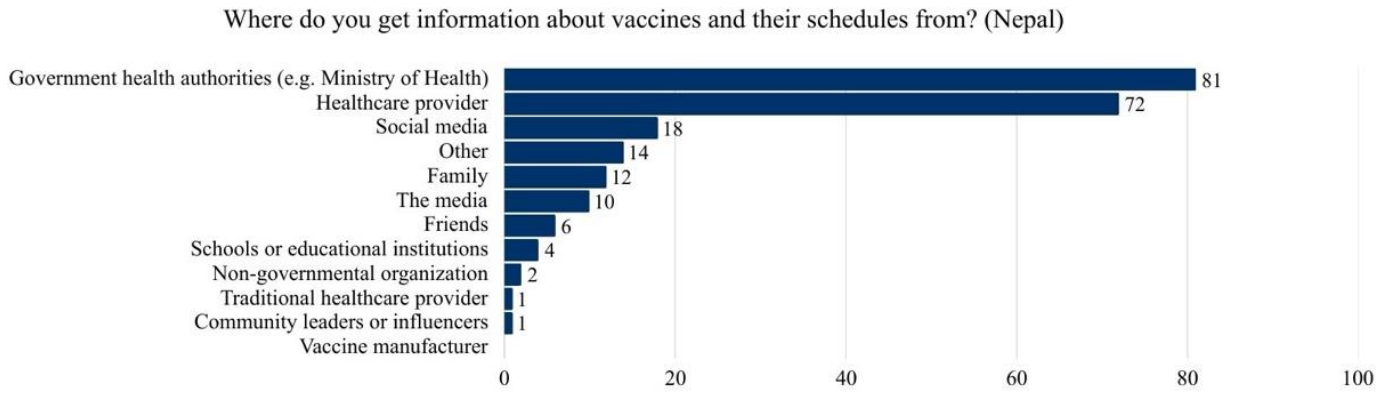
However, confidence in vaccine safety and effectiveness was closely linked to whether vaccines had been tested in Nepal. Although there was opposition to Nepal being used as a testing site for new vaccines, *"If they develop a vaccine and try to test it in Nepal, even the government should not allow it!"* [Participant 6-20], some participants favoured vaccines that had undergone local trials to ensure their effectiveness in, and relevance to, Nepal; *"even if it*

has been used in underdeveloped countries, it won't be administered in Nepal unless researched here" [Participant 6-29]. " Others placed confidence in the expertise of researchers, trusting that proper testing ensured safety. *"I did not feel any risks… the research will be done by an expert team from different agencies"* [Participant 6-10]. Generally, the parents in this study emphasised the importance of vaccines being relevant to Nepal's specific environmental and health context, with a preference for vaccines that had been tested locally to ensure their effectiveness. But despite this, there was still hesitancy around vaccine testing in Nepal.

4.3.5 Vaccine schedule information needs

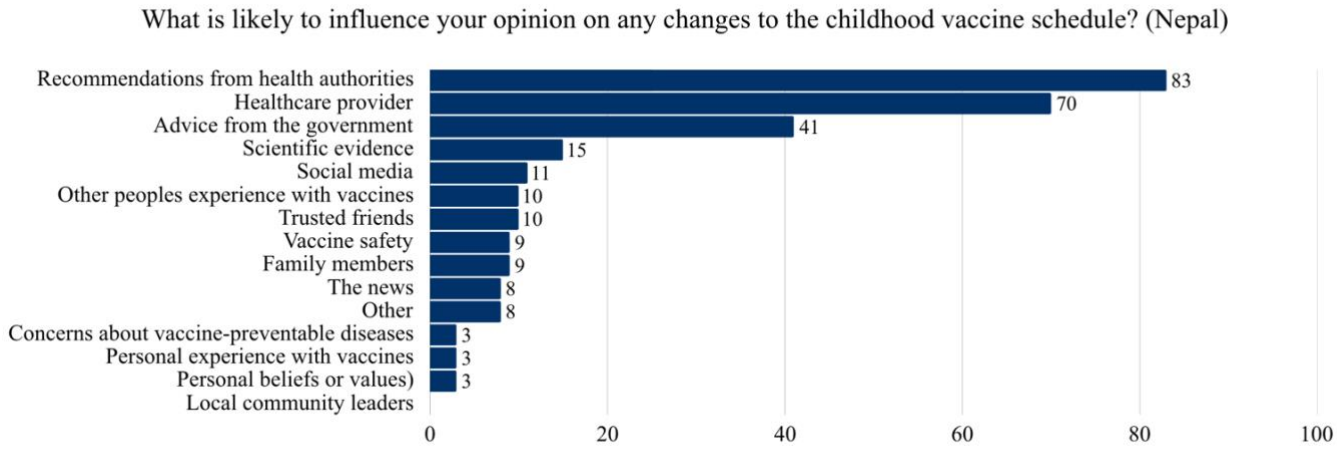
Participants reported various sources of information about vaccines and their schedules. The most common sources were government health authorities (81/100, 81%) and healthcare providers (72/100, 72%). Smaller proportions relied on social media (18/100, 18%), family (12/100, 12%), and the media (10/100, 10%).

Figure 4: Nepal participant's vaccine information sources



Several factors that could influence the participant's opinion on changes to the childhood vaccine schedule were noted. The most influential factors were recommendations from health authorities (83/100) and healthcare providers (70/100). A notable proportion also cited advice from the government (41/100) and scientific evidence (15/100).

Figure 5: Factors influencing opinions on changes to the childhood vaccination schedule in Nepal



Taken together, the Nepal findings demonstrate strong support for vaccination, alongside more careful evaluation when established schedules were changed. Vaccines were widely regarded as important, yet potential changes prompted parents to reflect on how such changes would affect their child, how they aligned with existing government recommendations, and whether they were appropriate for Nepal. Parents expressed uncertainty surrounding tolerability, institutional oversight, and national relevance in ways that were grounded in caregiving responsibility and prior experience. In this sense, schedule change activated contextualised reasoning shaped by trust, reliance, and judgements about legitimacy.

4.4 Uganda findings

Having outlined the findings from Nepal, this section turns to the Uganda dataset, exploring parental responses to immunisation schedule change within a distinct but comparable context. A total of 100 participants completed the interviewer-administered survey, and 20 participants completed the semi-structured interview. Demographic characteristics are summarised in Table 9 and 10.

Table 9: Demographic of Uganda survey participants

Demographics	N	Percent
Age		
18-24	36	36%
25-34	53	53%
35-44	10	10%
45-54	1	1%
Gender		
Male	2	2%
Female	98	98%
Religion		
Christianity	87	86%
Islam	13	13%
Highest level of education		
No education	1	1%
Primary Education	33	33%
Secondary Education	46	46%
Higher than secondary	20	20%
Type of work		
Business/Finance	20	20%
Agriculture	16	16%
Health	2	2%
Education, law, social, government services	11	11%
Sales and services	18	18%
Trades and transport	4	4%
Craft and related trades	2	2%

Unemployed	10	10%
Parent/homemaker	10	10%
Other	7	7%
Number of children		
1	20	20%
2	33	33%
3	21	21%
4	12	12%
5+	14	14%
Mode of transport		
Walk	1	1%
Public transport	99	99%
Distance travelled		
Less than 1 km (Less than 0.6miles)	6	6%
1-5 km (0.6-3.1miles)	51	51%
6-10 km (3.7-6.2miles)	28	28%
11-20 km (6.8-12.4miles)	10	10%
21-30 km (13.0-18.6miles)	1	1%
41-50 km (25.5-31.1miles)	2	2%
More than 50 km (More than 31.1miles)	2	2%

Table 10: Socio-demographics of Uganda interview participants

Characteristic	N =20	Percentage
Age		

18-24	1	5%
25-34	9	45%
35-44	10	50%
Sex		
Female	18	90%
Male	2	10%
Religion		
Catholic	9	45%
Protestant	3	15%
Muslim	3	15%
Anglican	2	10%
Born Again	2	10%
Adventist	1	5%
Highest Level of Education		
Primary education	6	30%
Secondary education	8	40%
Higher than secondary education	5	25%
No formal education	1	5%

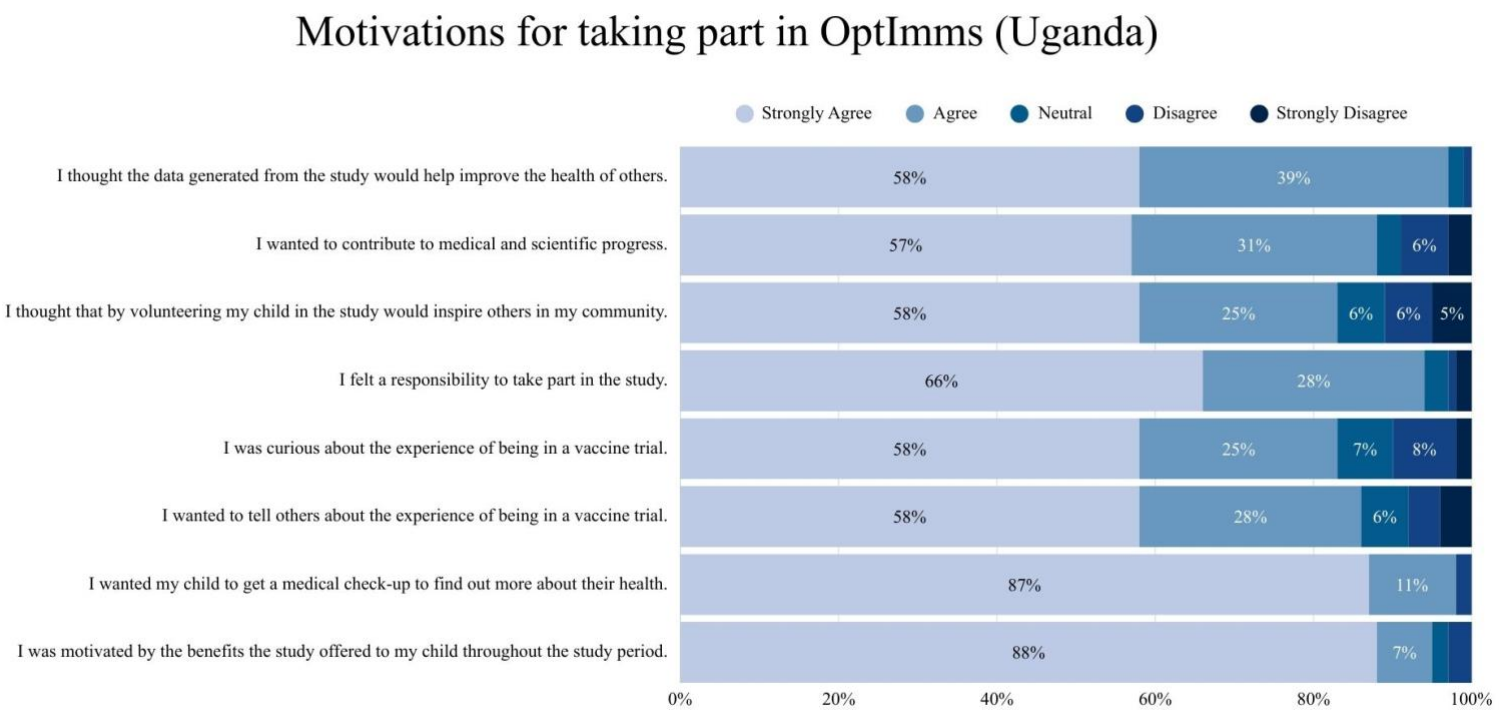
4.4.1 Vaccine research acceptability and motivations

The survey participants had limited prior exposure to vaccine research, with only 5% (5/100) of respondents reporting that they, or someone in their household, had ever participated in a clinical trial before, and just one having previously enrolled a child in any type of research before. Awareness of vaccine trials was low; 59% (59/100) of respondents described themselves as “not knowledgeable at all”, meaning they didn't know anything about vaccine

schedules. 45% described themselves as "not very knowledgeable", meaning they didn't know much about vaccine schedules, but knew their child needed vaccines, but still didn't know when or which ones were required. 33% (33/100) described themselves as “somewhat knowledgeable” — they knew a bit about vaccine schedules but weren’t sure about all the details. Finally, one considered oneself to be “very knowledgeable”.

Despite this limited background, participants expressed high levels of motivation to take part in the OPTIMMS vaccine study, reflecting both altruistic and self-interested reasoning. Agreement was consistently strong across all participation motivations (Figure 6): 98% (87%, 87/100 strongly agree, 11%, 11/100 agree) were motivated by the opportunity for medical checkups of their child, while 95% (88%, 88/100 strongly agree, 7% 7/1000 agree) agreed that they were motivated by the benefits the study offered to their child. However, 94% (58%, 58/100 strongly agree, 39%, 39/100 agree) also felt that participation would help improve the health of others, and 94% (66% strongly agree, 28% agree) felt a responsibility to take part. These data indicate a mixed motivational profile, combining community-oriented values with individualistic motivators. Consequently, participation in this vaccine trial should not be interpreted as evidence of an inherently more compliant or research-trusting population. Rather, it reflects practical engagement, rooted in personal benefit and altruism, suggesting that while Ugandan parents were receptive to vaccine-related research, this orientation does not automatically translate into uncritical acceptance of vaccine schedule changes.

Figure 6: Uganda participant's motivations for taking part in OptImms



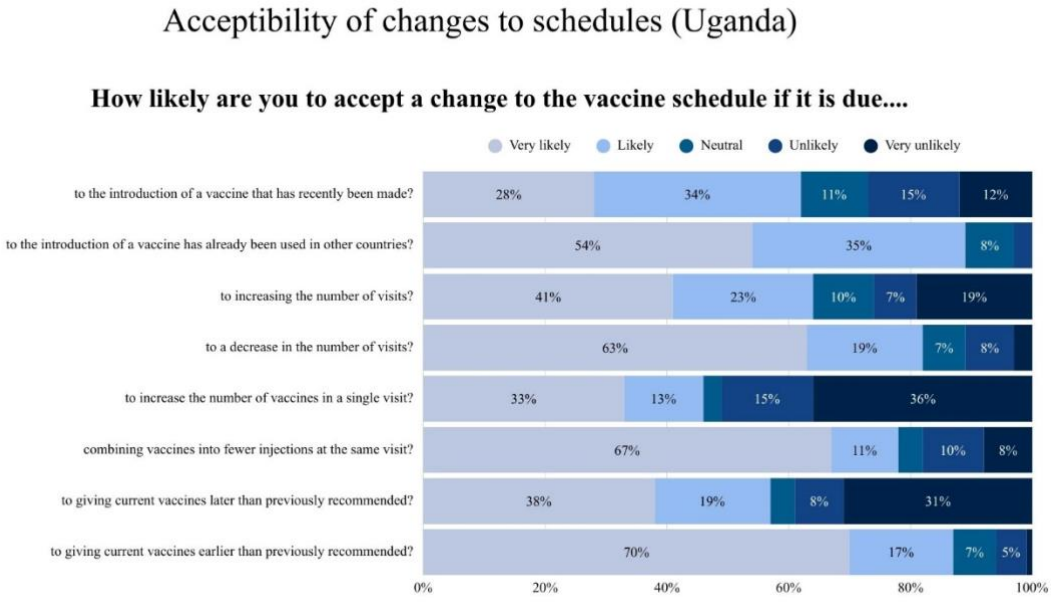
4.4.2 Acceptability of vaccines

Vaccine acceptability among parents reflected a strong recognition of the value of immunisation. Survey findings indicated that nearly all respondents (98%, 98/100) viewed vaccines as very important to their children's health, and 93% (93/100) articulated that they wanted their children to receive all recommended vaccines. Social influence also played a reinforcing role, with 93% (93/100) of participants reporting that family and friends encouraged vaccination, suggesting that community norms largely align with pro-vaccine attitudes.

4.4.3 Acceptability of vaccine schedule changes

Participants' willingness to accept changes to the national immunisation schedule was conditional, depending on perceived legitimacy and safety. Overall, only 37% (37/100) of participants were aware of any recent changes to the national vaccination schedule. However, over half the respondents were likely (28%, 28/100 very likely, 34%, 34/100 likely) to accept a new vaccine; this increased dramatically if the vaccine had already been used in other countries (54%, 54/100 very likely, 34% 34/100 likely). Reducing the number of clinic visits was also deemed to be highly acceptable, with 63% (63/100) of participants very likely to accept this change, and 19% (19/100) likely. Similarly, giving vaccines earlier than previously recommended was highly accepted by the survey participants, with 87% (87/100) likely to accept this change (70%, 70/100 very likely, 17%, 17/100 likely). This reduced to 57% (38%, 38/100 very likely, 19%, 19/100 likely) when faced with giving vaccines later than currently recommended. Acceptance was also high for combining multiple vaccines into fewer injections at one visit (67%, 67/100 very likely, 11%, 11/100 likely). Full responses can be found in Figure 7.

Figure 7: Uganda participant's acceptability of schedule changes



4.4.4 Perceptions of vaccine schedule changes

4.4.4.1 Authority, history, and trust

Uganda's immunisation programme has undergone substantial expansion since the establishment of UNEPI in 1983, with vaccination becoming closely associated with reductions in childhood illness and mortality. At the same time, the programme has developed within a context shaped by historical disruptions to healthcare delivery, uneven access to services, and ongoing efforts to strengthen community engagement and introduce new vaccines. Contemporary immunisation policy in Uganda therefore combines strong institutional authority with continued adaptation of the national schedule in response to emerging public health priorities. These historical and institutional conditions formed an important backdrop to how parents interpreted vaccine schedule change, particularly in relation to trust in government decision-making, perceptions of legitimacy, and expectations of state responsibility for children's health.

In the semi-structured interviews, participants' perceptions of vaccine schedule changes were shaped by several interrelated themes. The first of these centred on institutional authority and historical experience, illustrating how parents placed decision-making power in the hands of health workers and government agencies *"If there is a new change in the vaccine schedule, I will have no option but to go with what the government has decided,"* said one mother (Ug-F-35). A perception of government paternalism emerged, with participants suggesting that authorities act in the best interests of children: *"Because government's major goal is to keep healthy children. They cannot accept or adopt vaccines that will be harmful to the health of the children"* (Ug-F-41). Others explained that they trusted doctors to know what was best:

"I trust doctors; they know better than me. If they explain to me and I understand, it's okay" (Ug-F-43).

However, this conviction was often accompanied by a sense of limited autonomy in health decision-making. Many participants described vaccination as something to be followed rather than questioned, reflecting an unequal power dynamic between parents and the institutions responsible for vaccine policy. One caregiver stated, *"I already surrendered my children to be vaccinated. Even their older vaccine schedules—it's not me who planned it"* (Ug-F-43). This sense of limited agency suggests that compliance with immunisation guidance stems not only from confidence in authority but also from necessity. "*This is because I cannot start being defiant… I don't like that timing? I will just have to go with what they have decided"* (Ug-F-29). Parents adhered to the national programme because they felt they had little alternative.

Historical experience further shaped how parents interpreted vaccine safety and legitimacy. Several participants recalled negative vaccination stories, while not necessarily reflecting verified events, they illustrate how collective memory and local narratives about past vaccination harms continue to influence present-day vaccine perceptions: *"There was a time when they immunised children with a certain vaccine and all those children died. That can't leave you the same,"* one mother recalled (Ug-F-28). Such memories, whether based on direct experience or community narratives, created a lasting impression that "new" vaccines required careful scrutiny. Historical experiences of infectious diseases also moulded participants' decision-making processes when it comes to deciding whether to accept vaccines or not. COVID-19 specifically was described, where individuals decided against vaccination, yet then experienced the disease: *"You see, you may refuse to take on those*

vaccines, then in the future the illness attacks you, that is what happened with covid" (UG-F-29). However, this reliance on institutional trust and past experience underscores broader structural asymmetries, where global disparities in vaccine access and information can further shape how trust and agency are negotiated at the local level.

4.4.4.2 Global inequality and vaccine hierarchies

In part, parents evaluated vaccine safety and effectiveness in relation to their geographical and previous use. Vaccines already used in other countries were viewed as safer and more reliable: *"I would not have a problem with it since other countries are already using it, it is encouraging" (Ug-F-38)*. This was further emphasised when the vaccine had already been used in a high-income country: "*those countries are ahead of us in good medication, so if we got some of their medications, it would do us well"* (Ug-F-43). By contrast, vaccines introduced first or exclusively in Uganda raised anxiety, with one parent asking, *"When other children are not getting it elsewhere in the world, where is this drug made from? What if their aim is to kill Ugandans?"* (Ug-F-38). These statements indicate that parents evaluated vaccine safety through reference to where and how a vaccine had previously been used. Prior use in other countries, particularly high-income settings, was treated as evidence that the vaccine had undergone sufficient testing and oversight. For some parents, the fact that a vaccine was already being administered elsewhere signalled that it had been 'proven' and therefore posed less risk. By contrast, the idea of a vaccine being introduced first or exclusively in Uganda prompted anxiety. In these instances, parents questioned why their children would receive a vaccine not yet used in other parts of the world, expressing concern that domestic introduction could imply insufficient testing or unequal treatment. These

accounts show that perceptions of safety were closely tied to assumptions about prior use, alongside regulatory scrutiny and comparative global positioning.

At the same time, some parents expressed pride and aspiration in aligning Uganda's health practices with international norms: *"We want our country to level up to the high-income countries… using the same vaccines gives us confidence"* (Ug-F-41). For these parents, using vaccines that were also administered in high-income countries signalled progress, modernity, and participation in global standards of care. Confidence was therefore shaped not only by assessments of safety, but by how Uganda's immunisation practices were perceived in relation to other countries. Acceptance was linked to a sense that inclusion within widely adopted vaccination programmes reflected equal treatment and shared standards, rather than marginalisation.

4.4.4.3 Safety, side effects, and comfort

Concerns about vaccine safety and tolerability were significant to individual decision-making. As described in the survey, parents overwhelmingly supported immunisation, but in the semi-structured interviews, some expressed hesitation about the physical and emotional effects of vaccines on their children. Many associated multiple injections with pain, potential side effects, or an 'overload' of medicine: *"I would feel bad because the more you give a child many vaccines, the more the drug content in their body, which is not good. Injections are also painful to the child"* said one mother (Ug-F-35).

The discomfort children experienced during vaccination was emotionally significant to many caregivers; as one participant noted, *"It takes away peace of mind… after many injections…"*

(Ug-F-38). Reducing the number of injections per visit or combining vaccines into a single shot was therefore seen as a positive adjustment: *"When the child is injected less, there is less pain, and I think fewer vaccines could be a result of combination. The child still benefits the same"* (Ug-M-41). However, the idea of reducing the number of injections per visit, thus increasing the overall number of visits, prompted discussion around practicality.

Frequent clinic visits were described as tiring and costly due to transport expenses and time away from work. *"I would feel bad because it's tiring to go to the hospital all the time; it interrupts my peace and schedule,"* explained one mother (Ug-F-35). In contrast, reduced visits were viewed as convenient and time-saving: *"it is also beneficial in a way of reduced transport. It helps someone to have to travel less",* said one father (Ug-M-41). A smaller number of participants accepted more frequent visits if convinced that such changes were medically justified. *"That would mean there are new diseases they have discovered which have to be vaccinated against. I have no problem with that arrangement,"* noted another (Ug-F-29). These responses show that practical barriers did not necessarily lead to rejection but required sufficient explanation and reassurance to sustain confidence.

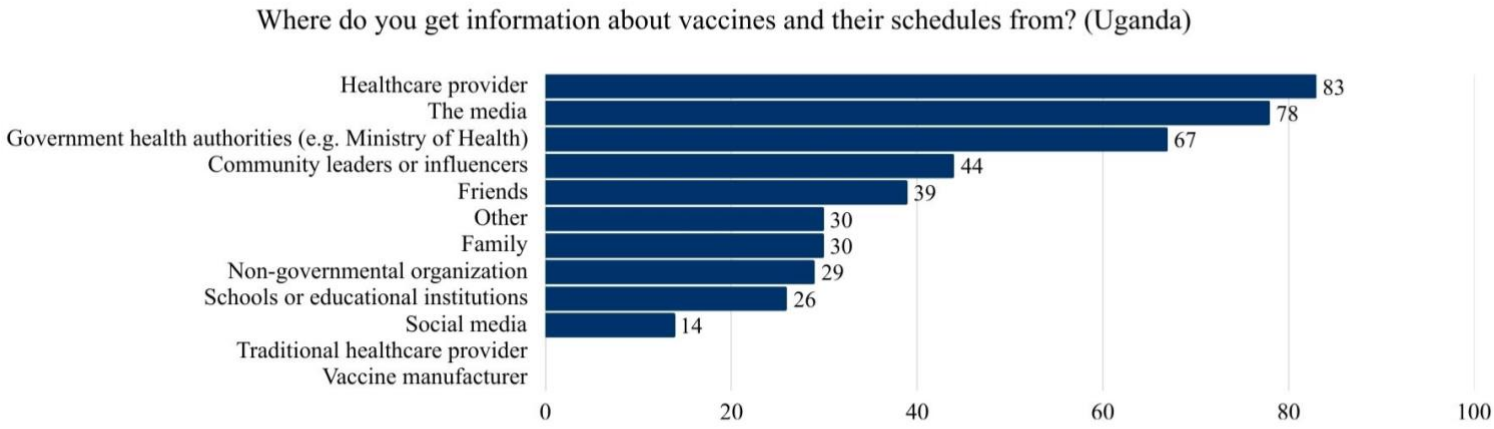
Few participants expressed unconditional acceptance of all vaccine changes as long as they prevented disease, *"I have no problem as long as it's protecting my child from a deadly disease"* (Ug-F-43), but the majority balanced this sense of duty with concern for comfort and safety. Acceptance of change was therefore contingent on parental confidence that the vaccine schedule change would not cause unnecessary pain or risk to their children, how feasible the change was practically, and how this was then communicated to them.

4.4.5 Vaccine schedule information needs

Communication, especially surrounding the rationale for change, strongly influenced how parents responded to the prospect of immunisation schedule changes. Most participants expressed a desire for clear explanations and advance notice before any changes were introduced. *"We need to know the different vaccine schedules and the vaccines being given to our child,"* one mother said (Ug-F-29). Another parent added, *"I would not feel good about it if they changed things without telling us. But if they explain, then I would understand"* (Ug-M-41). Several participants emphasised that communication should reach beyond clinical settings to the wider community. They called for early, accessible sensitisation through mass media, noting that awareness campaigns would help ensure understanding and acceptance. As one father suggested, "We would like the child to be vaccinated at the right time. But this can be successful if they organise sensitisation programs and create awareness on televisions and radios" (Ug-M-41). Complementing this view, another participant highlighted the continuing need for interpersonal guidance, especially from healthcare workers, explaining, "I would first think about it, and ask the health worker; if it's good, you go by it" (Ug-F-29).

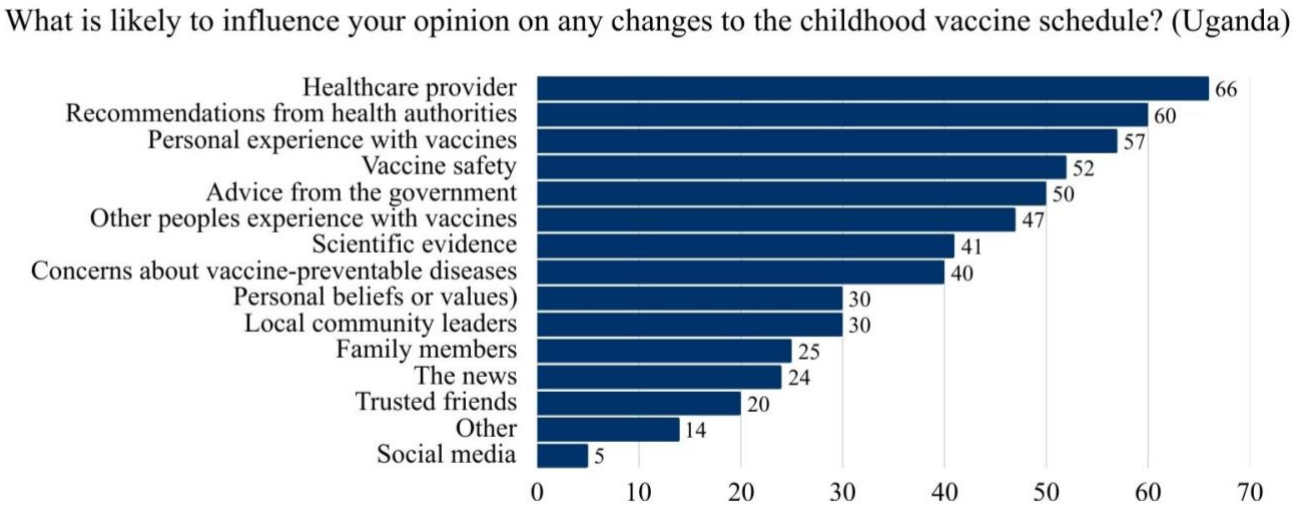
Survey data reinforced these themes; health workers and government channels were overwhelmingly cited as the most trusted sources of information (Figure 8). Most participants reported receiving vaccine information from health care providers (83%), media (78%), and government health authorities (67%), whereas none identified traditional healers or vaccine manufacturers as sources.

Figure 8: Uganda participant's vaccine information sources



When asked what was most likely to influence their opinion on any changes to the childhood vaccine schedule, participants identified a range of trusted reference points reflecting both institutional and personal experience. Two-thirds (66%) said they would rely primarily on advice from a health care provider, and 60% cited recommendations from national health authorities as a key influence. More than half (57%) said their own or their child's previous vaccine experience would guide their views, while 52% indicated that the vaccine's safety profile would be a major consideration. These findings suggest that decision-making around schedule changes is shaped by a combination of expert authority and lived experience. Full item lines can be found in Figure 9.

Figure 9: Factors influencing opinions on changes to the childhood schedule in Uganda



Taken together, the Uganda findings demonstrate strong baseline support for childhood vaccination alongside conditional engagement with schedule change. Like Nepal, vaccination was widely regarded as important in Uganda, but potential schedule changes prompted parents to reassess their own perceptions regarding institutional authority, safety, and practical feasibility in light of their own experiences.

4.5 Discussion

The discussion proceeds thematically across both Nepal and Uganda. By bringing the two country contexts into dialogue, this discussion seeks to explain not only whether schedule changes were acceptable, but also how and under what conditions they were negotiated by parents.

This section first considers the role of trust, authority, and parental agency in shaping responses to schedule change, before exploring how vaccine safety was constructed through

embodied and geopolitical concerns. It then examines the influence of vaccine memory and historical experience on perceptions of legitimacy, followed by an analysis of communication practices and parental information needs at moments of change. Finally, this discussion considers how different forms of caregiver burden shaped assessments of feasibility. Together, these themes address the chapter objectives and highlight that changes to childhood immunisation schedules are experienced by parents as socially embedded interventions that require context-sensitive engagement.

4.5.1 Trust, authority, and structurally situated parental agency

Trust in health systems and institutions played a central role in shaping parental responses to changes in childhood immunisation schedules in both Nepal and Uganda. Across the two contexts, parents commonly framed vaccination decisions as the responsibility of doctors and government authorities, reflecting the institutionalised nature of immunisation programmes. However, the ways in which trust was articulated, enacted, and negotiated differed markedly between settings, with important implications for how parents engaged with schedule changes.

In Uganda, trust was frequently expressed through deference to institutional authority and a sense of obligation to follow government guidance. Parents described vaccination as something that was decided by health authorities rather than negotiated at the household level. This form of acceptance was closely linked to constrained choice; parents perceived few viable alternatives to participation and therefore oriented themselves towards compliance. Previous research has shown that not all parental vaccination decisions are experienced as active or deliberative. In a systematic review of UK qualitative studies, Forster et al. [2016] describe a form of “non-deliberative” decision-making in which parents perceived childhood vaccination as routine, inevitable, or already decided by health

authorities, rather than as a choice requiring negotiation within the household. For these parents, compliance with the national immunisation programme was often described as the default or only viable option. In these data from Nepal and Uganda, parental agency in this context was exercised within structural limits, through adaptation to programme requirements and continued participation despite uncertainty. Acceptance was thus pragmatic and relational, shaped by trust in institutional intentions and by the necessity of engaging with public health systems to secure care for children.

While this authority-based model of trust has become the norm, its limitations became more apparent when parents were faced with potential disruption to the established routines. Parents reported confusion and unease when schedule changes were hypothesised without adequate explanation or advance notice, suggesting that institutional trust alone was insufficient to sustain confidence at moments of change. In this context, acceptance appeared fragile, dependent on health authorities maintaining transparent communication and reinforcing the legitimacy of decisions that parents felt unable to influence. This aligns with Gowda and Dempsey [2013], who explained that ongoing changes to immunisation schedules can fuel parental uncertainty and doubt, especially when alterations are not accompanied by clear explanations of why recommendations have changed, highlighting the limits of institutional authority alone in sustaining confidence. These Ugandan findings indicate that compliance should not be conflated with confidence, and that high uptake may coexist with uncertainty or discomfort when parents are not meaningfully engaged. Anderson and Creanza [2023] demonstrate that vaccine mandates constitute a salient example of this phenomenon, highlighting how high vaccination coverage can be sustained despite considerable vaccine hesitancy. As a result, coverage data may obscure latent concerns that become more visible when immunisation schedules change.

In Nepal, trust in immunisation systems was also strongly institutional, and explicitly evaluative and conditional. Parents generally regarded government-led vaccination programmes as legitimate and beneficial, yet they described actively assessing schedule changes in relation to vaccine safety, regulatory oversight, and their child's wellbeing. Trust was therefore not assumed, but continually reinforced through reassurance, observation, and the perceived credibility of healthcare settings. Previous evidence from Nepal similarly underscores that trust in vaccination programmes is not automatic: Paul et al. [2022], in a qualitative study of barriers to and facilitators of full immunisation among children in Nepal's Makwanpur District, identified mutual trust as a key pathway to full immunisation coverage, noting that confidence is reinforced through credible healthcare settings and the removal of both social and structural barriers to engagement. Participants' accounts suggest that acceptance depended on the availability of information that allowed parents to judge whether changes were appropriate. This evaluative orientation extended beyond government provision, with parents comparing public services to private providers or research teams, and, in some cases, shifting their reliance when alternatives appeared to offer greater reassurance.

Across both contexts, expressions of trust in national immunisation programmes and the healthcare institutions responsible for delivering vaccines were often intertwined with forms of practical dependency. Vaccination was widely accepted, but often not because parents felt fully empowered within decision-making processes. Instead, acceptance frequently reflected reliance—termed 'passive acceptance' by Nichter [1995]—on institutions that controlled access to vaccines and defined programme parameters, rather than confidence grounded in active understanding or desire. Distinguishing analytically between trust and dependency or reliance is therefore important.

Trust implies confidence sustained through transparency, understanding, and perceived accountability, whereas dependency reflects compliance in the absence of viable alternatives. In social and health systems scholarship [Gilson, 2003], trust is understood as a voluntary orientation toward another actor, grounded in expectations about their future behaviour and involving an acceptance of risk. As Luhmann et al. [1979] argued, trust functions to reduce uncertainty through expectations of reliability and accountability, whereas power enables action even when trust is absent, by structuring available choices and constraining alternatives. Trust, where present, must therefore be understood as relational and contingent, while dependency reflects 'involuntary' compliance [Gilson, 2003]. Immunisation programmes that rely primarily on dependency may achieve high uptake under stable conditions, but they are likely to be more vulnerable to misunderstanding, resistance, or erosion of confidence when schedules change, when communication is perceived as inadequate, or when competing sources of authority emerge. These dynamics of trust, dependency, and power were particularly evident in how parents constructed and evaluated vaccine safety and tolerability in the context of schedule change.

4.5.2 Constructions of vaccine safety and tolerability

Perceptions of vaccine safety were central to how parents in both Nepal and Uganda evaluated changes to childhood immunisation schedules. However, rather than reflecting a single or uniform understanding of risk, safety was articulated through multiple, contextually grounded concerns that shaped how schedule changes were interpreted and negotiated.

In Uganda, concerns about vaccine safety were frequently articulated through references to past vaccination campaigns, community narratives, and perceptions of global inequality. For example, parents expressed unease about vaccines that were introduced locally before being widely used elsewhere, drawing on shared narratives and prior experiences to interpret

novelty. Previous research [Amodan et al., 2025] in Uganda has documented similar concerns, with participants reporting low levels of trust in vaccine manufacturers to provide safe and effective vaccines. In these studies, a substantial proportion of respondents expressed suspicion regarding manufacturers' motives, and over one-third (588 of 1,728 participants) reported beliefs that vaccines were being tested on African populations before wider global use, reinforcing perceptions of inequality and experimentation within global vaccine development and distribution processes. Safety, in this context, was therefore closely linked to questions of legitimacy and fairness, with parents evaluating vaccines not only in terms of potential side effects, but also in relation to where they had been developed, how they were introduced, and whose interests they were perceived to serve.

These broader constructions of safety shaped parental responses to changes in immunisation schedules. Alterations to established routines prompted questions about whether new vaccines or combinations had been adequately tested and appropriately introduced, particularly when changes were perceived to occur without sufficient explanation. These concerns resonate with previous qualitative research in Uganda [Amodan et al., 2025], which has shown that rapid vaccine development timelines can fuel uncertainty and mistrust, particularly where individuals question whether vaccines have undergone adequate testing and regulatory scrutiny.

In Nepal, parents also raised concerns about vaccine safety, but these were more often articulated through discussion of the child's immediate experience of vaccination. Parents spoke about pain, side effects, and observable changes in behaviour or wellbeing following vaccination, and described emotional responses to seeing their child distressed. Previous qualitative research in Sierra Leone and Cameroon has shown that caregivers frequently focused on pain, fever, swelling, and changes in behaviour or wellbeing following

vaccination, and described emotional distress associated with seeing their child cry or appear unwell after immunisation [Jalloh et al., 2022, Ames et al., 2017]. These considerations were frequently used to reason through hypothetical changes to immunisation schedules, particularly when parents were asked to consider the administration of multiple vaccines at a single visit or alterations to familiar routines.

Overall, constructions of vaccine safety were rational, situated, and responsive to local experience, rather than indicative of misinformation or opposition to vaccination. While Ugandan and Nepali parents tended to emphasise different aspects of safety in their accounts, these framings were overlapping rather than hierarchical. Parents in both settings expressed concern for their child's well-being while also engaging with broader questions of trust, legitimacy, and appropriate use. What differed was not the importance of safety itself, but the lenses through which safety was made meaningful in relation to schedule change. In particular, parents' assessments of safety were closely connected to their memories of previous vaccination experiences and to their evaluations of the institutions and actors responsible for introducing change, including how national programmes were positioned in relation to international standards. These institutional and historical dimensions are examined in the following section.

4.5.3 Vaccine history, legitimacy, and global positioning

Parents' responses to changes in childhood immunisation schedules were shaped not only by immediate concerns about safety and tolerability, but also by how vaccines were situated within longer histories of vaccination and broader understandings of national and global positioning. In both Nepal and Uganda, parents drew on past experiences, collective memories, and comparisons with other countries to assess the legitimacy of schedule changes.

In Uganda, participants frequently referenced past vaccination campaigns and circulating community narratives when discussing changes to immunisation schedules. These accounts, which included stories of harm, or unintended consequences, functioned as a form of collective memory through which parents interpreted present-day vaccination practices. While such narratives were not always grounded in direct personal experience or verifiable events, they nonetheless shaped how novelty was received. Similar patterns have been documented in earlier Ugandan research. Braka et al. [2012] and Kamya et al. [2022] describe how caregivers drew on memories and stories from past mass immunisation campaigns, including accounts of children becoming ill or allegedly dying following vaccination, as well as broader suspicions regarding vaccine safety, and motives of external actors. These narratives persisted despite acknowledged benefits of immunisation and were frequently invoked to make sense of repeated or intensified vaccination activities, particularly where explanations were perceived as insufficient.

If changes were to be introduced without prior explanation, parents described how they would feel unsettled or suspicious. Parents often compared vaccines introduced locally with those used in higher-income countries, expressing greater confidence when vaccines were perceived to align with international standards or to have been widely used elsewhere. Conversely, the idea that vaccines might be introduced first or exclusively in Uganda raised questions about fairness and intent. Such comparisons reflect an awareness of global inequalities in health and medicine, and illustrate how legitimacy was assessed through transnational reference points as well as national authority. Drawing on research conducted in African contexts, Leach et al. [2022] also noted that concerns about vaccine safety and quality were shaped by perceptions of global hierarchy and unequal recognition, including suspicions that donated vaccines were inferior or politically motivated, and that vaccines not recognised by high-income countries were therefore less legitimate. These policy and

distribution asymmetries served to reinforce local narratives that evaluated vaccines not only on biomedical grounds, but through their positioning within global systems of power and credibility.

In Nepal, historical experience and global positioning were also relevant, but were articulated differently. Parents frequently emphasised the importance of vaccines being appropriate to the Nepali context, drawing attention to the distinct mountainous geography, changing environment, and local disease patterns. For some, perceptions of legitimacy were strengthened when vaccines were understood to have been evaluated or endorsed within Nepal, which was taken as evidence of relevance and effectiveness for Nepali children. Previous research has shown that perceptions of disease risk play an important role in shaping vaccination behaviour [Larson et al., 2014], and these findings align with the present dataset in which assessments of vaccination were situated within locally meaningful understandings of disease and public health priorities.

However, these discussions also revealed divergent responses to Nepal's position within global vaccine development. While some parents expressed ambivalence, viewing local research involvement as potentially beneficial but requiring reassurance, others articulated more explicit concerns about foreign-led testing, framing vaccine research as a site of unequal power and potential exploitation. These perspectives highlight how assessments of safety and legitimacy were shaped not only by national relevance, but also by sensitivities to global hierarchies and historical asymmetries in medical research, echoing wider LMIC narratives that reject being treated as "guinea pigs" in vaccine development [Unfried and Priebe, 2024, Archibong and Annan, 2021]. Across both contexts, vaccine legitimacy emerged as a relational and historically informed judgement rather than a purely technical assessment. Schedule changes were situated within broader narratives of past experience,

national capacity, and global inclusion or exclusion. Importantly, these considerations did not operate independently of trust or safety concerns, but intersected with them, shaping how parents made sense of change and uncertainty.

4.5.4 Burden and access

These assessments of legitimacy were closely connected to how parents experienced the practical demands of immunisation in everyday life. Caregiver burden was a key consideration in how parents in both Nepal and Uganda evaluated the acceptability and feasibility of changes to childhood immunisation schedules. While parents generally supported vaccination, their assessments of schedule change were shaped by how proposed modifications intersected with everyday caregiving responsibilities and constraints. Importantly, caregiver burden was not understood abstractly, but articulated through locally meaningful concerns that reflected different social, economic, and relational contexts.

In Uganda, parents most often described caregiver burden in practical and logistical terms. Travel distance, transport costs, time spent waiting at clinics, and the challenge of balancing vaccination appointments with work and household responsibilities featured prominently in discussions of schedule change. Proposed increases in the number of clinic visits were therefore evaluated in relation to their impact on daily routines and financial resources. Although such constraints did not necessarily lead to rejection of schedule changes, they shaped parents' perceptions of feasibility and influenced whether changes were seen as manageable within existing circumstances. These accounts are consistent with previous research in Uganda, which has identified distance to immunisation centres, transport challenges, and difficult terrain as key barriers to timely attendance at vaccination appointments. Malande et al. [2019], for example, document how long travel distances,

inadequate transport facilitation for outreach services, and the large geographical size of some sub-counties constrained both caregivers' ability to attend immunisation sessions and health workers' capacity to deliver services effectively, contributing to missed appointments rather than deliberate refusal. In line with evidence from a systematic review and meta-analysis in LMICs demonstrating that community engagement interventions can improve outcomes related to routine childhood immunisation [Jain et al., 2022], some parents in this study suggested alternative delivery approaches. These included community-based services, which were framed as practical ways to reconcile programme requirements with everyday constraints rather than as expressions of resistance to immunisation itself.

In Nepal, caregiver burden was more frequently articulated through the emotional and relational dimensions of caring for a child during and after vaccination. Parents described distress associated with seeing their child experience pain or discomfort, and expressed concern about side effects that required additional care at home. This emphasis on emotional and relational dimensions of care echoes findings from Ansah et al. [2025] who reported that even when mothers understood the benefits of vaccination, many expressed concerns about the pain and discomfort their children experienced during the process, underscoring how embodied experiences with vaccine procedures contribute to caregiver worry and shape interpretations of vaccination beyond abstract assessments of risk.

These experiences shaped how parents reasoned through hypothetical schedule changes, particularly when considering the number of injections administered at a single visit. While some parents acknowledged that fewer clinic visits could be logistically convenient, this was often weighed against concerns about the child's comfort and well-being. For many, the emotional labour involved in caring for a distressed child was an important factor in determining whether a schedule change was acceptable. Across both contexts, caregiver

burden influenced acceptability in ways that extended beyond conventional measures of access or convenience. Burden encompassed economic, temporal, emotional, and relational dimensions, all of which shaped how parents engaged with proposed changes to immunisation schedules.

4.6 Limitations

This chapter has several limitations that should be considered when interpreting the findings across both country contexts. First, participants in both Nepal and Uganda were recruited through clinical trial settings. As a result, their experiences and perspectives may not be fully representative of parents in the general population who have not engaged with vaccine research or trial-related health services. Parents connected to clinical trials may have greater exposure to biomedical information, more frequent interaction with healthcare providers, or increased familiarity with vaccination processes compared to those accessing routine services alone. However, participation in clinical trials should not be interpreted as indicating uncritical acceptance of vaccination or immunisation schedule change. Across both contexts, parents frequently described engagement with trials as motivated by access to healthcare, services, or material benefits, rather than intrinsic endorsement of research activities or programme decisions. This suggests that the study captures forms of pragmatic engagement with highly institutionalised immunisation and research systems, which may be particularly relevant for understanding how schedule changes are negotiated. At the same time, parents who were more disengaged from health services or distrustful of research may be under-represented.

Second, the study was conducted in specific geographic and social settings that do not encompass the full diversity of either Nepal or Uganda. In Nepal, data were collected in an urban setting in Kathmandu, while in Uganda, data were collected in Masaka, which is located in the Southwestern region of Uganda. The findings may therefore not fully reflect the experiences of parents in other areas, regions with weaker health infrastructure, or communities with different histories of interaction with vaccination programmes or medical research.

Third, it was not possible to compare the demographic characteristics of parents included in this study with the full demographic profile of the clinical trial populations. This limits the ability to assess representativeness in terms of socioeconomic status, education, or prior vaccination experience. Finally, the quantitative components of the study were modest in scale in both settings, which limits the extent to which survey findings can be generalised beyond the study populations. The surveys were designed to map patterns of attitudes and information needs within specific contexts rather than to produce nationally representative estimates. When interpreted alongside the qualitative findings, they provide structured insight into the distribution of responses to immunisation schedule change, but should not be read as population-level prevalence data. Future research would benefit from larger, more representative samples, including parents not engaged in clinical trials or research-linked programmes, to strengthen external validity and deepen understanding of how immunisation schedule change is experienced across diverse populations.

4.7 Conclusion

This chapter has shown that parents' responses to changes in childhood immunisation schedules in Nepal and Uganda were shaped by contextually grounded processes of sense-making. Schedule changes function as a moment in which existing relationships with vaccination systems were re-examined. In doing so, questions of safety became intertwined with trust in providers, and past vaccination experiences shaped judgements of legitimacy. Schedule change therefore acted as a catalyst through which existing expectations were reconsidered.

Across both settings, vaccination itself was widely supported. However, engagement with schedule change was negotiated under differing structural and historical conditions. In Uganda, participation was often organised through institutional authority and constrained choice, producing forms of compliance that coexisted with uncertainty. In Nepal, parents more explicitly evaluated schedule changes in relation to safety, regulatory oversight, and perceived national relevance. These contrasting patterns suggest a useful analytic distinction between trust and dependency. Trust can be understood as confidence sustained through transparency and perceived accountability, whereas dependency may describe participation shaped by structural power and limited alternatives. This distinction offers one way of interpreting how immunisation programmes can maintain high uptake while remaining potentially vulnerable when schedules change or communication falters.

The chapter further demonstrates that vaccine safety was not assessed as a singular biomedical evaluation, but interpreted through specific, locally meaningful, frames of reference. In Uganda, safety was frequently understood through collective memories of past campaigns and narratives of global inequality, while in Nepal it was more often grounded in embodied and relational experiences of caring for a child during and after vaccination. These framings were rational and overlapping, reflecting different ways in which parents situated

questions of risk within their lived experience, understood responsibility as shared between families and institutions, and assessed the credibility of those introducing or endorsing schedule changes, rather than simply expressing misinformation or opposition to vaccination.

Caregiver burden emerged as a final, critical dimension shaping how schedule changes were judged. In Uganda, burden was articulated primarily through logistical constraints; in Nepal, through the emotional and relational labour of managing children's discomfort and side effects. Across both contexts, parents' suggestions for alternative delivery approaches reflected rational efforts to align programme demands with what is feasible for parents to manage. Overall, this chapter shows that parental responses to immunisation schedule change in Nepal and Uganda were contextually grounded by processes of evaluation. Parents reassessed safety of the schedule change in light of their prior experience, they judged institutional credibility through lenses of trust and global comparison, and weighed programme demands against practical and relational caregiving responsibilities. While vaccination itself remained widely supported, immunisation schedule change emerges as a socially embedded intervention that brings into view underlying dynamics of trust, dependency, authority, and care. The next chapter extends this analysis to a different context, examining how the introduction of a proposed gonorrhoea vaccine programme in the UK is interpreted by adult sexual health service users. While distinct in population and setting, this case similarly considers how acceptability is shaped when vaccines are introduced or repurposed within established health systems.

5 Attitudes and perceptions of a gonorrhoea vaccine programme among UK sexual health service users

5.1 Introduction

Gonorrhoea is an urgent global public health challenge. In the United Kingdom, diagnoses reached a record high of 85,370 in 2023, a burden that disproportionately affects gay, bisexual, and other men who have sex with men (GBMSM) [UK Health Security Agency, 2025a]. Rising levels of AMR in *Neisseria gonorrhoea,* exemplified by the 14 ceftriaxone-resistant *Neisseria gonorrhoeae* cases reported within the first five months of 2025, surpassing the total for all of 2024, further underscore the need for preventive approaches [UK Health Security Agency, 2025b]. In response, the UK Joint Committee on Vaccination and Immunisation (JCVI) recommended the targeted use of the four-component meningococcal serogroup B (4CMenB) vaccine, Bexsero, as a preventive intervention against gonorrhoea [Joint Committee on Vaccination and Immunisation, 2023].

Genetic and phenotypic similarities exist between the two pathogens, *Neisseria gonorrhoeae* and *Neisseria meningitidis,* in their outer membrane vesicle (OMV). Given that this is contained in Bexsero, there is a theoretical likelihood of cross-protection through vaccination. A study of an earlier OMV containing vaccine, MeNZB demonstrated incidental evidence of possible cross-protection against gonorrhoea in teenagers and young adults, with an effectiveness estimate of 31% (95% CI: 21% to 39%) [Petousis-Harris et al., 2017]. Other studies have given effectiveness estimates ranging from 33.2% to 59% [Wang et al., 2023, Abara et al., 2022a, Bruxvoort et al., 2022, Longtin et al., 2017, Raccagni et al., 2023]. Recent RCT data from DOXYVAC, the first randomised controlled trial of 4CMenB for the

prevention of gonorrhoea, showed more modest effectiveness than observational studies [Luetkemeyer et al., 2025, White et al., 2024]. The UK Government has since accepted the JCVI's recommendation, and a targeted vaccination programme for GBMSM and other individuals at high risk of bacterial sexually transmitted infections (STIs) who attend sexual health clinics commenced in August 2025 [England, 2025].

5.1.1 UK sexual health service context

In the UK, sexual health services are free and confidential, delivered predominantly through specialist clinics (genitourinary medicine or sexual health clinics) and integrated within the NHS. As part of routine care, these services offer targeted vaccination against HPV and hepatitis B for eligible groups, and respond to outbreaks with timely vaccination campaigns, such as the targeted Mpox and hepatitis A immunisation programmes [NHS, 2025].

Over the past decade, sexual health services in England have undergone substantial organisational change. Following the Health and Social Care Act 2012, commissioning responsibilities became distributed across multiple bodies, contributing to a more fragmented service landscape alongside increasing demand and financial pressures. During this period, services increasingly adopted digital and remote models of care delivery, including online postal self-sampling for STIs such as chlamydia, gonorrhoea, HIV, and syphilis. While these approaches have expanded access for some populations, evidence suggests that inequalities in engagement persist across lines of deprivation, ethnicity, and service accessibility [Gibbs et al., 2026]. These institutional and service-delivery conditions formed an important backdrop to how participants interpreted the introduction of a gonorrhoea vaccination programme

5.1.2 Programme acceptability

Programme success is dependent on whether key target groups, such as GBMSM, will widely accept the 4CMenB vaccine, particularly in light of its relatively low predicted effectiveness [Shen and Zhang, 2022]. Acceptability has become an increasingly prominent concept in the evaluation of health interventions, reflecting recognition that an intervention's effectiveness depends not only on clinical efficacy but also on how interventions are perceived and experienced by those who interact with them. In the context of vaccination, acceptability has been used to explore factors shaping public and caregiver responses to immunisation, including confidence in vaccine safety, perceptions of necessity, and practical considerations such as access and convenience [Sherman et al., 2023, Abara et al., 2022b, Adhikari et al., 2022, Asmare, 2022]. Whilst partially protective gonorrhoea vaccines offer promise, scientific uncertainties may hinder public confidence.

Notably, previous research on the HPV vaccine has demonstrated that perceived inefficacy of the vaccine can contribute to vaccine hesitancy and reduce vaccine acceptance [Walker et al., 2020], while the COVID-19 experience showed knowledge of vaccine effectiveness positively correlates with uptake [Robertson et al., 2021]. This highlights the importance of transparent communication about vaccine benefits. Recent analyses from a large, community-based survey of GBMSM in the UK found that while uptake of STI and viral hepatitis vaccinations such as HPV, hepatitis A, and hepatitis B was relatively high (two-thirds), there remained considerable gaps, particularly among younger individuals, bisexual men, and those with lower financial or social capital [Baldry et al., 2024]. GBMSM communities historically show high engagement with public health interventions [Checchi et al., 2019], reflected in the rapid mpox vaccine uptake during an mpox outbreak in 2022 [May et al., 2023, Biesty et al.,

2024]. However, STI-associated stigma may deter vaccination, and international experience raises equity concerns about access among vulnerable populations [Firth et al., 2025].

A study in the United States [Abara et al., 2022b] of 4,951 MSM found that 83.5% would be willing to receive a gonorrhoea vaccine, representing one of the few empirical studies to directly assess how acceptable a gonorrhoea vaccine is within a specific population. Evidence beyond this is limited and fragmented, with only a small number of additional studies conducted in specific populations, such as incarcerated women [Bonney et al., 2007]. Furthermore, repurposing a 4CMenB vaccine may introduce unique acceptance barriers. A study in Japan examining willingness to receive the smallpox vaccine for protection against mpox found low intention to accept the vaccine [Hori et al., 2023], highlighting the nuances in vaccine acceptability. Reflecting these gaps, experts have explicitly called for contemporary, context-specific research on gonorrhoea vaccine acceptability to inform implementation strategies [Harvey et al., 2021]. Given the scientific uncertainty of the vaccine effectiveness, potential health inequities, and the complex dynamics of trust in sexual health services and public health institutions, a mixed-methods study was conducted with the aim of examining the acceptability and perceptions of a gonorrhoea vaccine programme among UK sexual health service users in the UK.

5.2 Methods

5.2.1 Design and population

This chapter (MSD IDREC 947232) employed mixed-methods, comprising an online survey and semi-structured interviews, with UK adults who self-reported as sexual health service

users. The study was grounded in a pragmatic paradigm, enabling the integration of quantitative and qualitative data to comprehensively explore both the prevalence and contextual drivers of vaccine attitudes. Attitudes, perceptions, and acceptability of a 4CMenB vaccine repurposing for gonorrhoea prevention were examined. Eligible participants were aged ≥18 years, UK residents, with a history of using sexual health services. Disclosure of sexual behaviour or infection history was not a requirement for participation. The research team was comprised of individuals with backgrounds in health sociology, sexual health, and clinical vaccine research. Reflexivity was supported through regular team discussions and integration of public contributor perspectives during the design of study materials.

5.2.2 Patient and public involvement

Two adult public contributors with lived experience of UK sexual health services supported the development of the research aims and shaped the focus on vaccine accessibility, stigma, and communication. They contributed to the design of the survey and interview guides, reviewing wording, tone, and structure to ensure sensitivity and clarity. Public contributors also advised on recruitment materials and channels, helping to tailor posters and social media posts to relevant audiences. They reviewed the estimated time required for survey and interview participation and confirmed the burden was appropriate. Although not involved in data collection, they played an active role in ensuring the study was respectful and participant centred.

5.2.3 Sampling and sample size

For the quantitative component, the required sample size was calculated to estimate the proportion of health service users who would accept a gonorrhoea vaccination programme with adequate precision. Using the standard formula for population proportions:

$$n = [z^2\alpha/2 \times p(1-p)] / E^2$$

Where n is the required sample size, $z^2\alpha/2 = 1.96$ for 95% confidence level, $p = 0.5$ (conservative estimate for maximum variability when the true acceptance rate is unknown), and $E = 0.05$ (5% margin of error) [Cochran, 1977]. This calculation yielded a target sample size of 385 participants. To account for potential incomplete responses, a 25% oversampling buffer was applied, consistent with recommendations for online survey research [Cook et al., 2000].

For the qualitative component, a mixed sampling approach was utilised. Initially, interview participants were contacted sequentially from the list of survey respondents who expressed interest. However, recognising that early respondents were all a similar demographic, purposive sampling was adopted to improve demographic variation, particularly seeking participants with diverse educational backgrounds and ethnicities where possible. Thematic saturation, with an initial target of 12 interviews, was sought, based on empirical evidence suggesting that 9-17 interviews typically achieve saturation in studies with relatively homogeneous populations and focused research objectives [Hennink et al., 2017], with Guest et al. demonstrating that 92% of themes are typically identified within the first 12 interviews [Guest et al., 2006].

5.2.4 Data handling and storage

Survey data were collected using a bespoke REDCap (version 5.0.35) database, and semi-structured interviews were conducted on Microsoft Teams. Survey links were distributed through displaying posters in various sexual health clinics and hospitals across the UK, as well as through paid and organic social media posts. Participants had the option read a fact sheet about the repurposing of a MenB vaccine for gonorrhoea (Appendix 16). Participants were first presented with a participant information sheet outlining the purpose of the research, their rights, and data protection procedures (Appendix 17). Participants were not permitted to proceed without first confirming their consent.

The survey instrument (Appendix 18) was structured into five key sections. Firstly, demographic questions, then the validated Vaccination Attitudes Examination (VAX) Scale [Martin and Petrie, 2017], which assesses general attitudes toward vaccination across four domains: mistrust of vaccine benefit, worries about unforeseen future effects, concerns about commercial profiteering, and preference for natural immunity. Subsequent sections focused on domain-specific content. The third section explored attitudes toward vaccination in the context of sexual health, the fourth section examined attitudes toward a potential gonorrhoea vaccination programme using the 4CMenB vaccine, and the final section focused on vaccine communication and education.

Upon completion, participants were invited to leave their email address if they were willing to be contacted for a follow-up interview. Selected participants were invited to participate in a one-to-one semi-structured interview lasting approximately 30–45 minutes; they were provided with another participant information sheet (Appendix 19). These interviews sought

to gain deeper insight into participants' views, experiences, and informational needs related to gonorrhoea vaccination and broader sexual health vaccination contexts. Interviews were conducted online, audio recorded with consent, transcribed verbatim, and anonymised via transcription, and followed a topic guide (Appendix 20). Interview consent form can be found in Appendix 21).

5.2.5 Data analysis

Quantitative data were exported from REDCap and were analysed using IBM SPSS Statistics (version 30.0.0.0 (171)). Prior to analysis, the dataset was cleaned to remove incomplete responses and checked for inconsistencies. Descriptive statistics were used to summarise participant characteristics and item responses. Frequencies and percentages were calculated as appropriate. The free-text answers were printed out and key recurring ideas and themes were highlighted.

Qualitative data from the semi-structured interviews were analysed thematically using NVivo (version 15) following the six-phase approach outlined by Braun and Clarke [Braun and Clarke, 2006]. Transcripts were first read in full to ensure familiarity, followed by open coding of the text line-by-line. Initial codes were inductively generated and then grouped into broader categories through a process of constant comparison. A coding framework was iteratively developed and refined through regular discussions among members of the research team.

Data integration was undertaken through triangulation of the survey and interview findings. Quantitative results were used to inform and contextualise qualitative insights, and vice versa,

enabling a more comprehensive understanding of participants' attitudes and perceptions. This integration enabled interpretation of survey findings through the lens of lived experience, revealing how structural and social barriers shaped otherwise high levels of stated vaccine acceptability.

5.2.6 Ethical consideration

This research received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee (Ethics reference: MSD IDREC 947232)

5.3 Results

5.3.1 Participant characteristics

Between 6 April and 1 May 2025, a total of 500 individuals initiated the online survey. Following the exclusion of incomplete responses, 395 fully completed surveys (10 more than the minimum required of 385) were retained for analysis. The demographic characteristics of these participants are presented in Table 11. The sample was predominantly male (92.7%, 366/395), aged 25-34 (41.5%, 164/395) and 35-44 years (38.5%, 152/395), and white British/Irish (72.7%, 287/395). Most participants were employed full-time (77.7%, 307/395) and had no children (95.7%, 378/395).

Between June and July 2025, a total of 15 individuals took part in a semi-structured interview; the full demographic characteristics of these participants are presented in Table 12. The sample largely identified as male (80%, 12/15), were aged 25-34 years (60%, 9/15), and

were white British/Irish (53.3%, 8/15). 66.7% (10/15) of the participants followed no religion, and 73.3% (11/15) were employed full-time. All the participants had no children (100%, 15/15), and most had either a postgraduate master's degree (40%, 6/15) or an undergraduate degree (or equivalent) (33.3%, 5/15).

Table 11: Socio-demographic of UK survey participants

Characteristic	N = 395	Percentage
Age		
25-34 years	164	41.5%
35-44 years	152	38.5%
45-54 years	54	13.7%
55-64 years	13	3.3%
18-24 years	8	2.0%
65 years and over	4	1.0%
Sex		
Male	366	92.7%
Female	16	4.1%
Non-binary or other	12	3.0%
Prefer not to say	1	0.3%
Ethnicity		
White (British or Irish)	287	72.7%
White (Other European)	66	16.7%
Asian or Asian British (e.g., Indian, Pakistani, Bangladeshi)	14	3.5%
Mixed (e.g., White and Black Caribbean, White and Black African, White and Asian)	11	2.8%
Other	9	2.3%
Black or Black British (e.g., Caribbean, African)	4	1.0%
Chinese	4	1.0%
Religion		
None	287	72.7%
Christian (e.g., Church of England, Catholic, Protestant)	57	14.4%
Prefer not to say	23	5.8%
Buddhist	8	2.0%

Muslim	7	1.8%
Other	6	1.5%
Jewish	5	1.3%
Hindu	1	0.3%
Sikh	1	0.3%
Employment Status		
Employed Full-Time	307	77.7%
Self-Employed	35	8.9%
Employed Part-Time	20	5.1%
Student	16	4.1%
Unemployed	13	3.3%
Prefer not to say	4	1.0%
Number of Children		
None	378	95.7%
1 child	9	2.3%
2 children	5	1.3%
3 or more children	3	0.8%

Table 12: Demographic of UK interview participants

Characteristic	N = 15	Percentage
Age		
25-34 years	9	60%
35-44 years	4	26.7%
45-54 years	2	13.3%
Sex		
Male	12	80%
Female	2	13.3%
Non-binary or other	1	6.7%
Ethnicity		
White (British or Irish)	8	53.3%
White (Other European)	3	20%
Mixed (e.g., White and Black Caribbean, White and Black African, White and Asian)	2	13.3%
Asian or Asian British (e.g., Indian, Pakistani, Bangladeshi)	1	6.7%
Black or Black British (e.g., Caribbean, African)	1	6.7%
Religion		
None	10	66.7%
Christian (e.g., Church of England, Catholic, Protestant)	2	13.3%
Prefer not to say	2	13.3%
Muslim	1	6.7%
Employment Status		
Employed Full-Time	11	73.3%
Self-Employed	2	13.3%
Student	1	6.7%
Unemployed	1	6.7%

Number of Children		
None	15	100%
Highest Level of Education		
Master's Degree / Post-graduate Diploma / Level 7	6	40%
Undergraduate Degree / HND / Level 6	5	33.3%
A-Levels / Level 3 BTEC / NVQ	3	20%
GSCE / O-Level / CSE	1	6.7%

5.3.2 Attitudes to vaccines (VAX Scale)

5.3.2.1 Trust in vaccines

Participants showed high confidence in the effectiveness and safety of vaccines. A majority agreed that they feel safe after being vaccinated (72.3%, strongly agreed, 21.8% agreed). Nearly all (92.5%) strongly agreed or agreed that they can rely on vaccines to stop serious infectious diseases, and 92.9% strongly agreed or agreed that they feel protected after vaccination. These findings suggest widespread trust in the core function of vaccines as preventive health tools, with very few participants expressing doubt or uncertainty about their protective value.

5.3.2.2 Worries about unforeseen future effects

Concerns about long-term or undiscovered vaccine side effects were relatively low among participants. Only a small proportion strongly agreed that vaccines may have yet-to-be-discovered problems (8.4% strongly agree, 12.9% agree, 30.1% somewhat agree), could cause unforeseen problems in children (1% strongly agree, 1.3% agree, 16.7% somewhat

agree), or might have unknown effects in the future (1.3% strongly agree). In contrast, a noteworthy number strongly disagreed with these concerns, particularly regarding unknown future effects (44.0%). This indicates that, while a minority hold cautious views, most participants were not influenced by fear of hidden or long-term harms.

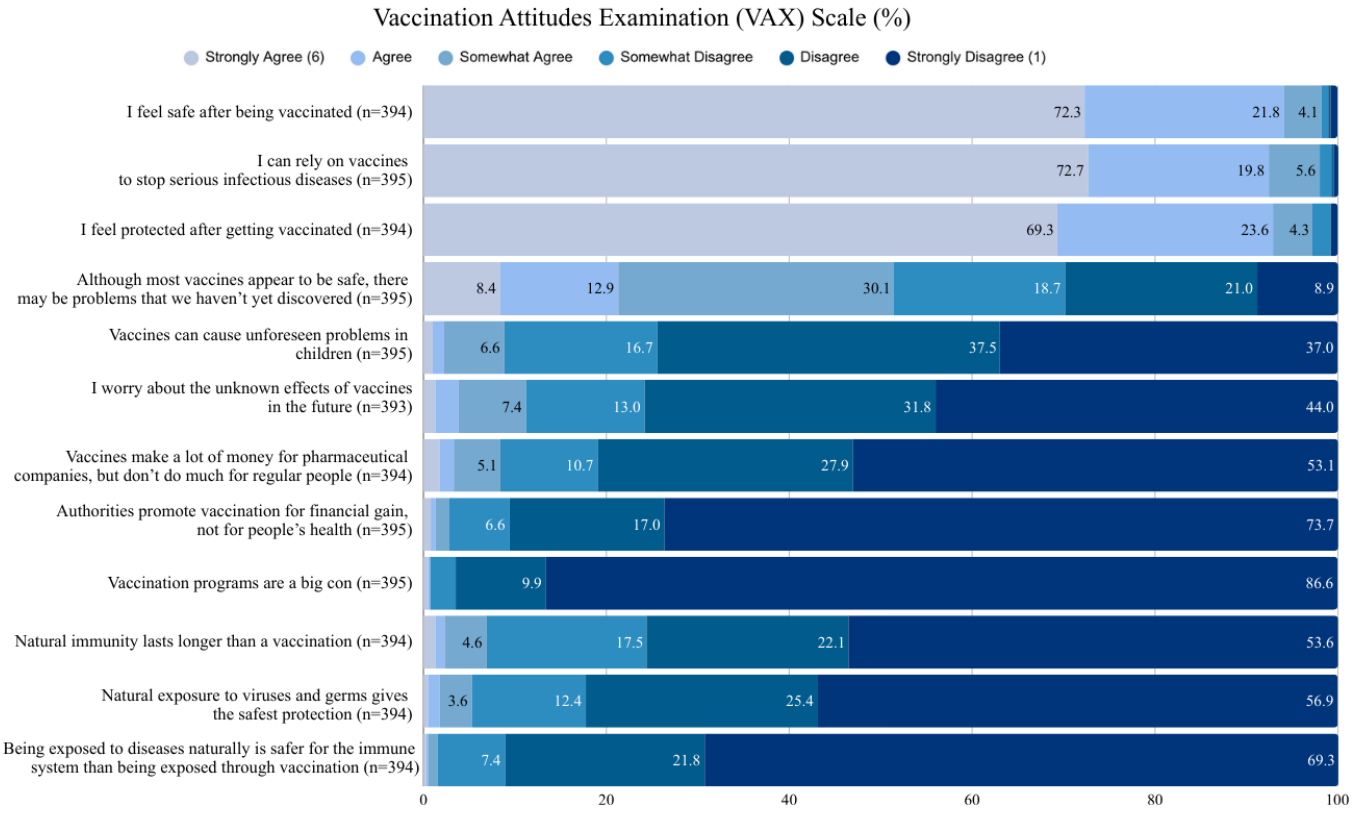
5.3.2.3 Concerns about commercial motives

Scepticism toward the motives of pharmaceutical companies or health authorities was limited. Just over half of participants (53.1%) strongly disagreed that vaccines mainly benefit companies rather than people, and 73.7% strongly disagreed that vaccination is promoted for financial gain rather than health. The statement that "vaccination programmes are a big con" received even less endorsement, with an overwhelming 86.6% strongly disagreeing. These results reflect a high level of institutional trust and low endorsement of profit-driven, or even conspiratorial narratives.

5.3.2.4 Preference for natural immunity

Participants generally rejected the idea that natural exposure is superior to vaccination. The majority strongly disagreed that natural immunity lasts longer than vaccine-induced immunity (54.6%) or that natural exposure gives the safest protection (56.9%). Most participants (61.9%) disagreed that natural exposure is safer for the immune system. Overall, the VAX scale responses demonstrate strong vaccine confidence and low levels of mistrust or hesitancy, reinforcing that any concerns about a gonorrhoea vaccine are likely to be programme-specific rather than ideologically rooted. (Figure 10).

Figure 10: Stacked bar chart showing participant responses to the Vaccination Attitudes Examination (VAX) Scale.



The bars represent the distribution of responses across each VAX subscale item, illustrating levels of agreement or disagreement. Colours correspond to Likert-scale categories, from strong disagreement to strong agreement. Note: Percentages are rounded to one decimal place and may not sum to exactly 100% due to rounding.

5.3.3 Gonorrhoea vaccination programme acceptability

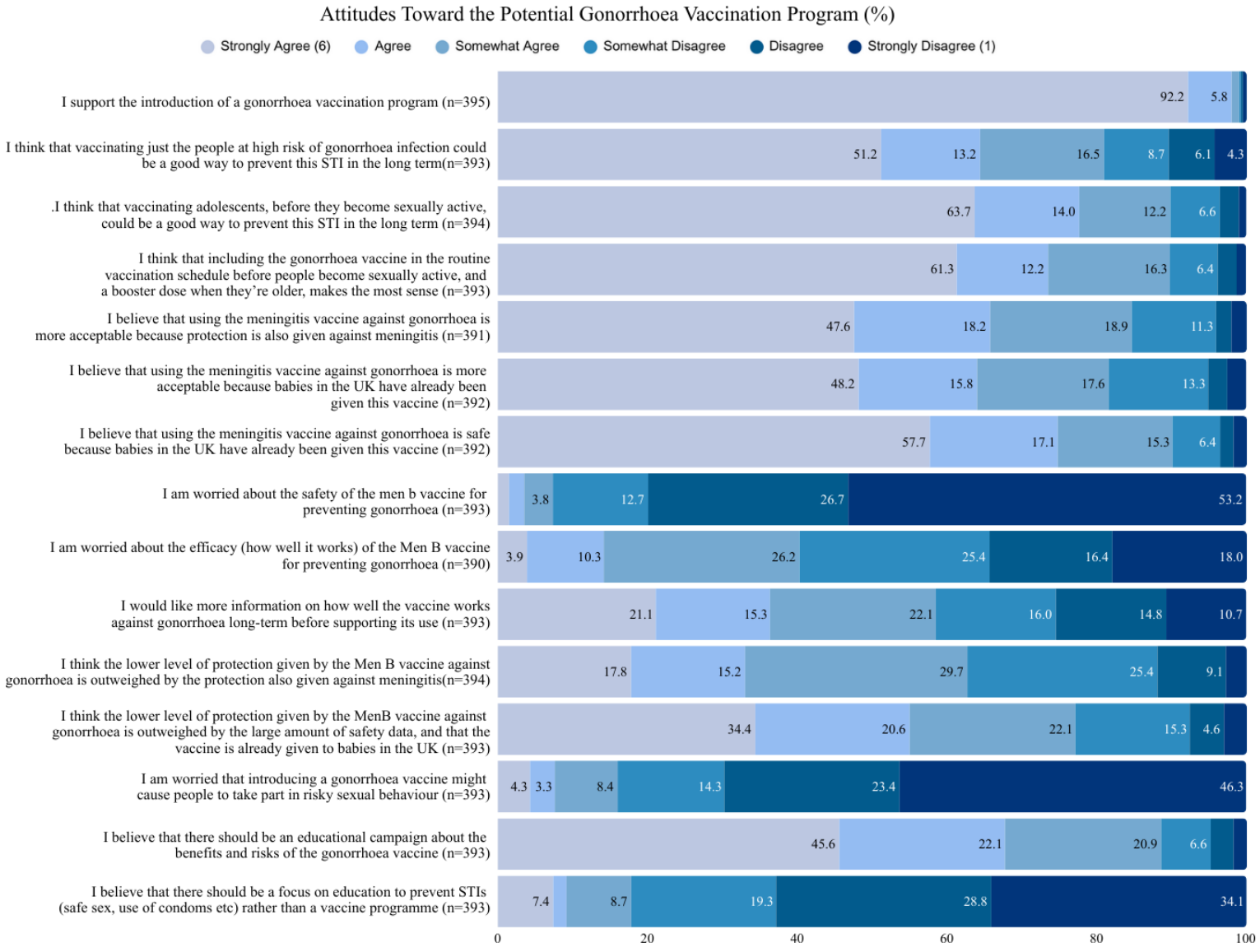
5.3.3.1 Overall support and programme features

Participants had the option to read a fact sheet about using meningitis B vaccines as gonorrhoea vaccines before completing the survey (Appendix 16). Support for gonorrhoea vaccination was nearly universal, with 92.2% strongly agreeing to the introduction of the programme. In the free-text answers, one participant stated: *"I would walk through fire to get this vaccine, this would be a huge improvement to the sexual health of LGBT people"* (Male, 35-44). Over half of the participants strongly endorsed the programme for targeting high-risk populations (51.2%), with a slightly higher proportion (63.7%) preferring an adolescent vaccine programme.

5.3.3.2 Efficacy concerns and reservations

Despite overall support, effectiveness concerns emerged as the primary reservation. Just 34.4% of respondents responded strongly disagree, or disagree, in response to the statement, "I am worried about the efficacy of the MenB vaccine for preventing gonorrhoea". The remaining 3.9% strongly agreed, 10.3% agreed, 26.2% somewhat agreed, and 25.4% somewhat disagreed. However, to some extent, this was mitigated by the dual protection also offered against meningitis (17.8% strongly agree, 15.2% agree, 29.7% somewhat agree). Just over half (57.7%) of participants strongly agreed that the 4CMenB vaccine is safe, as it is already used in babies. The mixed responses highlight an important tension: even among a population broadly supportive of vaccination, uncertainty around vaccine purpose, performance, and public messaging contributed to conditional forms of acceptance, and 45.6% of participants strongly agreed that an educational campaign that explains the benefits and risks of gonorrhoea vaccination is necessary. Full item-level responses are presented in Figure 11.

Figure 11. Stacked bar chart illustrating participant attitudes toward a potential gonorrhoea vaccine programme.



Responses are grouped by level of agreement with key statements related to vaccine acceptability, delivery preferences, and perceived need. Colours represent Likert-scale categories from strong disagreement to strong agreement. Note: Percentages are rounded to one decimal place and may not sum to exactly 100% due to rounding.

5.3.4 Attitudes and perceptions towards a gonorrhoea vaccine programme in the semi-structured interviews

5.3.4.1 AMR and sexual behaviour as programme justifications

Throughout the semi-structured interviews, participants broadly perceived the introduction of a vaccine against gonorrhoea as a necessary and timely public health intervention, primarily due to escalating concerns about AMR. The threat of gonorrhoea becoming untreatable was a key motivating factor in vaccine acceptance, with respondents framing AMR as an urgent risk necessitating a preventative solution: *"There's a degree of antibiotic resistance to certain infections… whatever we can do to cut down the spread of them is probably the most sensible thing"* (Male, 45-54). This perspective clearly demonstrates participants' pragmatic recognition of a need to mitigate the escalating public health threat posed by AMR. The idea that gonorrhoea could become untreatable was described as both credible and frightening: *"The fact that this is becoming incurable would scare people… they need to be scared, and they should be scared realistically"* (Female, 25-34).

A minority advocated for deliberately provocative public health messaging to grab attention and shift perceptions: "*Whatever we give you, it's not going to work. Your [genitals] will melt… I think that could be a really good campaign hook"* (Male, 35-44 years). However, this shock-based approach was tempered by concerns about misinformation. Participants warned against framing that might exaggerate the vaccine's effectiveness: *"You'd need to avoid a confusing message where people believe… they're some kind of Superhuman who's never going to catch either"* (Male, 35-44). This pragmatism extended beyond the health messaging into participants' broader understanding of population health, with several participants explicitly linking AMR to the need for pre-emptive, system-wide action*: "If it*

becomes completely antibiotic resistant and then spreads like wildfire through the community… we're going to be in a really scary, very dangerous place" (Male, 35-44).

Such views were closely tied to an acknowledgement that current behavioural prevention methods, especially condoms and oral prophylaxis such as HIV Pre-exposure prophylaxis (PrEP), are inherently limited by user adherence and situational constraints:

"[Condoms] are effective if used. They're very user dependent.… It's all event based" (Male, 25-34), and *"You forgot [PrEP] on holiday… your protection goes down. So if there is anything that could be administered once and worked for [a] prolonged period… that would be really helpful"* (Male, 35-44).

While HIV PrEP was recognised as highly effective in preventing HIV transmission, several participants observed that its availability had reduced condom usage, inadvertently increasing susceptibility to other sexually transmitted infections:

"Clearly one of the things about the availability of [HIV] PrEP now is that it clearly helps to alleviate one problem, but it makes the problem of sexually transmitted infection with other infections more likely now" (Male, 35-44).

Overall, participants viewed vaccination as a complementary strategy capable of mitigating the real-world limitations of individual adherence.

5.3.4.2 Acceptance rooted in trust, transparency, confidence and safety

The acceptability of a gonorrhoea vaccine was underpinned by a strong degree of trust in the institutions responsible for providing vaccines. Participants consistently expressed confidence in UK regulatory processes to ensure the safety, efficacy, and ethical deployment of vaccines*:*

"I have a lot of confidence in the UK, in regulating them to make them safe… I don't know the data, but I know there will be lots of data behind [it] because they wouldn't be approved as [a] vaccine in the UK otherwise" (Male, 25-34).

This participant's quote underscores the broader theme of institutional trust, highlighting how acceptance was anchored in confidence in regulatory body oversight, and established vaccine governance mechanisms.

Trust operated not only at the level of individual clinicians, but at the level of national institutions perceived to act in the public interest and to uphold rigorous safety standards. Further confidence was derived from the MenB vaccine's prior use in infants, a population perceived as particularly vulnerable. This history of safe administration enhanced participants' belief in its safety for adult populations: *"Because the vaccine has already been in circulation for a different disease, it's already proved to be non-harmful"* (Non-binary/other, 25-34). The potential for dual protection, against both MenB and gonorrhoea, was received positively when framed as an unexpected advantage: *"It's like… opening your Cornetto ice cream box where they say… it's five and you find the sixth one*" (Male, 35-44). But participants did express concern about overwhelming people with excessive information in a single communication: "*If you push too much information in one go… the message… disappears"* (Male, 35-44). Messaging around vaccine effectiveness also required careful calibration. While participants understood that partial effectiveness was still meaningful*:*

"40% is better than zero… the question is, is it in preventing [gonorrhoea] completely or preventing the severity of the disease? Because even if it's, you know, it's 33% [effective] at preventing [gonorrhoea] completely. That's not bad at all" (Male, 35-44).

But this perception was not unanimous; some indicated that a low protection rate would necessitate greater personal deliberation: *"If it's only 40%, I think I would definitely take more time to consider"* (Female, 25-34). Participants favoured messages that were transparent and grounded in evidence, avoiding vague or euphemistic language often associated with public health campaigns. They saw clarity as a way to empower rather than frighten: *"It's not about panicking people, but people need to actually understand what this infection can do because most people think it's just an antibiotic and done"* (Male, 35-44). There was also recognition that effective communication should challenge the normalisation of risk, particularly in relation to practices such as condom-less oral sex, which many participants noted were common yet rarely discussed in public health materials: *"One of the risk factors for contracting gonorrhoea… will be people engaging in unprotected oral sex and that's probably the majority of people who practise oral sex anyway"* (Male, 35-44).

5.3.4.3 Stigma and cost as structural barriers to access

Stigma emerged as a complex barrier to vaccine delivery, shaping where the participants felt safe accessing it. For many, discomfort stemmed from the broader sociocultural narratives that continue to frame certain sexual behaviours as deviant from the norm. Participants expressed fears of being judged by healthcare providers, particularly in settings where sexual health was not routinely discussed, rooted in past experiences or historical memory,

particularly among gay men who had lived through the HIV/AIDS epidemic. One participant's reflection powerfully captured this intersection of stigma, history, and healthcare access:

"It's not just the judgment. As a gay man growing up in the 90s at the height of the AIDS pandemic, there is stigma and there is still a lot of negative advertising around gay sex and promiscuity. I don't want people in places like pharmacies or GP providing less appropriate service because of what they think of me" (Male, 35-44).

This illustrates how stigma continues to influence not only perceptions of care but also the actual behaviour of service users. The lingering effects of AIDS-era rhetoric have, for some, entrenched a sense of vulnerability and conditional belonging within mainstream healthcare services. This led to strong preferences for sexual health clinics (GUM clinics) delivering the gonorrhoea vaccine programme, which were considered less judgmental than general practices or high-street pharmacies: *"Any GUM clinic would work. I definitely don't want to do it at my local pharmacy"* (Male, 35-44). Some participants referred to prior outreach initiatives as evidence that non-clinical settings could support engagement with the vaccine programme*: "Perhaps in bars or clubs, potentially in gay saunas in particular… sexual health clinics do pop up in those places…that's probably well worth considering"* (Male, 35-44). Alongside this, a clear preference emerged for peer-to-peer communication, particularly from individuals with shared identities or lived experiences. This was grounded in trust, relatability, and perceived authenticity:

"I would definitely trust fellow gays…definitely gay influencers… people on other platforms like TikTok or Instagram and whatnot who are very openly gay and who talk about, trials and tribulations of being gay" (Male, 35-44).

The use of prominent queer public figures, especially those with a track record of advocacy, were also described as powerful in increasing visibility and acceptance of the vaccine programme*: "I'd love to see those, you know, Sir Ian McKellen, on one of those posters… going grassroots could really have a great effect"* (Male, 35-44).

However, some participants explicitly stated that local pharmacies would be a more convenient option: *"I think pharmacy is convenient and they're, you know, they're everywhere"* (Male, 35-44), with others also emphasising how important ease of getting the vaccine in their decision to take it: *"I just want to book in with a nurse, get the jab, out I go…. I don't want to have to travel half an hour… because I will likely just take the risk"* (Female, 25-34). Participants expressed discomfort with having to justify their request for a sexual health vaccine: *"I don't want to have to sit in the doctor, talk about why I'm doing this. Obviously, if I want to be protective against gonorrhoea because I wanna have sex, that's it"* (Female, 25-34). In this way, stigma functioned as both a potential psychological and structural barrier to uptake. Another perceived structural barrier to vaccination against gonorrhoea was cost; while some participants stated they could personally afford to pay: *"Even if there were just a nominal cost to the vaccine, I think I would gladly bear it"* (Male, 35-44), others emphasised how even modest costs would disproportionately exclude vulnerable populations: *"I would [pay], but… if there were a cost associated with it, a lot of people [would] forgo it… someone on 21–24k a year, where every penny counts"* (Male, 35-44). Some participants explicitly invoked the current economic realities affecting them:

"People already don't have enough money for things like food.... I'm not gonna drop £25 on a vaccine" (Female, 25-34). These perspectives amalgamated into a strongly articulated belief that preventive sexual health services should be considered a basic entitlement: *"Health in general is a human right… Nobody should be rejected… on the basis of their financial positioning"* (Female, 25-34), highlighting the public's perceived value of a vaccine capable of reducing gonorrhoea cases. A summary table of qualitative findings is provided in the supplementary material 4.

5.4 Discussion

This mixed-methods study found broad support among sexual health service users in the UK for a gonorrhoea vaccination programme using a 4CMenB vaccine. Support was influenced by concerns regarding AMR, trust in UK healthcare bodies, equitable access, previous stigmatisation of marginalised groups in healthcare access, and targeted communication and outreach strategies.

The participants in this study predominantly identified as male and were aged under 55 years. It is plausible that the predominance of male respondents reflects a perception of gonorrhoea as largely a male issue, or at least more salient for GBMSM communities. Women may not perceive themselves at risk for STIs, even when prevalence is nontrivial, particularly because infection may be asymptomatic. For example, a UK national survey [Clifton et al., 2018] found that 73% of women rated themselves as "not at all at risk" for STIs, compared with lower rates among men (64%), even though women may experience serious complications as a result of gonorrhoea, including infertility [Freeman-Romilly et al., 2025].

5.4.1 Programme-specific acceptance and AMR framing

Findings from the VAX scale indicated that, among this group of participants, vaccine hesitancy was shaped by context-specific considerations rather than by ideological opposition to vaccination. Participants distinguished between general confidence in vaccines and reservations related to particular programmes, suggesting that concerns were not rooted in fundamental rejection of vaccination, but were contingent on how vaccination was positioned and justified. This distinction implies that acceptance may be supported programme specific factors rather than strategies aimed at countering entrenched opposition to vaccination.

AMR emerged as the primary driver of acceptance, with participants framing vaccination as a suitable biomedical intervention. This aligns with international public health AMR discourse [Waltmann et al., 2024], however, an existing literature review [Colquhoun et al., 2024] suggests that the consequences of AMR are often experienced by the public as distant and abstract, making them difficult to fully grasp, while understanding of the scientific processes that drive resistance is frequently incomplete or inaccurate. Further, the review [Colquhoun et al., 2024] indicates that communication is central to increasing awareness of AMR more broadly, but evidence on how to tailor AMR communications across populations and settings is still limited. Suggesting that for some, increasing awareness of the consequences of AMR, could increase the acceptance of the gonorrhoea vaccine programme.

5.4.2 Vaccination as a complementary approach

Participants frequently framed existing STI behavioural and biomedical prevention strategies, such as condom use and PrEP, as effective in principle but constrained in practice by the demands of sustained adherence. In particular, these interventions were understood as requiring ongoing, routine action that could be disrupted by everyday life, changes in routine, or social context. This framing mirrors existing qualitative research in the UK [Young et al., 2014] on PrEP use, which has identified adherence as a central challenge, shaped by factors such as irregular daily schedules, forgetfulness, changes in environment, and concerns about privacy and stigma associated with the medication use.

Against this backdrop, vaccination, despite the acknowledgement that PrEP offers protection only against HIV, was positioned by participants as a complementary form of prevention that did not rely on continual individual adherence in the same way. Rather than replacing behavioural approaches, it was understood as operating in parallel with them, particularly in contexts where daily or event-based adherence was difficult to sustain. This framing reflects broader HIV prevention literature recognising the value of combining biomedical and behavioural strategies to address both biological vulnerability and the practical limitations of sustained behavioural adherence simultaneously [Brown et al., 2014]

This positioning reflects a broader idea of combination prevention, in which different strategies are understood to address different dimensions of risk. Vaccination was valued as a means of redistributing responsibility for prevention, shifting some of the burden away from constant individual action and towards biomedical and institutional provision. From a sociological perspective, vaccination can be situated within broader processes of biomedicalisation, through which responsibility for managing health risks is increasingly organised through biomedical and institutional systems rather than individual action [Clarke

et al., 2003]. Importantly, framing vaccination as complementary also allowed participants to accommodate uncertainty about vaccine effectiveness. Partial protection was seen as meaningful when situated alongside other preventive measures, particularly given the perceived challenges of maintaining perfect adherence to behavioural interventions

5.4.3 Trust and reservations

As similarly observed during the development of COVID-19 vaccines [Skafida and Heins, 2024], acceptance in the gonorrhoea vaccine programme was underpinned by institutional trust in UK regulatory processes. Participants' confidence was shaped by familiarity with the Medicines and Healthcare products Regulatory Agency (MHRA), the NHS, and established vaccine governance structures. This institutional trust was further reinforced by the use of 4CMenB, a vaccine with an established safety profile in the UK immunisation programme [Ladhani et al., 2024], which reduced perceptions of novelty and risk despite its proposed repurposing for a new indication. These findings are consistent with existing literature demonstrating that trust in the quality and safety of vaccines, and in the institutions responsible for their delivery, is critical to willingness to be vaccinated [Adhikari et al., 2022]. However, the present findings extend this literature by illustrating how institutional trust can also mitigate uncertainty associated with programme innovation, particularly where vaccines are repurposed rather than newly developed.

Participants' concerns about relatively low vaccine effectiveness underscored the importance of clear and realistic communication about what the vaccine could and could not offer. Participants emphasised that benefits needed to be framed carefully to avoid creating a false sense of complete protection, while still conveying the value of partial protection within a

broader prevention strategy. These concerns point to the need for messaging that acknowledges uncertainty and limitation, rather than overstating effectiveness, in order to support informed acceptance and appropriate use alongside other preventive measures. Consistent with previous research [Lutrick et al., 2022], individuals do value vaccine efficacy information; those who hold more positive perceptions of vaccine safety and efficacy are more likely to receive vaccination.

Perceptions of universal accessibility emerged as essential, highlighting the high value participants placed on this programme, with some identifying potential cost as a barrier to receiving the vaccine, and therefore worsening inequalities. The notion of universal accessibility reflects the broader NHS Constitution for England [Department of Health and Social Care, 2023], which emphasises equitable provision imperatives supported by health equity research, and is also consistent with wider health equity reports demonstrating that financial and structural barriers can undermine the reach and impact of preventive health interventions [Michael Marmot, 2020].

5.4.4 Stigma-free access and communication

Stigma represented potential significant psychological and structural barriers, with various GBMSM (as self-identified during the semi-structured interview) participants expressing preferences for specialised sexual health services over general healthcare settings, as they were perceived as less stigmatising and more affirming of their sexual health needs than general healthcare settings. Participants emphasised that destigmatising efforts would be most effective when combined with local, grassroots strategies, such as drop-in clinics, and events held in partnership with lesbian, gay, bisexual, transgender, queer, and other sexual and

gender minority identities (LGBTQ+) venues. Previous research has described how these community-based approaches are important in making healthcare services more accessible and welcoming [Clifton et al., 2018].

In addition to destigmatising vaccine delivery, strong endorsement emerged for peer-led dissemination of information through community leaders, influencers, and grassroots organisations, considered central rather than supplementary to institutional efforts. The emphasis on peer-to-peer communication, particularly within LGBTQ+ communities, suggests a viable avenue for promoting vaccine acceptance. Peer-led activism and community groups were regarded as highly persuasive, particularly for populations already marginalised within health systems. As demonstrated by Biesty et al. [2024], engagement through trusted community groups and visible peers can enhance credibility and acceptability of public health interventions among groups with prior experiences of marginalisation. Well-known figures from within the LGBTQ+ community were also seen as uniquely positioned to bridge the gap between clinical settings and community realities, and as suggested in previous research, queer celebrities are powerful agents for raising awareness of LGBTQ+ issues [Botha and Nichols, 2024]. Overall, community mobilisation and peer influence were considered central to effective dissemination alongside institutional efforts, particularly for reaching those who might otherwise distrust formal systems, avoid clinical encounters due to stigma, or simply not engage with conventional public health messaging.

To ensure the success of a gonorrhoea vaccination programme, these findings suggest some recommendations which include targeting actions across delivery, communication, and outreach. The vaccine should be offered free of charge and delivered through trusted settings such as sexual health clinics and mobile pop-ups in LGBTQ+ venues, which were perceived

as less stigmatising. Low-barrier access models should be integrated into routine sexual health appointments. Communication should be transparent about the vaccine's partial efficacy, framing it as a meaningful layer of protection, as part of a wider package of preventative measures. Finally, peer-led campaigns featuring LGBTQ+ influencers could be successful in building trust, normalising uptake, and extending reach to those not engaged with traditional health messaging in this community.

5.4.5 Limitations

Several limitations should be noted in interpreting these findings. First, a limitation of the mixed-methods design is that while the qualitative data added valuable depth to interpretation, it was collected from a smaller and more demographically homogeneous subset of survey participants, which may limit representativeness. Further, the majority of participants in this study identified as male, reflecting the targeted focus of the gonorrhoea vaccination programme towards gay, bisexual, and other men who have sex with men (GBMSM). While our predominantly male sample reflected the epidemiological concentration of gonorrhoea amongst GBMSM in the UK, including more women may have yielded different perceptions of vaccine acceptability, given there are broader implications of infection which extend to other demographics. Modelling studies have also shown that adolescent vaccination programmes could provide substantial population-level protection [Looker et al., 2023], and so future research should explore the acceptability of adolescent gonorrhoea vaccination or population-wide approaches.

Second, sexual orientation was not explicitly collected from participants; however, the inclusion criterion of prior experience with sexual health services aligns well with the

programme's broad target demographic—individuals at elevated risk of bacterial STIs who attend sexual health clinics. Additionally, the online recruitment strategy may have introduced self-selection bias, potentially attracting individuals with stronger or more polarised views on vaccination, thus affecting the representativeness of the findings.

Lastly, although the quantitative sample was statistically powered to ensure accuracy and reliability, it was not stratified by specific demographics. Therefore, findings should be interpreted with caution when generalising beyond the sampled population. Future research should explore vaccine perceptions, knowledge, and acceptability among a broader cross-section of the population, including women, adolescents, and groups that are traditionally underserved by sexual health services, to inform more inclusive and effective public health strategies. These include those from lower socioeconomic communities, minority ethnic groups, and refugees and asylum seekers [Mawson et al., 2025, Kaneoka and Spence, 2020].

5.5 Conclusion

The findings of this chapter demonstrate high overall acceptability of the 4CMenB vaccine among the study participants, particularly when delivery is trusted, stigma-free, and supported by transparent communication and peer-led outreach. Specifically, this chapter highlights the importance of addressing intersecting behavioural, structural, and social factors that influence vaccine acceptability and access. To support equitable and effective delivery, we recommend specific policy actions including ensuring free and universal access, prioritising delivery through trusted low-stigma settings, implementing peer-led outreach, and clearly communicating the vaccine programme’s potential benefits and limitations. Monitoring of uptake across diverse populations will be critical to guide responsive

adjustments and prevent disparities. Monitoring is needed to evaluate the impact of population-wide vaccination approaches and refine targeting strategies. Lessons from this pioneering programme will shape future responses to the growing challenge of AMR gonorrhoea and the broader role of vaccination in STI control.

6 Discussion

This thesis has explored how changes to immunisation programmes are understood and experienced across different global health contexts. Chapters 3, 4, and 5 approached this question across different empirical settings, focusing on different actors, using different methods. Chapter 3 systematically reviewed parental and recipient perceptions of changes to childhood immunisation schedules, identifying recurring themes related to trust, perceptions of safety, communication, and social context. Chapter 4 examined parental perceptions of immunisation schedule change in Nepal and Uganda, showing how established schedules are embedded within everyday caregiving practices and relationships with health systems, and how proposed changes can prompt uncertainty even where support for vaccination is high. Chapter 5 explored attitudes towards a proposed gonorrhoea vaccine programme in the UK, illustrating how similar questions about acceptability arise when vaccines are introduced in new populations or for new purposes, despite differences in disease context, life stage, and delivery setting.

These chapters suggest that while vaccination is widely supported across these contexts, changes to immunisation schedules often represent moments in which existing assumptions about vaccines are revisited. Rather than being experienced simply as technical or purely programmatic adjustments, schedule changes prompt reflection and questioning among caregivers and vaccine recipients. Importantly, these responses are not well captured by approaches that focus solely on vaccine confidence or hesitancy. Conventional frameworks tend to conceptualise acceptance and refusal as positions along a spectrum of belief, often operationalised through measures of uptake, delay, or stated intention [Dubé et al., 2013, Bedford et al., 2018]. However, the findings presented here show that uncertainty about schedule change frequently emerges among individuals who otherwise express high

confidence in vaccines and strong support for immunisation programmes. What is at issue is not vaccination as a principle, but the reconfiguration of established routines, timings, and institutional arrangements through which vaccination is delivered. By treating such responses as hesitancy, existing approaches risk obscuring the ways in which concern can reflect engagement with change rather than opposition to vaccination itself.

The aim of this discussion chapter is to bring together findings from the different contexts and to examine how acceptability—understood here as how individuals make sense of and respond to changes in immunisation programmes—is negotiated in the context of immunisation schedule change. While the empirical chapters present findings through thematic analysis, the broader analytical orientation of the thesis remained informed by a constructivist grounded theory approach. Thematic analysis was used within individual case studies as a flexible and transparent approach for organising patterns within the data and structuring the presentation of findings. However, themes were not treated as descriptive endpoints. Rather, the discussion chapter now draws these findings into iterative comparison across contexts, attending to how meanings, relationships, and forms of uncertainty were constructed and negotiated within different social, institutional, and historical settings. And so constructivist grounded theory informed the interpretive synthesis of the thesis as a whole, particularly through its emphasis on process, context, reflexivity, and the co-construction of meaning. The comparative analysis developed across chapters, therefore, moved beyond identifying recurring themes to examining how trust, authority, care, legitimacy, and responsibility interacted during moments of immunisation programme change, and how these processes were differently configured across settings.

In particular, it develops a distinction between the acceptability of vaccines and the acceptability of change, suggesting that it is often change itself that generates uncertainty and requires negotiation. The chapter examines how, at an individual level, uncertainty is experienced in the face of schedule change, and how trust functions as a mechanism through which that uncertainty is managed. Rather than eliminating doubt, trust enables individuals to proceed with vaccination by providing confidence in the competence and intentions of healthcare providers and institutions. From a societal perspective, this chapter also examines how collective experience can inform expectations around care and civic duty, and finally, how these processes interact across different contexts.

By drawing together evidence from childhood immunisation programmes in LMIC settings and from adult vaccination in a high-income context, this discussion highlights both commonalities and differences in how immunisation programme change is experienced. In doing so, it frames acceptability as a relational and context-dependent process, and positions moments of programme change as particularly revealing of the social, ethical, and institutional dimensions of vaccination.

6.1 Acceptability of vaccines versus acceptability of change

Across the empirical chapters, participants consistently expressed strong support for vaccination. Immunisation programmes in Nepal and Uganda were widely regarded as important and necessary, and participants in the UK articulated high levels of support for vaccination as a means of preventing disease and addressing public health challenges such as AMR. However, this support did not extend unproblematically to changes in immunisation schedules. Instead, moments of programme change materialised as points at which uncertainty, concern, and reflection were articulated, even among those who otherwise expressed confidence in vaccination.

This pattern points to an important analytical distinction between the ‘acceptability of vaccines’ and the ‘acceptability of change’. Vaccines are not encountered solely as biomedical technologies, but as sociotechnical objects that have become embedded within routines, infrastructures, and everyday life. Established immunisation schedules can be understood as infrastructure in the sense described by Bowker and Star [1999]: they are embedded, taken-for-granted systems that stabilise and align expectations between diverse actors—policy-makers, health workers, vaccine recipients, caregivers—about how vaccination should be delivered and what can be anticipated without requiring ongoing deliberation.

As infrastructural devices, schedules translate complex scientific, regulatory, and programmatic decisions into standardised timelines that organise practice at scale. When implemented without disruption—such that vaccines are available, appointments proceed as expected, and health workers follow established routines—these timelines render expert justification and discussion largely invisible. For example, a caregiver attending a routine vaccination appointment is typically not required to engage with the epidemiological modelling, cost-effectiveness analyses, or regulatory decisions that determined the timing and composition of the schedule. These complexities are folded into the appointment itself, experienced simply as "your child’s next vaccine is due." Therefore, the acceptability of vaccines is not sustained through continual evaluation, but rather through familiarity and routinisation.

Within this framing, immunisation schedules also resemble what Beck [1992] describes as expert systems that stabilise “manufactured risks”: their authority remains largely unquestioned so long as they function predictably, but becomes subject to scrutiny when disruption exposes underlying uncertainty. Like other infrastructures—roads, classification

systems, or school term dates—schedules become visible primarily when they break down or change. When schedules are altered or new programmes introduced, vaccines are re-encountered as objects that must once again be interpreted and re-situated within existing expectations about timing, safety, and responsibility, as well as within established relationships between caregivers, healthcare providers, and institutions. This dynamic reflects what Bowker and Star [1999] term "infrastructural inversion" whereby the normally invisible background systems that organise practice become visible at moments of breakdown or reconfiguration. However, where Bowker and Star's examples often involve formal classification systems (such as disease taxonomies or racial categories), the present analysis extends their framework to encompass the dimensions of immunisation schedules—not only what vaccines are given, but when, by whom, and through what institutional arrangements. Schedule change thus involves not merely reclassification but the renegotiation of expectations about timing, responsibility, and care.

From this perspective, expressions of concern during periods of programme change should not be understood as straightforward indicators of vaccine hesitancy or opposition. Rather, they reflect engagement with the sociotechnical reconfiguration that schedule modification entails.

Change alters established expectations about how vaccination is organised and who holds responsibility, prompting caregivers and recipients to reassess whether these new arrangements align with their prior experiences and understandings. Across the empirical chapters, participants' questions were directed less at the act of vaccination itself than at the processes through which decisions were made, implemented, and evaluated, and how these changes to the schedule differ to their current expectations. Caregivers in Nepal and Uganda sought to understand how altered schedules related to children's wellbeing and to the

responsibilities of health systems, while participants in the UK study queried the evidence base, governance, and implications of repurposing existing vaccines across different settings. These concerns were oriented towards making sense of change, rather than rejecting vaccination as an act itself.

Reframing concern in this way shifts analytical attention away from individual deficits in knowledge or confidence and towards examining how change reshapes prior expectations within immunisation schedules. Concern can be understood as a reasonable response to the destabilisation of previously taken-for-granted sociotechnical configurations through which immunisation schedules organise care, distribute responsibility between caregivers, health workers, and institutions, and stabilise institutional authority. Acceptability of change thus emerges as a negotiated outcome of interactions between scientific evidence, institutional practice, and everyday experience.

This distinction between the acceptability of vaccines and the acceptability of change provides the conceptual foundation for the discussion that follows. The remainder of this chapter examines how the acceptability of change is produced and contested. By treating change as a moment of sociotechnical reconfiguration—that is, a reorganisation of the timing, number of injections, delivery structures, or institutional justifications through which vaccination is coordinated—the discussion seeks to illuminate how immunisation programmes are sustained, adapted, and sometimes contested in the context of ongoing efforts to expand and strengthen immunisation services globally.

6.2 Discussion part I: Individual response to schedule changes

At the individual level, immunisation schedule change was experienced as a disruption that required interpretation and adjustment. The following sections examine uncertainty as an immediate response to change and the role of trust as a mechanism of negotiation.

6.2.1 Uncertainty

Changes to immunisation schedules were most immediately experienced as uncertainty. Schedules organise vaccination practices and coordinate caregivers, health workers, and institutions around shared expectations of timing and responsibility. Change disrupts these established expectations about vaccination, prompting individuals to reconsider what risks it might entail, and how it would affect their own bodies or those of their children.

Uncertainty has long been recognised as a central feature of medical practice and healthcare decision-making rather than a temporary absence of knowledge to be eliminated [Han, 2021]. In medicine, uncertainty may arise from incomplete scientific evidence, but also from ambiguity surrounding risk and future outcomes. Han [2021] argues that individuals differ in their tolerance of uncertainty, and how they interpret and negotiate uncertainty within healthcare interactions. The findings of this thesis align with this broader literature. Participants frequently sought to understand how and why changes had occurred, whether institutions remained trustworthy, and how new arrangements aligned with existing expectations of care and protection.

In the childhood immunisation settings of Nepal and Uganda, uncertainty centred on children's bodily experiences of vaccination. Parents expressed concern about whether changes to schedules would increase pain, introduce additional injections, or intensify side effects. Questions of tolerability were prominent, with caregivers asking whether altered

schedules would be too much for children or whether children would recover as expected following vaccination. These concerns reflected attentiveness to children's immediate comfort and well-being rather than doubts about the value of vaccination itself. In Nepal, uncertainty also extended to the implications of schedule change for caregiving practices. Parents described concerns about how children might respond after vaccination, including whether side effects would require prolonged care or disrupt household routines.

In Uganda, similar concerns were articulated around pain and recovery, with parents attentive to how changes might alter familiar patterns of response. Established schedules had provided a degree of predictability, allowing caregivers to anticipate typical side effects and plan accordingly. When schedules were modified, this predictability was unsettled, and parents were required to reassess what risks were reasonable to accept in relation to their responsibility to protect children from both disease and harm.

In the UK context, uncertainty associated with a proposed gonorrhoea vaccine programme was oriented towards different questions. Participants focused less on immediate bodily effects and more on uncertainty about protection. As the schedule change examined was the repurposing of a vaccine to protect against a different bacteria, concerns centred on how effective the vaccine would be, how long protection might last, and whether vaccination could create a false sense of security for those who had been vaccinated. Given the longstanding use of the vaccine for a different age group, participants weighed uncertainty about effectiveness against expectations of benefit and against existing prevention practices, rather than the safety of the vaccine.

Across all contexts, uncertainty emerged at moments when established expectations were disrupted. Long-standing immunisation schedules had allowed many aspects of vaccination to become familiar and predictable, but change reactivated attention to risk by interrupting

this familiarity. These uncertainties were experienced as part of a process of adjustment, and help clarify why schedule change can prompt concern even where vaccines remain widely accepted. Changes do not challenge vaccination as such, but unsettle what individuals have come to expect from immunisation programmes. The following section examines how trust can shape whether this uncertainty remains manageable or becomes destabilising during periods of schedule change.

6.2.2 Trust (or dependency)

Trust has been conceptualised in social theory and health systems scholarship as a relational and processual phenomenon rather than a fixed attribute. Gilson [2003] argues that trust is central to the functioning of health systems, sustained through perceptions of competence and accountability within institutional relationships. Similarly, Möllering [2006] describes trust as a dynamic process involving interpretation, expectation, and a provisional "leap of faith" that enables action under conditions of uncertainty. From this perspective, trust is neither blind confidence nor static belief, but an ongoing accomplishment that must be reproduced through experience and institutional performance. In this thesis, these perspectives were drawn upon to understand trust as an active process through which individuals assess whether institutions and actors are behaving in ways that warrant continued confidence. This framing is particularly relevant to immunisation schedule change, where established trust may be tested by new uncertainties and where the response of institutions—whether transparent, dismissive, or absent—shapes whether trust is sustained, deepened, or eroded.

Trust emerged across the empirical chapters as an important mechanism through which individuals navigated the uncertainty induced by immunisation schedule change. However, trust, whether that be interpersonal, institutional, or embedded in vaccination schedules

themselves, was not expressed as stable or unconditional. Instead, it was relational, situational, and actively negotiated. Schedule change prompted participants to reassess both the vaccines themselves and the institutions and actors responsible for delivering them.

In the childhood immunisation contexts of Nepal and Uganda, trust in vaccination programmes was closely tied to the legitimacy and proven impact of routine immunisation. Established schedules were widely regarded as normal and expected, reflecting their long-standing integration into public health systems; participants often described this familiarity as contributing to their confidence in immunisation programmes. At the same time, the data suggest that what appeared as trust was sometimes closely intertwined with dependency on health systems. In settings where alternatives to public immunisation services were limited, for example, through a distrust or limited financial or geographical access to private facilities, caregivers' acceptance of vaccination and schedule changes was shaped by their reliance on state programmes, rather than a deep-rooted trust. In Nepal, there was evidence that, in some cases, this parental dependency was liable to shift from the governmental health facilities to other providers, for example, through engagement with clinical trials. Parents described volunteering their children for vaccine trials, explicitly because they offered material benefits such as access to medical care, diagnostic testing, and vaccines that were not routinely available through the national immunisation programme.

In the UK context, trust operated through different institutional arrangements but played a similar role in mediating responses to change. Participants expressed high levels of confidence in the NHS and in the UK's scientific and regulatory expertise, and vaccination delivered through sexual health services was generally assumed to be legitimate and evidence-based. But again, this trust brought to light expectations rather than passive

acceptance. Participants expected transparency around evidence, clarity about effectiveness and limitations, and ethical governance of new vaccine programmes. Trust was closely linked to perceptions of accountability and openness. Participants described being willing to accept uncertainty around efficacy or duration of protection if they believed that institutions were being transparent and responsive. This aligns with broader literature on communicating medical uncertainty, which emphasises that openness about uncertainty and limitation can help sustain trust and engagement within healthcare interactions [Bleakley, 2019, Medendorp et al., 2021].

Frontline health workers occupied a critical position within these processes. In both low- and middle-income and high-income settings, they acted as intermediaries between policy decisions and actual individual experience, serving as the most viible and tangible embodiment of the health system through which institutional authority and care were encountered in practice. While Lipsky [2010] did not write specifically about immunisation services, their concept of "street-level bureaucracy" provides a useful lens for understanding how frontline public service workers interpret and enact policy in everyday encounters, exercising discretion that shapes how institutional decisions are experienced in practice. Participants' accounts in this thesis frequently referenced health workers as the primary source of explanation, reassurance, and legitimacy at moments of schedule change, illustrating how institutional policy was encountered, enacted, and finally interpreted at the point of care, rather than at the level of formal guidance. Health workers ability to explain changes and demonstrate care shaped how change was received. However, their ability to perform this role will depend on the information and support they themselves received from institutions, highlighting the layered nature of trust within immunisation systems.

Across contexts, established immunisation programmes benefited from accumulated trust built through repetition and routine. Programme change disrupted this routine, creating uncertainty and requiring institutions to demonstrate continued competence and alignment with recipients' expectations. Trust, therefore, cannot be assumed to persist unchanged through periods of schedule modification. Instead, trust operates as a mechanism through which uncertainty is managed, though not eliminated. It enables individuals to live with uncertainty where change is perceived as reasonable, justified, and appropriately governed. Where vaccination rests primarily on dependency or habit, rather than on transparent and accountable relationships, this trust may be more fragile during periods of change. Understanding trust as relational and conditional thus helps explain why programme modification can prompt concern even in contexts where vaccination itself remains widely accepted.

6.3 Discussion part II: Societal and collective dimensions of acceptability

The preceding sections focused on individual responses to immunisation schedule change, examining how disruption to established schedules generated uncertainty and how trust in institutions shaped whether such uncertainty was deemed manageable. However, individual experiences of schedule change did not occur in isolation. They were embedded within broader social, moral, and political contexts that shaped how vaccination was understood and how individuals reasoned about appropriate action.

This second part of the discussion, therefore, shifts attention to the collective and societal dimensions of acceptability, beginning with an examination of power and governance that interact with immunisation systems. It considers how national and global health hierarchies,

state responsibility, and institutional authority shape expectations about who decides, who benefits, and who bears responsibility for risk. These power relations provide the conditions under which vaccination is understood as legitimate and under which certain forms of care become morally expected.

The discussion then turns to care and civic responsibility, examining how individuals and communities reason around appropriate action within these contexts. By exploring the dimensions of power and care, this section shows how moral expectations around caregiving, protection, and responsibility —shared understandings of parents' duty to safeguard children's health and participate in public health programmes— are produced and sustained through broader political and institutional arrangements, rather than arising independently of them.

6.3.1 Power

While immunisation schedule change was experienced by individuals as uncertainty and managed through relationships of trust, these responses were shaped by broader arrangements through which vaccination was organised, delivered, and authorised. These arrangements influenced how responsibility was understood, who was expected to make decisions, and how the benefits and risks of vaccination were distributed. Power and hierarchies operate largely in the background of everyday practice and became more visible when individuals were faced with such uncertainty.

In both Uganda and Nepal, routine childhood immunisation was widely understood as part of the government's responsibility to care for its citizens. Vaccination schedules were often

taken as evidence that the state was fulfilling its obligation to protect children's health, and participation in immunisation programmes was framed as consistent with this responsibility. Authority over vaccination decisions was therefore largely delegated to governmental institutions and was rarely questioned when programmes were stable. Power in this context was experienced through expectations of state provision and continuity rather than through active negotiation or critique. Schedule change thus prompted reassessment of whether established obligations were still being met, revealing how state responsibility structured acceptability at a societal level.

Questions of power and legitimacy surrounding immunisation programme change were also closely linked to concerns about vaccine testing and evidence generation. In Nepal, participants' confidence in vaccine safety and effectiveness was often tied to whether vaccines had been tested in Nepal. Local testing was understood by some as a means of ensuring that vaccines were appropriate, effective, and relevant to the Nepali context, particularly given differences in health systems, environments, and population. However, vaccine testing also emerged as a source of concern in both Uganda and Nepal, revealing how power relations within global health shaped perceptions of immunisation programme change. Some participants expressed apprehension about their country being used as a site for testing new vaccines, articulating suspicion that vaccines introduced into the country might be intended primarily for experimentation rather than for immediate public health benefit.

Such accounts reflected anxieties about uneven global health power relations, in which lower-income countries may be positioned as locations for research and testing for interventions developed elsewhere. Participants questioned whether their community's role in vaccine testing reflected equal partnership in global health decision-making or a more peripheral

position within international systems of research and regulation. Schedule change, particularly the introduction of new vaccines, therefore prompted reflection on whose interests were being served through these processes. Participants raised explicit questions about whether new vaccines were being introduced because they addressed local health needs, or because their country was considered an appropriate site for testing prior to wider rollout. These concerns drew attention to the governance of vaccine research and deployment, including how oversight was exercised and how benefits and risks were allocated. At the same time, the fact that such concerns were articulated alongside recognition of Nepal's reliance on external vaccine development highlights the constrained choices available within global health systems. Vaccine testing therefore became a focal point through which broader questions about the legitimacy of decision-making processes, the authority of national and international actors, and the unequal distribution of power within global health systems were brought into view during periods of immunisation programme change.

In the UK context, power was experienced primarily through institutional authority and the organisation of sexual health services. Participants expressed confidence in the NHS and in national scientific and regulatory systems, and vaccination delivered through sexual health services was generally assumed to be legitimate and appropriately governed. Authority was accepted as part of routine healthcare provision, and programme change was evaluated within expectations that decisions would be evidence-based and ethically managed. However, participants' accounts also reflected an awareness of how vaccination programmes might intersect with stigma, particularly in relation to sexuality. Discussions of a proposed gonorrhoea vaccine raised questions about who would be offered the vaccine, how eligibility would be determined, and in what contexts the vaccine would be delivered. These concerns were not framed as opposition to vaccination, but as attentiveness to how programme design

could reinforce existing forms of marginalisation within sexual health settings. In this sense, power was experienced through the capacity of institutions to define who was 'at risk' of certain infections, and therefore eligible for the vaccine. Acceptability of programme change was therefore closely tied to how vaccination would be implemented in practice—specifically, whether eligibility criteria would be applied in ways that avoided reinforcing stigma, whether delivery settings would protect confidentiality, and whether communication would frame vaccination as inclusive rather than targeting or labelling particular groups.

Across all contexts, immunisation schedule change brought these background arrangements into view. Change disrupted this invisibility, prompting attention to how decisions were made, who was responsible for ensuring protection, and how care was organised. Power became visible not through overt resistance, but through scrutiny of institutional authority—particularly the authority of governments, regulatory bodies, international organisations, and healthcare providers to determine vaccine policy and implementation. These findings suggest that the acceptability of immunisation schedule change is shaped by the governance structures through which vaccination is delivered, including who holds authority to define eligibility and timing, how decisions are justified, and how accountability is maintained. State responsibility and global health infrastructures therefore condition how change is interpreted and what forms of care are considered legitimate. These institutional contexts provide the conditions within which collective moral reasoning about care and responsibility takes place, which is examined in the following section.

6.3.2 Care and civic responsibility

Shared expectations about care and civic responsibility also shaped responses to immunisation programme change. While trust influenced whether institutions were perceived as legitimate, care and civic responsibility structured how individuals and communities understood what constituted appropriate action in relation to vaccination. Across contexts, vaccination was embedded within normative assumptions about who should care, for whom, under what conditions, and to what extent. These assumptions played a central role in shaping how uncertainty associated with schedule change was interpreted and tolerated.

In the childhood immunisation contexts of Nepal and Uganda, vaccination was widely framed by the participants as part of the social responsibilities of caregiving. Parents described immunisation as an expected aspect of looking after children, oriented towards protecting their child's health over the long term. At the same time, caregiving was understood as involving attentiveness to children's immediate well-being. Concerns about pain, side effects, and the cumulative burden of injections reflected shared expectations about what a "good" parent ought to prioritise—both protection from future harm and minimisation of present distress. Decisions about vaccination therefore drew on moral reasoning about parental duty and appropriate care, rather than relying on biomedical data alone.

These moral expectations became more visible during periods of immunisation schedule change. Alterations to timing, dosing, or vaccine prompted parents to reassess whether schedules continued to align with their understanding of what responsible care entailed. In these moments, concerns were not directed at vaccination as a practice, which remained broadly accepted, but at whether changes remained appropriate for children's bodies and circumstances. Parents described weighing anticipated benefits against discomfort and uncertainty, situating acceptance of change within a broader sense of responsibility for children's welfare.

In the UK context, reasoning around vaccination was framed through expectations of civic responsibility towards others. Participants in the gonorrhoea vaccine study described vaccination as contributing to collective well-being, particularly by reducing transmission and addressing AMR. Accepting vaccination was therefore understood as acting responsibly within society, even where individual benefit was uncertain. At the same time, acceptance of vaccination in the UK context was conditional on expectations that authority would be exercised ethically and in the public interest. Participants emphasised the importance of transparency, accountability, and respect, particularly given the potential for stigma associated with sexually transmitted infections. Moral reasoning in this context involved assessing whether vaccination programmes aligned with shared values of inclusion and responsible governance.

Across all contexts, reasoning around care and civic responsibility provided a framework through which uncertainty associated with immunisation programme change could be accommodated. Acceptability was shaped by whether schedule changes could be reconciled with existing societal expectations of care, responsibility, and protection. Where changes aligned with these expectations, uncertainty was more readily tolerated. Where they appeared to undermine assumptions about who should care, how risk should be managed, or whose interests were prioritised, concern became more pronounced. Understanding vaccination as a moral practice—that is, as an activity shaped by shared beliefs about what parents and citizens ought to do—helps explain how immunisation programmes are sustained despite ongoing change. Moral reasoning does not eliminate uncertainty, nor replace the need for trust, but situates it within broader social obligations and institutional arrangements, allowing individuals and communities to act in ways that remain meaningful and justified as programmes evolve.

Overall, the analyses presented in this chapter show that acceptability of immunisation programme change is produced through interactions between individual experience and broader societal arrangements. Uncertainty emerged as a common response to disruption of established schedules, trust shaped whether that uncertainty could be managed, and power and moral reasoning structured how responsibility and care were understood across contexts. By bringing these strands together, this thesis presents the argument of how programme change functions as a critical moment in immunisation systems, one in which the assumptions that underpin routine delivery are rendered visible. The concluding chapter builds on this synthesis to reflect on the broader contributions of the thesis, its limitations, and the implications for future research and global health practice.

7 Conclusion

This thesis set out to examine how changes to immunisation programmes are understood, experienced, and negotiated by vaccine recipients, parents and caregivers across diverse global health contexts. While vaccination has long been recognised as a cornerstone of public health, and extensive scholarship has examined vaccine confidence and hesitancy, comparatively less attention has been paid to how people respond when established immunisation schedules change. Yet such changes are now a routine feature of contemporary immunisation programmes, driven by ongoing vaccine innovation, shifting disease epidemiology, and evolving programmatic priorities.

By focusing on immunisation schedule change rather than vaccination as a static intervention, this thesis reframes the problem of acceptability. Rather than asking why people accept or reject vaccines, it asks how people make sense of change to systems that have become familiar, routinised, and embedded within everyday life. In doing so, the thesis challenges approaches that interpret expressions of concern primarily through the lens of vaccine hesitancy, which tend to frame uncertainty as a deficit in knowledge, confidence, or trust at the level of the individual. The findings presented here suggest that such frameworks may obscure the ways in which concern arises not from opposition to vaccination itself, but from the disruption of established routines, institutional arrangements, and expectations about timing, authority, and care. By repositioning concern as engagement with programme modification rather than as reluctance toward vaccination, the thesis offers a more context-sensitive account of acceptability in moments of change.

7.1 Summary of key findings

Across the empirical components of the thesis, vaccination itself was widely supported. Childhood immunisation programmes in Nepal and Uganda were regarded as important and necessary, while participants in the United Kingdom expressed strong support for vaccination as a response to public health challenges, such as AMR. The strong support of vaccination could partly be explained by the research population – research engaged parents in Nepal and Uganda, and sexual health service users in the UK. Nevertheless, high baseline support for childhood vaccination is consistent with global survey data, which indicate that in most countries over 70% of respondents consider childhood vaccination important, and in many settings this figure exceeds 90% [Ritchie, 2019] . However, in this thesis, vaccination support did not extend unproblematically to changes in immunisation schedules.

Moments of schedule change consistently prompted uncertainty, questioning, and reflection, even among individuals who expressed confidence in vaccination more generally. At the individual level, schedule change was experienced as a disruption. In childhood vaccination contexts, uncertainty centred on children's bodily experiences, including pain, side effects, tolerability, and the practical demands placed on caregivers. In the UK, uncertainty associated with a proposed gonorrhoea vaccine programme focused on vaccine effectiveness, duration of protection, and the possibility of false reassurance. These uncertainties were grounded in lived experience of managing sexual health risk—particularly through condom use and PrEP—and in their anticipation of how a new vaccine might reshape existing prevention practices.

Trust emerged as a key mechanism through which individuals navigated this uncertainty. But importantly, trust was not expressed as stable or unconditional, but as relational and situational, shaped by past experience with health systems, institutional transparency, and

interactions with frontline health workers. In Nepal, what appeared as trust was sometimes closely intertwined with dependency on state or externally supported health systems, including clinical trials that provided access to care not routinely available. In the UK, trust was closely linked to expectations of ethical governance, transparency, and accountability. Across contexts, trust enabled uncertainty to be managed, though not eliminated.

At a societal level, responses to schedule change were shaped by broader arrangements of power, governance, and moral responsibility. In Nepal and Uganda, questions of legitimacy were mediated through global health hierarchies and concerns about vaccine testing and external influence, alongside recognition of reliance on international expertise. In the UK, institutional authority operated within a context shaped by concerns about stigma and categorisation related to sexuality. In each setting, power was rarely named directly by participants, but it became visible when established schedules were altered and previously backgrounded authority structures came into view. This was evident in questions about who had the right to decide eligibility and timing, in concerns about whether national authorities were acting independently or under external influence, and in the way institutional actors defined who was “at risk” and therefore targeted for vaccination.

Moral reasoning around care and civic responsibility provided an additional framework through which uncertainty was accommodated. Parents balanced responsibilities to protect children from disease against obligations to minimise immediate harm and distress. In adult vaccination contexts, acceptance was framed through responsibility to others and to public health goals. Across contexts, moral reasoning did not remove uncertainty nor replace the need for trust, but situated decision-making within shared expectations about care, responsibility, and appropriate action.

7.2 Implications for global health policy and practice

The preceding sections have shown that acceptability of immunisation programme change is shaped by individual uncertainty, relationships of trust, and broader societal arrangements of power and care. Taken together, these findings have implications for how immunisation programme change is conceptualised and governed in global health policy and practice. Rather than offering prescriptive recommendations, this section draws out implications for policy design, implementation, and evaluation that follow from a process-oriented understanding of acceptability.

7.2.1 Distinguishing concern about programme change from opposition to vaccination

The findings of this thesis indicate that immunisation policy and programme design must more clearly distinguish between concern arising from schedule changes and opposition to vaccination itself. Across all empirical contexts, expressions of uncertainty and questioning (rather than outright rejection) were triggered by changes to established schedules. Treating such responses as indicators of vaccine hesitancy risks mischaracterising legitimate engagement with change and may prompt responses that focus on correcting attitudes rather than addressing the concerns underlying.

For policy and practice, this distinction matters because it shapes how concerns are interpreted and managed during programme rollout. Signals of concern following schedule modification should be understood as prompts to attend to explanation and support, rather than as evidence of declining confidence. Approaches that conflate concern about change with opposition to vaccination may undermine trust by failing to recognise the social and practical work required to adapt to new arrangements.

7.2.2 Treating programme change as a distinct phase of immunisation governance

The findings also suggest that immunisation programme change should be treated as a distinct phase within vaccination systems, rather than as a routine technical adjustment. Established schedules benefit from familiarity and accumulated legitimacy, allowing vaccination to become embedded within everyday practice. When schedules change, this familiarity is disrupted, creating a period of heightened uncertainty, reassessment, and attention to institutional decision-making. As Bowker and Star [1999] argue in their analysis of classification systems, infrastructures stabilise practice by embedding assumptions about categories, timing, and responsibility into routine action; it is often only at moments of disruption that these underlying organisational logics become visible. Immunisation schedules can be understood in similar terms, as classificatory and infrastructural devices that organise care and distribute responsibility until modification exposes their normative and practical foundations.

Recognising programme change as a discrete phase has implications for how immunisation systems plan and resource adaptation. Rather than relying on the legitimacy of existing programmes to carry new interventions, policy frameworks should explicitly account for the social, organisational, and ethical dimensions of schedule change. Socially, this involves recognising that changes to timing, dosing, or eligibility may unsettle established expectations and require renewed explanation. Organisationally, it requires preparing frontline health workers to respond to questions, ensuring consistency of messaging across delivery settings, and anticipating potential strain on caregivers in relation to visit frequency or injection burden. Ethically, it involves transparent communication about the rationale for change, acknowledgement of uncertainty, and sensitivity to how eligibility criteria or delivery arrangements may reinforce existing inequalities. This also entails building in mechanisms to

assess how responses to change evolve over time—for example, through ongoing engagement with communities, structured feedback from providers, and iterative review of communication strategies during and after implementation.

7.2.3 Investing in trust as a prerequisite for sustainable programme change

Across contexts, trust in immunisation systems was built through routine experience, care, and consistent service delivery, rather than generated at the moment of programme change. Where trust was grounded in long-standing relationships with health systems and health workers, uncertainty associated with change was more readily accepted. Where trust was uneven or rooted primarily in dependency, change was more likely to be experienced as destabilising.

These findings suggest that trust-building should be understood as a prerequisite for programme change, rather than as a reactive response to controversy. For global health policy, this implies investing in the everyday functioning of immunisation systems, including continuity of care, support for frontline health workers, and transparent institutional practices. Trust-building is therefore part of system strengthening and should be treated as enabling future adaptation.

7.2.4 Maintaining trust during and after implementation

Trust must also be actively maintained during schedule change and beyond initial rollout. The findings show that trust is relational and conditional, and cannot be assumed to exist and persist unchanged through periods of disruption. During schedule change, institutions are required to demonstrate continued competence, accountability, and alignment with population expectations.

In practice, this involves supporting frontline health workers as intermediaries between policy decisions and everyday experience, equipping them to explain the rationale for change, respond to questions, and signal institutional accountability. Trust maintenance also requires consistency in service provision and communication so that caregivers do not encounter abrupt shifts in accessor support. In contexts where enhanced care is provided through trials or pilot programmes, attention to transition and continuity is particularly important. Failure to address what happens after such programmes end may undermine trust and reinforce perceptions of vulnerability or abandonment. Trust maintenance should therefore be understood as an ongoing institutional responsibility rather than a time-limited task.

7.3 Limitations and future research

This thesis advances a conceptual framework for understanding how immunisation schedule change is experienced and negotiated across contexts. As with any empirically grounded study, its conclusions are shaped by specific methodological and contextual choices. Reflecting on these boundaries does not diminish the analytic contribution; rather, it clarifies the conditions under which the findings hold and strengthens their value. The following sections outline the limitations of the study, while also considering how its core insights may inform future research and practice beyond the cases examined here.

7.3.1 Contextual specificity, comparative scope, and analytic generalisation

Although this thesis adopts a comparative approach, its empirical scope is necessarily limited to specific contexts: childhood immunisation in Nepal and Uganda, and adult vaccination in the UK. These cases were selected to illuminate how immunisation programme change operates across different health systems, life stages, and global health settings, rather than to

provide comprehensive coverage of all vaccination contexts. The comparison is therefore intended to support analytic generalisation, identifying processes and mechanisms that may travel across settings, rather than statistical generalisation to broader populations.

As a result, the findings should be interpreted as contextually grounded, but they offer conceptual insights that may resonate beyond the specific settings studied. While the processes identified, such as uncertainty arising from disruption, trust as a mechanism for managing change, and moral reasoning shaped by power and care, are likely to be relevant beyond the study settings, their specific expression reflects local institutional arrangements, histories of immunisation, and relationships with health systems. The thesis does not capture experiences in humanitarian or conflict settings, highly privatised health systems, or contexts with sustained vaccine opposition, where different dynamics may shape acceptability of change. Future research could seek to address these gaps, by addressing perceptions and attitudes towards schedule change in different contexts.

7.3.2 Methodological trade-offs in research design

The quantitative components of the thesis were designed to support different analytical purposes across contexts. In the UK study, the quantitative component was powered to examine attitudes and acceptability within a defined population of sexual health service users. This allowed for robust analysis of patterns and associations relevant to the proposed gonorrhoea vaccine programme, and strengthened the internal validity of findings within this specific context.

However, the UK quantitative sample was not intended to be representative of the general population. While this limits population-level generalisability, it enhances the relevance of the findings to the settings and populations in which a gonorrhoea vaccine programme would most likely be implemented. The trade-off in this case was therefore not between power and depth, but between generalisability to the wider population and analytic precision within a policy-relevant group.

In contrast, the quantitative components associated with childhood immunisation in Nepal and Uganda were not designed to produce statistically representative estimates of acceptability. Rather, they were used to contextualise qualitative findings and to explore patterns within populations with recent experience of immunisation programme change. This reflects a deliberate analytical choice to prioritise insight into processes of acceptability during periods of change over population-level inference across two contexts. These differing quantitative approaches reflect the aims of the thesis as a whole. Future research could aim to create statistically generalisable quantitative data across various contexts.

7.3.3 Clinical trial populations are analytically relevant but not representative

In Nepal and Uganda, participants were recruited through involvement in a clinical trial. These populations are not representative of all caregivers within national immunisation programmes, particularly in terms of access to healthcare, exposure to biomedical research, and interaction with external actors. However, these populations are analytically relevant to the research questions addressed in this thesis. The clinical trial participants had recent and direct experience of immunisation programme change. Their accounts provide insight into how acceptability is negotiated in contexts where change, uncertainty, and external influence

are particularly salient. At the same time, the reliance on trial-exposed populations limits the extent to which findings can be extrapolated to caregivers with no engagement in research or enhanced care. The analysis is therefore attentive to the ways in which trial participation may amplify certain dynamics, such as heightened trust in expertise or concern about withdrawal of care, and avoids treating these experiences as universally representative, but future research could be conducted in these same country contexts with non-clinical trial participants.

7.4 Concluding reflections

This thesis has argued that immunisation programme change is not a peripheral or purely technical aspect of vaccination systems, but a critical moment through which their social, ethical, and institutional dimensions become visible. Rather than treating vaccination, and thus attitudes towards it, as fixed or static, the analysis has examined how established immunisation arrangements are interpreted and renegotiated when schedules are changed. In doing so, the thesis has shown that uncertainty, questioning, and conditional acceptance are not signs of system failure or outright vaccine hesitancy, but ordinary features of how people engage with systems they broadly support when those systems change.

Reframing acceptability of immunisation schedule change as an ongoing process, rather than as an individual disposition, allows for a different understanding of public engagement with immunisation programmes. Across contexts, participants did not assess immunisation schedule changes in isolation. Instead, they reasoned about schedules, institutions, responsibilities, and care, drawing on past experience and shared expectations. Programme change disrupted familiarity and prompted reassessment, bringing into view how trust is

negotiated, how authority is exercised, and how moral and civic responsibility were invoked in participant's reasoning.

By bringing together childhood immunisation in Nepal and Uganda and adult immunisation in the UK, this thesis has demonstrated that while the content of concerns varies across settings, the underlying processes through which acceptability is produced show important commonalities. Uncertainty emerged in response to disruption; trust shaped whether that uncertainty could be lived with; authority structures influenced which actors were perceived as entitled to define eligibility and timing; and moral reasoning situated vaccination within broader expectations of care and civic responsibility. These processes cut across income settings, disease contexts, and life stages, underscoring the value of a comparative and process-oriented approach to immunisation research.

As global immunisation programmes continue to expand and adapt through new vaccines, changing schedules, and evolving delivery strategies—attention to how change is experienced and governed will become increasingly important. Sustaining immunisation systems over time requires not only scientific innovation and investment in logistical capacity, but also engagement with the social conditions that underpin acceptance Recognising uncertainty as meaningful, trust as conditional, and care as socially organised opens space for more ethically attentive and resilient approaches to immunisation governance—approaches that anticipate disruption, prioritise transparency and dialogue, and treat schedule change as a relational process rather than a purely technical update.

In foregrounding programme change as an object of analysis, this thesis does not seek to eliminate contestation. Rather, it aims to clarify how it might arise, why it matters, and how it

may be navigated. In doing so, it shifts the focus towards a more nuanced understanding of how people live with, reason about, and adapt to change within public health systems that are both trusted and imperfect.

Ultimately, this thesis argues that moments of schedule change are not *just* programmatic changes, but are critical points of exposure. Interruptions to immunisation systems are the points at which their social life becomes visible—revealing the expectations, relationships, and responsibilities that routine delivery silently sustains.

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9 Supplementary material

9.1 Appendix 1: PRISMA checklist
9.2 Appendix 2: Full search string
9.3 Appendix 3: Data extraction form
9.4 Appendix 4: OptImms survey Nepal; participant information sheet
9.5 Appendix 5: OptImms participant survey Nepal consent form
9.6 Appendix 6: OptImms survey Nepal
9.7 Appendix 7: OptImms Interview participant information sheet Nepal
9.8 Appendix 8: OptImms interview consent form Nepal
9.9 Appendix 9: OptImms Interview topic guide Nepal
9.10 Appendix 10: OptImms Survey Uganda; participant information sheet
9.11 Appendix 11: OptImms Survey Uganda; consent form
9.12 Appendix 12: OptImms SURVEY Uganda
9.13 Appendix 13: OptImms Interview participant information sheet Uganda
9.14 Appendix 14: OptImms interview consent form Uganda
9.15 Appendix 15: OptImms interview topic guide Uganda
9.16 Appendix 16: NAVIGATE 'men b as a gonorrhoea vaccine' fact sheet
9.17 Appendix 17: NAVIGATE survey participant information sheet
9.18 Appendix 18: NAVIGATE participant survey
9.19 Appendix 19: NAVIGATE interview participant information sheet
9.20 Appendix 20: NAVIGATE: interview guide
9.21 Appendix 21: NAVIGATE: interview consent form

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	P50
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	n/a
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	P50-51
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	P52
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	P54
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	P55
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix 2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	P55-56
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	P56
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	P54
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	P56
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	P55-56
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	N/A
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	P56
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	P56
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	P56
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	P56

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	P62-67
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	N/A
Study characteristics	17	Cite each included study and present its characteristics.	Appendix 3
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Appendix 3
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	P66
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Appendix 3
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	P68-81
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	P81-86
	23b	Discuss any limitations of the evidence included in the review.	P85-86
	23c	Discuss any limitations of the review processes used.	P85-86
	23d	Discuss implications of the results for practice, policy, and future research.	P86
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	P57
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	P57
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	IX
Competing interests	26	Declare any competing interests of review authors.	IX
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	P61

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. This work is licensed under CC BY 4.0. To view a copy of this license, visit https://creativecommons.org/licenses/by/4.0/

Appendix 2: Full systematic review search string

Final searches run 20240529

MEDLINE

CF MEDLINE search 20240326

Medline (Ovid MEDLINE¬Æ Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE¬Æ Daily and Ovid MEDLINE¬Æ) 1946 to present

1 Adolescent/ or exp Child/ or exp Infant/ 4052536
2 (infan* or baby* or babies or toddler* or boy* or girl* or kid or kids or child* or adolescen* or juvenil* or youth* or teen* or pubescen* or pediatric* or paediatric* or peadiatric* or school* or prepub* or pre-pub* or preschool* or pre-school* or kindergarten* or nursery* or preadolescen* or pre-adolescen*).ti,ab,kf. 2964094
3 1 or 2 4983082
4 exp Immunization/ 216337
5 ((vaccinat* or immuni?ation or dose* or dosing or administration or booster* or revaccinat* or inoculat*) adj4 (schedule* or timing* or timetable* or program* or policy* or period* or interval* or routine or routines or type*)).ti,ab,kf. 123458
6 4 or 5 316659
7 (accept* or chang* or amend* or modif* or new or alter* or adapt* or against or agree* or attitude* or aware* or anxious or anxiety or barrier* or belief* or believe* or challenge* or concern* or decide* or decision* or decline or emotion* or expect* or experience* or feel* or hesita* or object or objection or opinion* or opportunit* or perception* or perceiv* or perspective* or reject* or refus* or resist* or think* or uncertain* or understand* or view* or willing*).ti,ab,kf. 16237770
8 exp Family/ or Caregivers/ or exp Health Personnel/ 981190
9 (patient* or surrogate* or proxy or proxies or parent* or mother* or father* or (family adj4 member*) or guardian* or relative* or grandparent* or grandmother or grandfather or carer* or caregiver* or "care provider*" or ((health or healthcare or health-care) adj4 (worker* or professional*)) or physician* or nurse* or p?ediatrician* or "medical staff" or gp or "family doctor*" or "health visitor*").ti,ab,kf. 11055617
10 8 or 9 11443969
11 3 and 6 and 7 and 10 24108
12 limit 11 to (english language and yr="2013 -Current") 12823
13 Interviews as Topic/ or Focus Groups/ or Narration/ or "Surveys and Questionnaires"/ or exp Qualitative Research/ or Health Care Surveys/ or Self Report/ 786084
14 ((questionnaire* or survey* or "focus group*" or qualitative or mixed method* or mixed-method* or ethnograph* or fieldwork or "field work" or ("semi-structured" or semistructured or unstructured or informal or in-depth or indepth or face-to-face)) adj4 (interview* or discussion*)).ti,ab,kf. 224724
15 13 or 14 911993
16 12 and 15 2375

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=3GRC7H2xz1wswrNE7mnmWfwQQYPNA3TzLPsKACFOpY96PncF8WfBljnzDEbCLSYfA

Embase

CF Embase search 202400514

Embase 1974 to present

1 exp adolescent/ or exp child/ 4093639
2 (infan* or baby* or babies or toddler* or boy* or girl* or kid or kids or child* or adolescen* or juvenil* or youth* or teen* or pubescen* or pediatric* or paediatric* or peadiatric* or school* or prepub* or pre-pub* or preschool* or pre-school* or kindergarten* or nursery* or preadolescen* or pre-adolescen*).ti,ab,kf. 3672332
3 1 or 2 5254854
4 exp immunization/ 395316
5 ((vaccinat* or immuni?ation or dose* or dosing or administration or booster* or revaccinat* or inoculat*) adj4 (schedule* or timing* or timetable* or program* or policy* or period* or interval* or routine or routines or type*)).ti,ab,kf. 171900
6 4 or 5 522519
7 (accept* or chang* or amend* or modif* or new or alter* or adapt* or against or agree* or attitude* or aware* or anxious or anxiety or barrier* or belief* or believe* or challenge* or concern* or decide* or decision* or decline or emotion* or expect* or experience* or feel* or hesita* or object or objection or opinion* or opportunit* or perception* or perceiv* or perspective* or reject* or refus* or resist* or think* or uncertain* or understand* or view* or willing*).ti,ab,kf. 20210225
8 exp family/ or caregiver/ or exp health care personnel/ 2690619
9 (patient* or surrogate* or proxy or proxies or parent* or mother* or father* or (family adj4 member*) or guardian* or relative* or grandparent* or grandmother or grandfather or carer* or caregiver* or "care provider*" or ((health or healthcare or health-care) adj4 (worker* or professional*)) or physician* or nurse* or p?ediatrician* or "medical staff" or gp or "family doctor*" or "health visitor*").ti,ab,kf. 15376274
10 8 or 9 16272020
11 3 and 6 and 7 and 10 44726
12 limit 11 to (english language and yr="2013 -Current") 28255
13 exp qualitative research/ or exp interview/ or exp verbal communication/ or exp questionnaire/ or health care survey/ or health survey/ or self report/ 2020034
14 ((questionnaire* or survey* or "focus group*" or qualitative or mixed method* or mixed-method* or ethnograph* or fieldwork or "field work" or ("semi-structured" or semistructured or unstructured or informal or in-depth or indepth or face-to-face)) adj4 (interview* or discussion*)).ti,ab,kf. 277369
15 13 or 14 2088526
16 12 and 15 6543

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=2EawiN5q4a4vZn4TwcWzcgutdSg6Wfk7mHrqFwbjtdWktn28Z9oAUfNCPGBRcvevi
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Global Health

CF Global Health search 20240523

Global Health <1973 to 2024 Week 21>

1 exp adolescents/ or exp children/ or exp infants/ 492740
2 (infan* or baby* or babies or toddler* or boy* or girl* or kid or kids or child* or adolescen* or juvenil* or youth* or teen* or pubescen* or pediatric* or paediatric* or peadiatric* or school* or prepub* or pre-pub* or preschool* or pre-school* or kindergarten* or nursery* or preadolescen* or pre-adolescen*).ti,ab,cw. 635622
3 1 or 2 670427
4 exp immunization/ or immunization programmes/ 123434
5 ((vaccinat* or immuni?ation or dose* or dosing or administration or booster* or revaccinat* or inoculat*) adj4 (schedule* or timing* or timetable* or program* or policy* or period* or interval* or routine or routines or type*)).ti,ab,cw. 37474
6 4 or 5 137265
7 (accept* or chang* or amend* or modif* or new or alter* or adapt* or against or agree* or attitude* or aware* or anxious or anxiety or barrier* or belief* or believe* or challenge* or concern* or decide* or decision* or decline or emotion* or expect* or experience* or feel* or hesita* or object or objection or opinion* or opportunit* or perception* or perceiv* or perspective* or reject* or refus* or resist* or think* or uncertain* or understand* or view* or willing*).ti,ab,cw. 2598689
8 exp parents/ or exp health care workers/ 169019
9 (patient* or surrogate* or proxy or proxies or parent* or mother* or father* or (family adj4 member*) or guardian* or relative* or grandparent* or grandmother or grandfather or carer* or caregiver* or "care provider*" or ((health or healthcare or health-care) adj4 (worker* or professional*)) or physician* or nurse* or p?ediatrician* or "medical staff" or gp or "family doctor*" or "health visitor*").ti,ab,cw. 1425143
10 8 or 9 1452448
11 3 and 6 and 7 and 10 18847
12 limit 11 to (english language and yr="2013 -Current") 11516
13 exp qualitative techniques/ or surveys/ or self-reporting/ 125032
14 ((questionnaire* or survey* or "focus group*" or qualitative or mixed method* or mixed-method* or ethnograph* or fieldwork or "field work" or ("semi-structured" or semistructured or unstructured or informal or in-depth or indepth or face-to-face)) adj4 (interview* or discussion*)).ti,ab,cw. 73503
15 13 or 14 189117
16 12 and 15 1902

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=5aEmcJ24OXQz7Gnkop9hUEgczVtil0biX7iizDB9LKy2tPEyg7yRCJS1tAUpm4B49

Cochrane

Search Name: CF Cochrane search 20240520
Date Run: 29/05/2024 11:20:24
Comment:

ID Search Hits
#1 [mh ^Adolescent] OR [mh Child] OR [mh Infant] 204754
#2 (infan*:ti,ab,kw OR baby*:ti,ab,kw OR babies:ti,ab,kw OR toddler*:ti,ab,kw OR boy*:ti,ab,kw OR girl*:ti,ab,kw OR kid:ti,ab,kw OR kids:ti,ab,kw OR child*:ti,ab,kw OR adolescen*:ti,ab,kw OR juvenil*:ti,ab,kw OR youth*:ti,ab,kw OR teen*:ti,ab,kw OR

pubescen*:ti,ab,kw OR pediatric*:ti,ab,kw OR paediatric*:ti,ab,kw OR peadiatric*:ti,ab,kw OR school*:ti,ab,kw OR prepub*:ti,ab,kw OR pre-pub*:ti,ab,kw OR preschool*:ti,ab,kw OR pre-school*:ti,ab,kw OR kindergarten*:ti,ab,kw OR nursery*:ti,ab,kw OR preadolescen*:ti,ab,kw OR pre-adolescen*:ti,ab,kw) 378807
#3 #1 OR #2 378807
#4 [mh Immunization] 7306
#5 ((vaccinat*:ti,ab,kw OR immuni?ation:ti,ab,kw OR dose*:ti,ab,kw OR dosing:ti,ab,kw OR administration:ti,ab,kw OR booster*:ti,ab,kw OR revaccinat*:ti,ab,kw OR inoculat*:ti,ab,kw) NEAR/4 (schedule*:ti,ab,kw OR timing*:ti,ab,kw OR timetable*:ti,ab,kw OR program*:ti,ab,kw OR policy*:ti,ab,kw OR period*:ti,ab,kw OR interval*:ti,ab,kw OR routine:ti,ab,kw OR routines:ti,ab,kw OR type*:ti,ab,kw)) 61651
#6 #4 OR #5 66514
#7 (accept*:ti,ab,kw OR chang*:ti,ab,kw OR amend*:ti,ab,kw OR modif*:ti,ab,kw OR new:ti,ab,kw OR alter*:ti,ab,kw OR adapt*:ti,ab,kw OR against:ti,ab,kw OR agree*:ti,ab,kw OR attitude*:ti,ab,kw OR aware*:ti,ab,kw OR anxious:ti,ab,kw OR anxiety:ti,ab,kw OR barrier*:ti,ab,kw OR belief*:ti,ab,kw OR believe*:ti,ab,kw OR challenge*:ti,ab,kw OR concern*:ti,ab,kw OR decide*:ti,ab,kw OR decision*:ti,ab,kw OR decline:ti,ab,kw OR emotion*:ti,ab,kw OR expect*:ti,ab,kw OR experience*:ti,ab,kw OR feel*:ti,ab,kw OR hesita*:ti,ab,kw OR object:ti,ab,kw OR objection:ti,ab,kw OR opinion*:ti,ab,kw OR opportunit*:ti,ab,kw OR perception*:ti,ab,kw OR perceiv*:ti,ab,kw OR perspective*:ti,ab,kw OR reject*:ti,ab,kw OR refus*:ti,ab,kw OR resist*:ti,ab,kw OR think*:ti,ab,kw OR uncertain*:ti,ab,kw OR understand*:ti,ab,kw OR view*:ti,ab,kw OR willing*:ti,ab,kw) 1133746
#8 [mh Family] OR [mh ^Caregivers] OR [mh "Health Personnel"] 29039
#9 (family:ti,ab,kw NEAR/4 member*:ti,ab,kw) OR guardian*:ti,ab,kw OR relative*:ti,ab,kw OR grandparent*:ti,ab,kw OR grandmother:ti,ab,kw OR grandfather:ti,ab,kw OR carer*:ti,ab,kw OR caregiver*:ti,ab,kw OR (care NEXT provider*):ti,ab,kw OR ((health:ti,ab,kw OR healthcare:ti,ab,kw OR health-care:ti,ab,kw) NEAR/4 (worker*:ti,ab,kw OR professional*:ti,ab,kw)) OR physician*:ti,ab,kw OR nurse*:ti,ab,kw OR p?ediatrician*:ti,ab,kw OR "medical staff":ti,ab,kw OR gp:ti,ab,kw OR (family NEXT doctor*):ti,ab,kw OR (health NEXT visitor*):ti,ab,kw 238827
#10 #8 OR #9 251845
#11 #3 AND #6 AND #7 AND #10 with Cochrane Library publication date Between Jan 2013 and Dec 2024, in Cochrane Reviews, Cochrane Protocols, Trials, Clinical Answers, Editorials, Special Collections 1711
#12 [mh ^"Interviews as Topic"] OR [mh ^"Focus Groups"] OR [mh ^Narration] OR [mh ^"Surveys and Questionnaires"] OR [mh "Qualitative Research"] OR [mh ^"Health Care Surveys"] OR [mh ^"Self Report"] 43946
#13 ((questionnaire*:ti,ab,kw OR survey*:ti,ab,kw OR (focus NEXT group*):ti,ab,kw OR qualitative:ti,ab,kw OR mixed-method*:ti,ab,kw OR ethnograph*:ti,ab,kw OR fieldwork:ti,ab,kw OR "field work":ti,ab,kw OR (semi-structured:ti,ab,kw OR semistructured:ti,ab,kw OR unstructured:ti,ab,kw OR informal:ti,ab,kw OR in-depth:ti,ab,kw OR indepth:ti,ab,kw OR face-to-face:ti,ab,kw)) NEAR/4 (interview*:ti,ab,kw OR discussion*:ti,ab,kw)) 18672
#14 #12 OR #13 59275
#15 #11 AND #14 165

Cochrane Database of Systematic Reviews = 4; Cochrane Central Register of Controlled Trials = 161

Scopus

CF Scopus search 20240529 (unable to save in Scopus)

((TITLE-ABS-KEY((infan* OR baby* OR babies OR toddler* OR boy* OR girl* OR kid OR kids OR child* OR adolescen* OR juvenil* OR youth* OR teen* OR pubescen* OR pediatric* OR paediatric* OR peadiatric* OR school* OR prepub* OR pre-pub* OR preschool* OR pre-school* OR kindergarten* OR nursery* OR preadolescen* OR pre-adolescen*))) AND (TITLE-ABS-KEY(((vaccinat* OR immuni*ation OR dose* OR dosing OR administration OR booster* OR revaccinat* OR inoculat*) W/4 (schedule* OR timing* OR timetable* OR program* OR policy* OR period* OR interval* OR routine OR routines OR type*)))) AND (TITLE-ABS-KEY((accept* OR chang* OR amend* OR modif* OR new OR alter* OR adapt* OR against OR agree* OR attitude* OR aware* OR anxious OR anxiety OR barrier* OR belief* OR believe* OR challenge* OR concern* OR decide* OR decision* OR decline OR emotion* OR expect* OR experience* OR feel* OR hesita* OR object OR objection OR opinion* OR opportunit* OR perception* OR perceiv* OR perspective* OR reject* OR refus* OR resist* OR think* OR uncertain* OR understand* OR view* OR willing*))) AND (TITLE-ABS-KEY((patient* OR surrogate* OR proxy OR proxies OR parent* OR mother* OR father* OR (family W/4 member*) OR guardian* OR relative* OR grandparent* OR grandmother OR grandfather OR carer* OR caregiver* OR "care provider*" OR ((health OR healthcare OR health-care) W/4 (worker* OR professional*)) OR physician* OR nurse* OR p*ediatrician* OR "medical staff" OR gp OR "family doctor*" OR "health visitor*"))) AND (TITLE-ABS-KEY(((questionnaire* OR survey* OR "focus group*" OR qualitative OR mixed-method* OR ethnograph* OR fieldwork OR "field work" OR (semi-structured OR semistructured OR unstructured OR informal OR in-depth OR indepth OR face-to-face)) W/4 (interview* OR discussion*)))) AND PUBYEAR > 2012 AND PUBYEAR < 2025 AND (LIMIT-TO (LANGUAGE,"English"))) 704

Global Index Medicus

(infan* OR baby* OR babies OR toddler* OR boy* OR girl* OR kid OR kids OR child* OR adolescen* OR juvenil* OR youth* OR teen* OR pubescen* OR pediatric* OR paediatric* OR peadiatric* OR school* OR prepub* OR pre-pub* OR preschool* OR pre-school* OR kindergarten* OR nursery* OR preadolescen* OR pre-adolescen*) AND ((vaccinat* OR immuni?ation OR dose* OR dosing OR administration OR booster* OR revaccinat* OR inoculat*) AND (schedule* OR timing* OR timetable* OR program* OR policy* OR period* OR interval* OR routine OR routines OR type*)) AND (accept* OR chang* OR amend* OR modif* OR new OR alter* OR adapt* OR against OR agree* OR attitude* OR aware* OR anxious OR anxiety OR barrier* OR belief* OR believe* OR challenge* OR concern* OR decide* OR decision* OR decline OR emotion* OR expect* OR experience* OR feel* OR hesita* OR object OR objection OR opinion* OR opportunit* OR perception* OR perceiv* OR perspective* OR reject* OR refus* OR resist* OR think* OR uncertain* OR understand* OR view* OR willing*) AND (patient* OR surrogate* OR proxy OR proxies OR parent* OR mother* OR father* OR "family member" OR "family members" OR guardian* OR relative* OR grandparent* OR grandmother OR grandfather OR carer* OR caregiver* OR "care

provider" OR "health worker" OR "health workers" OR "healthcare worker" OR "healthcare workers" OR "health-care worker" OR "health-care workers" OR "health professional" OR "health professionals" OR "healthcare professional" OR "healthcare professionals" OR "health-care professional" OR "health-care professionals" OR physician* OR nurse* OR p?ediatrician* OR "medical staff" OR gp OR "family doctor" OR "family doctors" OR "health visitor" OR "health visitors") AND (questionnaire* OR survey* OR "focus group" OR qualitative OR mixed-method* OR ethnograph* OR fieldwork OR "field work" OR (("semi-structured" OR semistructured OR unstructured OR informal OR in-depth OR indepth OR face-to-face) AND (interview* OR discussion*))) AND (year_cluster:[2013 TO 2024]) AND (la:("en")) 440

Appendix 3: Data extraction form

Due to the size of the data extraction form, this is available via the below SharePoint link:

https://unioxfordnexus-my.sharepoint.com/:x:/r/personal/paed1198_ox_ac_uk/Documents/Appendix%203%20systematic%20review%20data%20extractopm.xlsx?d=w4647db6c9be9402f99cf6a314c287bc4&csf=1&web=1&e=qYlNuy

Appendix 4

OPTIMMS Participation Survey
SURVEY PARTICIPANT INFORMATION SHEET

This study has been reviewed by, and received ethics clearance through Nepal Health Research Council, NHRC Ref No: 95/2020 and the University of Oxford Tropical Research Ethics Committee, OxTREC Reference Number: 12/20.

Why are we doing this survey?

Patan Hospital / Teaching Hospital and The Oxford Vaccine Group are investigating participant attitudes towards their participation in the OPTIMMS vaccine trial. You are invited to participate in a separate research study about the motivations and views of individuals who volunteered their child to take part in the OPTIMMS vaccine trial. We hope the study findings will help us better understand trial participation and inform future trials and engagement about vaccines. Your participation in this survey, and the responses you give to survey questions, won't affect the involvement of your child in the OPTIMMS trial, or your previous/upcoming clinic visits.

This survey may ask some questions that you have already answered during the screening process for the OPTIMMS vaccine trial. This is because your answers to this current questionnaire are completely separate and unlinked to your data, or your child's data, included in the vaccine trial.

Do I have to take part?

Taking part is voluntary. You can withdraw at any point for any reason, up to the submission of your answers by closing the browser. Please note that once you have finished completing the survey, we will be unable to identify and remove your data, as all the information you provide is recorded without direct identifiers. If the survey is administered during a scheduled visit, you will receive Rs 500 for additional time that you have to spend for the survey during the visit. However, if a separate visit is required, you will be reimbursed NPR 1500 for travel and your time. The responses you give won't affect your child's involvement in the OPTIMMS Vaccine Trial.

What will happen during this survey?

You will be asked to answer questions about your demographic information, your previous experience with vaccine trials, your motivations for taking part in the OPTIMMS trial, and your knowledge of childhood vaccine schedules. It should take about 15-20 minutes and no background knowledge is required. The questions may be completed on a tablet or other internet-connected device and will be administered by trained study staff. You can choose to not answer any question, or end the survey at any point during the survey.

We would like to follow up this survey with a short interview (up to 1 hour each) to understand these questions further. If you would be willing to take part in an interview, at the end of the

survey we provide further information and if you are happy to take part we will ask you for your contact information so that we can contact you. Not everyone will be contacted for an interview; we will carry out interviews until we have collected enough data, but we expect to interview 10-20 people.

How will my data be used?

The research team including the researchers, transcribers and translators from Patan Hospital (PAHS), TU Teaching Hospital (IOM) and the University of Oxford will have access to the research data. Responsible members of the University of Oxford and research ethics committees may be given access to data for monitoring and/or audit of the research.

- Your answers to the survey and interview question will not include direct identifiers and we will take steps to make sure that your responses remain confidential. However, if you take part in an interview after the survey, your responses to the survey will have the potential to be linked to your contact details.
- Your data will be stored on password-protected and encrypted research computers.
- Your data will only be used for non-commercial purposes, to inform academic research and publications.
- Research data will be stored for three years after publication or public release of the findings of the research. Because the data will not include direct identifiers we will not be able to act upon any individual responses to the survey.
- The research teams at Patan Hospital/Teaching Hospital and University of Oxford together will determine how the collected data will be used in the study for the purpose of the research outlined. Research is a task that we perform in the public interest.
- Further information about your rights with respect to your personal data is available from https://compliance.admin.ox.ac.uk/individual-rights. We can provide you with a copy of this should you require.
- Your personal information and data collected in this study will not be shared with other researchers or organizations.

What if there is a problem?

If you have a concern about any aspect of this project, please contact us at Patan Hospital (PAHS) and TU Teaching Hospital (IOM) or info@ovg.ox.ac.uk and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with.

If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford or Nepal Health Research Council: ethics@medsci.ox.ac.uk (Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD) and/or, the Ethical Review Board, Nepal Health Research Council, Maharajgunj, Ramshahpath, Phone No. 977-1-5327460.

Risks/benefits

We do not perceive any risks to your participation in this research. If we are able to complete this survey at the scheduled visit for OPTIMMS vaccine trial, you will be reimbursed for your additional time with Rs. 500. If you need to come to the hospital again at a different time than a scheduled visit, we will reimburse NPR 1500 for your travel costs and time spent.

How do I find out about the results?

We will provide information about the results of this study through the Oxford Vaccine Group website (https://www.ovg.ox.ac.uk/).
Oxford Vaccine Group: info@ovg.ox.ac.uk

Contact details

Patan Hospital
Patan Academy of Health Sciences
Pediatric Research Unit,
Department of Pediatrics
Lagankhel, Lalitpur
Phone numbers: 977-1-5522278, 5522266, 9808797165

TU. Teaching Hospital,
Institute of Medicine
Department of Pediatrics
Maharajgunj, Kathmandu
Phone number: 977-1-4512202

Appendix 5

OPTIMMS PARTICIPANT SURVEY CONSENT FORM **Participant ID: ……..**

1	I confirm that I have read and understand the participant information sheet.	Yes/ No
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without penalty. However, if I do not give my contact details I understand that my survey responses cannot be identified and deleted.	Yes / No
3	I understand that research data collected during the study may be looked at by authorised people outside the research team. I give permission for these individuals to access my data for monitoring and/or audit of the research.	Yes / No
4	I agree to take part in the study.	Yes/ No

NB: All answer must be 'YES' for survey to start.

OPTIONAL: I agree to be contacted in the future for follow up interview.

By signing/marking my name here, I confirm what is written above.

Signature of Participant:	Full Name:	Date of Signature:
x_____	x_____	____/____/_____

Witness:

I confirm that Consent is voluntary and freely given by the participant, guardian or legally-authorized representative and that I am not a family member or part of the study staff

Signature of Witness:	Full Name:	Date of Signature:
x_____	x_____	____/____/_____

For study staff:

I, the undersigned, have fully explained the relevant information of this study to the person named above and will provide her/him with a copy of this signed and dated informed consent form.

Signature of Investigator	Full Name	Date of Signature
x_____	x_____	___/____/_____

Appendix 6

SURVEY

To read to the participant: Thank you for agreeing to take part in this survey. Four small sections cover: general background information, experience of clinical trials, motivations for taking part in a clinical trial, and attitudes towards changing vaccine schedules. We refer to the phrase 'vaccine schedule' throughout this survey, this is referring to the national vaccine program, and includes things like what vaccines are given, how many doses are given, and the timing of when they are given.

Your answers to the questions are confidential and are recorded using a number that is different to your main study number. If you don't understand what a question means, please ask me to explain. If you don't want to answer a particular question, please let me know and we can move on.

Section A - This part of the survey will ask you for some general background information.

- What was your age group when you enrolled your child in the OPTIMMS study?
  - Under 18
  - 18-24
  - 25-34
  - 35-44
  - 45-54
  - 55 years and above

  What is your gender?

  - Male
  - Female
  - Prefer not to say

- What is your religion?
  - Christianity
  - Islam
  - Hinduism
  - Buddhism
  - Judaism
  - Sikhism
  - None/Atheist
  - Other (Free Text)
  - Prefer not to say

- Who lives in your household? Please select all that apply:
  - Spouse or Partner
  - Children

    - Parents
    - Siblings
    - Relatives (Specify relationship, e.g., grandparents, aunts, uncles)
    - Friends
    - Other (Free Text)

- What is the highest level of education you have received?
    - No education
    - Primary
    - Secondary
    - Higher than secondary
    - Other (Free Text)

- What is the highest level of education other members of your household have received?
    - No education
    - Primary
    - Secondary
    - Higher than secondary
    - Other (Free Text)

- What type of work do you do?
    - Management
    - Business/Finance
    - Agriculture
    - Science
    - Health
    - Education, law, social, government services
    - Sales and services
    - Trades and transport
    - Plant and machine operators
    - Craft and related trades
    - Student
    - Unemployed
    - Retired
    - Parent/homemaker
    - Carer for another household member
    - Other (Free Text)

- What types of work or occupations are held by the other members of your household? (select all that apply)
    - Management
    - Business/Finance
    - Agriculture
    - Science
    - Health
    - Education, law, social, government services
    - Sales and services
    - Trades and transport
    - Plant and machine operators

- Craft and related trades
- Student
- Unemployed
- Retired
- Parent/homemaker
- Carer for another household member
- Other (Free Text)

- How many children do you have?
  - 1
  - 2
  - 3
  - 4
  - 5+

- What are the ages of your children?
  - <Free Text>

- What mode of transport did you use to get to the vaccine clinic today?
  - <Free Text>

- How far did you have to travel from your home to the vaccine clinic? (in KM)
-
  - Less than 1 km (Less than 0.6 miles)

  - 1-5 km (0.6-3.1 miles)
  - 6-10 km (3.7-6.2 miles)
  - 11-20 km (6.8-12.4 miles)
  - 21-30 km (13.0-18.6 miles)
  - 31-40 km (19.3-24.9 miles)
  - 41-50 km (25.5-31.1 miles)
  - More than 50 km (More than 31.1 miles)

Carry on to section B

Section B – This part of the survey will ask about your previous experience with clinical trials and how you heard about the OPTIMMS trial.

Note: A Clinical Trial is a type of research technique where we try to find out whether new drugs, vaccines and treatment modalities are safe and effective.

- Have you ever enrolled your child (currently in OPTIMMS) or another child in research before?
  - Yes
  - No
  - Unsure

- If yes, how many other studies have they participated in? (Give any details of the study that you might remember):

- 1
- 2
- 3
- More than 3

Details (free text)

- Have you, or anyone in the household, ever taken part in a clinical trial before? (give details)
    - Yes
    - No
    - Unsure

Details (free text)

- Has anyone you know ever taken part in a clinical trial before?
    - Yes
    - No
    - Unsure

- Before this study, what was your knowledge of vaccine trials?
    - Very knowledgeable: I had a deep understanding of vaccine trials, including their purpose, phases, and how they become approved for use.
    - Somewhat knowledgeable: I had a basic understanding of vaccine trials and why they're important. I knew that vaccines undergo lots of testing before approval, but I may not have been familiar with the specific phases of clinical trials or the regulatory bodies involved.
    - Not very knowledgeable: I had limited knowledge of vaccine trials. While I understood the general idea of testing vaccines to make sure they're safe, I may not have been aware of the detailed processes involved or the criteria for selecting participants in trials.
    - Not knowledgeable at all: I had no prior knowledge of vaccine trials. I was unaware of how vaccines are tested before being approved for public use.
    - Other: I had some knowledge from personal or professional experiences. (Specify: _)

- How did you hear about this study?
    - Information leaflet from immunisation clinic.
    - Verbal information from regional immunisation clinic/office
    - Poster/leaflet in hospital
    - I heard from my family and friends
    - A doctor told me by phone
    - Other. Specify_____

- Did you discuss your decision to enrol your child in this study with anyone else?
    - Yes
    - No

- If yes, who did you discuss it with? Specify_____
- If yes, when you discussed volunteering, what were the responses you received (complete for every person you discussed with)
    - Mostly Positive
    - Neutral
    - Mostly Negative
    - Notes: Free Text for details of discussion with each person)

- Did anyone you discussed volunteering with try to discourage you from signing up?
    - Yes
    - No

    <Free Text> _____

Carry on to section C

Section C – This section will ask about your motivations for taking part

The following questions will ask you about your reasons for volunteering your child for this study. Rate each of the statements, from strongly agree to strongly disagree, based on how much you agree with them.

- I thought the data generated from the study would help improve the health of others.
    - Strongly Agree
    - Agree
    - Neutral
    - Disagree
    - Strongly Disagree

- I wanted to contribute to medical and scientific progress.
    - Strongly Agree
    - Agree
    - Neutral
    - Disagree
    - Strongly Disagree

- I thought that by volunteering my child in the study would inspire others in my community to take part
    - Strongly Agree
    - Agree
    - Neutral
    - Disagree
    - Strongly Disagree

- I felt a responsibility to take part in the study
    - Strongly Agree
    - Agree
    - Neutral
    - Disagree
    - Strongly Disagree

- I was curious about the experience of being in a vaccine trial.
  - Strongly Agree
  - Agree
  - Neutral
  - Disagree
  - Strongly Disagree

- I wanted to tell others about the experience of being in a vaccine trial.
  - Strongly Agree
  - Agree
  - Neutral
  - Disagree
  - Strongly Disagree

- I wanted my child to get a medical check-up to find out more about their health.
  - Strongly Agree
  - Agree
  - Neutral
  - Disagree
  - Strongly Disagree

- I was motivated by the benefits the study offered to my child throughout the study period (i.e. free treatment if they became ill).
  - Strongly Agree
  - Agree
  - Neutral
  - Disagree
  - Strongly Disagree

What were your other motivations or reasons for volunteering for the study?

○ Other. Specify_____
○
Carry on to section D

Section D – This section will ask about your knowledge of and attitudes to vaccines, and changing childhood vaccine schedules

This first set of questions aims to understand your vaccine knowledge.

- Before this study, what was your knowledge of childhood vaccine schedules?
  Very knowledgeable: I knew a lot about when vaccines should be given and why it's important. For example, I knew when my child should get their diphtheria vaccine and why it's needed.
    - Somewhat knowledgeable: I knew a bit about vaccine schedules, but I wasn't sure about all the details. For instance, I knew that children need vaccines at certain times, but I wasn't sure about the exact timing for each one.

- Not very knowledgeable: I didn't know much about vaccine schedules. I knew my child needed vaccines, but I didn't know when or which ones were required.
- Not knowledgeable at all: I didn't know anything about vaccine schedules.
- Other. Specify____

- If you have more than one child, has this familiarity with the vaccine schedule changed after having each child?
  - <Free Text>
- Are you aware of any recent changes to the national vaccination schedule?
- Yes
- No

  If yes, what were the changes? <Free Text>
  If yes, what were/are your opinions on these changes? <Free Text>

- Where do you get information about vaccines and their schedules from?
  - Government health authorities (e.g Ministry of Health) Healthcare provider
  - Traditional healthcare provider
  - Non-governmental organisation
  - The media
  - Social media
  - Community leaders or influencers
  - Schools or educational institutions
  - Vaccine manufacturers
  - Friends
  - Family
  - Other/Specify further _____

What information would you like to receive to better your understanding on changes in childhood vaccine schedules<Free Text>

- How would you like to receive this information?
  - <Free Text>

This second set of questions refers to your attitudes and opinions about vaccines and their schedules.

- How important do you think vaccines are for your child's health?
  - Not at all important
  - A little important
  - Moderately important
  - Very important

- Do you think most of your close family and friends want you to get your child vaccinated?
  - Yes
  - No
- Nepal has a schedule of recommended vaccines for children. Do you want your child to get none of these vaccines, some of these vaccines, or all of these vaccines?
  - None
  - Some
  - All

- Do you know where to go to get your child vaccinated?
    - Yes
    - No

- How easy is it to pay for the associated costs of vaccination? Please consider the cost of getting there, plus the cost of taking time away from work etc.
    - Not at all easy
    - A little easy
    - Moderately easy
    - Very easy

What is likely to influence your opinion on any changes to the childhood vaccine schedule? (Select all that apply) Scientific evidence
    - Recommendations from health authorities
    - Personal beliefs or values
    - Family members
    - Trusted friends
    - Healthcare provider
    - Local community leaders
    - Social media
    - News sources
    - The advice from the government
    - Personal experience with vaccines
    - Other people's experience with vaccines
    - Vaccine safety
    - Concerns about vaccine-preventable diseases
    - Other. Specify_____

In the following scenarios, relating to potential changes in childhood vaccinations, please rate your answers from very likely to very unlikely.

Introduction of new vaccines

- How likely are you to accept a change to the vaccine schedule if it is due to the introduction of a vaccine that has recently been made?
    - Very likely
    - Likely
    - Neutral
    - Unlikely
    - Very unlikely

- How likely are you to accept a change to the vaccine schedule if the new vaccine has already been used in other countries?
    - Very likely
    - Likely
    - Neutral
    - Unlikely
    - Very unlikely
-

- What is your reasoning behind this?
    - <Free text>

Change in visits

- How likely are you to accept a change to the vaccine schedule if it is due to increasing the number of visits?
    - Very likely
    - Likely
    - Neutral
    - Unlikely
    - Very unlikely

- How likely are you to accept a change to the vaccine schedule if it is due to a decrease in the number of visits?
    - Very likely
    - Likely
    - Neutral
    - Unlikely
    - Very unlikely

- What is your reasoning behind this?
    - <Free text>

Changes in number of vaccines per visit

- How likely are you to accept a change to the vaccine schedule if it is due to increasing the number of vaccines in a single visit?
    - Very likely
    - Likely
    - Neutral
    - Unlikely
    - Very unlikely

- How likely are you to accept a change to the vaccine schedule if it is due to combining vaccines into fewer vaccines at the same visit?
    - Likely
    - Neutral
    - Unlikely
    - Very unlikely

- What is your reasoning behind this?
    - <Free text>

Changes in the timing of vaccines

- How likely are you to accept a change to the vaccine schedule if it is due to changing the timing of current vaccines, so that your child would receive the vaccine later than previously recommended?
    - Very likely
    - Likely

- Neutral
- Unlikely
- Very unlikely

- How likely are you to accept a change to the vaccine schedule if it is due to changing the timing of current vaccines, so that your child would receive the vaccine earlier than previously recommended?
  - Very likely
  - Likely
  - Neutral
  - Unlikely
  - Very unlikely

  - What is your reasoning behind this?

  - <Free text>

Would you be happy for us to contact you in the future to expand upon your answers in an informal interview?
- Yes
- No

LINK TO INTERVIEW PIS
PIS

Appendix 7

OPTIMMS Participation Interview
OPTIMMS
PARTICIPANT INFORMATION SHEET

This study has been reviewed by, and received ethics clearance through Nepal Health Research Council, NHRC Ref No: 95/2020 and the University of Oxford Tropical Research Ethics Committee, OxTREC Reference Number: 12/20.

Why are we doing this interview?

Patan Hospital (PAHS) and TU Teaching hospital (IOM) and The Oxford Vaccine Group and are investigating participant's attitudes towards their participation in the OPTIMMS vaccine trial. Thank you for completing our survey; you are now invited to participate in a short voice-recorded interview to discuss your motivations and views further. We hope these findings will help us better understand reasons for trial participation and inform future trials and engagement about vaccines. Your participation in the survey and interview, and the responses you gave to survey questions, or might give to the interview questions, won't affect the involvement of your child in the OPTIMMS trial, or your previous/upcoming clinic visits.

This interview may ask some questions that you have already answered during the screening process for the OPTIMMS vaccine trial. This is because your answers to the survey and interview are completely separate and unlinked to your data, or your child's data included in the vaccine trial.

Do I have to take part?

Participation in this interview is optional – you don't have to agree to take part. You can ask any questions you want before the interview (either by email, phone call, or by speaking to a member of the research team in person) or during the interview. All contact details can be found below. You can also withdraw at any stage during the interview without giving a reason and withdraw your information/data before the end of the interview. The responses you give won't affect your child's involvement in the OPTIMMS Vaccine Trial. You will receive NPR 1500 as a reimbursement for your travel expenses incurred while coming for the interview and time you will spend with us.

What will happen during this interview?

We will schedule up to one hour to complete the interview, however, they are likely to last 30-45 minutes. We will ask a range of questions that follow from your survey answers. The questions will cover general background information about yourself, your previous experience with research and clinical trials, your motivation for volunteering your child to take part in OPTIMMS, and your knowledge and attitudes about changing childhood vaccine schedules.
The interviews will be recorded using an audio recording device. The audio will then be transcribed (put into writing), and then translated if needed, before being analysed by the research team to understand your answers. The transcribed interview will be anonymised.

The interviewer will have seen your survey responses and may want to explore some of your answers in more detail. If you feel uncomfortable at any point or would prefer not to answer a question, please indicate this to the interviewer - you are not obliged to answer all the questions. Let the interviewer know if you would like to take a break or move onto the next question.
It is also possible to end the interview at any time and you can choose to withdraw from the study. If you choose to withdraw from the study, the interview recording will be deleted. Once the interview has been transcribed and anonymized, it will no longer be possible to withdraw. If you decide you would like to withdraw once your interview has completed, please contact us within 1 week.

How will my data be used?

The research team (including the researchers, transcribers and translators from Patan Hospital (PAHS), TU Teaching Hospital (IOM) and the University of Oxford) will have access to the research data. Responsible members of the University of Oxford and research ethics committees may be given access to data for monitoring and/or audit of the research.

- Your answers to the survey and interview question will not include direct identifiers and we will take steps to make sure that your responses remain confidential. However, if you take part in an interview after the survey, your responses to the survey will have the potential to be linked to your contact details.
- Your data will be stored on password-protected and encrypted research computers.
- Your data will only be used for non-commercial purposes, to inform academic research and publications.
- Research data will be stored for three years after publication or public release of the findings of the research. Because the data will not include direct identifiers we will not be able to act upon any individual responses to the survey.
- The research teams at Patan Hospital/Teaching Hospital and University of Oxford together will determine how the collected data will be used in the study for the purpose of the research outlined. Research is a task that we perform in the public interest.
- Further information about your rights with respect to your personal data is available from https://compliance.admin.ox.ac.uk/individual-rights. We can provide you with a copy of this should you require.
- Your personal information and data collected in this study will not be shared with other researchers or organizations.

Risks/benefits

We do not perceive any risks to you taking part, but you can decide to not answer any question, or end the interview at any point. You will be reimbursed with NRs. 1500/- for your time and travel to take part.

What if there is a problem?

If you have a concern about any aspect of this project, please contact us at Patan Hospital (PAHS) and TU Teaching Hospital (IOM) or info@ovg.ox.ac.uk and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford: ethics@medsci.ox.ac.uk (Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD) and/or, the Ethical Review Board, Nepal Health Research Council, Maharajgunj, Ramshahpath, Phone No. 977-1-5327460.

How do I find out about the results?

We will provide information about the results of this study through the Oxford Vaccine Group website (https://www.ovg.ox.ac.uk/).

Contact details
Oxford Vaccine Group: info@ovg.ox.ac.uk

Contact details:

Patan Hospital
Patan Academy of Health Sciences
Pediatric Research Unit,
Department of Pediatrics
Lagankhel, Lalitpur
Phone numbers: 977-1-5522278, 5522266, 9808797165

TU. Teaching Hospital,
Institute of Medicine
Department of Pediatrics
Maharajgunj, Kathmandu
Phone number: 977-1-4512202

Oxford Vaccine Group: info@ovg.ox.ac.uk

Appendix 8

OPTIMMS PARTICIPANT INTERVIEW CONSENT FORM **Participant ID: …….**

1	I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information carefully, ask questions and have had these questions answered satisfactorily.	Yes/No
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without penalty.	Yes/No
3	I agree to the use of direct quotes, anonymously attributed, in research outputs.	Yes/No
4	I understand that an audio recording of my interview will be made and I agree to this.	Yes/No
5	I understand that research data collected during the study may be looked at by authorised people outside the research team. I give permission for these individuals to access my data for monitoring and/or audit of the research.	Yes/No
6	I understand who will have access to personal data provided, how the data will be stored and what will happen to the data at the end of the project.	Yes/No
7	I understand how to raise a concern or make a complaint.	Yes/No
8	I agree to take part in the study.	Yes/No
9.	OPTIONAL: I agree to be contacted in the future for similar studies to the OPTIMMS participant interview.	Yes/No

By signing/marking my name here, I confirm what is written above.

Signature of Participant:	Full Name:	Date of Signature:
x_____	x_____	____/____/_____

Witness: I confirm that Consent is voluntary and freely given by the participant, guardian or legally-authorized representative and that I am not a family member or part of the study staff

Signature of Witness:	Full Name:	Date of Signature:
x_____	x_____	____/____/_____

For study staff:

I, the undersigned, have fully explained the relevant information of this study to the person named above and will provide her/him with a copy of this signed and dated informed consent form.

Signature of Investigator	Full Name	Date of Signature
x_____	x_____	___/____/_____

Appendix 9

OPTIMMS Participation Interview

INTERVIEW TOPIC GUIDE

(Please read the questions and suggested text well beforehand and use them as a guide to structure the conversation. There is no need to read the questions word-for-word).

Introduction:

Hello [x], my name is [x] from the OPTIMMS Study team. Thank you for completing the survey and agreeing to speak with me today.

We are interested in your motivations for taking part in the OPTIMMS vaccine trial, and we want to know more about what you think about changing vaccine schedules. We have already asked you similar questions in the form of a survey but would like to explore these topics in more detail to gain further insight into your views.

I would like to highlight a few key points about the interview.

- I will be recording the audio from our interview onto a digital recorder and the recording will be stored securely using your study number; this is a different study number to the one your child will have received during the OPTIMMS trial.
- I have your survey responses with me and may refer to these during the interview.
- You do not need to answer every question. If you do not want to answer a question, please ask me to move on and we can.
- If you would like to end the study at any point do let me know.

Do you have any questions before we begin the interview? (answer all questions)

Are you happy for me to start recording? [Await confirmation]

<START RECORDING>

This is an interview with participant number: XXXXX on DD/MMM/YYYY

Could you please confirm that you have read the interview participant information sheet?

[Await confirmation].

Can you please confirm you consent to take part in this recorded interview?

[Await confirmation].

1. Recruitment:

- How did you hear about OPTIMMS study?
- Why did you decide to take part?
- Have you seen other trials advertised? If so, where?
- What kind of trial advert is most likely to attract you?

2. Initial thoughts about OPTIMMS

- What was your first response to the idea of the OPTIMMS study?
- Can you tell me more about that?
- Did your opinion stay the same over time? If no, what factors changed your opinion? If yes, no further question in this part
- Have you heard anything about the study in the media?
  - If yes, how was it portrayed?
  - If no, how do you think the media might portray the study?
- Did you discuss your child's participation with anyone else?
  - What was their opinion?
  - Did anyone try to convince you not to take part? How did you respond to this?

3. Scientific justification

Do you think there is a strong reason to do this type of research?

- If so, why?
- If not, tell me more about your answer.

4. Risks/Safety

- How would you describe your attitude to risk?
- What do you see are the risks of taking part in the study?
- What do you think about the risks in this study? (do you think the risks are high?)
- Do you think the study is safe? Explain
- Do you think there are any benefits to taking part? Explain

5. Attitudes to vaccines

What are your views about vaccination?

- What sources of information have informed your views on vaccination?

6. Clinical trial justification

- Before this study, what was your knowledge of clinical trials? (heard, or knew about them)
- Have you been in a clinical trial before? What was it about?
- Have any of your children been in a clinical trial before this one? What was it about
- What was your experience of being a trial participant like?
- Do your previous experiences make you more or less likely to take part in another trial? And why?

7. Attitudes to changing vaccine schedules

Can you think of any time that the vaccine schedule might have changed previously? How did you feel about this, and how this information was conveyed to you?

- How would you feel if as part of the national schedule your child had to take a new vaccine that hadn't been used in any other countries? (and why?)
- How would you feel if as part of the national schedule your child had taken a new vaccine, that had been used in other countries? (and why?)
- Would it make a difference to you if this vaccine had been used in higher-income countries vs lower-income countries? (and why?)
- How would you feel if you had to bring your child to more appointments to receive their vaccines as part of the national schedule? (and why?)
- How would you feel if you had to bring your child to less appointments to receive their vaccines as part of the national schedule? (and why?)
- How would you feel if your child had to get the vaccines later (compared to the present time points), with the change in the national schedule? (and why?)
- How would you feel if your child could get their vaccines earlier (than the present time point) as part of the national schedule? (and why?)
- How would you feel if your child had to receive more vaccines at one visit as part of the national schedule? (and why?)
- How would you feel if your child had to receive fewer vaccines at one visit as part of the national schedule? (and why?)
- If you weren't happy with these changes, would you still get the vaccines anyway as that is what would be recommended? (Why?)
- Would you seek out an alternative schedule? Perhaps by visiting a private clinic? (And why?)

8. Vaccine information

- How do you currently receive vaccine information from? (prompt: healthcare workers, family, the media etc)
- How would you prefer to receive vaccine information?
- Who would be the ideal messenger to deliver this information to you?
- Can you think of any times where you would have liked to receive more information about vaccines but couldn't find it? Or a time where you have – and where did you find it?

9. Survey responses

- In your questionnaire responses, on the answers you have chosen can I ask you to explain a bit more about that?
  (for example, you answered 'yes' to your familiarity of the childhood vaccine schedule changing after you have had more children. Can you explain more about that?)

10. Conclusion

- Is there anything else that you would like to comment on what I haven't already asked you about? Or any questions about this study?

Thank you very much for your time and the information you shared today.

<STOP RECORDING>

Appendix 10

MRC/UVRI and LSHTM Uganda Research Unit

Participant ID | Initials

OPTIMMS Participation Survey Informed Consent

SECTION A
SURVEY PARTICIPANT INFORMATION SHEET

This project has been reviewed by, and received ethics clearance through Uganda Virus Research Unit Ethics committee **GC/127/19/12/754**and the University of Oxford Tropical Research Ethics Committee (OxTREC) [Reference Number: X]

Why are we doing this survey?

MRC/ UVRI & LSHTM Uganda Research unit and The Oxford Vaccine Group are investigating participant attitudes towards their participation in the OPTIMMS vaccine trial. You are invited to participate in a separate research study about the motivations and views of individuals who volunteered their child to take part in the OPTIMMS vaccine trial. We hope the study findings will help us better understand trial participation and inform future trials and engagement about vaccines. Your participation in this survey, and the responses you give to survey questions, won't affect the involvement of your child in the OPTIMMS trial, or your previous/upcoming clinic visits.

This survey may ask some questions that you have already answered during the screening process for the OPTIMMS vaccine trial. This is because your answers to this current questionnaire are completely separate and unlinked to your data, or your child's data, included in the vaccine trial.

Do I have to take part?

Taking part is voluntary. You can withdraw at any point for any reason, up to the submission of your answers by closing the browser. Please note that once you have finished completing the survey, we will be unable to identify and remove your data, as all the information you provide is recorded without direct identifiers. If the survey is administered during a scheduled visit, you will not receive any reimbursement for taking part. However, if a separate visit is

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Email: mrc@mrcuganda.org | Website: www.mrcuganda.org

required, you will be reimbursed for your time and travel. The responses you give won't affect your child's involvement in the OPTIMMS Vaccine Trial.

During this survey

You will be asked to answer questions about your demographic information, your previous experience with vaccine trials, your motivations for taking part in the OPTIMMS trial, and your knowledge of childhood vaccine schedules. It should take about 15-20 minutes and no background knowledge is required. The questions may be completed on a tablet or other internet-connected device and will be administered by trained study staff. You can choose to not answer any question, or end the survey at any point during the survey.

We would like to follow up this survey with a short interview (up to 1 hour each) to understand these questions further. If you would be willing to take part in an interview, at the end of the survey we provide further information and if you are happy to take part we will ask you for your contact information so that we can contact you. Not everyone will be contacted for an interview; we will carry out interviews until we have collected enough data, but we expect to interview 10-20 people.

How will my data be used?

The research team (including the researchers, transcribers and translators from MRC/ UVRI & LSHTM Uganda Research unit and the University of Oxford) will have access to the research data. Responsible members of the University of Oxford and research ethics committees may be given access to data for monitoring and/or audit of the research.

- Your answers to the survey will not include direct identifiers and we will take steps to make sure that your responses remain confidential. However, if you take part in an interview after the survey, your responses to the survey will have the potential to be linked to your contact details.
- Your data will be stored on password-protected and encrypted research computers.
- Your data will only be used for non-commercial purposes, to inform academic research and publications.

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- Your Internet Protocol (IP) address will not be stored.
- Research data will be stored for three years after publication or public release of the findings of the research. Because the data will not include direct identifiers we will not be able to act upon any individual responses to the survey.
- The University of Oxford is the data controller with respect to your personal data (contact details, if you provide them), and in coordination with MRC/ UVRI & LSHTM Uganda Research unit will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest.
- Further information about your rights with respect to your personal data is available from https://compliance.admin.ox.ac.uk/individual-rights. We can provide you with a copy of this should you require.
- Your personal information and data collected in this study will not be shared with other researchers or organisations.

What if there is a problem?

If you have a concern about any aspect of this project, please contact us on on 0417-704000 or Dr Freddie Mukasa Kibengo on +256 772 435251 or Dr. Mary Nyantaro 0708050381 or info@ovg.ox.ac.uk and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford: ethics@medsci.ox.ac.uk (Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD).

Risks/benefits

We do not perceive any risks to your participation in this research. You will be reimbursed for your time and travel.

How do I find out about the results?

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Participant ID Initials

We will provide information about the results of this study through <insert in country website/dissemination methods> and the Oxford Vaccine Group website (https://www.ovg.ox.ac.uk/).

Contact details

MRC/UVRI & LSHTM Uganda Research Unit Masaka site, Plot 2-5 Ntikko Road Masaka Town or contact the Principal Investigators, Prof Alison Elliott on Phone number: +256 417 704000 or Dr Freddie Mukasa Kibengo on +256 772 435251.

Oxford Vaccine Group: info@ovg.ox.ac.uk

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Appendix 11

MRC/UVRI and LSHTM Uganda Research Unit

Participant ID | Initials

SECTION B: OPTIMMS PARTICIPANT SURVEY CONSENT FORM
I confirm the following:

		Participant initial or thumb print
1	I confirm that I have read and understand the participant information sheet.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without penalty. However, if i do not give my contact details I understand that my survey responses cannot be identified and deleted.	
3	I understand that research data collected during the study may be looked at by authorised people outside the research team. I give permission for these individuals to access my data for monitoring and/or audit of the research.	
4	I agree to take part in the study.	
	NB: All answer must be 'YES' for survey to start.	

here, I confirm what is written above.

Signature of Participant:	Full Name:	Date of Signature:
x_____	x_____	____/____/_____

Witness:

I confirm that Consent is voluntary and freely given by the participant, guardian or legally-authorized representative and that I am not a family member or part of the study staff

Signature of Witness:	Full Name:	Date of Signature:

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x_____	x_____	____/____/_____

For study staff:

I, the undersigned, have fully explained the relevant information of this study to the person named above and will provide her/him with a copy of this signed and dated informed consent form.

Signature of Investigator	Full Name	Date of Signature
x_____	x_____	___/____/_____

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Appendix 12

MRC/UVRI and LSHTM Uganda Research Unit

Medical Research Council

Uganda Virus Research Institute

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Participant ID Initials

OPTIMMS PARTICIPATION SURVEY

To read to the participant: *Thank you for agreeing to take part in this survey. Four small sections cover: general background information, experience of clinical trials, motivations for taking part in a clinical trial, and attitudes towards changing vaccine schedules. We refer to the phrase 'vaccine schedule' throughout this survey, this is referring to the national vaccine program, and includes things like what vaccines are given, how many doses are given, and the timing of when they are given.*

Your answers to the questions are confidential and are recorded using a number that is different to your main study number. If you don't understand what a question means, please ask me to explain. If you don't want to answer a particular question, please let me know and we can move on.

Section A - This part of the survey will ask you for some general background information.

- What was your age group when you enrolled your child in the OPTIMMS study?
  - Under 18
  - 18-24
  - 25-34
  - 35-44
  - 45-54
  - 55+

- What is your gender?
  - Male
  - Female
  - Prefer not to say

- What is your religion?
  - Christianity
  - Islam
  - Hinduism
  - Buddhism
  - Judaism
  - Sikhism
  - None/Atheist
  - Other (Free Text)
  - Prefer not to say

- Who lives in your household? Please select all that apply:
  - Spouse or Partner
  - Children
  - Parents
  - Siblings

- Relatives (Specify relationship, e.g., grandparents, aunts, uncles)
- Friends
- Other (Free Text)

- What is the highest level of education you have received?
  - No education
  - Primary
  - Secondary
  - Higher than secondary
  - Other (Free Text)

- What is the highest level of education other members of your household have received?
  - No education
  - Primary
  - Secondary
  - Higher than secondary
  - Other (Free Text)

- What type of work do you do?
  - Management
  - Business/Finance
  - Agriculture
  - Science
  - Health
  - Education, law, social, government services
  - Sales and services
  - Trades and transport
  - Plant and machine operators
  - Craft and related trades
  - Student
  - Unemployed
  - Retired
  - Parent/homemaker
  - Carer for another household member
  - Other (Free Text)

- What types of work or occupations are held by the other members of your household? (select all that apply)
  - Management
  - Business/Finance
  - Agriculture
  - Science
  - Health
  - Education, law, social, government services
  - Sales and services
  - Trades and transport

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- Plant and machine operators
- Craft and related trades
- Student
- Unemployed
- Retired
- Parent/homemaker
- Carer for another household member
- Other (Free Text)

- How many children do you have?
  - 1
  - 2
  - 3
  - 4
  - 5+

- What are the ages of your children?
  - <Free Text>

- What mode of transport did you use to get to the vaccine clinic today?
  - <Free Text>

- How far did you have to travel from your home to the vaccine clinic? (in KM)
  - Less than 1 km (Less than 0.6 miles)
  - 1-5 km (0.6-3.1 miles)
  - 6-10 km (3.7-6.2 miles)
  - 11-20 km (6.8-12.4 miles)
  - 21-30 km (13.0-18.6 miles)
  - 31-40 km (19.3-24.9 miles)
  - 41-50 km (25.5-31.1 miles)
  - More than 50 km (More than 31.1 miles)

Carry on to section B

Participant ID | Initials

Section B – This part of the survey will ask about previous experience with clinical trials and how you heard about the OPTIMMS trial.

- Have you ever enrolled your child (currently in OPTIMMS) or another child in research before?
  - Yes
  - No
  - Unsure

- If yes, how many other studies have they participated in? (Give any details of the study that you might remember)
  - 1
  - 2
  - 3
  - More than 3
  - Other. Specify_____

- Have you, or anyone in the household, ever taken part in a clinical trial before? (give details)
  - Yes
  - No
  - Unsure
  - Other. Specify_____

- Has anyone you know ever taken part in a clinical trial before?
  - Yes
  - No
  - Unsure
  - <Free Text>

- Before this study, what was your knowledge of vaccine trials?
  - Very knowledgeable: I had a deep understanding of vaccine trials, including their purpose, phases, and how they become approved for use.
  - Somewhat knowledgeable: I had a basic understanding of vaccine trials and why they're important. I knew that vaccines undergo lots of testing before approval, but I may not have been familiar with the specific phases of clinical trials or the regulatory bodies involved.
  - Not very knowledgeable: I had limited knowledge of vaccine trials. While I understood the general idea of testing vaccines to make sure they're safe, I may not have been aware of the detailed processes involved or the criteria for selecting participants in trials.
  - Not knowledgeable at all: I had no prior knowledge of vaccine trials. I was unaware of how vaccines are tested before being approved for public use.

- Other: I had some knowledge from personal or professional experiences. (*Specify: ____)*

- How did you hear about this study?
  - Information leaflet from regional immunisation clinic/office
  - Verbal information from regional immunisation clinic/office
  - Poster/leaflet in hospital
  - I heard from my family and friends
  - A doctor told me by phone
  - Other. Specify_____

- Did you discuss your decision to enrol your child in this study with anyone else?
  - Yes
  - No

- If yes, who did you discuss it with?
  - Specify_____

- If yes, when you discussed volunteering, were the responses you received (complete for every person you discussed with)
    - Mostly Positive
    - Neutral
    - Mostly Negative

  - (Notes: *Free Text for details of discussion with each person*)

- Did anyone you discussed volunteering with try to discourage you from signing up?
  - Yes
  - No

    <Free Text>

Carry on to section C

Participant ID | Initials

Section C – This section will ask about your motivations for taking part

The following questions will ask you about your reasons for volunteering your child for this study. Rate each of the statements, from strongly agree to strongly disagree, based on how much you agree with them.

- I thought the data generated would help improve the health of others.
  - Strongly Agree
  - Agree
  - Neutral
  - Disagree
  - Strongly Disagree

- I wanted to contribute to medical and scientific progress.
  - Strongly Agree
  - Agree
  - Neutral
  - Disagree
  - Strongly Disagree

- I thought that by volunteering my child, it would inspire others in my community to take part
  - Strongly Agree
  - Agree
  - Neutral
  - Disagree
  - Strongly Disagree

- I felt a responsibility to take part
  - Strongly Agree
  - Agree
  - Neutral
  - Disagree
  - Strongly Disagree

- I was curious about the experience of being in a vaccine trial.
  - Strongly Agree
  - Agree
  - Neutral
  - Disagree
  - Strongly Disagree

- I wanted to tell others about the experience of being in a vaccine trial.
  - Strongly Agree
  - Agree
  - Neutral







Participant ID Initials

- Disagree
- Strongly Disagree

- I wanted my child to get a medical check-up to find out more about their health.
  - Strongly Agree
  - Agree
  - Neutral
  - Disagree
  - Strongly Disagree

- I was motivated by the benefits the study offered to my child throughout the study period (i.e. free treatment if they became ill).
  - Strongly Agree
  - Agree
  - Neutral
  - Disagree
  - Strongly Disagree

What were your other motivations or reasons for volunteering for the study?

- Other. Specify_____

Carry on to section D

Participant ID | Initials

Section D – This section will ask about your knowledge of and attitudes to vaccines, and changing childhood vaccine schedules

This first set of questions aims to understand your vaccine knowledge.

- Before this study, what was your knowledge of childhood vaccine schedules?
  - Very knowledgeable: *I knew a lot about when vaccines should be given and why it's important. For example, I knew when my child should get their diphtheria vaccine and why it's needed.*
  - Somewhat knowledgeable: *I knew a bit about vaccine schedules, but I wasn't sure about all the details. For instance, I knew that children need vaccines at certain times, but I wasn't sure about the exact timing for each one.*
  - Not very knowledgeable: *I didn't know much about vaccine schedules. I knew my child needed vaccines, but I didn't know when or which ones were required.*
  - Not knowledgeable at all: *I didn't know anything about vaccine schedules.*
  - Other. Specify____

- If you have more than one child, has this familiarity with the vaccine schedule changed after having each child?
  - <Free Text>

- Are you aware of any recent changes to the vaccination schedule?
  - Yes
  - No
    - If yes, what were the changes?
      - <Free Text>
    - If yes, what were/are your opinions on these changes?
      - <Free Text>

- Where do you get information about vaccines and their schedules from?
  - Government health authorities (e.g. Ministry of Health)
  - Healthcare provider
  - Non-traditional healthcare provider
  - Non-governmental organisation
  - The media
  - Social media
  - Community leaders or influencers
  - Schools or educational institutions
  - Vaccine manufacturers
  - Friends
  - Family
  - Other/Specify further _____

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- What information would you like to receive to better understand changes in childhood vaccine schedules?
  - <Free Text>

- How would you like to receive this information?
  - <Free Text>

This second set of questions refers to your attitudes and opinions about vaccines and their schedules.

- How important do you think vaccines are for your child's health? Would you say…
  - Not at all important
  - A little important
  - Moderately important
  - Very important

- Do you think most of your close family and friends want you to get your child vaccinated?
  - Yes
  - No

- <Country name> has a schedule of recommended vaccines for children. Do you want your child to get none of these vaccines, some of these vaccines, or all of these vaccines?
  - None
  - Some
  - All

- Do you know where to go to get your child vaccinated?
  - Yes
  - No

- How easy is it to pay for the associated costs of vaccination? Please consider the cost of getting there, plus the cost of taking time away from work etc. Would you say...
  - Not at all easy
  - A little easy
  - Moderately easy
  - Very easy

- What is likely to influence your opinion on any changes to the childhood vaccine schedule? (Select all that apply)
  - Scientific evidence

- Recommendations from health authorities
- Personal beliefs or values
- Family members
- Trusted friends
- Healthcare provider
- Local community leaders
- Social media
- News sources
- The advice from the government
- Personal experience with vaccines
- Other people's experience with vaccines
- Vaccine safety
- Concerns about vaccine-preventable diseases
- Other. Specify_____

In the following scenarios, relating to potential changes in childhood vaccinations, please rate your answers from very likely to very unlikely.

Introduction of new vaccines

- How likely are you to accept a change to the vaccine schedule if it is due to the introduction of a vaccine that has recently been made?
  - Very likely
  - Likely
  - Neutral
  - Unlikely
  - Very unlikely

- How likely are you to accept a change to the vaccine schedule if the new vaccine has already been used in other countries?
  - Very likely
  - Likely
  - Neutral
  - Unlikely
  - Very unlikely

- What is your reasoning behind this?
  - <Free text>

Change in visits

- How likely are you to accept a change to the vaccine schedule if it is due to increasing the number of visits?
  - Very likely
  - Likely
  - Neutral
  - Unlikely

- Very unlikely

- How likely are you to accept a change to the vaccine schedule if it is due to a decrease in the number of visits?
  - Very likely
  - Likely
  - Neutral
  - Unlikely
  - Very unlikely

- What is your reasoning behind this?
  - <Free text>

Changes in number of vaccines per visit

- How likely are you to accept a change to the vaccine schedule if it is due to increasing the number of vaccines in a single visit?
  - Very likely
  - Likely
  - Neutral
  - Unlikely
  - Very unlikely

- How likely are you to accept a change to the vaccine schedule if it is due to combining vaccines into fewer vaccines at the same visit?
  - Very likely
  - Likely
  - Neutral
  - Unlikely
  - Very unlikely

- What is your reasoning behind this?
  - <Free text>

Changes in the timing of vaccines

- How likely are you to accept a change to the vaccine schedule if it is due to changing the timing of current vaccines, so that your child would receive the vaccine later than previously recommended?
  - Very likely
  - Likely
  - Neutral
  - Unlikely
  - Very unlikely

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- How likely are you to accept a change to the vaccine schedule if it is due to changing the timing of current vaccines, so that your child would receive the vaccine earlier than previously recommended?
  - Very likely
  - Likely
  - Neutral
  - Unlikely
  - Very unlikely

- What is your reasoning behind this?
  - <Free text>

Would you be happy for us to contact you in the future to expand upon your answers in an informal interview?

- Yes
- No

LINK TO INTERVIEW PIS

Appendix 13

MRC/UVRI and LSHTM Uganda Research Unit

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OPTIMMS Participation Interview informed consent document

SECTION A

INTERVIEW PARTICIPANT INFORMATION SHEET

This project has been reviewed by, and received ethics clearance through Uganda Virus Research Unit Ethics committee **GC/127/19/12/754**, and the University of Oxford Tropical Research Ethics Committee (OxTREC) [Reference Number: X]

Why are we doing this interview?

MRC/UVRI&LSHTM Uganda Research unit and The Oxford Vaccine Group and are investigating participant's attitudes towards their participation in the OPTIMMS vaccine trial. Thank you for completing our survey; you are now invited to participate in a short voice-recorded interview to discuss your motivations and views further. We hope these findings will help us better understand reasons for trial participation and inform future trials and engagement about vaccines. Your participation in the survey and interview, and the responses you gave to survey questions, or might give to the interview questions, won't affect the involvement of your child in the OPTIMMS trial, or your previous/upcoming clinic visits.

This interview may ask some questions that you have already answered during the screening process for the OPTIMMS vaccine trial. This is because your answers to the survey and interview are completely separate and unlinked to your data, or your child's data included in the vaccine trial.

Do I have to take part?

Participation in this interview is optional – you don't have to agree to take part. You can ask any questions you want before the interview (either by email, phone call, or by speaking to a member of the research team in person) or during the interview. All contact details can be found below. You can also withdraw at any stage during the interview without giving a reason and withdraw your information/data before the end of the interview. You will be reimbursed for

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your time and travel. The responses you give won't affect your child's involvement in the OPTIMMS Vaccine Trial.

During this interview

We will schedule up to one hour to complete the interview, however, they are likely to last 30-45 minutes. We will ask a range of questions that follow from your survey answers. The questions will cover general background information about yourself, your previous experience with research and clinical trials, your motivation for volunteering your child to take part in OPTIMMS, and your knowledge and attitudes about changing childhood vaccine schedules.

The interviews will be recorded using an audio recording device. The audio will then be transcribed (put into writing), and then translated if needed, before being analysed by the research team to understand your answers. The transcribed interview will be anonymised.

The interviewer will have seen your survey responses and may want to explore some of your answers in more detail. If you feel uncomfortable at any point or would prefer not to answer a question, please indicate this to the interviewer - you are not obliged to answer all the questions. Let the interviewer know if you would like to take a break or move onto the next question.

It is also possible to end the interview at any time and you can choose to withdraw from the study. If you choose to withdraw from the study, the interview recording will be deleted. Once the interview has been transcribed and anonymized, it will no longer be possible to withdraw. If you decide you would like to withdraw once your interview has completed, please contact us within 1 week.

How will my data be used?

The MRC/UVRI &LSHTM Uganda Research Unit and University of Oxford team (including the researchers, transcribers and translators) will have access to the research data. Responsible

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members of the University of Oxford and ethics research committee may be given access to data for monitoring and/or audit of the research.

- Your answers to the survey and interview questions will not include direct identifiers and we will take steps to make sure that your responses remain confidential. However, if you take part in an interview after the survey, your responses to the survey will have the potential to be linked to your contact details.
- Your data will be stored on password-protected and encrypted research computers.
- Your data will only be used for non-commercial purposes, to inform academic research and publications.
- Your Internet Protocol (IP) address will not be stored.
- Research data will be stored for three years after publication or public release of the findings of the research. Because the data will not include direct identifiers we will not be able to act upon any individual responses to the survey.
- The University of Oxford is the data controller with respect to your personal data (contact details, if you provide them), and in co-ordination with MRC/UVRI & LSHTM Uganda Research Unit will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest.
- Further information about your rights with respect to your personal data is available from https://compliance.admin.ox.ac.uk/individual-rights. We can provide you with a copy of this should you require.
- Your personal information and data collected in this study will not be shared with other researchers or organisations.

Risks/benefits

We do not perceive any risks to you taking part, but you can decide to not answer any question, or end the interview at any point. You will be reimbursed for your time and travel to take part in this interview.

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What if there is a problem?

If you have a concern about any aspect of this project, please contact us on 0417-704000 or Dr Freddie Mukasa Kibengo on +256 772 435251. info@ovg.ox.ac.uk, and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact

Uganda Virus Research Institute Ethics Review committee, Chairperson of UVRI REC, Dr Tom Lutalo on telephone number: 0414 321962 or the Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford: ethics@medsci.ox.ac.uk (Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD).

How do I find out about the results?

We will provide information about the results of this study through dissemination workshops and the Oxford Vaccine Group website (https://www.ovg.ox.ac.uk/).

Contact details

MRC/UVRI & LSHTM Uganda Research Unit Masaka site, Plot 2-5 Ntikko Road Masaka Town or contact the Principal Investigators, Prof Alison Elliott on Phone number: +256 417 704000 or Dr Freddie Mukasa Kibengo on +256 772 435251.

infor@ovg.ox.ac.uk

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SECTION B: OPTIMMS PARTICIPANT INTERVIEW CONSENT FORM

I confirm the following:

		Participant Initials/Thumb print
1	I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information carefully, ask questions and have had these questions answered satisfactorily.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without penalty.	
3	I agree to the use of direct quotes, anonymously attributed, in research outputs.	
4	I understand that an audio recording of my interview will be made and I agree to this.	
5	I understand that research data collected during the study may be looked at by authorised people outside the research team. I give permission for these individuals to access my data for monitoring and/or audit of the research.	
6	I understand who will have access to personal data provided, how the data will be stored and what will happen to the data at the end of the project.	

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7	I understand how to raise a concern or make a complaint.	
8	I agree to take part in the study.	
9.	OPTIONAL: I agree to be contacted in the future for similar studies to the OPTIMMS participant interview.	

By signing/marking my name here, I confirm what is written above.

Signature of Participant:	Full Name:	Date of Signature:
x_____	x_____	____/____/_____

Witness:

I confirm that Consent is voluntary and freely given by the participant, guardian or legally-authorized representative and that I am not a family member or part of the study staff

Signature of Witness:	Full Name:	Date of Signature:
x_____	x_____	____/____/_____

For study staff:

I, the undersigned, have fully explained the relevant information of this study to the person named above and will provide her/him with a copy of this signed and dated informed consent form.

Signature of Investigator	Full Name	Date of Signature
x_____	x_____	___/____/_____

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Appendix 15

OPTIMMS Participation Interview

INTERVIEW TOPIC GUIDE

(Please read the questions and suggested text well beforehand and use them as a guide to structure the conversation. There is no need to read the questions word-for-word).

***Introduction**:*

Hello [x], my name is [x] from the OPTIMMS Study team. Thank you for completing the survey and agreeing to speak with me today.

We are interested in your motivations for taking part in the OPTIMMS vaccine trial, and we want to know more about what you think about changing vaccine schedules. We have already asked you similar questions in the form of a survey but would like to explore these topics in more detail to gain further insight into your views.

I would like to highlight a few key points about the interview.

- I will be recording the audio from our interview onto a digital recorder and the recording will be stored securely using your study number; this is a different study number to the one your child will have received during the OPTIMMS trial.
- I have your survey responses with me and may refer to these during the interview.
- You do not need to answer every question. If you do not want to answer a question, please ask me to move on and we can.
- If you would like to end the study at any point do let me know.

Do you have any questions before we begin the interview? (answer any questions)

Are you happy for me to start recording? [Await confirmation]

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<START RECORDING>

This is an interview with participant number: XXXXXX on DD/MMM/YYYY

Could you please confirm that you have read the interview participant information sheet.
[Await confirmation].

Can you please confirm you consent to take part in this recorded interview?
[*Await confirmation].*

1. Recruitment

- How did you hear about this study?
- Why did you decide to take part?
- Have you seen other trials advertised? If so, where?
- What kind of trial advert is most likely to attract you?

2. Initial thoughts about OPTIMMS

- What was your first response to the idea of the OPTIMMS study?
- Can you tell me more about that?
- Did your opinion stay the same over time? What factors changed your opinion?
- Have you heard anything about the study in the media?
    - If yes, how was it portrayed?
    - If no, how do you think the media might portray the study?
- Did you discuss your child's participation with anyone else?
    - What was their opinion?
    - Did anyone try to convince you not to take part? How did you respond to this?

3. Scientific justification

- Do you think there is a strong reason to do this type of research?
    - If so, why?
    - If not, tell me more about your answer.

4. Risks/Safety

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- How would you describe your attitude to risk?
- What do you see are the risks of taking part in the study?
- What do you think about the risks in this study? (do you think the risks are high?)
- Do you think the study is safe? Explain
- Do you think there are any benefits to taking part? Explain

5. Attitudes to vaccines

- What are your views about vaccination?
- What sources of information have informed your views on vaccination?

6. Clinical trial justification

- Before this study, what was your knowledge of clinical trials? (heard, or knew about them)
- Have you been in a clinical trial before? What was it about?
- Have any of your children been in a clinical trial before this one? What was it about
- What was your experience of being a trial participant like?
- Do your previous experiences make you more or less likely to take part in another trial? And why?

7. Attitudes to changing vaccine schedules

- Can you think of any time that the vaccine schedule might have changed previously? How did you feel about this, and how this information was conveyed to you?
- How would you feel if your child had to a new vaccine that hadn't been used in any other countries as part of the national schedule? (and why?)
- How would you feel if your child had to a new vaccine that had been used in other countries as part of the national schedule? (and why?)
- Would it make a difference to you if this vaccine had been used in higher-income countries vs lower-income countries? (and why?)
- How would you feel if you had to bring your child to more appointments to receive their vaccines as part of the national schedule? (and why?)

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- How would you feel if you had to bring your child to less appointments to receive their vaccines as part of the national schedule? (and why?)
- How would you feel if your child had to get the vaccines later (compared to the present time points), with the change in the national schedule? (and why?)
- How would you feel if your child could get their vaccines earlier (than the present time point) as part of the national schedule? (and why?)
- How would you feel if your child had to receive more vaccines at one visit as part of the national schedule? (and why?)
- How would you feel if your child had to receive fewer vaccines at one visit as part of the national schedule? (and why?)
- If you weren't happy with these changes, would you still get the vaccines anyway as that is what would be recommended? (Why?)
- Would you seek out an alternative schedule? Perhaps by visiting a private clinic? (why?)

8. Vaccine information

- Who do you currently receive vaccine information from? (prompt: healthcare workers, family, the media etc)
- How would you prefer to receive vaccine information?
- Who would be the ideal messenger to deliver this information to you?
- Can you think of any times where you would have liked to receive more information about vaccines but couldn't find it? Or a time where you have – and where did you find it?

9. Survey responses

- In your questionnaire responses you answer X….. please can I ask you to explain a bit more about that?

  (for example, you answered 'yes' to your familiarity of the childhood vaccine schedule changing after you have had more children. Can you explain more about that?)

10. Conclusion

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- Is there anything else that you would like to comment on what I haven't already asked you about? Or any questions about this study?

Thank you very much for your time and the information you shared today.

<STOP RECORDING>

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Appendix 16

Men B as a Gonorrhoea Vaccine Fact Sheet

The 4CMenB vaccine is used to prevent meningitis B – a potentially life-threatening bacterial infection that can cause swelling of the brain and spinal cord. The licensed version of this vaccine, Bexsero® is given to babies in the UK. The '4C' means the vaccine contains four components, or four parts, from the bacteria that cause Meningitis B.

There are some similarities between the meningitis B bacteria and the bacteria that cause gonorrhoea. Vaccines that contain these similar parts, such as the 4CMenB vaccine, have been shown to prevent both meningitis and gonorrhoea.

The 4CMenB vaccine is referred to as the Men B vaccine in the rest of this fact sheet.

In November 2023, the Joint Scientific Committee on Vaccination and Immunisation (JCVI) recommended the use of Men B vaccine to prevent gonorrhoea in people who are more likely to get an STI (especially gay, bisexual, and other men who have sex with men).

As of October 2024, none of the JCVI's recommendations for a Men B vaccine gonorrhoea prevention programme have been implemented in the UK.

Mathematical modelling studies that aim to predict the potential impact of vaccination programmes have shown that vaccinating teenagers, alongside a booster programme for young adults, could also be effective at preventing cases of gonorrhoea.

Key Facts

- Research shows that the Men B vaccine can prevent gonorrhoea.
- The vaccine was originally designed to protect people against meningococcal B bacteria – the bacteria that causes some type of meningitis.
- Evidence suggests that the Men B vaccine has between 32.7 to 42% effectiveness against gonorrhoea.
- The vaccine could be particularly useful for people who are at the highest risk of getting gonorrhoea.
- The vaccine could also help save the NHS time and money by reducing the number of cases of gonorrhoea that need to be treated.
- The vaccine, if effective at preventing gonorrhoea in the UK, could slow the increase in antimicrobial-resistant cases of gonorrhoea – sometimes also called 'super gonorrhoea'.
- Vaccination for gonorrhoea prevention is not yet available on the NHS.

Appendix 17

NAVIGATE: Navigating Attitudes to Vaccination Implementation for Gonorrhoea in the UK: Acceptability, Trust and Engagement

SURVEY PARTICIPANT INFORMATION SHEET

Central University Research Ethics Committee Approval Reference: [MSD IDREC 947232]

1. Introductory paragraph

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

2. Why is this research being conducted?

The UK government is considering a vaccination programme to prevent gonorrhoea, a sexually transmitted infection, primarily targeting gay and bisexual men and other men who have sex with men (GBMSM) – this is because they are at a higher risk of infection from gonorrhoea. Studies have shown that the vaccine usually used to prevent meningitis in young children, can offer some protection against gonorrhoea

It's important to understand what people think about vaccination against gonorrhoea, if they would accept the vaccine, what information they would need to make this decision, and how to make it easy for the vaccine recipients to receive the vaccine logistically.

To do this, researchers plan to ask questions to gather information from different perspectives to help make decisions about the vaccine programme. By understanding what people think, and if they would find this programme acceptable, researchers can make sure the programme is effective and well-received by the public if it goes ahead.

3. Why have I been invited to take part?

You have been invited to take part in this research because you have identified as a user of sexual health services and are aged 18 years and over.

4. Do I have to take part?

No. It is up to you to decide whether to take part. You can withdraw yourself from the research without giving a reason by not completing the survey. Once the survey has been submitted, it will not be possible to withdraw your answers from the study; this is because no personally identifiable data will be collected, and therefore we will be unable to find out which survey answers need to be withdrawn.

5. What will happen to me if I take part in the research?

You will be asked to read through this participant information sheet before taking part. If you decide you would like to continue and take the survey, we will ask you to fill in an online consent form. You will then be able to access the survey – this should take you roughly 10-15 minutes to complete. You will be able to pause the survey, or exit the survey, should you wish you no longer want to take part. It is also possible to skip any questions you do not want to answer.

You will also be asked if you would like to take part in a separate online interview to expand upon some of the questions we would like to ask. This is optional, and we will interview the first 20-30 participants who express interest. Interview participants will be given a voucher for their time. We will ask for your name and contact details so we can arrange the interview to discuss your answers in more detail. If you provide this information, we will be able to link your survey responses to your contact details.

6. What are the possible disadvantages and risks in taking part?

In this survey, we will ask you questions about a potential vaccination programme against gonorrhoea, therefore, topics around sexually transmitted infections will be discussed. We understand that some people might find this topic embarrassing or difficult to talk about, but you can choose not to answer any of the questions.

7. Are there any benefits in taking part?

While there are no immediate benefits for those participating in the research, it is hoped that this research will inform discussions around future gonorrhoea vaccination programmes.

8. What information will be collected and why is the collection of this information relevant for achieving the research objectives?

We are interested in the thoughts of various groups of people about how acceptable, and how feasible, an adolescent gonorrhoea programme would be. We also want to find out what information you would like to receive about this vaccination, and how you would like to receive, should this programme go ahead. We will be asking questions to this effect.

The data we will collect that could identify you will be your contact details, should you wish to express interest in completing the optional interview.

Your IP address will not be stored. We will take all reasonable measures to ensure that data remain confidential.

The responses you provide will be stored in a password-protected electronic file on University of Oxford secure servers. Identifiable information will be deleted as soon as it is no longer required for the research. Research data will be stored for 3 years after publication or public release of the work of the research.

9. Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research will/may be written up into a thesis, academic papers, conference presentations, or other publication methods (such as poster presentations etc). Policy recommendations will also be written and delivered to the government as a result of this research. This will ensure that if this vaccine program does go ahead, it will be informed by the thoughts of the people the program is aimed at. No personally identifiable data will be published.

A copy of my thesis/ dissertation will be deposited both in print and online in the Oxford University Research Archive where it will be publicly available to facilitate its use in future research.

10. Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the research. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from the University's Information Compliance website at https://compliance.admin.ox.ac.uk/individual-rights.

11. Who is funding the research?

This research is being funded by the National Institute for Health Research (NIHR).

12. Who has reviewed this research?

This research has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: **MSD IDREC 947232)**.

13. Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this research, please contact Dr Katrina Pollock, principal investigator, or Charlie Firth, DPhil Student, and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) team at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

14. Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Prof Katrina Pollock
MRC Clinician Scientist in Vaccinology, Honorary Consultant in Sexual Health.
Katrina.pollock@paediatrics.ox.ac.uk

Charlie Firth
DPhil Student
charlie.firth@paediatrics.ox.ac.uk

Department of Paediatrics, Oxford University
Level 2, Children's Hospital, John Radcliffe
Headington, Oxford, OX3 9DU

Appendix 18

NAVIGATE: Navigating Attitudes to Vaccination Implementation for Gonorrhoea in the UK: Acceptability, Trust and Engagement

Sexual health service user survey

Introduction and Consent Confirmation

Welcome to the survey!

Thank you for participating in this survey about your thoughts about vaccines for gonorrhoea. This survey is designed to gather your opinions on vaccinations, particularly in the context of sexual health vaccines. Your responses will help guide decisions on future vaccine programs.

Your answers are private and will only be used for research purposes. No personally identifiable information will be linked to your responses.

Taking part in this survey is entirely voluntary. You can skip any question you do not wish to answer or exit the survey at any time.

Consent: By clicking "Next" and proceeding with this survey, you confirm that you have read and understood the participant information sheet provided and you consent to participate in this survey.

Demographic Information

1. **Do you identify as...?**
    - Female
    - Male
    - Non-binary or other
    - Prefer not to say

2. **Age Group:**
    - Under 18 years
    - 18-24 years
    - 25-34 years
    - 35-44 years
    - 45-54 years
    - 55-64 years
    - 65 years and over.

3. **Ethnic Group:**
    - Asian or Asian British (e.g., Indian, Pakistani, Bangladeshi)
    - Black or Black British (e.g., Caribbean, African)
    - Chinese
    - Mixed (e.g., White and Black Caribbean, White and Black African, White and Asian)
    - White (British or Irish)

- White (Other European)
- Other
- Prefer not to say

3a. If you selected "Other," please specify:

4. **Religion:**
   - Buddhist
   - Christian (e.g., Church of England, Catholic, Protestant)
   - Hindu
   - Jewish
   - Muslim
   - Sikh
   - None
   - Other
   - Prefer not to say

   4a. If you selected "Other," please specify:

5. **First Half of Your Postcode:**

6. **Highest Level of Education:**
   - No formal qualifications
   - GSCE / O-Level / CSE
   - A-Levels / Level 3 BTEC / NVQ
   - Foundation Degree / Diploma / Level 5
   - Undergraduate Degree / HND / Level 6
   - Masters Degree / Post-graduate Diploma / Level 7
   - PhD
   - Other

7. **Employment Status**
   - Employed Full-Time
   - Employed Part-Time
   - Self-Employed
   - Unemployed
   - Student
   - Prefer not to say

8. **Household Income:**
   - Less than £15,000
   - £15,000 - £24,999
   - £25,000 - £34,999
   - £35,000 - £44,999
   - £45,000 - £54,999
   - £55,000 - £64,999
   - £65,000 or more
   - Prefer not to say

9. **Number and Ages of Children:**
   - None
   - 1 child (age)

- 2 children (ages)
- 3 or more children (ages)
- Prefer not to say

Section 1: General Attitudes Toward Vaccination (VAX – Vaccine Attitudes Examination)

These questions are designed to help us better understand people's beliefs about vaccinations. Please mark the choices that most accurately reflect your feelings or beliefs. There are no right or wrong responses.

1. **I feel safe after being vaccinated.**
   - Strongly Disagree (1)
   - 2
   - 3
   - 4
   - 5
   - Strongly Agree (6)

2. **I can rely on vaccines to stop serious infectious diseases.**
   - Strongly Disagree (1)
   - 2
   - 3
   - 4
   - 5
   - Strongly Agree (6)

3. **I feel protected after getting vaccinated.**
   - Strongly Disagree (1)
   - 2
   - 3
   - 4
   - 5
   - Strongly Agree (6)

4. **Although most vaccines appear to be safe, there may be problems that we haven't yet discovered.**
   - Strongly Disagree (1)
   - 2
   - 3
   - 4
   - 5
   - Strongly Agree (6)

5. **Vaccines can cause unforeseen problems in children.**
   - Strongly Disagree (1)
   - 2
   - 3
   - 4
   - 5

- Strongly Agree (6)

6. **I worry about the unknown effects of vaccines in the future.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

7. **Vaccines make a lot of money for pharmaceutical companies, but don't do much for regular people.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

8. **Authorities promote vaccination for financial gain, not for people's health.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

9. **Vaccination programs are a big con.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

10. **Natural immunity lasts longer than a vaccination.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

11. **Natural exposure to viruses and germs gives the safest protection.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5

- Strongly Agree (6)

12. **Being exposed to diseases naturally is safer for the immune system than being exposed through vaccination.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

Section 2: Attitudes Toward Sexual Health Vaccination

These questions are designed to help us better understand your beliefs about sexually transmitted infections and vaccines. Please mark the choices that most accurately reflect your feelings or beliefs. There are no right or wrong responses.

Attitudes Toward Sexually Transmitted Infections (STIs)

1. **I believe sexually transmitted infections (STIs) are a serious public health issue.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

2. **STIs can have severe long-term health consequences.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

3. **The risk of contracting an STI is high among sexually active individuals.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

4. **The risk of contracting an STI is high among individuals who have sexual contact with multiple people.**
    - Strongly Disagree (1)
    - 2
    - 3

- 4
- 5
- Strongly Agree (6)

5. **I am concerned about the spread of STIs in my community.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

6. **STIs are preventable through proper education and preventive measures.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

Attitudes Toward Vaccines for Sexually Transmitted Infections (STIs)

6. **Vaccines are an effective way to prevent sexually transmitted infections (STIs).**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

7. **I support the development of vaccines to prevent STIs.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

8. **Vaccines for STIs should be widely available.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

9. **I am concerned about the safety of vaccines for STIs.**
    - Strongly Disagree (1)

- 2
- 3
- 4
- 5
- Strongly Agree (6)

10. **The benefits of vaccines for STIs outweigh potential side effects or risks.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

11. **Vaccines for STIs should be a part of routine healthcare.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

12. **Vaccinating against STIs could lead to risky sexual behaviour.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

Attitudes Toward Getting Vaccinated for Gonorrhoea

13. **Before this survey, I knew what gonorrhoea was.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)
    -

14. **People at risk of infection should be vaccinated against sexually transmitted infections.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

15. **I am comfortable getting a vaccine against gonorrhoea**

- Strongly Disagree (1)
- 2
- 3
- 4
- 5
- Strongly Agree (6)

16. **Vaccinating against gonorrhoea could protect from serious health problems in the future.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

17. **Vaccinating people against STIs could encourage them to engage in sexual activity**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

18. **I am more likely to accept a vaccine if the symptoms of the disease it prevents are severe.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

19. **I am more likely to accept a vaccine if the disease it prevents cannot be cured.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

20. **I think my family would be supportive of me receiving a vaccine against gonorrhoea**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5

- Strongly Agree (6)

20. **I think my friends would support me getting vaccinated against gonorrhoea**.
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

Section 3: Attitudes Toward the Potential Gonorrhoea Vaccination Program

This section is to help us understand what you think about a possible program that would offer you a vaccine for gonorrhoea using the men b vaccine. The men b vaccine is already used in babies to protect against meningitis and has shown some protection against gonorrhoea. The idea is to offer this vaccine to people who are at a high risk of bacterial STI infections, or who have had one recently, to try and prevent future infection.
Please mark the choices that are the closest to how you feel. There are no right or wrong responses.

Support for the Gonorrhoea Vaccination Program

1. **I support the introduction of a gonorrhoea vaccination program.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

2. **I think that vaccinating just the people at high risk of gonorrhoea infection could be a good way to prevent this STI in the long term.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

3. **I think that vaccinating adolescents, before they become sexually active, could be a good way to prevent this STI in the long term.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5

- Strongly Agree (6)

4. **I think that including the gonorrhoea vaccine in the routine vaccination schedule before people become sexually active, and a booster dose when they're older, makes the most sense**
   - Strongly Disagree (1)
   - 2
   - 3
   - 4
   - 5
   - Strongly Agree (6)

5. **I believe that using the meningitis vaccine against gonorrhoea is more acceptable because protection is also given against meningitis**
   - Strongly Disagree (1)
   - 2
   - 3
   - 4
   - 5
   - Strongly Agree (6)
   -
6. **I believe that using the meningitis vaccine against gonorrhoea is more acceptable because babies in the UK have already been given this vaccine.**
   - Strongly Disagree (1)
   - 2
   - 3
   - 4
   - 5
   - Strongly Agree (6)

7. **I believe that using the meningitis vaccine against gonorrhoea is safe because babies in the UK have already been given this vaccine.**
   - Strongly Disagree (1)
   - 2
   - 3
   - 4
   - 5
   - Strongly Agree (6)

Concerns and Considerations

8. **I am worried about the safety of the men b vaccine for preventing gonorrhoea.**
   - Strongly Disagree (1)
   - 2
   - 3
   - 4
   - 5

- Strongly Agree (6)

9. **I am worried about the efficacy (how well it works) of the men b vaccine for preventing gonorrhoea.**
   - Strongly Disagree (1)
   - 2
   - 3
   - 4
   - 5
   - Strongly Agree (6)

10. **I would like more information on how well the vaccine works against gonorrhoea long-term before supporting its use**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

11. **I think the lower level of protection given by the MenB vaccine against gonorrhoea is outweighed by the protection also given against meningitis**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)
12. **I think the lower level of protection given by the MenB vaccine against gonorrhoea is outweighed by the large amount of safety data, and that the vaccine is already given to babies in the UK**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

13. **I am worried that introducing a gonorrhoea vaccine might cause people to take part in risky sexual behaviour.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

14. **I believe that there should be an educational campaign about the benefits and risks of the gonorrhoea vaccine.**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

15. **I believe that there should be a focus on education to prevent STIs (safe sex, use of condoms etc) rather than a vaccine programme**
    - Strongly Disagree (1)
    - 2
    - 3
    - 4
    - 5
    - Strongly Agree (6)

Implementation and Accessibility

16. **How important is convenience in deciding whether to get vaccinated?**
    - Extremely important
    - Very important
    - Moderately important
    - Slightly important
    - Not important

17. **How would you prefer to book an appointment for a vaccine?** (Check all that apply)
    - Online booking system (via website/app)
    - Walk-in without an appointment
    - By phone call
    - Through a healthcare provider referral
    - Other (please specify)

18. **What are the most convenient times for you to schedule a vaccine appointment?** (Check all that apply)
    - Morning (8 am - 12 pm)
    - Afternoon (12 pm - 4 pm)
    - Evening (4 pm - 8 pm)
    - Weekends
    - Anytime during the day

19. **How far would you be willing to travel to get vaccinated?**
    - Less than 5 minutes
    - 5-10 minutes
    - 10-20 minutes
    - 20-30 minutes
    - Over 30 minutes

20. **Where would you prefer to get vaccinated?** (Check all that apply)
    - Pharmacy
    - GP surgery
    - Sexual health clinic
    - Hospital
    - University/College campus
    - Pop-up vaccination site (e.g., shopping centre, community centre)
    - Drive-through vaccination site
    - Other (please specify)

21. **What would make it easier for you to access a vaccination site?** (Check all that apply)
    - Easy public transportation options
    - Free transportation services (e.g., bus pass, taxi voucher etc)
    - Short waiting times
    - Flexible appointment times (e.g., late evenings, weekends)
    - Availability of walk-in appointments
    - Clear information on location and availability
    - Other (please specify)

22. **How important is it that the cost of the gonorrhoea vaccine should be covered by public health services to ensure everyone who wants it can get it?**
    - Extremely important
    - Very important
    - Moderately important
    - Slightly important
    - Not important

Section 4: Vaccine Communication and Education
This section aims to understand where you get your information about vaccines and STIs and how much you trust these sources (click all that are relevant).
.

Education Requirements

1. **What type of educational content do you think is necessary for you about the potential gonorrhoea vaccination program?**
    - Basic information about the men b vaccine
    - Details about gonorrhoea (cases, symptoms, long-term effects)
    - Information about the effectiveness and safety of the vaccine
    - Explanation of how the vaccine fits into the existing vaccination schedule
    - The importance of vaccination for STI prevention
    - Other (please specify): _____

Who Should Deliver the Education?

3. **Who do you believe is the most suitable for delivering educational content about the gonorrhoea vaccination to you?**
    - Healthcare workers (e.g., doctors, nurses)
    - School teachers, university lecturers, or counsellors

- Peer educators (e.g., other students)
- Public health officials
- Online resources (e.g., websites, social media)
- Parents or caregivers
- Other (please specify): _____

Message Framing

5. **How should the message about the gonorrhoea vaccination be explained to make it most effective?**
   - Emphasise the dual protection against meningitis and gonorrhoea
   - Focus on the prevention of gonorrhoea specifically
   - Highlight the benefits of including it in the routine vaccination schedule
   - Stress the importance of preventing STIs as part of overall health
   - Stress the importance of preventing STIs as part of public health (health of everyone in the country)
   - Stress the importance of preventing STIs as part of global health (health of everyone in the world)
   - Other (please specify): _____

6. **Which aspects of the vaccine should be emphasised in communications to ensure acceptance and understanding?**
   - The safety and efficacy of the men b vaccine
   - The potential long-term benefits of preventing gonorrhoea
   - Information on the current rates of gonorrhoea and antimicrobial resistance
   - The integration of the vaccine into the existing vaccination schedule
   - Success stories or evidence from similar vaccination programs
   - Other (please specify): _____

Information to Provide

7. **What specific information about gonorrhoea should be included in educational materials?**
   - Current number of gonorrhoea cases
   - Symptoms and health consequences of gonorrhoea
   - Information on antimicrobial resistance and treatment challenges
   - How gonorrhoea is transmitted and prevented
   - The benefits of early vaccination and its impact on public health
   - The impact of gonorrhoea on health in developing countries
   - Other (please specify): _____

8. **What specific information about the men b vaccine should be included?**
   - How the vaccine works and how well it works
   - Potential side effects and safety
   - The process and schedule for vaccination
   - Any known interactions with other vaccines
   - Comparisons to other STI prevention methods
   - Other (please specify): _____

Delivery Methods

8. **What methods would be most effective for delivering educational content to you?**
    - School/college/university-based programs and presentations
    - Peer-led education sessions
    - Online resources and interactive tools
    - Educational videos and social media campaigns
    - Health education classes or modules
    - Other (please specify): _____

Current information sources

9. **If you wanted to get information about vaccines and STIs, where would you get this from? (Select all that apply)**
    - School/College/University
    - Parents/Guardians
    - Friends
    - Social Media
    - Health Professionals (e.g., doctors, nurses)
    - Websites
    - Other (please specify):
    - Prefer not to say

10. **How much do you trust the following sources for information about vaccines and STIs?**

    - School/College/Universities
        1. Not at all
        2. A little
        3. Moderately
        4. Very much
    - Parents/Guardians
        1. Not at all
        2. A little
        3. Moderately
        4. Very much

    - Friends
        1. Not at all
        2. A little
        3. Moderately
        4. Very much

    - Social Media
        1. Not at all
        2. A little
        3. Moderately
        4. Very much

    - Health Professionals (e.g., doctors, nurses)
        1. Not at all

2. A little
3. Moderately
4. Very much

- Websites
    1. Not at all
    2. A little
    3. Moderately
    4. Very much

11. How easy do you find it to get information about vaccines or STIs from each of the following sources?

- School/College/Universities
    1. Not at all easy
    2. Slightly easy
    3. Moderately easy
    4. Very easy

- Parents/Guardians
    1. Not at all easy
    2. Slightly easy
    3. Moderately easy
    4. Very easy

- Friends
    1. Not at all easy
    2. Slightly easy
    3. Moderately easy
    4. Very easy

- Social Media
    1. Not at all easy
    2. Slightly easy
    3. Moderately easy
    4. Very easy

- Health Professionals (e.g., doctors, nurses)
    1. Not at all easy
    2. Slightly easy
    3. Moderately easy
    4. Very easy

- Websites
    1. Not at all easy
    2. Slightly easy
    3. Moderately easy
    4. Very easy

Section 5: Final Thoughts

1. Do you have any additional comments or thoughts about gonorrhoea vaccination for young adults?

Thank you for taking part in our survey – we really appreciate it.

Once we have analysed all the data, our findings will be available on www.ovg.ox.ac.uk

We will also be conducting semi-structured interviews to explore the topics covered in this survey in more depth. We will be conducting c20 interviews. If you would like to be contacted to potentially take part in an online interview, please include your email address below.

Appendix 19

NAVIGATE: Navigating Attitudes to Vaccination Implementation for Gonorrhoea in the UK: Acceptability, Trust and Engagement

INTERVIEW PARTICIPANT INFORMATION SHEET

Central University Research Ethics Committee Approval Reference: [Ethics Approval MSD IDREC 947232]

1. Introductory paragraph

Thank you for taking part in our previous survey; you are now being invited to take part in a short interview to expand upon some of your answers. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

2. Why is this research being conducted?

The UK government is considering a vaccination programme to prevent gonorrhoea, a sexually transmitted infection, primarily targeting gay and bisexual men and other men who have sex with men (GBMSM) – this is because they are at a higher risk of infection from gonorrhoea. Studies have shown that the vaccine usually used to prevent meningitis in young children, can offer some protection against gonorrhoea.

It's important to understand what people think about vaccination against gonorrhoea, if they would accept the vaccine, what information they would need to make this decision, and how to make it easy for the vaccine recipients to receive the vaccine logistically.

To do this, researchers plan to ask questions to gather information from different perspectives to help make decisions about the vaccine programme. By understanding what people think, and if they would find this programme acceptable, researchers can make sure the programme is effective and well-received by the public if it goes ahead.

3. Why have I been invited to take part?

You have been invited to take part in this research because you have identified as a user of sexual health services, aged 18 years and over, and have expressed interest in taking part in an interview to expand upon the answers you gave in your survey.

4. Do I have to take part?

No. It is up to you to decide whether to take part. You can withdraw yourself from the research without giving a reason.

5. What will happen to me if I take part in the research?

If you decide you would like to continue and take part in the interview, we will arrange a time that's mutually convenient to carry out the interview. This will be conducted online and will last roughly 30-45 minutes, but we will schedule up to 60 mins as a precaution. You will be asked verbally whether you consent to take part during the interview. You can decline to answer any question or end the interview at any time you wish.

With your consent, an audio recording of the interview will be made to ensure we have an accurate note of your views and we may quote you anonymously. The recording will be made using a separate audio recording device – the teams call will not be recorded. If you do not consent to take part, the interview will not go ahead. All your responses will be stored using a unique participant number only. We will not record your name or any other identifiable information with your responses.

6. What are the possible disadvantages and risks in taking part?

In this interview, we will ask you questions about a potential vaccination programme against gonorrhoea, therefore, topics around sexually transmitted infections will be discussed. We understand that some people might find this topic embarrassing or difficult to talk about, but you can choose not to answer any of the questions and end the interview at any moment.

7. Are there any benefits in taking part?

It is hoped that this research will inform discussions around the potential gonorrhoea vaccination programmes.

8. Expenses and payments

You will receive a £25 e-gift card for taking part.

9. What information will be collected and why is the collection of this information relevant for achieving the research objectives?

We are interested in the thoughts of various groups of people about how acceptable, and how feasible, an adolescent gonorrhoea programme would be. We also want to find out what information you would like to receive about this vaccination, and how you would like to receive, should this programme go ahead. We will be asking questions to this effect.

We will collect this data via audio recordings which will be transcribed. We will store both the audio file and the transcription on a secure, university-encrypted drive. Once the recordings have been transcribed, the original audio recording will be deleted.

We will store your email address and consent form on a password-protected drive on the secure university server. These will be deleted 3 years after the study is completed.

The research team (including the researchers and supervisors) will have access to the research data. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the research.

10. Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research will be written up into a thesis, academic papers, conference presentations, or other publication methods, such as poster presentations etc. Policy recommendations will also be written and delivered to the government as a result of this research. This will ensure that if this vaccine program does go ahead, it will be informed by the thoughts of the people the program is aimed at. No personally identifiable data will be published.

A copy of my thesis will be deposited both in print and online in the Oxford University Research Archive where it will be publicly available to facilitate its use in future research.

11. Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the research. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from the University's Information Compliance website at https://compliance.admin.ox.ac.uk/individual-rights.

12. Who is funding the research?

This research is funded by the National Institute for Health and Care Research (NIHR)

13. Who has reviewed this research?

This research has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: **MSD IDREC 947232)**.

14. Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this research, please contact Prof Katrina Pollock, Principal Investigator, or Charlie Firth, DPhil Student, and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) team at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

15. Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Prof Katrina Pollock
MRC Clinician Scientist in Vaccinology, Honorary Consultant in Sexual Health.
katrina.pollock@paediatrics.ox.ac.uk

Charlie Firth
DPhil Student
charlie.firth@paediatrics.ox.ac.uk

Department of Paediatrics, Oxford University
Level 2, Children's Hospital, John Radcliffe
Headington, Oxford, OX3 9DU

Appendix 20

NAVIGATE: Navigating Attitudes to Vaccination Implementation for Gonorrhoea in the UK: Acceptability, Trust and Engagement

Sexual Health Service User Interview Guide

Introduction and Consent Confirmation

- Briefly introduce the purpose of the interview and reassure confidentiality and take consent for audio recording. " Can you please confirm you are happy for me to record our conversation using an external audio recorder? I will then make a note of this consent, and send you the completed consent form after our conversation".
- Thank you for taking part in this interview about your views on a potential vaccination program for adolescents to prevent gonorrhoea.

Section 1: General Attitudes Toward Vaccination (VAX)

General Vaccination Perceptions

- Can you share your general thoughts about vaccines?
- How do you feel about the role of vaccines in preventing diseases?
- Do you trust vaccines to protect against serious illnesses?

Section 2: Attitudes Toward Sexual Health Vaccination

STI Perceptions

- How serious do you think sexually transmitted infections (STIs) are for individuals and the community as a whole?
- How do you feel about the current methods available for preventing STIs? Are they effective enough?

STI Vaccine Acceptance

- If vaccines were available to prevent STIs, how supportive would you be of making them part of routine healthcare?
- What are your thoughts on the safety and effectiveness of STI vaccines in general?

Gonorrhoea Vaccine-Specific Questions

- How comfortable or willing would you be to get a vaccine specifically for gonorrhoea?
- How do you perceive the severity of gonorrhoea symptoms and its resistance to treatment? Does this affect your willingness to get vaccinated?
- Would the opinions of family and friends influence your decision to get a gonorrhoea vaccine?

Section 3: Attitudes Toward a Potential Gonorrhoea Vaccination Program

General Support for a Gonorrhoea Vaccination Program

- Would you generally support a gonorrhoea vaccination program, particularly for high-risk individuals or adolescents?

Concerns About a Gonorrhoea Vaccine Program

- Do you have any thoughts regarding the safety or effectiveness of a gonorrhoea vaccine?

- How would you feel about taking a vaccine that offers less than 50% protection?
- Do you think that the acceptability of taking a vaccine that offers lower levels of protection against gonorrhoea is higher when the vaccine also offers protection against another disease too? Why/why not?
- What are your thoughts on the use of a low efficacy vaccine if it is already licensed and used in babies, and therefore there are data available regarding the safety in a general population?
- Do you think that having a gonorrhoea vaccine available might encourage risky sexual behaviours? Why or why not?

Section 5: Implementation and Accessibility

Convenience and Accessibility

- How important is it for you that getting vaccinated is convenient (e.g., easy booking, location accessibility)?

Appointment Preferences

- How would you prefer to book an appointment for a vaccination: online, walk-in, phone, or referral?

Preferred Locations

- Where would you feel most comfortable getting a gonorrhoea vaccine? (Pharmacies, GP surgeries, sexual health clinics, etc.)

Cost Coverage

- How important is it to you that the cost of the gonorrhoea vaccine is covered by public health services?
- Have you ever received private health services? Would you pay for a gonorrhoea vaccine?

Section 6: Vaccine Communication and Education

Education and Information Needs

- What type of information would you need to feel informed about a gonorrhoea vaccine (e.g., details about the vaccine, facts about gonorrhoea)?

Preferred Educators

- Who would you trust most to deliver information about the vaccine? (Healthcare workers, teachers, peer educators, online resources)

Message Framing

- What kind of messages would you find most persuasive about getting a gonorrhoea vaccine? (e.g., dual protection against gonorrhoea and meningitis, routine healthcare inclusion, impact on global health)

Delivery Methods

- How should education about a gonorrhoea vaccine be delivered? (prompts: school programs, peer-led sessions, online tools, social media)

Section 7: Current Information Sources

Sources of Information

- Where do you currently get your information about sexual health and vaccines? (School, parents, social media, health professionals, websites)

Trust in Information Sources

- Which sources of information do you trust most? (School, parents, friends, social media) Why?

Closing Remarks

- Thank the participant for their time and input.
- Ask if they have any final thoughts or questions about gonorrhoea vaccination.
- Remind them they can reach out if they want to discuss anything further or access more information.

NAVIGATE: Navigating Attitudes to Vaccination Implementation for Gonorrhoea in the UK: Acceptability, Trust and Engagement

Consent Form

Appendix 21

Name of Researcher: *If you agree, please initial box*

1. I confirm that I have read the information sheet dated..... (version.....) for this study. I have had the opportunity to consider the information, ask questions, and have these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, up until the point of anonymisation of the recording. This will be directly after the interview has completed.	
3. I understand who will have access to my personal data that I have provided, how the data will be stored, and what will happen to the data at the end of the project.	
4. I understand the extent to which I could be identifiable from any publications or academic presentations resulting from this study.	
5. I consent to the interview being audio recorded.	
6. I understand how audio recordings will be used in research outputs	
7. I agree to the use of none-identifiable quotations to be used in research outputs	
8. I understand how to raise a concern or make a complaint	
9. I agree to take part.	

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Name of Person taking Consent	*Date*	*Signature*