



FACTORS INFLUENCING THE POTENTIAL INTRODUCTION OF A GONORRHOEA
VACCINE IN SOUTH AFRICA.

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Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of
Master of Science in Medicine in the field of Vaccinology.

DECLARATION

I Bafana Sydwell Mdhuli declare that this Research Report is my own, unaided work. It is being submitted for the Degree of Master of Science in Medicine in the field of Vaccinology. at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



(Signature of candidate)

_____ 28 ____ day of ____ October _____ 20_25 _____ in ____ Johannesburg _____

DEDICATION

In memory of my late father
Nkosinathi Kingsley Mdhuli
(1967/03/28 – 2023/12/16)
Thank you for everything.

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I would like to extend my heartfelt appreciation to all the participants who graciously contributed their time and provided invaluable insights to this study. Their willingness to share made this work possible.

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ABSTRACT

Gonorrhoea is a major public health concern due to its high prevalence, rising antimicrobial resistance (AMR), and the limits of current syndromic treatment (SM) in low- and middle-income countries (LMICs). As such, it is essential to develop vaccines to control and prevent gonorrhoea. This qualitative study sought to explore health system perspectives on factors most likely to influence the introduction of a gonorrhoea vaccine. Purposive sampling was used to conduct in-depth interviews with health care providers (n = 6) and key informants (n = 6) with expertise in vaccines and/or STI prevention and control. Participants discussed gonorrhoea incidence, challenges with detecting asymptomatic cases, and the importance of AMR for vaccine development. They identified potential barriers to gonorrhoea vaccine introduction included sexually transmitted infections (STIs) related stigma, insufficient healthcare infrastructure, vaccine hesitancy, and financial resources. Integrating a vaccine into current immunization platforms like the Expanded Programme on Immunisation (EPI) and school-based HPV vaccination, might boost practicality, while a phased rollout focusing on high-risk groups could refine tactics for broader deployment. Precise, localized disease surveillance and intersectoral coordination are crucial to improve logistical preparation and policy support. Overall, the study suggests that a gonorrhoea vaccine could be used to lower gonorrhoea rates and limit AMR in South Africa if stakeholders address finance, healthcare capacity, and societal acceptability. By identifying these enablers and impediments, this study provides useful insights that will guide strategic planning for the future introduction of a gonorrhoea vaccine in South Africa.

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Nomenclature

AMR	Antimicrobial Resistance
CDC	Centers for Disease Control and Prevention
ECVP	Evidence Considerations for Vaccine Policy
EPI	Expanded Programme on Immunisation
GARDP	Global Antibiotic Research and Development Partnership
GBV	Gender-Based Violence
HCP	Healthcare Provider
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
HPCSA	Health Professions Council of South Africa
KI	Key Informant
LMICs	Low-and Middle-Income Countries
MenACWY	Meningococcal vaccine serogroups A, C, W, Y
MenB	Meningococcal B
MSM	Men who have Sex with Men
<i>N. gonorrhoeae</i>	<i>Neisseria gonorrhoeae</i>
NAGI	National Advisory Group for Immunisation
NDoH	National Department of Health
NGO	Non-Governmental Organization
NICD	National Institute for Communicable Diseases
NITAG	National Immunization Technical Advisory Group
PDVAC	Product Development Vaccines Advisory Committee
PrEP	Pre-Exposure Prophylaxis
RCT	Randomized Controlled Trial
SAGE	Strategic Advisory Group of Experts
SAHPRA	South African Health Products Regulatory Authority
SANC	South African Nursing Council
SAPC	South African Pharmacy Council
STI	Sexually Transmitted Infection
WHO	World Health Organization

CHAPTER 1: Introduction

1.1 Introduction

1.1.1 Incidence and demographic factors of gonorrhoea

The World Health Organisation (WHO) estimates that among individuals aged 15 to 49, gonorrhoea causes 82.4 million new cases worldwide each year (WHO, 2024). Research indicates that the age group between 25 and 34 years old has the highest recorded incidence of gonorrhoea infections worldwide with 37% of cases reported, while those between the ages of 20 to 24 years account for 22% and 35 to 44 years account for 19% (European Centre for Disease Prevention and Control, 2024). (CDC, 2024). Moreover, females are more commonly diagnosed than males, a phenomenon that could be attributed to biological disparities and inequalities that impact healthcare-seeking behaviour (Unemo et al., 2017). When compared to other regions, Sub-Saharan Africa has the highest rates of gonorrhoea incidence (Zheng et al., 2022; Lin et al., 2021). The National Institute of Communicable Disease (NICD) reported an estimate of 2.3 million new cases of gonorrhoea in South Africa during the year 2017 (kularatne et al., 2018).

1.1.2 Pathophysiology of gonorrhoea

Gonorrhoea is a sexually transmitted infection (STI) caused by the bacterium *Neisseria gonorrhoeae* (*N. gonorrhoeae*) (Vicentini et al., 2019). *N. gonorrhoeae* primarily affects the mucous membranes of the urogenital tract, but it can also infect the mouth, throat, eyes, and rectum (WHO, 2023). The infection is transmitted through sexual contact, including vaginal, anal, and oral sex. This pathogen was first identified by Albert Neisser in 1879 (Vicentine et al., 2019). Although the infection is usually asymptomatic, gonorrhoea is associated with substantial morbidity and some serious complications particularly in women, including pelvic inflammatory disease, chronic pelvic pain, ectopic pregnancy, and infertility (Whelan et al., 2021). Additionally, *N. gonorrhoeae* infection during pregnancy can lead to adverse neonatal outcomes, including severe conjunctivitis, low birth weight, preterm birth, and neonatal sepsis, which can be life-threatening (Vallely et al., 2021).

1.1.3 Antimicrobial resistance challenge in gonorrhoea.

In 2013, the Centre for Disease Control (CDC) established a priority list of antibiotic-resistant microorganisms. This list divided 18 drug-resistant infections into three crisis categories:

urgent, serious, and concerning. is included among the urgent category of bacteria, requiring prompt and vigorous intervention owing to the gravity of the harm they represent (CDC, 2013). Lin et al., (2021) suggested that the bacterium's survival over time is due to its ability to evade anti-microbial agents, as well as the immune system. Recognising the severe challenge of antibiotic resistance, the WHO has named *N. gonorrhoeae* as one of the top ten infections that require immediate attention to develop novel and effective therapies (WHO, 2017).

South African research has shown substantial resistance of *N. gonorrhoea* to older antibiotics such as penicillin, tetracycline, and ciprofloxacin, as well as resistance to newer ones such as azithromycin (Kularatne et al., 2018; Yakobi et al., 2024). This may likely be as a result of inappropriate use of antibiotics. At present, gonorrhoea in South Africa is susceptible to ceftriaxone (Peters et al., 2022).

1.1.4 Limitations of syndromic treatment of STI and inappropriate use of antibiotics in South Africa

According to McKeever (2023), South Africa is the most economically unequal nation in the globe. Denyer Willis and Chandler (2019), made claims that the inappropriate use of antibiotics is significantly influenced by inequality and a lack of resources. It is probable that clinicians will prescribe antibiotics as a "quick fix" for inequalities in economically deprived individuals who are unlikely to return to the clinic for ongoing care.

Syndromic management (SM) is the current approach to diagnosing and treating sexually transmitted infections (STIs) in South Africa, including gonorrhoea (Peters et al., 2022). SM relies on the recognition and reporting of symptoms to prompt treatment, yet it lacks sufficient specificity—particularly for cervical infections in women—and thus often leads to overtreatment (Sharma & Gupta, 2019). For instance, women with vaginal discharge may receive antibiotics even when gonorrhoea or other bacterial pathogens are not present. In parallel, SM also risks missing infections that are asymptomatic or unrecognised; asymptomatic infection is common, especially among women and young people, who may not seek care because of stigma, lack of awareness, or failure to recognise symptoms (Newton-Levinson et al., 2016). These factors contribute to both overtreatment (and therefore potential misuse of antibiotics) and missed diagnoses. According to Kularatne et al. (2018), the absence of any sustained decrease in prevalence of gonorrhoea and chlamydia in South Africa since the introduction of SM underscores the need to re-evaluate this approach. Over time, the repeated

use of antibiotics in cases where gonococcal infection is not actually present can contribute to the broader development of antibiotic resistance.

1.1.5 Could a vaccine for Meningitis B be effective against gonorrhoea?

In clinical trials, no vaccine candidate for *N. gonorrhoeae* to date has demonstrated efficacy (Jefferson et al., 2021). The key reasons for this include the pathogen's numerous immune evasion techniques, the lack of an animal model that fully replicates the disease's natural course, and our inadequate understanding of the conditions required to generate a robust immune response (Whelan et al., 2021). Vaccines provide protection against specific diseases however their effects may occasionally surpass their intended scope. Several studies, including case-control and cohort designs, have found that individuals who received the OMV based vaccines against men B showed a 30-40% decrease in gonorrhoea diagnosis compared to unvaccinated controls (Abara et al., 2022; Ladhani et al., 2024; Ong et al., 2022).

The initial studies indicating a correlation between MenB vaccination and a decrease in gonorrhoea rates originated from New Zealand, where a case-control study evaluating data from a national MenB vaccination initiative revealed a 31% vaccine efficacy in lowering gonorrhoea rates (Petousis-Harris et al., 2017). Subsequent studies from numerous countries have confirmed similar findings, with varied levels of efficacy depending on vaccination type and research design (Table 1.1). For example, a Norwegian ecological study revealed that the MenBvac vaccination was 40% effective (Whelan et al., 2016), but a Canadian ecological study indicated that the 4CMenB vaccine was 59% effective (Longtin et al., 2017). In the United States (USA), Abara et al. (2022) and Bruxvoort et al. (2022) showed 40% and 46% efficacy rates, respectively. These two studies used distinct case-control and matched cohort research methods respectively. Wang et al. (2022) conducted an Australian case-control study and discovered efficacy rates between 33 and 34% for 4CMenB against gonorrhoea. Case-control research done in Italy among males living with HIV Show a 42% effectiveness (Raccagni et al., 2023). Even though other studies, such as those done by Pérez et al., (2009) in Cuba, did not publish efficacy rates, they do show the potential benefit of MenB vaccinations on gonorrhoea prevalence reduction.

Table 1.1 Observational evidence for MenB vaccine against N. Gonorrhoea

Location	Study Author(s), Year	Study Design	Vaccine	Effectiveness Against NG (%)
Cuba	Pérez et al., 2009	Ecological	VA-MENGOC-BC	Not reported

Location	Study Author(s), Year	Study Design	Vaccine	Effectiveness Against NG (%)
Norway	Whelan et al., 2016	Ecological	MenBvac	40
New Zealand	Petousis-Harris et al., 2017	Case control	MeNZB	31
Canada	Longtin et al., 2017	Ecological	4CMenB	59
USA	Abara et al., 2022	Case control	4CMenB	40
Australia	Wang et al., 2022	Case control	4CMenB	32
USA	Bruxvoort et al., 2022	Matched cohort	4CMenB	46
Italy	Raccagni et al., 2023	Case control	4CMenB	42

OMV-based vaccines employ outer membrane vesicles naturally shed by *Neisseria* to present multiple surface antigens in a near-native conformation, often alongside recombinant subcapsular proteins to broaden coverage. Current MenB vaccines exemplify this platform: 4CMenB includes an OMV component plus recombinant antigens, whereas other products rely primarily on recombinant proteins. The explanation for the effectiveness of MenB vaccines against gonorrhoea may be attributed to the similar biological features between *N. meningitidis* and *N. gonorrhoeae*. These bacteria demonstrate considerable genetic and structural similarity, especially in their outer membrane vesicles (OMVs) and the Neisseria Heparin Binding Antigen (NHBA) (Marjuki et al., 2019). The 4CMenB vaccine comprises both outer membrane vesicles (OMVs) and Neisseria heparin-binding antigen (NHBA), which possess homologous proteins in *N. gonorrhoeae*, suggesting a potential mechanism for cross-protection. Numerous investigations corroborate this view. Sera from people immunized with 4CMenB demonstrate cross-reactivity with *N. gonorrhoeae*, identifying several conserved antigens, including as PilQ, BamA, MtrE, NHBA, PorB, and Opa (Leduc et al., 2020; Petousis-Harris et al., 2017).

Furthermore, research on mice by Leduc et al. (2020) revealed that 4CMenB-immunized animals exhibited enhanced clearance of *N. gonorrhoeae* and decreased bacterial load in both the upper and lower reproductive tracts. This protection correlated with a four-fold elevation in serum bactericidal titers, as well as serum IgG and vaginal IgA/IgG responses, indicating both systemic and mucosal immunity against *N. gonorrhoeae*. The immunological responses, facilitated by vaccine-induced antibodies, likely enhance serum bactericidal activity against gonococcal infections. While 4CMenB is not explicitly intended for gonorrhoea prevention, cross-protective immunity may be utilized in future vaccine

development, potentially improving the efficacy of gonorrhoea-specific vaccines by including conserved antigens such as NHBA and OMV proteins. Considering the escalating threat of antibiotic-resistant *N. gonorrhoeae*, investigating meningococcal vaccinations as a technique for gonorrhoea prevention may yield significant public health advantages.

While observational evidence indicates that the Men B vaccine may contribute to a reduction in gonorrhoea rates, strong evidence from randomized controlled trials (RCTs) is crucial for informing policy decisions, and such trials are presently in progress. WHO's Product Development for Vaccines Advisory Committee (PDVAC) emphasized the necessity for RCTs evidence in its 2023 recommendations (PDVAC, 2023), particularly in women in LMIC who bear the burden of disease, as well as among people living with HIV. Multiple RCTs are currently in progress to evaluate the efficacy of the 4CMenB vaccine against *N. gonorrhoeae* (Table 1.2). These studies encompass a variety of populations and settings, including Australia, the United States, Thailand, Malawi, Hong Kong, and South Africa.

Table 1.2 Trials of 4CMenB efficacy vs *N. gonorrhoeae*

Trial Number	Study Name	Location, Number	Expected Completion
ACTRN12619001478101	MenGO: Does the licensed meningococcal vaccine Bexsero® provide cross-protection against gonorrhoea?	Australia, 130	2025
NCT04415424	GoGoVax: Efficacy study of 4CMenB Bexsero® to prevent gonorrhoea infection in gay and bisexual men	Australia, 730	2025
NCT04350138	MAGI: Safety and efficacy study of meningococcal group B vaccine rMenB+OMV NZ Bexsero to prevent gonococcal infection	USA, Thailand, Malawi, 2,200	2026
NCT05766904	Efficacy Trial on Meningococcal B Vaccine for Preventing Gonorrhea Infections	Hong Kong, 150	2025
NCT05294588	Efficacy of Immunization With 4C-MenB in Preventing Experimental Urethral Infection With <i>N. gonorrhoeae</i>	USA, 140	2028
	BIYELA: efficacy 4CMenB vaccine for gonorrhoea prevention in individuals assigned female at birth	South Africa, 1,100	2026

Modelling studies by Baba et al. (2024) indicate that a vaccine with low efficacy may still provide substantial benefits. Modelling studies indicate that a vaccine that provides 25% efficacy with 10% annual uptake and five-year protection could halve *N. gonorrhoeae* prevalence within a decade if administered to all individuals aged 15–49 (Padeniya et al., 2023). In parallel, MSM-focused clinic-delivery models indicate that a vaccine offering moderate protection (~60%) with a 10-year duration would still yield >30% reductions in gonorrhoea burden within 10 years (Whittles et al., 2020; Whittles et al., 2022).

In South Africa, *Neisseria meningitidis* serogroup B is the leading cause of invasive meningococcal disease, with a notable bimodal distribution of cases—peaking in early childhood and again in adolescence (Meiring et al., 2017). Until recently, the only approved meningococcal vaccines were polysaccharide-protein conjugates targeting serogroups A, C, W, and Y (MenACWY) (WHO, 2021). Given the relatively low incidence of invasive meningococcal disease, MenACWY vaccination has not been included in the Expanded Program on Immunization (EPI) because it is not considered cost-effective under current conditions (Meiring et al., 2017). However, the MenB vaccine, Bexsero, was approved by the South African Health Products Regulatory Authority (SAHPRA) in 2023 for prevention against meningitis caused by men B (SAHPRA, 2023). Should forthcoming evidence confirm that Bexsero also protects against *N. gonorrhoeae*, this additional benefit might substantially enhance cost-effectiveness and support its inclusion in the EPI to prevent both MenB and gonorrhoea (Gray et al., 2022). Evidence from the United Kingdom shows that the cost-effectiveness of MenB vaccination is highly price-sensitive, with modelled value for money shifting markedly as the per-dose price changes and the Joint Committee on Vaccination and Immunisation (JCVI) recommended that use of the vaccine in high risk for cost effectiveness (JCVI, 2014; Christensen, Trotter, Hickman, & Edmunds, 2014). South Africa's programme costs will there largely hinge on the negotiated price per dose. At present, there is no public Bexsero tender price for South Africa.

Vaccine adoption rates vary greatly throughout the world, with LMICs and regions such as Africa frequently encountering major barriers to universal immunisation. There is little information on the prioritisation and willingness to introduce a gonorrhoea vaccine in many LMICs (Wallace & Kipiriri, 2017). While global immunisation programmes have made significant progress in reducing child mortality from preventable diseases, disparities remain. LMICs often face constraints such as limited healthcare infrastructure, vaccine

hesitancy, and inadequate funding, which hinder optimal vaccine coverage (WHO, 2022). Additionally, conflicts, logistical challenges in reaching rural communities, and disinformation campaigns further restrict vaccine uptake, particularly in Africa (Ghebreyesus, 2021). To address these challenges, the WHO recently conducted a vaccine prioritisation exercise to guide the introduction of new vaccines based on disease burden, feasibility, and cost-effectiveness (Hasso-Agopsowicz et al., 2024). As research into the 4CMenB vaccine for *N. gonorrhoeae* progresses, understanding and overcoming these adoption challenges will be essential to ensuring equitable access and impact.

1.2 Literature Review

1.2.1 Summary of key studies addressing vaccine introduction

Research on vaccine introduction in LMICs particularly SSA is limited, with studies highlighting various challenges and facilitators. This literature review consolidates existing studies, identifying trends, gaps, and areas requiring further exploration, particularly within the South African context. Table 1.3 summarizes key studies addressing vaccine introduction in LMICs, highlighting their designs, involved populations, and main findings.

Table 1.3 Summary key studies addressing vaccine introduction.

Year	Author(s)	Location/Scope	Study Design	Populations (n)	Vaccine(s)	Key Findings
2006	Wright et al.	Global review	Review-based ana	Not stated	Vaccines in general.	- Identified the following crucial factors influencing vaccine introduction: - Vaccine purchase - Service delivery - Finance policies - Political will
2010	Piñeros et al.	Colombia	Qualitative (In-depths interview)	Polymakers, Health officials (n=14)	HPV	- Political pressure significantly influenced HPV vaccine introduction, often overriding technical guidelines. - Equity and knowledge gaps were challenges.
2012	Makinen et al.	12 LMICs, 3 UMICs	Qualitative (Semi-structured interview)	Polymakers, NITAG members (n=208)	Hib, pneumococcal conjugate, rotavirus and HPV	- Key factors for vaccine adoption include: - WHO recommendations - Availability of local epidemiological data - Affordability - Cost-effectiveness, and overall programme cost - NITAGs play a crucial advisory role, though their resources and capacities differ across countries. - Both country decision-makers and vaccine manufacturers view pooled procurement mechanisms as beneficial for vaccine purchases. - Recommendations for countries and the international community: - Improve access to epidemiological data and vaccine market information. - Build and strengthen countries' analytical capacities. - Support effective purchasing mechanisms, including pooled procurement
2012	Burchett et al.	Bangladesh, Cameroon, Guatemala, Kenya, South Africa	Qualitative	Decision-makers, (n=95)	WHO recommended vaccines.	- Political factors and donor dependence strongly influenced vaccine adoption, often over technical recommendations. - International initiatives can support evidence-based decisions, but their effectiveness should be demonstrated, not taken for granted.
2018	Delany-Morethwe	South Africa	Program evaluation	Healthcare system (n=34)	HPV	- Highlighted the importance of strong healthcare system preparedness, including. - Cold chain management - Strong leadership - Preparedness for misinformation spread via social media about HPV vaccination
2019	Sambala et al.	Africa	Review and analysis	Polymakers/ Vaccinees (n=46)	Hib, IPV, HPV, Rotavirus, Varicella, PCV 13	- Financial sustainability and logistical constraints critical - Gavi funding essential but potentially unsustainable. - Recommended regional manufacturing
2021	Otieno et al.	Kenya	Qualitative (Interviews)	Policy makers and (n=29)	Maternal Vaccines	- Decentralization impacted maternal vaccine policy implementation. - Highlighting communication gaps and sociocultural barriers
2022	Castañeda-Orjuela	Latin America and	Cross-sectional survey	EPI managers (n=26)	HPV	- High disease burden and cost-effectiveness prioritized. - Equity concerns noted. - Recommended stronger NITAGs
2024	Chawana et al.	Africa	Multiple case study	Vaccine manufacturers (n=18)	Vaccines in general	- Institutional dynamics (regulations, profitability, affordability) influenced vaccine production and distribution. - Regional production essential

n refers to number of participants in the study.

1.2.2 Policy and Decision Making

Policy decisions are not solely driven by data and evidence but are also shaped by a range of social, institutional, economic, and political factors. Makinen et al. (2012) conducted a qualitative study based on KI interviews in 15 countries, including 12 LMICs and 3 UMICs, and concluded that WHO recommendations and NITAGs typically govern vaccine implementation decisions. This was supported by Castañeda-Orjuela et al. (2022), who found that decision-making frameworks mostly rely on global health organizations such as the WHO. Given such, and the WHO's position on the gonorrhoea vaccine, consideration for adoption would be possible.

In contrast, Burchett et al. (2012) argues that it is not the case for most donor dependent countries in LMICs, and that political influence and Gavi eligibility had a significant impact on vaccination acceptance, often surpassing technical advice, in a survey of 95 key informants from Bangladesh, Cameroon, Ethiopia, Guatemala, Kenya, Mali, and South Africa. Similarly, Piñeros et al. (2010) found that the introduction of HPV vaccination in Colombia was mostly political, disregarding scientific advice (Guillaume et al., 2022).

In South Africa, NAGI makes submissions to National Health Council (NHC) through the director-general or their deputy (National Department of Health, Republic of South Africa, 2020). The law in South Africa dictates that the Minister of Health and the Director-General have the responsibility of establishing main health priorities which are guided by the advice of NAGI, through the NHC (Hofman et al., 2015; National Health Act No. 61 of 2003, 2004). Even though these systems are in place, decision makers are said to commonly deviate from the advice given by these structures. For example, in 2007 advice was given to the then minister of health in South Africa to only introduce pneumococcal vaccine to the EPI in 2010, after NAGI reviewed evidence for pneumococcal and rotavirus vaccines. However, the minister announced at the World Health Assembly in 2008, that both vaccines will be rolled out within three months. This phenomenon was observed by Burchett et al. (2012) in her research, where she further contends that political pressures such as upcoming elections or poor performance on Millennium Development Goals (MDGs) often take precedence over technical rationale in LMICs, thus reflecting an overemphasis on political considerations. This shows us that while scientific evidence would be important to convince NITAG structures such as NAGI, to convince the South African government to adopt gonorrhoea vaccine will require further steps

such as political briefs that pairs scientific evidence with political ambitions both locally and internationally.

1.2.3 The importance of the disease and the burden

Accurate, current, and locally relevant epidemiological data on vaccine-preventable diseases are critical for guiding decision-making processes around vaccine introduction (Van Der Putten et al., 2019; Guillaume et al., 2022; Mantel & Wang, 2012; MacPhail et al., 2013). Researchers argue that such localized or regional data allow advisory bodies, NITAGs and EPI managers, to effectively prioritize interventions based on genuine need and allocate resources optimally, particularly to the most vulnerable populations (Nevhuthalu et al., 2001; Coetzee et al., 2021). Makinen et al. (2012) reinforces this viewpoint, highlighting that strengthening epidemiological analysis significantly impacts NITAG recommendations and subsequent vaccine introduction decisions. Similarly, Castañeda-Orjuela et al. (2022) identified disease burden as one of the primary criteria influencing vaccine prioritization, although they noted persistent challenges regarding data quality. Sambala et al. (2019) further affirms that robust disease burden data have been crucial in informing vaccine introductions across Africa, impacting both financial investment and logistical planning. Additionally, Otieno et al. (2021) illustrate that, in Kenya, maternal vaccine policy decisions were strongly driven by disease prevalence and local epidemiological data.

In principle, South African decision-makers should similarly utilize local disease burden data when considering introducing vaccines. Although gonorrhoea may not currently rank highest on priority lists by crude case counts, the combination of high infection and reinfection rates, downstream clinical sequelae, and the direct (and AMR-related) costs of treatment can make a compelling burden case for vaccination. Its connections to maternal and child health further strengthen the rationale. However, despite the theoretical centrality of epidemiological evidence, political factors and prioritization are frequently influential in vaccine adoption decisions in LMICs, including South Africa, often overshadowing technical advice (Guillaume et al., 2022; Burchett et al., 2012).

1.2.4 Financial Sustainability and Economic Considerations

According to Black (2013), as a result of newer vaccinations being more expensive than their older counterparts, economic analyses have gained significance in deciding whether vaccines should be developed or regularly administered. Burchett et al. (2012) claims that financial sustainability is often not considered when introducing vaccines, particularly in LMICs. More

often governments tend to prioritize immediate funding options over long-term planning. Makinen et al. (2012) and Castañeda-Orjuela et al. (2022) found that while affordability and cost-effectiveness are essential, financial sustainability in vaccine introduction remains a challenge. Guignard et al. (2019) also voiced concern that the absence of sustainable financing sources has resulted in inconsistent vaccination efforts. Sambala et al. (2019) suggest that many African countries rely on Gavi funds for vaccine introduction, raising concerns about the program's sustainability if donor aid is discontinued. South Africa's position is comparatively unique, its reliance on foreign funding for vaccine programmes is minimal.

Sambala et al. (2019) further inferred that Africa's reliance on Gavi funding underscores the need for sustainable financing mechanisms. This is echoed by Chawana et al. (2024), who also suggested that regional manufacturing could play a crucial role in improving vaccine access. Guignard et al. (2019) also supported this and claimed that increasing local vaccine manufacturing investment might enhance the long-term affordability and economic viability of immunization programs in LMICs. Guignard et al. (2019) also pointed out that Sub-Saharan African countries that have embraced regional vaccine production have shown improvements in access and affordability. On the other hand, Makinen et al. (2012) claimed that even though the use varies by location, pooled procurement systems across multiple funding entities might assist in overcoming fiscal constraints.

Delivery, administration, and procurement are the cost categories that are most commonly examined and debated in Sub-Saharan Africa, according to De Micco et al. (2022). In South Africa, Amponsah-Dacosta et al. (2020) has demonstrated that the cost of administering vaccines to adolescents is higher compared to the cost of conventional children immunization. This suggests that, for a gonorrhoea vaccine, we should leverage existing platforms such as the EPI, HPV immunisation program and other HIV and SRH programs, both in the public and foreign-funded programmes in order to minimise cost of delivery and administration.

1.2.5 Health Systems and Infrastructure

Strong health systems with effective governance, a skilled workforce, and sustainable funding, are essential for achieving successful immunization programs, as is highlighted in a systematic review conducted by Amponsah-Dacosta et al. (2020). Delany-Moretlwe et al. (2018) underscored the importance of strong healthcare systems with capacity to carefully prepare, effectively coordinate, and maintain strong leadership, in an evaluation of the introduction of the HPV vaccination program in South Africa. Furthermore, the importance of tackling

challenges such as cold chain management, data reporting, and getting informed permission are highlighted (Delany-Moretlwe et al., 2018). Guignard et al. (2019) also highlighted supply chain constraints, such as cold chain demands and challenges with transportation, as significant barriers to vaccination accessibility. This was supported by Sambala et al. (2019), who discovered that logistical difficulties hinder vaccination delivery in several African nations. Wright et al. (2006) further stressed that inadequate infrastructure and poor distribution networks exacerbate these issues. Sub-Saharan Africa faces additional hurdles due to weaker health systems and infrastructure constraints, as noted by multiple studies (Sambala et al., 2019; Guignard et al., 2019). In contrast, Otieno et al. (2021) discovered that in South Africa, decentralized vaccination policies have enabled localized supply chain adjustments that have increased accessibility in certain locations, although coordination gaps persist. This experience suggests that potential supply-chain challenges could be reduced if a gonorrhoea vaccine were adopted.

Guillaume et al. (2022) also emphasized the importance of regional variations in supply chain efficiency, pointing out that certain LMICs have effectively used logistics models to increase distribution.

1.2.6 Equity and sociocultural barriers

Equity and sociocultural factors significantly influence decisions around vaccine introduction and implementation (Burchett et al., 2012). Guillaume et al. (2022) discovered that vaccine hesitancy, disinformation, and sociocultural attitudes had a detrimental influence on immunization introduction. Castañeda-Orjuela et al. (2022) emphasized the need of equality in vaccination distribution, especially among vulnerable communities. In a qualitative analysis of maternal vaccination policies in Kenya, Otieno et al. (2021) discovered that fragmented policy frameworks created communication gaps, hampering vaccine deployment. Similarly, Burchett et al. (2012) found that certain politicians emphasize political concerns over fair vaccination distribution, resulting in discrepancies in coverage. In contrast, well-designed communication methods might reduce these obstacles and increase vaccination acceptability (Guillaume et al., 2022). Piñeros et al. (2010) found that local political power and lobbying can shape public views, affecting vaccination acceptance. In support, Guinard et al. (2019) discovered that vaccination messages adapted to individual sociocultural situations were more successful in raising uptake than conventional worldwide advertising. Taken together, these insights place local authorities such as chiefs, faith leaders, and other community figures at the centre of

gonorrhoea vaccine adoption. Securing their buy-in early can build trust, legitimise the programme, and measurably improve uptake.

1.3 Rationale of the study

The necessity for a gonorrhoea vaccine is escalating due to the rising threat of AMR. AMR diminishes the effectiveness of existing treatments and escalates the need for alternate preventive strategies. The current research on the MenB vaccines is promising, with results anticipated in 2025 or 2026. A vaccine prioritization effort by the WHO highlighted the potential importance of gonorrhoea vaccinations in particular contexts. The WHO PDVAC emphasized the necessity of collecting data on the potential demand and acceptability of vaccinations across various contexts to guide vaccine introduction strategies (WHO, 2023).

Data from countries where there is a significant overlap in the prevalence of meningococcal B and gonorrhoea are particularly important, especially in cases where there is presently no MenB vaccination program in place. These data can determine if a MenB vaccine that targets both MenB and gonorrhoea might impact demand and prioritization, perhaps speeding up vaccination adoption and tackling both illnesses at the same time (Gottlieb et al., 2020).

Moreover, it is crucial to comprehend the determinants that affect the introduction of new vaccines, particularly if the target populations are not part of the traditional infant immunisation program. A range of local stakeholder viewpoints on the acceptability of vaccines, cost-effectiveness, logistical issues, and ethical implications are essential. This information is extremely helpful for identifying current knowledge gaps that might be essential for informing vaccine introduction, customizing implementation strategies to unique settings and ensuring the successful and fair distribution of vaccines.

The data obtained from this research will not only aid in making decisions about the use of 4CMenB vaccines for preventing gonorrhoea, but also provide valuable insights for the creation and application of future vaccines specifically targeting gonorrhoea. This study seeks to fill the existing gaps in knowledge about vaccine introduction in order to give crucial data to guide future policy making around the introduction of effective methods to prevent gonorrhoea and reduce the growing risk of AMR.

CHAPTER 2: METHODOLOGY

2.1 Study Aims and Objectives

2.1.1 Aims

The aim of this study is to describe factors that may influence the potential introduction of a gonorrhoea vaccine within the South African context from health system perspectives.

2.1.2 Objectives

The specific objectives of the study are:

1. To explore the perspectives of healthcare providers and key informants (Program managers, Policy makers and researchers) on the acceptability of a potential vaccine like Bexsero meningococcal B vaccine for gonorrhoea prevention in South Africa.
2. To explore the factors that may influence the introduction and feasibility of implementing a vaccine like the Bexsero meningococcal B vaccine for gonorrhoea prevention in South Africa.

2.2 Research Design

This qualitative study used a critical approach to explore the factors that may influence the introduction and feasibility of implementing the Bexsero menB vaccine or similar vaccine for gonorrhoea prevention in South Africa. A critical approach incorporates the use of theory and frameworks to examine how knowledge is constructed, highlight power relations, and challenge dominant ideologies within research and practice (Bourgeault et al., 2011). The Gavi Evaluation Framework for Endemic Disease Prevention (Gavi Framework) and the Evidence Considerations for Vaccine Policy (ECVP) were used to develop the interview guide and to conduct a deductive rapid analysis (Hamilton & Finley, 2019). Deductive analysis is aligned with a critical approach as it allows researchers to deliberately analyse qualitative data to match pre-existing ideas or conceptual frameworks to data (Braun & Clarke, 2023).

2.3 Sampling and Recruitment

Purposive and snowball sampling were used to recruit healthcare providers (doctors, clinical associates, and nurses) and key informants (program managers, policymakers, and researchers) involved in STI, HIV, and immunization programs in South Africa. The study aimed to recruit healthcare providers with direct experience in immunization programs and/or STI/STD

prevention and management, as their insights are crucial for understanding health system challenges, the impact of STIs on their communities, and the potential benefits of a novel vaccine. Nurses, clinical associates, and medical doctors were included to provide a range of distinct viewpoints regarding the acceptability of a new vaccine. Nurses and clinical associates were included to provide perspectives on patient care, vaccine administration, and health system experiences. Medical doctors were included to offer specific insight regarding the management of STIs, diagnostics, treatment protocols, and policy ramifications.

Pahwa et al. (2023) states that KIs may provide insights on history, policy, and organizational dynamics, while healthcare providers offer insight and perceptions based on prior experiences. Key informant selection was aimed at obtaining insight into factors leading to decision-making on interventions such as a new vaccine, and considerations in the implementation of a novel vaccine. Informants were carefully chosen because of their active participation in health departments and their positions in managing or administering immunization and/or STI/STD programs. This selection provided insight of professionals with direct expertise and practical experience in the formulation and execution of public health policies and initiatives pertinent to the prospective introduction of a new vaccine. In addition, individuals involved in research or the implementation of research outcomes in the domains of immunization or STI/STDs were intentionally incorporated. The key informants from NDoH, provincial departments of health and associated agencies were targeted for inclusion. Moreover, important informants were selected from organizations involved in public health activities or maintaining collaborative partnerships with health departments.

Purposive sampling methods were used to recruit participants. Recruitment proceeded only after obtaining formal institutional permission. Purposive sampling is a technique frequently employed in qualitative research, allowing researchers to deliberately choose participants who possess particular knowledge, experiences, or characteristics pertinent to the research question. This intentional choice enables the gathering of comprehensive, detailed data that aligns with the study's aims (Braun & Clarke, 2013) The initial participants were purposively identified based on their expertise and experience in relevant fields, and they were then encouraged to recommend other potential participants. Through purposeful sampling, the study prioritized a diverse range of professional characteristics, skill sets, and experience within the healthcare provider and key informant categories.

The target recruitment range was 12–20 participants, following qualitative study recommendations by Mellman et al. (2021). The study recruited 12 eligible participants. This final sample size was determined by data saturation, whereby no new themes or insights emerged from additional interviews (Lincoln & Guba, 1985).

Healthcare providers were recruited from various healthcare facilities and organizations in Gauteng Province, South Africa. Permission was granted from regional and provincial Departments of Health, with some permits specifying the clinic facilities from which recruitment could take place. Once permissions were obtained, formal invitations were sent to the approved facilities and specific individuals within them. Recruitment of participants at other private organisations proceeded only after obtaining formal institutional permission. Once granted, formal invitations were sent to these potential participants.

2.4 Theoretical framework

This study was informed by an integrated theoretical framework combining the newly introduced Gavi Evaluation Framework for Endemic Disease Prevention (Gavi Framework) and the Evidence Considerations for Vaccine Policy (ECVP). The Gavi Framework outlines critical factors for prioritizing vaccine introduction into priority countries, such as health impact, economic and social benefits, and global health security, as illustrated in Figure 2.1 (Gavi, 2023). These factors align closely with the elements identified through the literature review as influential in vaccine introduction in LMICs, making them particularly relevant for analysing the introduction of the Bexsero vaccine in South Africa.

The ECVP similarly addresses concepts found within the Gavi Framework, building upon, and expanding WHO Preferred Product Characteristics (PPC) recommendations, which define preferred attributes early in clinical vaccine development for LMICs (Kochhar et al., 2022). The ECVP specifically encourages early engagement and alignment among vaccine development stakeholders, regulatory bodies, policy makers, financial institutions, and national introduction entities (WHO, 2024). Given their complementary nature and practical applicability, both frameworks informed the design of the semi-structured interview guide and guided the analysis conducted in this study.

Ranking criteria:	Criteria	Indicators	Secondary criteria:	Criteria	Indicators
	Health impact	Total future deaths averted 2020-2035, and per 100,000 vaccinated		Other impact	Total U5 deaths averted 2020-2035, and per 100,000 vaccinated
		Total future cases averted 2020-2035, and per 100,000 vaccinated			Total DALYs averted 2020-2035, and per 100,000 vaccinated
	Value for money	Vaccine procurement cost per death averted		Gavi comparative advantage	Vaccine procurement cost per DALY averted
		Vaccine procurement cost per case averted			Degree of vaccine market challenges
	Equity and social protection impact	Disproportionate impact of disease on vulnerable groups		Implementation feasibility	Potential for Gavi support to catalyse additional investment
		Special benefits of vaccination for women and girls			Ease of supply chain integration
	Economic impact	Direct medical cost averted		Alternate interventions	Need for health care worker behaviour change
		Indirect cost averted	Feasibility of vaccination time point		
	Global health security impact	Epidemic potential of disease	Broader health system benefits	Acceptability in target population	
Impact of vaccination on antimicrobial resistance (AMR)		Long-term financial implications			
Financial implications:	Vaccine cost	Total procurement cost to Gavi and countries, 2020-2035			
	Operational cost	Incremental in-country operational costs per vaccinated person			
	Additional implementation costs	Additional costs for introduction			

3

3

Figure 2.1 Gavi Evaluation Framework for Endemic Disease Prevention (Gavi, 2023)

2.5 Data collection tool

The interview schedule was a semi-structured guide, intended to collect extensive qualitative data from healthcare professionals engaged in the management of STI and immunization activities. The interview guide began with demographic inquiries to ascertain the participant's background and experience, followed by open-ended questions exploring their perspectives of the prevailing challenges and obstacles to STI and immunization initiatives in South Africa (Appendix A). The interview focused on the prospective implications of a gonorrhoea vaccine, covering its practicality, acceptability, and potential impact on health outcomes, equity, and the healthcare system. The schedule explored the anticipated effects of a gonorrhoea vaccine, long-term health consequences, and potential additional benefits if dual protection against meningitis is demonstrated. It also examined the practical aspects of vaccination implementation, covering potential barriers, facilitators, and preferred delivery strategies. The guide examined the economic ramifications of a gonorrhoea vaccine, including cost-effectiveness, operational challenges, and prospective economic advantages. The schedule also evaluated wider health system advantages, including the improved functioning of surveillance systems and the mitigation of health inequities. It examined the social and behavioural dimensions of possible vaccine introduction, including the negative perceptions linked to gonorrhoea and the possible impact of affected communities on vaccine decision-making. The guide concluded with exploration of the knowledge deficiencies and educational requirements of both the public and healthcare professionals concerning a gonorrhoea vaccine, as well as the logistical obstacles related to a two-dose vaccination regimen.

2.6 Data Collection

In-depth interviews were conducted using the semi-structured interview guide described above. Interviews were conducted in English, online via Google Meet and MS Teams. The interviews lasted approximately 40-60 minutes and were audio or videorecorded with the participants' permission using the recording features of the meeting application in use. The interview guide comprised demographic close-ended questions and open-ended questions guided by the theoretical framework. Interview questions were adaptively administered, and this was guided by applicability of questions to the profession and experience of the participants.

2.7 Data Analysis

The deductive rapid analysis employed an initial set of domains derived from the GAVI Framework, supplemented by additional domains identified during the literature review, and integrated with the ECVP as framework guided matrix. Rapid qualitative analysis is a deductive approach employed to interpret qualitative data through the application of pre-existing theoretical frameworks or categories. This approach entails the prior identification of themes or concepts, facilitating a targeted and effective analysis of textual or narrative data (Nevedal et al., 2021). Segments of the transcripts that corresponded with the constructs and criteria specified in these frameworks and literature, including health impact, economic and social benefits, and global health security, along with factors pertaining to vaccine product characteristics, policy considerations, and stakeholder perspectives (Hamilton & Finley, 2019; St George et al., 2023). This The analysis adhered to a five-step methodology prescribe by Finley et al. (2022)

Step 1: Development of Neutral Domains

Neutral domains were established corresponding to each interview question, ensuring consistency with the constructs. Each domain was deliberately defined in a neutral, non-leading manner to enable objective summarization of participant responses.

Step 2: Development of a Summary Template

A standardized summary template was created. The template was organized according to the neutral domains and contained sections for structured notes on participant responses, relevant quotes, and any emerging insights. The objective was to optimize data collection while maintaining the depth and context of qualitative data.

Step 3: Summarization and Division of Transcript

Each transcript was summarized using the revised template, with careful consideration of both deductive domains.

Step 4: Development of the Matrix

Data were summarized and organized into a matrix format, with participants represented in rows and domains in columns. This matrix enabled comparative analysis and pattern recognition among various stakeholder viewpoints.

2.8 Ethical Considerations

Ethical approval for the study was obtained from the University of the Witwatersrand Human Research Ethics Committee (Wits HREC) (Appendix B). Informed consent was obtained from all participants before the interviews. Participants were sent a word document of the participant leaflet and Informed consent (Appendix C) and a digital Redcaptm informed consent form, with the same content. The participants were given time to read and understand the content, and they were given an opportunity to ask the researcher questions. Instructions on how to sign the informed consent on Redcaptm were sent via email.

Confidentiality and anonymity were maintained throughout the study. A document linking the participant identity and unique identifying number was stored separately from the data set. All data including audio recordings were stored in an access-controlled Microsoft Teams folder, with only the researcher and supervisors having access to them. Participants were informed of their right to withdraw from the study at any time without penalty.

CHAPTER 3: RESULTS

The study included 12 participants (Table 3.1), all of whom were registered HCP (n=6) or KI (n=6). HCPs included clinical associates, professional nurses, and doctors, and ranged from early-career professionals with less than two years of experience to seasoned practitioners with more than a decade in the sector.

KIs included policymakers, program managers, and researchers holding a variety of roles in from the National Department of Health, provincial health departments, commercial healthcare networks working with the government, and academic research institutions. Due to limited

institutional permission to recruit, healthcare providers were primarily recruited from the Gauteng province, while the key informants included participants sourced from Gauteng province, Mpumalanga Province, and national structures of the South African department of health.

All KIs had more than 10 years of experience in the field, and majority had more than 20 years of experience. The participants' ages ranged from 25 to older than 50 years. Notably, the research sample was mostly female, with only one male participant.

All participants were registered with professional bodies including HPCSA or SANC. Participants had diverse educational backgrounds, predominantly having postgraduate qualifications. Several held master's degrees in public health, Infectious Diseases, or Pathology, while others held postgraduate qualifications in HIV management, STI control, and public health. The majority of policymakers and program managers possessed advanced degrees in public health, epidemiology, or healthcare business administration.

Table 3.1 Participants characteristics table (N=12)

Participant characteristics		n
Sex	Male	1
	Female	11
Age	25-40 years old	6
	>40 years old	6
Years of experience in healthcare	<5 years	1
	5-10 years	4
	11-20 years	2
	>20 years	5
Highest qualification	Post-graduate diploma	4
	Bachelor's degree or	1
	Diploma	5
	Master's degree	2
	Doctoral degree	
Professional registration	HPCSA	8
	SANC	3
	SAPC	1

Participants shared views of both optimism and realism about a possible gonorrhoea vaccine, emphasizing the importance of structured planning, integration into existing healthcare programs, and strong political and financial backing.

The findings are structured through the pre-defined themes from the theoretical frameworks and literature (Table 3.2).

3.1 Perceptions of Disease Burden

All participants shared the view that STIs are a significant public health concern, and the majority identified gonorrhoea specifically as a public health issue, due to perceived high prevalence, asymptomatic infections, and the rise in AMR.

The high prevalence of gonorrhoea was a notable issue, recognized by the majority of participants,

“Gonorrhoea is one of the most commonly diagnosed STIs, and it has a very high prevalence. Many cases go undiagnosed because people are asymptomatic” - HCP04.

In contrast, one participant involved in vaccine adoption policy, expressed while gonorrhoea is a public health issue, a vaccine may be unnecessary due to other priorities.

“I don't know if we need a vaccine against gonorrhoea... you have to prioritize your vaccines.” – KI06

The growing concern of AMR and its threat to global health security was highlighted by the majority of participants, in particular KIs,

“AMR is a growing problem globally, and we are already seeing strains that are difficult to treat.” – KI02

3.1.1 Perceptions of the syndromic management of STIs

The approach currently used in STI management is syndromic management, and this was broadly recognized by participants as both beneficial and problematic. The concern of significant underreporting resulting from asymptomatic infections was identified by many participants, which was reported as complicating accurate diagnosis and subsequent management,

“They sometimes don't exhibit symptoms. So, you can be a carrier, transmit it to a partner, and then that's how you actually create an outbreak.” - HCP05.

The majority of participants acknowledged that syndromic management allows immediate treatment, however, many participants underscored its contribution to antibiotic misuse and potential resistance. One participant explained,

“The syndromic management approach is both beneficial and problematic. On one hand, it allows for immediate treatment without waiting for lab results, which is crucial in resource-limited settings. However, it also contributes to antibiotic misuse and potential resistance, as patients are often treated empirically without confirming the specific pathogen. This practice has led to over-treatment and increased resistance rates, particularly with gonorrhoea and other STIs” – KI04

3.1.2 Perceptions of Surveillance

A few participants mentioned limited surveillance as a contributing factor in AMR,

“Our surveillance is currently limited to three facilities, which is not enough. That is why we are expanding microbiological surveillance to other provinces” – KI06.

3.1.3 Potential Role of Vaccine on Disease burden

Most participants saw a possible gonorrhoea vaccination positively as they recognized it would help to lower STI incidence and AMR,

“I think it would be a game changer. Given the rise in antibiotic resistance, a vaccine could help control gonorrhoea and reduce the burden on our healthcare system” - HCP04.

A lot of participants mentioned that the vaccine could have other health benefits. A one participant expressed that the vaccine could indirectly reduce HIV rates and prevention of meningitis,

“A vaccine could significantly contribute by reducing overall STI rates and indirectly lowering HIV transmission” - KI05.

The majority of participants viewed a dual indicated vaccine for both meningitis and gonorrhoea as more likely to be accepted,

“Vaccines that prevent multiple conditions are more likely to be well-received by people than separate vaccines for each condition” - KI01.

One participant, involved in vaccine advisory work, expressed scepticism regarding the dual indication, stating that to be considered for gonorrhoea protection, it would need to be licenced for that indication, but that with current licensure, inclusion in EPI programs would only be possible if the goal was primarily meningococcal disease prevention, as opposed to gonorrhoea:

“The only reason to include it in the EPI is if we're trying to prevent meningococcal disease... gonorrhoea is a sexually transmitted disease... initially, I wouldn't think that the best place to introduce it is in the [general] population.” – KI06

A few participants expressed societal barriers disproportionately limit vulnerable populations from accessing such services. One participant pointed that undocumented immigrants and residents of informal settlements encounter hurdles such as disinformation, fear of deportation, and language barriers deterring them from acquiring healthcare services. These factors cause delayed diagnosis and missing immunization chances.

“In my area, I'd say it's lack of access to the facilities because usually the STIs are reported quite late. It's like maybe lack of knowledge to say there is a mobile unit that is coming... So, in that area mostly it's our fellow brothers and sisters from our neighbouring countries. They're unable to communicate with the language, language barrier, fear as well, because mostly they believe that you can't go to the clinic if you do not have papers.” - HCP02

3.2 Financial Considerations, Economic Factors, and Market Forces

While majority of participants indicated concerns about initial vaccine and implementation costs, some participants felt that the vaccine would be cost effective in the long term.

Participants involved in vaccine procurement identified that high initial investment would be required for a new vaccine, in a context of restrictive budget and other health priorities.:

“New vaccine introductions are expensive, and we need to ensure this is the best use of limited funds.” – KI06

Many participants expressed that government health expenditures are already constrained, and STI management is frequently overlooked in favour of diseases such as HIV and TB. One KI noted,

“STI management is a struggle because there isn't a dedicated budget for it, yet it is a significant issue. If I have to conduct training, I have to seek financial support from various sources. My response is slow due to budget constraints.” – KI04

Another participant expressed that financial sustainability was also a major factor. A previous example referenced the suspended distribution of a vaccine, which was discontinued mainly due to economic restrictions.

“The reason why they stopped giving the Meningococcal vaccine was due to cost constraints.” - HCP01.

Majority of participants expressed that the high operational costs related to supply chain logistics, energy reliability, and maintaining healthcare worker capacity were key barriers to seamless vaccine introduction.

“The money for human resources and then the money for the fridges for the right equipment for good quality equipment with great maintenance of the equipment. So, like fridges for vaccines, for example.” – KI06

Many participants suggested that given current resource constraints in healthcare strong proof of cost-effectiveness would be necessary. One participant said,

“The biggest player in most health systems is the cost. Is it cost-effective, whether you're doing a cost-effectiveness analysis or cost-benefit analysis?” – HCP06

A few participants also voiced concerns about difficulties in accessing the vaccines from manufacturers.

“I think accessibility and availability [are the biggest issues]. We don't have, as it stands now, those vaccines.” - HCP01

Many participants, however, felt that Bexsero, which may protect against both meningitis and gonorrhoea, could optimize long term cost-effectiveness.

“Vaccines that prevent multiple conditions are more likely to be well-received by people than separate vaccines for each condition. So yes, that's good news... for economic reasons, definitely. Also, from a logistical standpoint, giving multiple vaccines separately can be complicated. A vaccine addressing multiple conditions at once makes logistical sense.” - KI01

Majority of the participants acknowledged the potential cost savings from reduced antibiotic use. A participant noted,

“If we prevent gonorrhoea infections, we reduce the need for antibiotics, saving money in the long run.” – KI02

A few participants advocated for stronger public-private collaborations to improve vaccination financing and overcome financial constraints. One KI involved in programs said,

“Even though STIs are a major issue, they are not prioritized as highly as HIV... This model involves collaboration with the private sector, social sector, other health programs, non-governmental organizations, and traditional leaders. This is a key focus for us this year.” - KI04.

To address affordability, a one participant stressed exploring local vaccine production or negotiated pricing agreements as potential solutions to overcome economic barriers and enhance accessibility. One KI stated,

“Affordability is a major barrier, especially in low- and middle-income countries like South Africa. One way to overcome this is to explore local vaccine production or negotiated pricing agreements with manufacturers. This could significantly reduce costs and make vaccines more accessible to the public healthcare system”- KI02.

3.3 Implementation feasibility and broader health system benefits

3.3.1 Sociocultural and Behavioural Factors

The key themes that emerged included stigma, provider attitudes, gender dynamics, health-seeking behaviours, and systemic access barriers.

A recurring theme that was widely expressed by the majority of participants was stigma related to STIs. Participants consistently identified stigma as a significant barrier, notably affecting the interactions of both men and women with healthcare services related to sexual health.

“So, there is a certain level of stigma attached to it, and I think a lot of patients, particularly if, depending on their relationship with their partner or their multiple partners, might have a difficult time disclosing the fact that they have been diagnosed with suspected sexually transmitted infections” – HCP06.

A participant also noted that the stigma linked to STIs, stems from misconceptions and its association to HIV.

“There's definitely stigma. STIs are associated with people who are HIV positive. So, people think the only time you have a sexually transmitted infection is when you are HIV positive, which is not true. So, the lack of knowledge in our community—the fear” – HCP02

Additionally, stigma linked to misdiagnosis was described, emphasizing that women with certain conditions (such as genital schistosomiasis) face community stigma when symptoms mimic those of STIs. One participant elaborated,

“Women who have presented to healthcare facilities...these symptoms have been misdiagnosed as having an STI. Which has also created some sort of stigma in their communities. And what happens is even after they finish treatment, they still report these symptoms and some of them get treated again” – HCP06.

Another participant argued that it is internalised stigma and the inability for HCP to mitigate such thoughts, that create a barrier.

“I wouldn't say there is a strong stigma. More often, individuals stigmatize themselves rather than being openly stigmatized by others... People are self-diagnosing and self-stigmatizing. Even in health facilities, nurses are often not empowered to handle STIs properly... This leads to self-stigmatization and institutional stigma. Patients may avoid healthcare because they fear judgment or embarrassment” – KI04.

A KI running a vaccine delivery program, emphasized the role of HCP in creating barriers to STI health care and sited provider attitude as significant barrier to care.

“Many young people are scared to visit healthcare centres to get information about STD prevention or treatment once they suspect they might have a condition. Provider attitudes also play a big role, and the location of clinics relative to where young people live often determines whether they seek care. So, I think the biggest issue is provider interactions and attitudes” – KI01.

Gender based violence emerged as a significant factor. Many HCP observed many women in South Africa possess limited agency regarding their sexual health, attributable to power dynamics within their relationships. They encounter significant challenges in negotiating preventive behaviours, including condom use.

“Patients who are physically and emotionally abused cannot advocate for condom use. If he says he doesn't want it and this person is abusive to me, there is no way I'm going to say I'm not going to continue. Gender-based violence plays a role in all situations somehow... GBV contributes everywhere because they be afraid, and they can't verbalize how they feel and what they want” – HCP04.

Women, particularly those in abusive relationships, were noted to have limited power in negotiating condom use and STI treatment. A vaccine was therefore perceived by some participants as an empowering tool offering ‘silent protection’ that does not require negotiation with male partners, especially important in situations of gender-based violence or relationships lacking communication about sexual health. One participant stated,

“From a woman's perspective, working with women, and just gauging from what these women also think, the fact that they believe their prevention from gonorrhoea also protects them when they're in relationships where they are not free to talk about things like this. So, them being protected and them having access to something else is amazing. At least if there's that element of prevention instead of going to the clinic multiple times to treat gonorrhoea because your partner refuses to engage with you.” – HCP01

Health seeking behaviours differences along gender lines were highlighted by many participants. HCP noted that many individuals, especially males, exhibit reluctance to seek care for STIs, typically presenting to clinics only when symptoms worsen or become unbearable. One HCP stated,

“A lot of men tend to not come in for STIs; we mostly see a lot of females coming in. And when they go home and advise their partners to come in for treatment, a lot of them would be like, but you're treated, why should I? Especially when they are asymptomatic” – HCP03.

Majority of the participants shared that presenting the vaccine solely as an STI vaccine could reinforce stigma and reduce uptake,

“If the focus is on sexually transmitted infections, it might alienate people who don't want to be associated with that stigma. For instance, some might avoid the vaccine due to fear of being seen as sexually active” – KI01.

Some participants recommended presenting the vaccination as a dual-purpose intervention, so protecting both gonorrhoea and meningitis, so overcoming stigma and promoting uptake. This strategy could increase acceptability and lower opposition among the general people.

“If it prevents both meningitis and gonorrhoea, it makes a stronger case for inclusion in public immunization programs.” – KI01

The majority of participants underscored the importance of integrating public and private stakeholders and emphasizing community involvement and partnerships with local leaders and

NGOs to foster trust, ensure cultural appropriateness, and increase vaccine acceptance and uptake.

“Successful vaccine rollout requires collaboration beyond the health sector, involving government agencies, international organizations, private healthcare providers, and community groups. Existing STI and HIV prevention programs, such as PrEP initiatives, could serve as a model for integrating a gonorrhoea vaccine into existing health services.” - HCP01

Some participants, particularly most of HCP, expressed that socio-economic factors, including poverty, unemployment, healthcare infrastructure limitations, and the high cost of medical services, significantly impact healthcare accessibility, leading to delayed treatment and limited uptake of preventive measures. One participant expressed,

“The socio-economic profile in South Africa, we actually realise that most communities where low in the object forms of poverty and that actually influences the awareness component from a patient perspective.” – HCP04

3.3.2 Healthcare System and Infrastructure.

Participants provided a mixed assessment of South Africa’s healthcare system and infrastructure. While many recognized the strength of existing immunization programs like EPI and school-based HPV campaigns as a solid foundation for introducing a gonorrhoea vaccine, others highlighted system constraints. Key challenges included staff shortages, cold chain logistics, clinic capacity, and barriers to access for marginalized communities.

Some participants believed that South Africa has the infrastructure and capacity to implement the vaccine, particularly by leveraging existing vaccination programs and health services.

“We already have the infrastructure. It might need adaptation, but it's there.” – KI06

One participant used the covid-19 vaccine rollout as an example of the countries' capability.

“If rural areas were able to manage mass COVID-19 vaccination, we can adapt similar strategies to ensure equitable STI vaccine access.” – KI01

Many participants said that the EPI and school-based HPV vaccination programs provide a robust immunization framework for the nation. One participant stated,

“Because we have a really strong EPI program, it might be easier to vaccinate those hard-to-reach people. We have had real success with our HPV program in schools, so

there are definitely benefits in vaccinating specific populations where they receive health services.” – KI02

Some participants also advocated for positioning the vaccine as part of broader reproductive health interventions similar to the HPV vaccine, to enhance acceptability, particularly among parents and adolescents. This broader framing might alleviate concerns among parents that vaccination could inadvertently endorse sexual activity among adolescents.

“When HPV vaccination was introduced, there was resistance because people thought we were promoting sexual activity. Similarly, if the vaccine is framed as broader reproductive health intervention rather than purely an STI vaccine, it could improve acceptability, particularly in conservative communities” – KI03.

Many participants expressed scepticism about whether clinics could handle an additional vaccine, given long waiting times and limited personnel. One KI, stated.

“Our healthcare system is already struggling with human resource shortages. Any new vaccine program must be integrated in a way that does not overwhelm existing services.” – KI05

Across both HCP and KI, the issue of personnel shortage was a prominent concern, particularly in the face of a potential two dose vaccine. One KI stated,

“Nurses are already overwhelmed due to expanding responsibilities. A two-dose vaccine would require careful planning to avoid overburdening our healthcare staff.” – KI03

HCPs supported this, expressing that they already dealing with long queues of patients.

“We are dealing with long patient queues and staff shortages. If we introduce a new vaccine, we need to ensure clinics can handle the extra workload.” – HCP06

Some participants expressed that it is important to secure funding not only to ensure adequate staffing, but also to meet the cold chain demands of a new vaccine. One KI informant involved in vaccine adoption advisory work stated,

“I think so [human resource is a big problem]. The money for human resources and then the money for the fridges for the right equipment for good quality equipment with great maintenance of the equipment. So, like fridges for vaccines, for example. And then human resources so that there's enough staff that are well educated, well trained and

that they can support each other so that they're not overworked, stressed, shattered patients. And feel stressed all the time.” – KI06

Another KI responsible for vaccine delivery emphasised the need for enough personnel and logistical infrastructure and stated,

“For a successful implementation, we would also need: Pharmacists, Supply chain experts, Cold storage management. These are just some of the logistics we would need to sort out.” – KI04.

One participant highlighted concerns regarding vaccine storage and distribution, particularly in the context of South Africa’s energy and water crises. Maintaining stable cold chain infrastructure was said to be crucial to ensure vaccine efficacy, but frequent power and water disruptions pose significant risks.

“Energy and water shortages are major risks to vaccine delivery. Without stable infrastructure, maintaining vaccine efficacy could be difficult.” – KI06

To address some of the socio-economic barriers, the use of mobile healthcare units has been proposed as a strategy to improve vaccine accessibility in at-risk communities.

“Taking the service to the people really does help. With the mobile unit, they don’t have to take a taxi or go far. It makes access much easier.” - HCP02

3.3.3 Vaccine Introduction and Implementation

Participants also identified multiple barriers that might affect its feasibility. Many pointed out that rolling out new vaccinations has the challenge of maintaining constant stock levels in order to avoid supply chain interruptions.

“Vaccine supply issues happen all the time. If we roll this out, we must ensure stock levels are stable to maintain trust and adherence.” – HCP02

Other participants emphasized that healthcare workers lack adequate training on new vaccine implementation.

“Healthcare workers need to be empowered. We don’t have enough training to introduce new vaccines smoothly.” – KI04

Widely proposed by majority of the participants, was a gradual deployment strategy starting with high-risk groups such as sex workers, men who have sex with men, and young women, then extending to the broader public. This would enable pre-national rollout strategy adjustments and monitoring of efficacy.

“If resources are limited, we should begin with MSM, sex workers, and adolescents, then expand once more funding and data are available.” – KI04

Some participants stated that effective implementation necessitates robust frameworks such as clear policy guidelines, structured monitoring and evaluation processes, and coordination mechanisms among stakeholders alongside sufficient funding, and organized rollout strategies.

“For a successful implementation, we would also need: Pharmacists, Supply chain experts, Cold storage management... These are just some of the logistics we would need to sort out... This is not just a simple rollout—it requires a comprehensive strategy.” - KI04

Furthermore, participants highlighted that South Africa has established vaccine programs such as the EPI, and HPV school program, could be leveraged. The majority of participants recommended the inclusion of the potential vaccine into current sexual and reproductive health services, including HIV prevention, PrEP programs, and family planning services, thereby enhancing vaccine acceptance and accessibility. This strategy would serve to lower stigma and help normalise the vaccine.

“If we integrate the gonorrhoea vaccine into existing reproductive health services, it will be easier to implement and more widely accepted.” – HCP06

Many of the participants underlined the importance of monitoring initiatives to track AMR patterns over time and vaccination efficacy. Refining implementation tactics and guarantees long-term success depend on constant data collecting and review.

“Surveillance will be key to tracking vaccine impact and ensuring that it remains effective against resistant gonorrhoea strains.” – HC05

3.4 Policy, Governance, and Decision-Making

Some key informants highlighted that STI-related policies in South Africa are managed by multiple government bodies, including the Department of Health and SAHPRA,

“Any vaccine proposal must go through SAHPRA, cost-effectiveness assessments, and government funding evaluations before adoption.” - KI05

Another KI stressed that this multi-agency approach leads to slow, fragmented decision-making, delaying critical interventions such as vaccine adoption and prevention strategies,

“Government discussions on STI control remain fragmented, with more focus placed on treatment rather than prevention.” – KI01.

A concern that some participants had was that the government neglects gonorrhoea and AMR, despite mounting clinical concerns,

“To the government, it’s just gonorrhoea. It’s not seen as an emergency that needs immediate action.”

One KI in programs highlighted the lack of an organized national strategy to STI prevention and treatment.

“We lack a clear national strategy for STI control, making large-scale interventions like vaccination difficult to implement.” – KI04.

They also emphasized that, whereas HIV and TB receive major attention and resources from political leaders, STIs are frequently ignored in public health efforts. One person mentioned that.

“A lack of political leadership is a major factor. HIV and TB receive more attention, while STIs are often ignored. Even in national strategic plans, STIs are often added as an afterthought.” - KI04

Some HCP expressed frustration over the disconnect between clinical realities and policy responses regarding and AMR. One HCP stated,

“Clinicians are increasingly alarmed by antimicrobial-resistant gonorrhoea, yet the government doesn’t seem to share the same urgency. There is very little noise at the policy level about STI challenges.” – HCP01.

Another participant involved in vaccine advisory work, stressed that political decision-making is frequently influenced by financial and reputational factors rather than public health requirements.

“Political leaders always think about how much will it cost, how much will it take from my budget, and then what’s the risk? If STI clinics are still full, if people are showing

on social media that they're still getting the disease, then they see it as a political risk.”
- KI06

The participant suggested that gonorrhoea and meningitis dual-indication vaccine could increase political support. One participant stated,

“If we emphasize the broader health benefits of this vaccine, such as preventing meningitis alongside gonorrhoea, it would likely be more acceptable.”- KI03.

3.4.1 Alignment with Global and Regional Health Agendas

A lot of participants shared the view that South Africa largely aligns with global health guidelines and vaccination priorities set by the WHO. However, they consistently noted that alignment at a policy level does not always translate into implementation, due to barriers such as funding limitations, competing health priorities, and vaccine availability.

One participant shared,

“We definitely align with global guidelines, but vaccine availability and accessibility still remain barriers” - HCP01.

Despite global alignment, the implementation of new vaccines, encounters significant obstacles in the South African context. Participants frequently cited competing health priorities. One participant stated,

“Even if WHO recommends it, funding decisions will depend on which diseases are seen as more urgent.” - HCP04

Participants noted that global and local clinical evidence significantly influences national policy decisions related to vaccine implementation. One participant explicitly stated,

“The committee reviews global evidence and South African-specific data to collectively formulate recommendations on vaccine introduction.” - KI05

Another participant suggested that aligning the gonorrhoea vaccine with national and WHO AMR strategies could bolster political support for its adoption:

“Aligning the vaccine with national and WHO AMR strategies could increase political support for its adoption.” - KI06

The primary themes highlighted were the considerable public health issue presented by gonorrhoea, characterized by its high prevalence, asymptomatic features, and increasing AMR. The acceptability of a potential gonorrhoea vaccine was predominantly favourable, especially if implemented as a dual-purpose vaccine in conjunction with meningitis or incorporated into existing vaccination initiatives like school-based HPV immunization. A significant trend identified was the prioritization of vulnerable populations, including antenatal patients, sex workers, men who have sex with men, teenagers, and immunocompromised individuals, for the initial deployment of vaccines. Across participants, partial effectiveness was viewed as acceptable if accompanied by clear messaging, targeting to high-burden groups and evidence that vaccination reduces antibiotic use and downstream complications. Several respondents cautioned that expectations must be managed, emphasising the need for post-introduction monitoring of effectiveness and duration of protection.

Participants expressed a favourable perspective on the potential gonorrhoea vaccine, emphasizing its potential to decrease STI incidence, AMR, and indirectly reduce HIV transmission rates. A dual-indication vaccine for meningitis and gonorrhoea was favoured for its perceived broader benefits, suggesting greater acceptability. Integration into existing immunization strategies, such as school-based HPV vaccination, was strongly recommended; however, scepticism arose concerning the prioritization of gonorrhoea over other public health needs. Participants recommended prioritizing vulnerable populations for initial vaccine distribution, specifically antenatal patients, sex workers, men who have sex with men, teenagers, and immunocompromised individuals.

Table 3.2 Summary of the results

GAVI framework	Main Domain	Themes	Suggested Solutions and Strengths
Health impact (cases and deaths averted) Other health impacts (Total deaths and DALYS averted Global health security (epidemic potential of disease/impact on AMR)) Equity and social protection (impact on vulnerable groups and special benefits for women)	Disease Burden and Epidemiology	High prevalence, AMR, and asymptomatic infections complicate control	- Using AMR data to support advocacy. Strong clinical concern and awareness among stakeholders can drive urgency. - Syndromic management already in place offers quick care; training can reduce over-treatment while preserving speed. - Expand surveillance capacity. - Justify funding through cost-effectiveness and dual-benefit arguments. - Show association with priority conditions such as HIV and reproductive complications. - Engage local leaders and local influencers to address stigma. Curate community specific communication.
		Syndromic management contributes to resistance	
		Limited surveillance constrains effective response	
Economic impact (direct and indirect medical costs averted) Cost for vaccines, operations and introduction Value for money (cost per case and death averted) Degree of vaccine market challenges	Financial Considerations, Economic Factors, and Market Forces	High vaccine costs	- Bundle vaccine in reproductive health campaigns (e.g., HPV, antenatal care) - HPV and EPI programs show that infrastructure exists; funding cold chain and HR can strengthen the system. - Mobile units and multilingual community outreach improve reach to migrants and underserved groups. - Community health education can improve access. - Improving provider attitudes.
		Lack of STI-specific funding	
		Cost effectiveness	
		Public-Private collaboration	
Implementation feasibility	Sociocultural and Behavioural Factors	Stigma and misinformation limit uptake	

GAVI framework	Main Domain	Themes	Suggested Solutions and Strengths
Alternative interventions Broader health system benefits		Gender dynamics factors	• Better curated messaging, such as dual indication vaccine would improve on the stigma. • Engaging and consulting the community and its leaders • Leverage existing reproductive health and HIV programs can serve as platforms for vaccine delivery. • Phased rollouts allow adaptation and learning; starting with high-risk groups ensures impact and efficiency. • Leverage global and WHO strategies to influence local buy-in
		Framing and delivery settings affect acceptability	
	Healthcare System and Infrastructure	Human resource shortages and cold chain constraints	
		Access challenges for vulnerable populations (e.g., key populations)	
	Vaccine Introduction and Implementation	Poor supply chains and lack of HCP training are barriers to successful implementation.	
		Suggested integration With EPI, PreP programs and HPV vaccine	
Policy, Governance, and Decision-Making	Alignment with Global and Regional Health Agendas	Suggested phased rollout and integration with reproductive health	
		Global guidance influences but domestic priorities dominate	
	Fragmented leadership and weak STI prioritization	Convene agencies to unify STI control strategy;	
		Elevate STI vaccine in political agenda	

CHAPTER 4:DISCUSSION

4.1 Discussion of the result

This section discusses the key findings from the study and places them within the broader context of existing literature, considering implications for public health and policy in South Africa.

The findings of this study suggest that HCP and KI mainly perceive the possible introduction of the Bexsero Men B vaccination for gonorrhoea prevention in South Africa as acceptable and feasible. Participants supported the potential introduction of the vaccine despite potential implementation challenges. Participants universally acknowledged the considerable burden of gonorrhoea infection, noting limitations in the current syndromic management approach, which permits antibiotic overuse and contributes to increasing AMR. They also highlighted the potential of vaccination to mitigate AMR, stressing the importance of precise local epidemiological data to guide health intervention prioritization. This perspective aligns closely with existing studies by Makinen et al. (2012), Sambala et al. (2019), and Castañeda-Orjuela et al. (2022), which similarly emphasize the role of accurate local epidemiological data in effective vaccine prioritization and underscore vaccination as a critical strategy in reducing antibiotic reliance and combating antimicrobial resistance. Additionally, respondents recognized the broader health benefits of the vaccine beyond gonorrhoea, emphasizing its dual capacity to prevent meningitis and gonorrhoea. This dual indication was particularly valued, reflecting the broader literature suggesting interventions addressing multiple health issues are typically met with greater acceptability and political support, and could also help mitigate stigma by reframing the vaccine from an STI-specific intervention to one with broader protective health benefits (Makinen et al., 2012; Castañeda-Orjuela et al., 2022).

Participants further highlighted the opportunity for the vaccine to significantly impact populations typically vulnerable due to limited healthcare access and resources. This observation emphasizes the vaccine's potential equity-enhancing role, which resonates with broader global health priorities. Additionally, participants noted the potential for a gonorrhoea vaccine to reduce the risk of gender-based violence (GBV) that can arise following an STI diagnosis. Evidence suggests that discovering an STI can sometimes trigger blame, mistrust, or suspicion of infidelity in intimate relationships, potentially escalating to violence (John et al., 2017; Gonzalez-Guarda et al., 2019; Mathews et al., 2017). By preventing gonorrhoea

infection, the vaccine could help avert these conflict triggers and thereby diminish a pathway to partner violence. This highlights how vaccination may confer not only direct health benefits but also broader social benefits, including a reduction in GBV associated with STI diagnoses.

While participants recognized the vaccine's potential for cost-effectiveness, they identified significant concerns regarding affordability, supply chain costs, immediate financial outlay, and sustainability. These economic concerns align with broader discussions in global health literature, particularly about the challenges faced by lower-middle-income countries (Burchett et al., 2012; Sambala et al., 2019). Moreover, participants raised concerns about price and availability, however, they did not discuss the need to strengthen local or regional vaccine manufacturing capacity, another critical focus of vaccine introduction frameworks (Chawana et al., 2024). The issue of whether existing African manufacturing capabilities could meet demand, or whether partnerships with international manufacturers might be necessary, did not arise in participant responses.

Participants also identified potential barriers to vaccine access and uptake, notably stigma associated with STIs, vaccine hesitancy driven by misinformation, limited healthcare system capacity, and logistical challenges related to vaccine implementation. These concerns echo findings in existing studies (Delany-Moretlwe et al., 2018; Otieno et al., 2021; Guillaume et al., 2022; Guinard et al., 2019). Adopting a dual prevention approach may help address some of these barriers.

Notably, participants did not refer to several important considerations highlighted in the broader literature. While Makinen et al. (2012) and Sambala et al. (2019) emphasize that high-level political will as be crucial for new vaccine introduction, participant in this study explicitly mentioned the importance of sustained political commitment. Similarly, while participants expressed concerns about costs, they did not explicitly discuss the necessity of robust cost-effectiveness analyses, a factor repeatedly underscored by the literature (Castañeda-Orjuela et al., 2022). Moreover, the literature stresses how global recommendations (e.g., from WHO) can drive national vaccine adoption (Makinen et al., 2012), only participant explicitly cited official as a key influence in the potential introduction of this vaccine. Participants also did not address how decentralized governance might affect rollout an oversight noted as influential in vaccine decisions across various LMIC contexts (Otieno et al., 2021). These omissions suggest that continued stakeholder engagement should address such policy, economic, and governance considerations to ensure a comprehensive approach to the vaccine's introduction.

The study's findings highlight a careful balance between recognizing the substantial potential benefits of vaccination and acknowledging significant barriers to its implementation. Addressing these barriers, particularly through targeted, culturally sensitive communication and healthcare infrastructure strengthening, will be critical to successfully introducing the vaccine in South Africa.

4.2 Strengths and limitations

This study provides insights into the elements that influence the prospective introduction of a gonorrhoea vaccine, namely a Men B vaccination with cross-protection, in South Africa. The study's concept and implementation revealed a variety of strengths and weaknesses.

4.2.1 Strengths

4.2.1 Strengths

4.2.1.1 Diverse Participant Group

The purposive and snowball sampling strategy covered participants from diverse professional levels and backgrounds, including policy, program management, research, and frontline care. This methodological choice enhanced the robustness of the study by ensuring varied insights.

4.2.1.2 Application of a Rigorous Qualitative Framework

The use of a qualitative, in-depth interview design allowed thorough exploration of personal experiences, attitudes, and perceptions among HCP and KIs. This methodological rigor provided clear, detailed, and context-specific data essential for understanding a broad spectrum of perspectives on disease burden, healthcare system dynamics, and sociocultural influences.

4.2.1.3 Utilization of Established Frameworks

The adaptation of the existing Gavi Evaluation Framework for Endemic Disease Prevention and the ECVP ensured methodological clarity by guiding the development of the interview guide and structuring the subsequent analysis. This tailored, framework-oriented approach strengthened the study's credibility and facilitated a systematic interpretation of results.

4.2.1.4 Contextual Relevance

The timing and context of this study, conducted in anticipation of clinical trials for the Bexsero Men B vaccine, provided strategic methodological relevance. It offered valuable insights into data gaps and critical issues that should be considered in policy formulation.

4.2.2 Limitations

4.2.2.1 Sample Size and Transferability

While qualitative approaches often utilize smaller, more focused samples, the final sample size of 12 may restrict the findings' transferability. Although data saturation was achieved for the research objectives, caution is necessary when generalizing the findings to all areas or health sectors in South Africa.

4.2.2.2 Geographical and institutional constraints

The majority of participants were recruited from Gauteng Province (with an only one from Mpumalanga), which may have underrepresented opinions from more distant provinces facing distinct resource issues. Furthermore, institutional authorization limits meant that particular commercial or public facilities with different service delivery methods may have been excluded, potentially ignoring context-specific obstacles or facilitators.

4.2.2.3 Self-selection Bias

Participants who opted to participate may already be more involved in immunization or STI control, creating potential bias. Those who were less interested in, less informed about, or more dubious about new vaccinations may not have been represented evenly, thereby biasing the findings toward more favourable or policy-driven opinions.

4.2.2.4 Reliance on Self-Reported Perception

The study was based on participants' memories, beliefs, and views rather than direct observation or measurement of programmatic data (for example, actual vaccination uptake or real-world cost analyses). While self-reported data is crucial for capturing context, it can be impacted by recollection bias or social desirability bias, which causes participants to underreport stigma-related obstacles or overestimate their acceptance of vaccination.

4.2.2.5 Limited Triangulation

Although key informants, politicians, and HCPs provide complementary perspectives, more data sources such as community and patient focus groups, program records, or epidemiological surveillance data could have improved the findings' comprehensiveness. Greater triangulation using various sources may support or question the interpretations derived from interviews alone.

4.2.2.6 One Person Rapid Analysis

Rapid analysis was primarily conducted by a single analyst, which may introduce interpretive bias. We mitigated this through predefined templates, reflexivity memos, peer-debriefs with project supervisors.

4.2.2.7 Evolving Policy Context

South Africa's national policy climate is changing, particularly in terms of vaccine introduction and STI management. Changes in governmental goals, funds allocations, or global health recommendations may affect the practicality and acceptance of a gonorrhoea vaccination over time. As a result, the findings provide a snapshot of views, which may change in response to new research or shifting health priorities.

4.2.2.8 Exclusion of user perspective

While not the focus of this work, we did not collect patient perspectives, as these data are being captured in parallel by the parent trial. We acknowledge that this omission may limit triangulation and the ability to fully situate stakeholder views within patient experience. Future studies should explicitly include patient participants to strengthen interpretability and to inform implementation domains such as acceptability, feasibility, and equity.

4.3 Recommendations

This study's findings underscore the necessity for comprehensive strategies to facilitate the potential introduction and implementation of a gonorrhoea vaccine in South Africa. It is essential to improve surveillance by broadening data collection on gonorrhoea and AMR in various contexts, thereby providing substantial evidence on the local burden of disease to guide public health interventions. The health system's capacity must be improved in order to accommodate the gonorrhoea vaccine within current immunization frameworks, including the EPI, school-based HPV initiatives and adult sexual reproductive health programs. This integration necessitates sufficient personnel, effective cold-chain logistics, and robust patient

follow-up mechanisms. Addressing stigma and misinformation regarding STIs through culturally tailored communication campaigns and community partnerships can enhance trust and mitigate negative perceptions that hinder vaccine uptake. A phased rollout aimed at vulnerable, high-incidence groups (such as sex workers, men who have sex with men, and adolescents) can function as an effective pilot model. However, it remains important to consider whether targeting these high-incidence populations alone is sufficient or if broader, population-based strategies might also be necessary. Local epidemiological modelling could guide future implementation decisions with greater precision. This approach facilitates the refinement of delivery strategies and the evaluation of cost-effectiveness prior to wider implementation. Comprehensive local economic evaluations are essential to illustrate the long-term advantages of gonorrhoea vaccination in addressing the increasing challenge of AMR and the prevention of long-term sequelae of untreated or undiagnosed gonorrhoea, particularly among women. The investigation of public-private partnerships, negotiated pricing, and local manufacturing is crucial for ensuring sustainable financing. Enhancing alignment among government entities and promoting multi-sector collaboration, which includes policymakers, academia, NGOs, and private stakeholders, is essential for effective program planning and implementation. Ongoing operational research, including studies on acceptability, vaccine efficacy, and real-world impact, are essential for refining strategies, addressing emerging barriers, and maximizing the public health benefits of introducing a gonorrhoea vaccine in South Africa.

4.4 Conclusion

Participants in this study demonstrated significant awareness of the burden of gonorrhoea and the threat of AMR, similar to findings in comparable investigations. Concerns regarding stigma, limited resources, and de-prioritisation of STIs have surfaced as significant challenges, reflecting challenges observed in other LMICs. The findings correspond with current literature highlighting the necessity of comprehending health system perspectives, sociocultural norms, and the overarching policy landscape in the context of new vaccine introduction. Minor discrepancies in perspectives between respondents can be ascribed to variations in local demographics, the preparedness of health systems, and the level of stigma associated with STIs such as gonorrhoea compared to other diseases.

These insights are crucial for policymakers and health program managers focused on enhancing STI prevention efforts. The study explains the common and unique factors affecting vaccine

introduction in South Africa, offering a framework for targeted outreach, enhanced health education, and strategically planned implementation approaches. Recognizing the socio-behavioural and health system complexities surrounding the introduction of a gonorrhoea vaccine is essential for shaping effective policies, addressing existing gaps, and enhancing national efforts to control gonococcal antimicrobial resistance and reduce the burden of sexually transmitted infections.

REFERENCE

- Abara, W. E., Bernstein, K. T., Lewis, F. M. T., Schillinger, J. A., Feemster, K., Pathela, P., Hariri, S., Islam, A., Eberhart, M., Cheng, I., Ternier, A., Slutsker, J. S., Mbaeyi, S., Madera, R., & Kirkcaldy, R. D. (2022). Effectiveness of a serogroup B outer membrane vesicle meningococcal vaccine against gonorrhoea: a retrospective observational study. *The Lancet Infectious Diseases*, 22(7), 1021–1029. [https://doi.org/10.1016/s1473-3099\(21\)00812-4](https://doi.org/10.1016/s1473-3099(21)00812-4)
- Abara, W. E., Kirkcaldy, R. D., Bernstein, K. T., Zlotorzynska, M., & Sanchez, T. (2021). Acceptability of a Gonococcal Vaccine Among Sexually Active Men Who Have Sex With Men. *Sexually Transmitted Diseases*, 49(1), 76–80. <https://doi.org/10.1097/olq.0000000000001510>
- Amponsah-Dacosta, E., Kagina, B. M., & Olivier, J. (2020). Health systems constraints and facilitators of human papillomavirus immunization programmes in sub-Saharan Africa: a systematic review. *Health Policy and Planning*, 35(6), 701–717. <https://doi.org/10.1093/heapol/czaa017>
- Baba, I. A., Sani, M. A., Rihan, F. A., & Hincal, E. (2024). Modeling the impact of vaccination efficacy and awareness programs on the dynamics of infectious diseases. *Journal of Applied Mathematics and Computing*. <https://doi.org/10.1007/s12190-024-02297-9>
- Black, S. (2013). The role of health economic analyses in vaccine decision making. *Vaccine*, 31(51), 6046–6049. <https://doi.org/10.1016/j.vaccine.2013.08.008>
- Bourgeault, I. L., Dingwall, R., & De Vries, R. (2011). The SAGE handbook of qualitative methods in health research. *Choice Reviews Online*, 48(09), 48–4837. <https://doi.org/10.5860/choice.48-4837>
- Braun, V., & Clarke, V. (2016). Successful qualitative research: A practical guide for beginners. *QMIP Bulletin*, 1(21), 48–50. <https://doi.org/10.53841/bpsqmip.2016.1.21.48>
- Factors Influencing the Potential Introduction of a Gonorrhea Vaccine in South Africa
Research Report: 31 MAR 2025

- Burchett, H. E. D., Mounier-Jack, S., Griffiths, U. K., Biellik, R., Ongolo-Zogo, P., Chavez, E., Sarma, H., Uddin, J., Konate, M., Kitaw, Y., Molla, M., Wakasiaka, S., Gilson, L., & Mills, A. (2012). New vaccine adoption: qualitative study of national decision-making processes in seven low- and middle-income countries. *Health Policy and Planning*, 27(suppl 2), ii5–ii16. <https://doi.org/10.1093/heapol/czs035>
- Buthelezi, S., Ally, M., Hawkrige, A., Naidoo, P., Abrahamse, H., Loots, G., Mathee, A., Young, T., Gey Van Pittius, N., Tsoka-Gwegweni, J., Heunis, C., Matjila, M., Mbewe, M., Molefe, M., Andrews, G., Zondi, T., Muthivhi, T., & Malinga, L. (2021). *Health Research Priorities (Revised) for South Africa 2021-2024*.
- CDC. (2013). ANTIBIOTIC RESISTANCE THREATS in the United States, 2013. In CDC. Retrieved May 9, 2024, from <https://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf>.
- CDC. (2024, November 12). *National Overview of STIs in 2023*. STI Statistics. Retrieved March 4, 2025, from <https://www.cdc.gov/sti-statistics/annual/summary.html>.
- Coetzee, M., Ally, M., Hawkrige, A., Naidoo, P., Loots, G., Mathee, A., Young, T., Gey Van Pittius, N., Tsoka-Gwegweni, J., Heunis, C., Matjila, M., Abrahamse, H., Mbewe, M., Molefe, M., Andrews, G., & Buthelezi, S. (2021). *National Health Research Strategy: Research Priorities For South Africa 2021-2024*. <https://www.health.gov.za/wp-content/uploads/2021/04/NATIONAL-HEALTH-RESEARCH-STRATEGY-2021-2024.pdf>
- Creswell, J. W., & Poth, C. N. (2016). *Qualitative Inquiry and Research Design*. SAGE Publications.
- De Micco, P., Maraghini, M. P., & Spadafina, T. (2022). The costs of introducing a vaccine in sub-Saharan Africa: a systematic review of the literature. *International Journal of Health Governance*, 27(4), 391–409. <https://doi.org/10.1108/ijhg-01-2022-0004>

- De Oliveira, L. H., Toscano, C. M., Sanwogou, N. J., Ruiz-Matus, C., Tambini, G., Roses-Periago, M., & Andrus, J. K. (2013). Systematic documentation of new vaccine introduction in selected countries of the Latin American Region. *Vaccine*, *31*, C114–C122. <https://doi.org/10.1016/j.vaccine.2013.05.032>
- Delany-Moretlwe, S., Kelley, K. F., James, S., Scorgie, F., Subedar, H., Dlamini, N. R., Pillay, Y., Naidoo, N., Chikandiwa, A., & Rees, H. (2018). Human Papillomavirus Vaccine Introduction in South Africa: Implementation Lessons From an Evaluation of the National School-Based Vaccination Campaign. *Global Health Science and Practice*, *6*(3), 425–438. <https://doi.org/10.9745/ghsp-d-18-00090>
- Delany-Moretlwe, S., Mgodi, N., Bekker, L. G., Baeten, J., Pathak, S., Donnell, D., Lennon, D., Rose, S., Makgamathe, K., Kassim, S., Mukaka, S., Noble, H., Adeyeye, A., & Celum, C. (2019). O10.3 High curable STI prevalence and incidence among young african women initiating PrEP in HPTN 082. *Oral Presentations*. <https://doi.org/10.1136/sextrans-2019-sti.160>
- Denyer Willis, L., & Chandler, C. (2019). Quick fix for care, productivity, hygiene and inequality: reframing the entrenched problem of antibiotic overuse. *BMJ Global Health*, *4*(4), e001590. <https://doi.org/10.1136/bmjgh-2019-001590>
- Donadel, M., Panero, M. S., Ametewee, L., & Shefer, A. M. (2021). National decision-making for the introduction of new vaccines: A systematic review, 2010–2020. *Vaccine*, *39*(14), 1897–1909. <https://doi.org/10.1016/j.vaccine.2021.02.059>
- Etikan, I. (2016). Comparison of Convenience Sampling and Purposive Sampling. *American Journal of Theoretical and Applied Statistics*, *5*(1), 1. <https://doi.org/10.11648/j.ajtas.20160501.11>

- Fang, Y., Ma, T., Wu, M., & Tsuei, S. H. T. (2023). Mitigating donor interests in the case of COVID-19 vaccine: the implication of COVAX and DAC membership. *BMJ Global Health*, 8(1), e010188. <https://doi.org/10.1136/bmjgh-2022-010188>
- Ferrara, P., Stromillo, L., & Albano, L. (2018). Awareness, Attitudes, and Practices Toward Meningococcal B Vaccine among Pediatricians in Italy. *Medicina*, 54(6), 100. <https://doi.org/10.3390/medicina54060100>
- Finley, E., Hamilton, A., Kowalski, C., Midboe, A., Nevedal, A., Young, J., & Dr. Allison Lewinski. (2022). *Rapid Qualitative Methods in Implementation Science: Techniques and Considerations* (By 15th Annual Conference on the Science of Dissemination and Implementation in Health). https://academyhealth.confex.com/academyhealth/2022di/mediafile/Presentation/Session32968/Rapid%20Qual%20DI%20Workshop_FINAL.pdf
- GAVI. (2023). Gavi, the Vaccine Alliance: strategic updates UNICEF Vaccine Industry Consultation 2023 Ed Baker 13 September 2023. In *GAVI*. UNICEF Vaccine Industry Consultation 2023 Ed Baker. Retrieved May 5, 2024, from https://www.unicef.org/supply/media/19616/file/UNICEF_-_VIC2023_-_session_03_-_Gavi_update_-2023.pdf.
- Gerbase, A. C., Rowley, J. T., & Mertens, T. E. (1998). Global epidemiology of sexually transmitted diseases. *The Lancet*, 351, S2–S4. [https://doi.org/10.1016/s0140-6736\(98\)90001-0](https://doi.org/10.1016/s0140-6736(98)90001-0)
- Ghebreyesus, T. A. (2021). Five steps to solving the vaccine inequity crisis. *PLOS Global Public Health*, 1(10), e0000032. <https://doi.org/10.1371/journal.pgph.0000032>
- Ghebreyesus, T. A., & Russell, C. (2022). Opportunities in crisis for optimising child health and development. *The Lancet*, 399(10337), 1761–1763. [https://doi.org/10.1016/s0140-6736\(22\)00608-0](https://doi.org/10.1016/s0140-6736(22)00608-0)

Gonzalez-Guarda, R. M., Williams, J. R., Williams, W., Lorenzo, D., & Carrington, C. (2019).

Determinants of HIV and sexually transmitted infection testing and acquisition among female victims of intimate partner violence. *Journal of Interpersonal Violence*, 36(13–14), NP7547–NP7566. <https://doi.org/10.1177/0886260519827662>

Gottlieb, S. L., Ndowa, F., Hook, E. W., Deal, C., Bachmann, L., Abu-Raddad, L., Chen, X. S.,

Jerse, A., Low, N., MacLennan, C. A., Petousis-Harris, H., Seib, K. L., Unemo, M., Vincent, L., & Giersing, B. K. (2020). Gonococcal vaccines: Public health value and preferred product characteristics; report of a WHO global stakeholder consultation, January

2019. *Vaccine*, 38(28), 4362–4373. <https://doi.org/10.1016/j.vaccine.2020.02.073>

Green, A. (2021, March 1). *In-depth: What we know about SA's rampant gonorrhoea epidemic*.

Spotlight. Retrieved March 25, 2025, from <https://www.spotlightnsp.co.za/2021/03/01/in-depth-what-we-know-about-sas-rampant-gonorrhoea-epidemic/>.

Guillaume, D., Waheed, D. E. N., Schlieff, M., Muralidharan, K., Vorsters, A., & Limaye, R. (2022).

Key decision-making factors for human papillomavirus (HPV) vaccine program introduction in low-and-middle-income-countries: Global and national stakeholder perspectives. *Human Vaccines & Immunotherapeutics*, 18(7). <https://doi.org/10.1080/21645515.2022.2150454>

Hamilton, A. B., & Finley, E. P. (2019). Qualitative methods in implementation research: An

introduction. *Psychiatry Research*, 280,

112516. <https://doi.org/10.1016/j.psychres.2019.112516>

Hasso-Agopsowicz, M., Hwang, A., Hollm-Delgado, M., Umbelino-Walker, I., Karron, R. A., Rao,

R., Asante, K. P., Sheel, M., Sparrow, E., & Giersing, B. (2024). Identifying WHO global priority endemic pathogens for vaccine research and development (R&D) using multi-criteria decision analysis (MCDA): an objective of the Immunization Agenda 2030. *EBioMedicine*,

105424. <https://doi.org/10.1016/j.ebiom.2024.105424>

Factors Influencing the Potential Introduction of a Gonorrhea Vaccine in South Africa

Research Report: 31 MAR 2025

- Hendricks, L., Uwimana-Nicol, J., & Young, T. (2023). Decision makers perceptions and experiences of developing population-level interventions targeting risk factors for hypertension and diabetes in South Africa: a qualitative study. *BMC Health Services Research*, 23(1). <https://doi.org/10.1186/s12913-023-09135-x>
- Herzog, R., Álvarez-Pasquin, M. J., Díaz, C., Del Barrio, J. L., Estrada, J. M., & Gil, N. (2013). Are healthcare workers' intentions to vaccinate related to their knowledge, beliefs and attitudes? a systematic review. *BMC Public Health*, 13(1). <https://doi.org/10.1186/1471-2458-13-154>
- Heunis, C., Van Jaarsveldt, D., Chikobvu, P., Kigozi-Male, G., & Litheko, M. (2024). Exploring Health Research Priority Setting in a South African Province: A Nominal Group Technique Approach. *International Journal of Environmental Research and Public Health*, 21(7), 861. <https://doi.org/10.3390/ijerph21070861>
- Hofman, K. J., McGee, S., Chalkidou, K., Tantivess, S., & Culyer, A. J. (2015). *National Health Insurance in South Africa: relevance of a national priority-setting agency: editorial*. <http://reference.sabinet.co.za/proxy/DocumentView/aHR0cDovL3JlZmVyZW5jZS5zYWJpbmV0LmNvLnphL2RvY3VtZW50L0VKQzE3NTU3Ng%3D%3D/a%3A1%3A%7Bs%3A6%3A%22source%22%3Bs%3A3%3A%22RSS%22%3B%7D>
- Hoque, M. E., Monokoane, S., & Van Hal, G. (2014). Knowledge of and attitude towards human papillomavirus infection and vaccines among nurses at a tertiary hospital in South Africa. *Journal of Obstetrics and Gynaecology*, 34(2), 182–186. <https://doi.org/10.3109/01443615.2013.861395>
- Jefferson, A., Smith, A., Fasinu, P. S., & Thompson, D. K. (2021). Sexually Transmitted Neisseria gonorrhoeae Infections—Update on Drug Treatment and Vaccine Development. *Medicines*, 8(2), 11. <https://doi.org/10.3390/medicines8020011>

- John, S. A., Walsh, J. L., Cho, Y. I., & Weinhardt, L. S. (2017). Perceived risk of intimate partner violence among STI clinic patients: Implications for Partner notification and Patient-Delivered Partner Therapy. *Archives of Sexual Behavior*, 47(2), 481–492. <https://doi.org/10.1007/s10508-017-1051-0>
- Kahn, A. L., Steffen, C. A., Henaff, L., MacDonald, N. E., Morgan, C., Faden, R., Olayinka, F., & Desai, S. (2023). COVID-19 vaccine policy development in a sample of 44 countries – Key findings from a December 2021 survey of National Immunization Technical Advisory Groups (NITAGs). *Vaccine*, 41(3), 676–683. <https://doi.org/10.1016/j.vaccine.2022.11.029>
- Kapiriri, L., Schuster-Wallace, C., & Chanda-Kapata, P. (2018). Evaluating health research priority-setting in low-income countries: a case study of health research priority-setting in Zambia. *Health Research Policy and Systems*, 16(1). <https://doi.org/10.1186/s12961-018-0384-z>
- Kochhar, S., Barreira, D., Beattie, P., Cavaleri, M., Cravioto, A., Frick, M. W., Ginsberg, A. M., Hudson, I., Kaslow, D. C., Kurtz, S., Lienhardt, C., Madhi, S. A., Morgan, C., Momeni, Y., Patel, D., Rees, H., Rogalski-Salter, T., Schmidt, A., Semete-Makokotlela, B., . . . Giersing, B. (2022). Building the concept for WHO Evidence Considerations for Vaccine Policy (ECVP): Tuberculosis vaccines intended for adults and adolescents as a test case. *Vaccine*, 40(12), 1681–1690. <https://doi.org/10.1016/j.vaccine.2021.10.062>
- Kularatne, R., Maseko, V., Gumede, L., & Kufa, T. (2018). Trends in *Neisseria gonorrhoeae* Antimicrobial Resistance over a Ten-Year Surveillance Period, Johannesburg, South Africa, 2008–2017. *Antibiotics*, 7(3), 58. <https://doi.org/10.3390/antibiotics7030058>
- Kularatne, R. S., Niit, R., Rowley, J., Kufa-Chakezha, T., Peters, R. P. H., Taylor, M. M., Johnson, L. F., & Korenromp, E. L. (2018). Adult gonorrhea, chlamydia and syphilis prevalence, incidence, treatment and syndromic case reporting in South Africa: Estimates using the Factors Influencing the Potential Introduction of a Gonorrhea Vaccine in South Africa
- Research Report: 31 MAR 2025

Spectrum-STI model, 1990-2017. *PLOS ONE*, 13(10), e0205863. <https://doi.org/10.1371/journal.pone.0205863>

Kumar, P., Sharma, R., Prajapati, S., & Patel, B. (2016). Evaluation of skill-oriented training on enhanced syndromic case management (ESCM) of reproductive tract infections / sexually transmitted infections (RTI/STIs) of care providers from three-tier health-care system of Gujarat. *Indian Journal of Community Medicine*, 41(3), 183. <https://doi.org/10.4103/0970-0218.183594>

Ladhani, S. N., White, P. J., Campbell, H., Mandal, S., Borrow, R., Andrews, N., Bhopal, S., Saunders, J., Mohammed, H., Drisdale-Gordon, L., Callan, E., Sinka, K., Folkard, K., Fifer, H., & Ramsay, M. E. (2024). Use of a meningococcal group B vaccine (4CMenB) in populations at high risk of gonorrhoea in the UK. *The Lancet Infectious Diseases*. [https://doi.org/10.1016/s1473-3099\(24\)00031-8](https://doi.org/10.1016/s1473-3099(24)00031-8)

Leduc, I., Connolly, K. L., Begum, A., Underwood, K., Darnell, S., Shafer, W. M., Balthazar, J. T., Macintyre, A. N., Sempowski, G. D., Duncan, J. A., Little, M. B., Rahman, N., Garges, E. C., & Jerse, A. E. (2020). The serogroup B meningococcal outer membrane vesicle-based vaccine 4CMenB induces cross-species protection against *Neisseria gonorrhoeae*. *PLOS Pathogens*, 16(12), e1008602. <https://doi.org/10.1371/journal.ppat.1008602>

Lin, C., Mullen, J., Smith, D., Kotarba, M., Kaplan, S. J., & Tu, P. (2021). Healthcare Providers' Vaccine Perceptions, Hesitancy, and Recommendation to Patients: A Systematic Review. *Vaccines*, 9(7), 713. <https://doi.org/10.3390/vaccines9070713>

Lin, E. Y., Adamson, P. C., & Klausner, J. D. (2021). Epidemiology, Treatments, and Vaccine Development for Antimicrobial-Resistant *Neisseria gonorrhoeae*: Current Strategies and Future Directions. *Drugs*, 81(10), 1153–1169. <https://doi.org/10.1007/s40265-021-01530-0>

Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic Inquiry*.

SAGE. http://books.google.ie/books?id=2oA9aWlNeooC&printsec=frontcover&dq=Naturalistic+inquiry&hl=&cd=1&source=gbs_api

MacPhail, C., Venables, E., Rees, H., & Delany-Moretlwe, S. (2013). Using HPV vaccination for promotion of an adolescent package of care: opportunity and perspectives. *BMC Public Health*, 13(1). <https://doi.org/10.1186/1471-2458-13-493>

Mantel, C., & Wang, S. A. (2012). The privilege and responsibility of having choices: decision-making for new vaccines in developing countries. *Health Policy and Planning*, 27(suppl 2), ii1–ii4. <https://doi.org/10.1093/heapol/czs041>

Marjuki, H., Topaz, N., Joseph, S. J., Gernert, K. M., Kersh, E. N., & Wang, X. (2019). Genetic Similarity of Gonococcal Homologs to Meningococcal Outer Membrane Proteins of Serogroup B Vaccine. *mBio*, 10(5). <https://doi.org/10.1128/mbio.01668-19>

Mathews, C., Kalichman, M. O., Laubscher, R., Hutchison, C., Nkoko, K., Lurie, M., & Kalichman, S. C. (2017). Sexual relationships, intimate partner violence and STI partner notification in Cape Town, South Africa: an observational study. *Sexually Transmitted Infections*, 94(2), 144–150. <https://doi.org/10.1136/sextrans-2017-053434>

Matthias, K. A., Connolly, K. L., Begum, A. A., Jerse, A. E., Macintyre, A. N., Sempowski, G. D., & Bash, M. C. (2021). Meningococcal Detoxified Outer Membrane Vesicle Vaccines Enhance Gonococcal Clearance in a Murine Infection Model. *The Journal of Infectious Diseases*, 225(4), 650–660. <https://doi.org/10.1093/infdis/jiab450>

McKeever, M. (2023). Social stratification and inequality in South Africa. *Sociology Compass*, 18(2). <https://doi.org/10.1111/soc4.13173>

- Meiring, S., Hussey, G., Jeena, P., Parker, S., & Von Gottberg, A. (2017). Recommendations for the use of meningococcal vaccines in South Africa. *Southern African Journal of Infectious Diseases*, 32(3), 82–86. <https://doi.org/10.1080/23120053.2017.1359939>
- Muellmann, S., Brand, T., Jürgens, D., Gansefort, D., & Zeeb, H. (2021, March 9). *How many key informants are enough? Analysing the validity of the community readiness assessment*. BMC Research Notes. <https://doi.org/10.1186/s13104-021-05497-9>
- National Department of Health, Republic of South Africa. (2020). *Proposed Revision: Terms of Reference and Conditions for NAGI*.
- National Health Act No. 61 of 2003. (2004).
- Naude, C. E., Zani, B., Ongolo-Zogo, P., Wiysonge, C. S., Dudley, L., Kredo, T., Garner, P., & Young, T. (2015). Research evidence and policy: qualitative study in selected provinces in South Africa and Cameroon. *Implementation Science*, 10(1). <https://doi.org/10.1186/s13012-015-0315-0>
- Nevedal, A. L., Reardon, C. M., Widerquist, M. a. O., Jackson, G. L., Cutrona, S. L., White, B. S., & Damschroder, L. J. (2021). Rapid versus traditional qualitative analysis using the Consolidated Framework for Implementation Research (CFIR). *Implementation Science*, 16(1). <https://doi.org/10.1186/s13012-021-01111-5>
- Nevhuthalu, P., Makgoba, W., Mametja, D., Mekwa, J., Richter, L., Househam, K., Mbewu, A., Makubalo, L., Jeenah, M. S., Kuzwayo, P., Klugman, B., Tollman, S., Jinabhai, N., Mkhonto, S., Schneider, H., Ntsaluba, A., Ijsselmuiden, C., Netshidzivhani, P., Mulumba, R., & Ntuli, N. (2001). *HEALTH RESEARCH POLICY IN SOUTH AFRICA*. https://www.gov.za/sites/default/files/gcis_document/201409/healthresearch0.pdf
- Newton-Levinson, A., Leichliter, J. S., & Chandra-Mouli, V. (2016). Sexually Transmitted Infection Services for Adolescents and Youth in Low- and Middle-Income Countries: Perceived and Factors Influencing the Potential Introduction of a Gonorrhea Vaccine in South Africa
- Research Report: 31 MAR 2025

Experienced Barriers to Accessing Care. *Journal of Adolescent Health*, 59(1), 7–

16. <https://doi.org/10.1016/j.jadohealth.2016.03.014>

Ngcobo, N. J., Burnett, R. J., Cooper, S., & Wiysonge, C. S. (2019). Human papillomavirus vaccination acceptance and hesitancy in South Africa: Research and policy agenda. *South African Medical Journal*, 109(1), 13. <https://doi.org/10.7196/samj.2018.v109i1.13723>

Nowell, L. S., Norris, J. M., White, D. E., & Moules, N. J. (2017). Thematic Analysis. *International Journal of Qualitative Methods*, 16(1), 160940691773384. <https://doi.org/10.1177/1609406917733847>

Ong, J. J., Unemo, M., Choong, A. L., Zhao, V., & Chow, E. P. (2022). Is the end of gonorrhoea in sight? *The Lancet Infectious Diseases*, 22(7), 919–921. [https://doi.org/10.1016/s1473-3099\(22\)00002-0](https://doi.org/10.1016/s1473-3099(22)00002-0)

Pahwa, M., Cavanagh, A., & Vanstone, M. (2023). Key Informants in Applied Qualitative Health Research. *Qualitative Health Research*, 33(14), 1251–1261. <https://doi.org/10.1177/10497323231198796>

Peters, R. P., Garrett, N., Chandiwana, N., Kularatne, R., Brink, A. J., Cohen, K., Gill, K., Chidarikire, T., Wattrus, C., Nel, J. S., Moosa, M. Y., & Bekker, L. G. (2022). Southern African HIV Clinicians Society 2022 guideline for the management of sexually transmitted infections: Moving towards best practice. *Southern African Journal of HIV Medicine*, 23(1). <https://doi.org/10.4102/sajhivmed.v23i1.1450>

Petousis-Harris, H., Paynter, J., Morgan, J., Saxton, P., McArdle, B., Goodyear-Smith, F., & Black, S. (2017). Effectiveness of a group B outer membrane vesicle meningococcal vaccine against gonorrhoea in New Zealand: a retrospective case-control study. *The Lancet*, 390(10102), 1603–1610. [https://doi.org/10.1016/s0140-6736\(17\)31449-6](https://doi.org/10.1016/s0140-6736(17)31449-6)

- Plotnikoff, K. M., Ogilvie, G. S., Smith, L., Donken, R., Pedersen, H. N., Samji, H., & Grennan, T. (2020). Factors associated with interest in bacterial sexually transmitted infection vaccines at two large sexually transmitted infection clinics in British Columbia, Canada. *Sexually Transmitted Infections*, 96(7), 494–500. <https://doi.org/10.1136/sextrans-2019-054311>
- Read, R. C., Baxter, D., Chadwick, D. R., Faust, S. N., Finn, A., Gordon, S. B., Heath, P. T., Lewis, D. J. M., Pollard, A. J., Turner, D. P. J., Bazaz, R., Ganguli, A., Havelock, T., Neal, K. R., Okike, I. O., Morales-Aza, B., Patel, K., Snape, M. D., Williams, J., . . . Borrow, R. (2014). Effect of a quadrivalent meningococcal ACWY glycoconjugate or a serogroup B meningococcal vaccine on meningococcal carriage: an observer-blind, phase 3 randomised clinical trial. *The Lancet*, 384(9960), 2123–2131. [https://doi.org/10.1016/s0140-6736\(14\)60842-4](https://doi.org/10.1016/s0140-6736(14)60842-4)
- Saldana, J. (2021). *The Coding Manual for Qualitative Researchers*. SAGE.
- Sharma, V., & Gupta, V. (2019). Syndromic management of sexually transmitted infections: A critical appraisal and the road ahead. *The National Medical Journal of India*, 32(3), 147. <https://doi.org/10.4103/0970-258x.278691>
- Shrivastava, S., Shrivastava, P., & Ramasamy, J. (2018). World health organization releases global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics. *Journal of Medical Society*, 32(1), 76. https://doi.org/10.4103/jms.jms_25_17
- St George, S. M., Harkness, A. R., Rodriguez-Diaz, C. E., Weinstein, E. R., Pavia, V., & Hamilton, A. B. (2023). Applying rapid Qualitative analysis for health equity: Lessons learned using “EARS” with Latino communities. *International Journal of Qualitative Methods*, 22. <https://doi.org/10.1177/16094069231164938>

- Stephens, D. S. (2009). Biology and pathogenesis of the evolutionarily successful, obligate human bacterium *Neisseria meningitidis*. *Vaccine*, 27, B71–B77. <https://doi.org/10.1016/j.vaccine.2009.04.070>
- Uchenna, C., & Govender, I. (2018). Knowledge, attitudes and practices of doctors at Jubilee Hospital, Tshwane District, regarding the syndromic management guidelines for sexually transmitted infections. *South African Family Practice*, 60(5), 155–161. <https://doi.org/10.1080/20786190.2018.1487212>
- Unemo, M., Bradshaw, C. S., Hocking, J. S., De Vries, H. J. C., Francis, S. C., Mabey, D., Marrazzo, J. M., Sonder, G. J. B., Schwebke, J. R., Hoornenborg, E., Peeling, R. W., Philip, S. S., Low, N., & Fairley, C. K. (2017). Sexually transmitted infections: challenges ahead. *The Lancet Infectious Diseases*, 17(8), e235–e279. [https://doi.org/10.1016/s1473-3099\(17\)30310-9](https://doi.org/10.1016/s1473-3099(17)30310-9)
- Vallely, L. M., Egli-Gany, D., Wand, H., Pomat, W. S., Homer, C. S. E., Guy, R., Silver, B., Rumbold, A. R., Kaldor, J. M., Vallely, A. J., & Low, N. (2021a). Adverse pregnancy and neonatal outcomes associated with *Neisseria gonorrhoeae*: systematic review and meta-analysis. *Sexually Transmitted Infections*, 97(2), 104–111. <https://doi.org/10.1136/sextrans-2020-054653>
- Vallely, L. M., Egli-Gany, D., Wand, H., Pomat, W. S., Homer, C. S. E., Guy, R., Silver, B., Rumbold, A. R., Kaldor, J. M., Vallely, A. J., & Low, N. (2021b). Adverse pregnancy and neonatal outcomes associated with *Neisseria gonorrhoeae*: systematic review and meta-analysis. *Sexually Transmitted Infections*, 97(2), 104–111. <https://doi.org/10.1136/sextrans-2020-054653>
- Van Der Putten, I. M., Paulus, A. T., Hilgsmann, M., Hutubessy, R. C., & Evers, S. M. (2019). Evidence-informed vaccine decision making: The introduction of Human Papilloma Virus

(HPV) vaccination in the Netherlands. *Health Policy*, 123(3), 260–

266. <https://doi.org/10.1016/j.healthpol.2018.09.001>

Vicentini, C., Manfredini, S., Meritati, M., Di Nuzzo, M., & Contini, C. (2019). Gonorrhea, a

current disease with ancient roots: from the remedies of the past to future perspectives. *Infez*

Med, 27(2), 212–

221. [https://www.infezmed.it/index.php/article?Anno=2019&numero=2&ArticoloDaVisualizare=Vol_27_2_2019_212](https://www.infezmed.it/index.php/article?Anno=2019&numero=2&ArticoloDaVisualizzare=Vol_27_2_2019_212)

Wallace, L., & Kipiriri, L. (2017). How Are New Vaccines Prioritized in Low-Income Countries? A

Case Study of Human Papilloma Virus Vaccine and Pneumococcal Conjugate Vaccine in

Uganda. *International Journal of Health Policy and Management*, 6(12), 707–

720. <https://doi.org/10.15171/ijhpm.2017.37>

Whelan, J., Abbing-Karahagopian, V., Serino, L., & Unemo, M. (2021). Gonorrhoea: a systematic review of prevalence reporting globally. *BMC Infectious*

Diseases, 21(1). <https://doi.org/10.1186/s12879-021-06381-4>

Padeniya, T. N., Hui, B. B., Wood, J. G., Seib, K. L., & Regan, D. G. (2023). *The potential impact of a vaccine on Neisseria gonorrhoeae prevalence among heterosexuals living in a high*

prevalence setting. *Vaccine*, 41(38), 5553–

5561. <https://doi.org/10.1016/j.vaccine.2023.07.048>

Whittles, L. K., Didelot, X., & White, P. J. (2022). Public health impact and cost-effectiveness of gonorrhoea vaccination: an integrated transmission-dynamic health-economic modelling

analysis. *The Lancet Infectious Diseases*, 22(7), 1030–1041. [https://doi.org/10.1016/s1473-](https://doi.org/10.1016/s1473-3099(21)00744-1)

[3099\(21\)00744-1](https://doi.org/10.1016/s1473-3099(21)00744-1)

Whittles, L. K., White, P. J., & Didelot, X. (2020). Assessment of the Potential of Vaccination to

Combat Antibiotic Resistance in Gonorrhea: A Modeling Analysis to Determine Preferred

Factors Influencing the Potential Introduction of a Gonorrhea Vaccine in South Africa

Research Report: 31 MAR 2025

Product Characteristics. *Clinical Infectious Diseases*, 71(8), 1912–

1919. <https://doi.org/10.1093/cid/ciz1241>

WHO. (2023a, July 11). *Multi-drug resistant gonorrhoea*. Retrieved May 8, 2024, from <https://www.who.int/news-room/fact-sheets/detail/multi-drug-resistant-gonorrhoea>.

WHO. (2023b, July 18). *Gonorrhoea (Neisseria gonorrhoeae infection)*. Retrieved May 8, 2024, from [https://www.who.int/news-room/fact-sheets/detail/gonorrhoea-\(neisseria-gonorrhoeae-infection\)](https://www.who.int/news-room/fact-sheets/detail/gonorrhoea-(neisseria-gonorrhoeae-infection))

WHO. (2023c, July 18). *Immunization coverage*. Retrieved May 8, 2024, from <https://www.who.int/news-room/fact-sheets/detail/immunization-coverage>.

WHO. (2023d, December 12). *2023 meeting: WHO Product Development for Vaccines Advisory Committee Meeting (PDVAC)*. Retrieved May 16, 2024, from <https://www.who.int/news-room/events/detail/2023/12/12/default-calendar/2023-meeting-who-product-development-for-vaccines-advisory-committee-meeting-pdvac>.

WHO. (2024, May 28). WHO. Retrieved March 21, 2025, from <https://www.who.int/teams/immunization-vaccines-and-biologicals/product-and-delivery-research/evidence-considerations-for-vaccine-policy>.

WHO Product Development for Vaccines Advisory Committee. (2023). *WHO Product Development for Vaccines Advisory Committee Executive summary & recommendations*. https://cdn.who.int/media/docs/default-source/immunization/pdvac/pdvac-2024/who-pdvac-executive-summary-draft-12march-2024.pdf?sfvrsn=13639368_1

Wigle, J., Coast, E., & Watson-Jones, D. (2013). Human papillomavirus (HPV) vaccine implementation in low and middle-income countries (LMICs): Health system experiences and prospects. *Vaccine*, 31(37), 3811–3817. <https://doi.org/10.1016/j.vaccine.2013.06.016>

- World Health Organization (WHO). (2017, September 4). *Prioritization of pathogens to guide discovery, research and development of new antibiotics for drug-resistant bacterial infections, including tuberculosis*. World Health Organization. Retrieved May 2, 2024, from <https://www.who.int/publications/i/item/WHO-EMP-IAU-2017.12>.
- Yakobi, S. H., Magibile, Y. B., & Poee, O. J. (2024). A systematic review of *Neisseria gonorrhoeae* drug resistance development in South Africa. *Brazilian Journal of Microbiology*. <https://doi.org/10.1007/s42770-024-01281-6>
- Zheng, Y., Yu, Q., Lin, Y., Zhou, Y., Lan, L., Yang, S., & Wu, J. (2022). Global burden and trends of sexually transmitted infections from 1990 to 2019: an observational trend study. *The Lancet Infectious Diseases*, 22(4), 541–551. [https://doi.org/10.1016/s1473-3099\(21\)00448-5](https://doi.org/10.1016/s1473-3099(21)00448-5)
- Christensen, H., Trotter, C. L., Hickman, M., & Edmunds, W. J. (2014). Re-evaluating cost effectiveness of universal meningitis vaccination (Bexsero) in England: Modelling study. *BMJ*, 349, g5725. <https://doi.org/10.1136/bmj.g5725>
- Joint Committee on Vaccination and Immunisation. (2014, March 21). *JCVI position statement on use of Bexsero® (meningococcal B vaccine) in the UK*. UK Government / Department of Health. https://assets.publishing.service.gov.uk/media/5a7c6e3ae5274a5255bce97d/JCVI_Statement_on_MenB.pdf

CHAPTER 5:APPENDICES

5.1 Appendix A: Interview Schedule

1

Appendix B Interview Schedule

- Please could you tell me a little bit about yourself?
- How old are you? If you don't feel comfortable to share your age perhaps you could tell me which age category you fall into?
 - 1) 18-29,
 - 2) 30-39,
 - 3) 40-49,
 - 4) 50-59,
 - 5) 60+.
- Do you identify as Male, female or other?
- What is your highest level of Education?
 - 1) Matric,
 - 2) Diploma or bachelor's degree
 - 3) Master's degree or PhD
 - 4) other postgraduate training.
- What is your current Professional affiliation?
 - 1) HPCSA,
 - 2) SANC,
 - 3) Other (specify)
- How many years in your current profession? Alternatively would you say that you have been working in your current profession for:
 - 1) Less than 1 year
 - 2) 1-5 years
 - 3) 6-10 years
 - 4) 11-20 years
 - 5) 20+ years
- What is your current Job title?
- Please could you tell me a about your role in relation to the management of STIs or the vaccination program?
 - how long have you been involved in this?
- What do you think are the current challenges to STI prevention and control in South Africa
- What do you think are the current barriers to expanding vaccination beyond the current EPI program in South Africa?

Factors Influencing the Potential Introduction of a Gonorrhea Vaccine in South Africa: Interview Schedule version 1.0, 17 May 2024/English
Protocol Version: 1.0, 16 May 2024 Researcher name: Bafana Sydwell Mdluli

Global Health Security Impact

1. Given what you know about gonorrhoea and your experiences in your field, is gonorrhoea a public health problem?
 - a. Probe: And why do you think this is the case?
2. What is your experience or knowledge of current diagnostic and treatment methods for gonorrhoea?
 - a. Probe: What are the advantages
 - b. Probe: What are the disadvantages of the current methods?
3. Do you think that gonorrhoea has an epidemic potential?
 - a. Probe: What makes you say this ?
4. What has been your experience with drug-resistant gonorrhoea?
 - a. Probe: Have you heard of patients with antibiotic resistant gonorrhoea?
 - b. Probe: What do you think has led to antibiotic resistance in S. Africa
5. Do you think that a potential vaccine for gonorrhoea could combat gonorrhoea antimicrobial resistance?
 - a. Probe: what are the reasons for your response
6. Do you think AMR is a concern for the Department of Health?
 - a. Probe: do you think that the concerns about AMR would influence vaccine prioritisation?

Impact on health and health systems

1. Have you heard about the trials of 4CMenB for prevention of gonorrhoea before today/this interview?
 - a. Probe: Where did you hear about this?
2. What impact do you think a vaccine for gonorrhoea would have on the number of gonorrhoea infections within the populations you serve?
 - a. Probe: what is the prevalence and/or incidence of gonorrhoea in the population you serve?
 - b. Probe: who in your clinics is most affected by gonorrhoea?
 - c. Probe: why do you think this might be?

3. What impact do you think a vaccine might have on the potential long-term negative health outcomes of gonorrhoea infection on the South African population?
 - a. Probe: do you see the sequelae of untreated infection at your clinic?
 - b. Probe: what sequelae do you see most commonly?
 - c. Probe: what happens to patients with those sequelae in terms of additional care?
4. With respect to a vaccine for meningitis B that could also prevent gonorrhoea, do you see any benefits for the meningitis prevention programme?
 - a. Probe: what might those be?
 - b. Probe: do you consider meningitis B a substantial threat to health in South Africa?
 - c. Probe: Have you come across cases of meningitis B in your clinic?
 - d. Probe: have you had experience with seeing patients who experience the consequences of invasive meningitis B disease?
5. What are the key health outcomes that should be monitored to evaluate the success of 4CMENB vaccine in preventing gonorrhoea?
 - a. Probe: How would they influence the decision to introduce the vaccine in South Africa?
6. What do you think will be the impact of introducing a vaccine for gonorrhoea prevention on the healthcare system?
 - a. Probe: what might those be?

Equity and Social Protection Impact

1. Who do you think this vaccine should be offered to?
 - a. Probe: what age group should this be offered to
 - b. Probe: should this be offered to males, females or females only?
 - c. Any particular population groups?
 - d. Do you have experience with providing services to these populations?
2. Do you think that infections like gonorrhoeae are associated with stigma in the communities you work with?

- a. Probe: do you think stigma would be a barrier to introduction
 - b. Probe: could you explain your answer?
 - c. Probe: Do you think that the populations affected by gonorrhoea could influence decision-making about implementing this vaccine?
 - d. Probe: Are there effects of gonorrhoea on particular populations that might be more influential for vaccine introduction?
3. Do you think the framing of the vaccine is important? By this I mean, do you think it will be important to frame 4CMENB as a vaccine against meningitis with gonorrhoea prevention benefits? Or a gonorrhoea vaccine with meningitis benefits? Or something else?
 4. How might the introduction of a gonorrhoea vaccine address health disparities?
 - a. Probe: will there be any benefits for vulnerable groups such as young women and girls in South Africa?
 - b. Probe: benefits for key populations like men who have sex with men, transgender people, sex workers

Implementation Feasibility.

1. How do you think a gonorrhoea vaccine would be able to fit into the current immunisation programmes?
 - a. Probe: Would it replace an existing vaccine or meet a new need?
 - b. Probe: would it be better delivered as a mass vaccination strategy like HPV OR as a targeted vaccine for people seeking PrEP or HIV services? Please could you explain your answer
2. What are the potential challenges to the successful implementation of a GC specific vaccine in South Africa's existing healthcare framework?
 - a. Probe: Is this altered if we consider introduction of 4CMenB
3. What are the potential facilitators to the successful implementation of a GC vaccine in South Africa's existing healthcare framework?
 - a. Probe: Is this altered if we consider introduction of 4CMenB
2. What do you think are the advantages and disadvantages of a GC vaccine in preventing gonorrhoea infections compared to existing treatment modalities?

3. Would you recommend a gonorrhoea vaccine to your patients?
 - a. Probe: would you recommend the 4CMenB vaccine to your patients if it is effective against gonorrhoea?
4. How do you think your patients will perceive a meningococcal B vaccine for preventing gonorrhoea?
 - a. Probe: What do you think will be the advantages for this population
 - b. Probe: What would be the challenges with the vaccine?
 - c. Probe: Would it make a difference if this was a gonorrhoea-specific vaccine?
5. What knowledge gaps would need to be addressed among South Africans to make a GC vaccine acceptable to them,
 - a. Probe: what do you think are the best ways to address these gaps?
6. What are your thoughts on healthcare workers' readiness for such a vaccine?
 - a. What knowledge gaps would need to be addressed health care workers to make this vaccine acceptable to them?
 - b. Probe: what do you think are the best ways to address these gaps?
7. What key health outcomes should be monitored to evaluate the success of gonorrhoea vaccine?
 - a. Probe: in addition, what should be monitored if we used the 4CMenB vaccine for meningitis and gonorrhoea?
8. Considering the need for two doses administered two months apart, what logistical challenges do you anticipate?
 - a. Probe: How might the two-dose schedule impact vaccine uptake and adherence ?
 - b. Probe: How would you ensure patients return for their second dose after two months?

Financial implications, Value for Money, and Economic Impact.

1. What health outcomes do you think would be most influential in the introduction of a GC vaccine
 - a. Probe for infections OR sequelae of untreated infection like infertility OR effects on pregnancy and infant OR AMR
 - b. For the 4CMENB vaccine, if the additional benefit against meningitis B an important consideration?

2. Do you know the current price of the 4CMENB vaccine? In your opinion, would the cost of procuring the 4CMENB vaccine be justified by the potential reduction in gonorrhoea cases?
 - a. Probe Why or why not?
3. What operational challenges do you anticipate in the rollout of 4CMENB, and how could these affect the overall cost?
4. Could you elaborate on the economic benefits (for example human resources, space, and other resources) that the healthcare system might realize from the prevention of gonorrhoea using 4CMENB meningococcal B?

Broader Health System Benefits and broader health systems benefits

1. What broader impacts on the health system do you foresee if 4CMENB is introduced for gonorrhoea prevention?
 - a. Probe: Why do you think that might be?
2. In what ways might the introduction of 4CMENB for gonorrhoea prevention strengthen the overall health system in South Africa?
 - a. Probe: Why do you think that might be?
3. How do current surveillance systems need to adapt to incorporate new vaccines like 4CMENB?
 - a. Probe: Do you foresee that being feasible?

5.2 Appendix B: Ethics approval Wits HREC



UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

R14/49 Dr Bafana Mdhuli M240615

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M240615

NAME: Dr Bafana Mdhuli
(Principal Investigator)

DEGREE: Msc (Med) Vaccinology

STUDENT/STAFF NO: 481918

FACULTY/SCHOOL: Faculty of Health Sciences, School of Pathology

DEPARTMENT: Vaccinology

STUDY SITE (S): Quadcare Primary Health (Pty) Ltd, NDoH, GDoH, Ekurhuleni District Health, Tshwane Health District and JHB District Health

PROJECT TITLE: Factors influencing the potential introduction of a Gonorrhoea vaccine in South Africa

DATE CONSIDERED: 21/06/2024

DECISION: Approved unconditionally

CONDITIONS: Research can only be conducted at above listed study site(s) and specified groups in their private capacity

NOTE: Ethics Online System ref no MED24-05-500

SUPERVISOR: Prof Sinead Delany-Moretlwe and Miss Lisa-Marie Mills

APPROVED BY: 
Paul Ruff (Nov 8, 2024 11:39 GMT+2)
Prof P Ruff, Chairperson, HREC (Medical)

DATE OF APPROVAL: 11/09/2024, 01/10/2024, 08/11/2024 **EXPIRY DATE:** 11/09/2029

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to Committee. **I agree to submit a yearly progress report** in July each year until study is closed. Failure to submit annual report will result in ethics clearance certificate suspension. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in June and will therefore be due in the month of June each year. Unreported changes to the application invalidate the clearance given by the HREC (Medical). Email signed copy of this ethics clearance certificate prior to commencing with the study hrec-medical.researchoffice@wits.ac.za

 **Principal Investigator Signature** **10 Nov 2024**
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

5.3 Appendix C: Informed consent

Page 1 of 4

Participant Information Leaflet and Informed Consent Form

Factors Influencing the Potential Introduction of a Gonorrhea Vaccine in South Africa

Version 1.0 07 May 2024

RESEARCHER: Bafana Sydwell Mdhuli

SUPERVISORS: Prof. Sinead Delany-Moretlwe, Lisa-Marie Mills

INSTITUTION: Wits RHI, University of the Witwatersrand

SITE TELEPHONE NUMBER: 011 358 5300 or 067 674 5894 (24-hour emergency line)

To the potential Participant: This consent form may contain words that you do not understand. Please ask the investigator or any study staff to explain any words or information you do not understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision. Once you understand the study, and if you agree to take part, you will be asked to sign your name or make your mark on this form. You will be offered a copy to keep.

Factors Influencing the Potential Introduction of a Gonorrhea Vaccine in South Africa: Participant Information Leaflet and Informed Consent Form version 1.0, 10 May 2024/English
Protocol Version: 1.0, 16 May 2024 Researcher name: Bafana Sydwell Mdhuli
Approved by Wits HREC (Medical). Date of approval: 11/09/2024 Participant initials: _____

Hi, my name is Bafana Sydwell Mdhuli, and I am doing an MSc in medicine in the field of vaccinology at the University of Witwatersrand.

You are being invited to participate in a research study that is exploring perspectives around a potential gonorrhea vaccine. This research project aims to explore health system perspectives on factors that might influence the potential introduction of a vaccine for gonorrhea prevention in South Africa.

The purpose of this consent form is to give you the information you will need to help you decide if you want to participate in this study. Your participation is completely voluntary. You do not have to take part in the study if you do not want to. You are not required to participate in this study as part of your employment. You may decide to stop taking part in the study at any time without losing your employment.

KEY INFORMATION ABOUT PARTICIPATING IN THE STUDY

Purpose: Wits RHI is conducting a study called BIYELA – Bexsero Immunisation in Young Women in Africa. Should the BIYELA study show that Bexsero protects against gonorrhea, it would be important to learn what factors need to be considered and addressed if the vaccine were to be introduced into the health system in South Africa.

Gonorrhea is an STI caused by a bacteria called *Neisseria gonorrhea*. It is curable with antibiotics, but if it is not diagnosed and treated it can cause problems such as increased risk of HIV infection, difficulties with getting pregnant, difficulties during pregnancy such as premature birth, and health problems for the baby, including small size, illness, and infection of the eyes. The bacteria that cause gonorrhea can also develop resistance to antibiotics, meaning that infections may become more difficult to treat. These resistant bacteria can spread from person to person and as they become more common in the community, the antibiotics we use to cure gonorrhea will not work as well. Studies have shown high rates of gonorrhea, particularly in women in eastern and southern Africa.

1. Who will take part in the study?

The study will enroll 12 to 20 Professionals, including healthcare providers (i.e., doctors, clinical associates and nurses) and academic experts, program managers, and policy makers. Participants should be at least 18 years old and able to communicate in English.

2. What will I be expected to do in the study?

If you agree to participate and sign this consent, you will be asked a series of questions about your views on:

Factors Influencing the Potential Introduction of a Gonorrhea Vaccine in South Africa: Participant Information Leaflet and Informed Consent Form version 1.0, 10 May 2024/English
Protocol Version: 1.0, 16 May 2024 Researcher name: Bafana Sydwell Mdhuli
Approved by Wits HREC (Medical). Date of approval: 11/09/2024

- The extent of the health problem of sexually transmitted infections, particularly gonorrhea as a public health concern in South Africa and in the world
- Your perspectives on the implementational and adoption vaccines in South Africa.
- Considerations for cost and cost effectiveness of new vaccines in South Africa
- Potential implementation challenges for a new vaccine in the South African public health system.

There are no right and wrong answers to these questions; we are interested in hearing about your experiences and opinions. If any of the questions make you uncomfortable or upset, you do not have to answer. You may stop the interview at any time. If you'd like to speak to a counsellor, you will be provided with a referral.

The interview will take place in a location that is previously agreed upon and that will provide privacy and confidentiality. We may also ask your permission to conduct the interview remotely. **The interview should take approximately 60 minutes, and we will ask for your permission to audio-record the interview.**

3. Are there any potential risks or discomforts that I can expect during the interview?

The greatest risk may involve your privacy and confidentiality. To minimise any discomfort and to protect your privacy, the interview will be conducted in a private area that will allow you to speak comfortably without being overheard. Although we hope that you will be comfortable answering all the questions openly and honestly, please keep in mind that you may refuse to answer any of the questions, or stop the interview completely, at any time. Answers to questions will not be shared with employers and manager, and the final report will conceal participants identities.

4. How will my information be kept confidential?

Your data will be collected, processed and stored according to the South African Protection of Personal Information (POPI) Act of 2013. Every effort will be made to keep your personal information confidential. Your name, or anything else that might identify you personally, will not be used in any publication of information about this study.

To help assure that we get the best understanding possible from your answers during the interview, the entire interview will be audio-recorded. After the interview is finished, the recording will be typed. All identifying information will be removed from the transcript. Your name will not be included on the transcript. Recordings and transcripts will be saved electronically under password protection with limited access only to authorized representatives of Wits RHI and the University of Witwatersrand.

Recordings will be kept for 2 years after publication or 6 years if

Participant initials: _____

no publication. All transcripts will be saved electronically for up to 10 years according to local regulations.

Your records may be reviewed by representatives of the University of Witwatersrand and the Wits Human Research Ethics Committee who watch over this study to see that we are protecting participants' rights, keeping participants safe, and following the study plan. Your personal information may be disclosed if required by law. In this case, we will let you know of our plan to disclose such information to the relevant government authority.

5. What are the benefits, costs and reimbursement if I participate?

There will not be any direct benefit from participating in the in-depth interview; but you will have a chance to express your opinions and experiences which may assist in informing the introduction strategy for a future gonorrhea vaccine. You will not be paid to be in the study.

6. Will I be told about the results of the study?

This research project will be written up as a report available online through the university library website. If you wish to receive a summary of this report, I will be happy to send it to you at your request.

7. What are my rights if I agree to take part?

Your participation in this study is entirely voluntary and you can refuse to participate or end your participation at any time without stating any reason.

8. Who can I contact about problems or questions?

This study protocol has been submitted to the University of The Witwatersrand, Human Research Ethics Committee and written approval has been granted by the committee. If you have any questions about the interviews, you should contact:

Researcher: Bafana Sydwell Mdhuli email:

481918@students.wits.ac.za;

Tel: 0676745894

Supervisors: Prof Sinead Delany-Moretlwe

email: sdelany@wrhi.ac.za;

Tel 011 358 5300

Co-Supervisor : Ms Lisa-Marie Mills

email: lmills@wrhi.ac.za; Tel : 074 920 0067

If you have questions about your rights as a research participant while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact:

- **Prof. Paul Ruff**, Chair of the University of the Witwatersrand Human Research Ethics Committee (Medical), which is an independent committee established to help protect the rights of research participants on 011 717 2301.

Factors Influencing the Potential Introduction of a Gonorrhea Vaccine in South Africa: Participant Information Leaflet and Informed Consent Form version 1.0, 10 May 2024/English
 Protocol Version: 1.0, 16 May 2024 Researcher name: Bafana Sydwell Mdhuli
 Approved by Wits HREC (Medical). Date of approval: 11/09/2024 Participant initials: _____

SIGNATURE PAGE FOR PARTICIPANT INFORMATION LEAFLET AND INFORMED CONSENT FORM

Factors Influencing the Potential Introduction of a Vaccine for Gonorrhea Prevention in South Africa

Version 2.0; 07 May 2024

Participant's statement

I hereby confirm that I have read/had read to me the information provided in the Informed Consent Form. I have asked all the questions that I have at this time. My rights and responsibilities as a research participant have been explained to me. Please indicate your choice by inserting you initials in the table below:

PARTICIPANT CONSENT

Participant name and surname_____
Participant signature/mark and date (DD/MMM/YY)

Interviewer statement

By signing this form, I attest that I have provided the participant with information about this study. The participant has been given sufficient time to consider participation and I have answered any questions they had. The participant indicated that they understand the nature of the study, including risks and benefits of participating.

Staff name and surname_____
Staff signature and date (DD/MMM/YY)

WITNESS (IF APPLICABLE)

Witness name and surname_____
Witness signature and date (DD/MMM/YY)

*Witness is impartial and was present for the consent process.

	Participant Initials
I agree to be interviewed, and give my permission to have my interview audio-recorded	
I agree to be interviewed, but do not wish to have my interview audio recorded.	

Factors Influencing the Potential Introduction of a Gonorrhea Vaccine in South Africa: Participant Information Leaflet and Informed Consent Form version 1.0, 10 May 2024/English
 Protocol Version: 1.0, 16 May 2024 Researcher name: Bafana Sydwell Mdhuli
 Approved by Wits HREC (Medical). Date of approval: 11/09/2024 Participant initials: _____

5.4 Appendix D: Illustrative quotes

Theme	Illustrative quotes
Disease burden and epidemiology	
High Prevalence and Underreporting of Gonorrhoea	“Gonorrhoea is one of the most commonly diagnosed STIs, and it has a very high prevalence.” – HP03 “Many cases go undiagnosed because people are asymptomatic.” – HP05 “Gonorrhoea is difficult to diagnose because most people don’t have symptoms. If they don’t have symptoms, they don’t seek treatment.” – KI05 “Another issue is that some people don’t even know they have an STI.” – HP01 “A person will be asymptomatic and not know that they might have the infection. So, if you don't know that you have something, you would not seek help.” – HP04 “Not being able to diagnose gonorrhoea easily, and the complications that come with it, makes it a public health issue.” – KI04 “It’s tricky. I mean, yes. If we run out of antibiotics to treat patients, it will definitely end up being [an epidemic].” – HP06
Concern Over AMR	“AMR is a growing problem globally, and we are already seeing strains that are difficult to treat.” – KI02 “There is a high antibiotic resistance, which makes it hard to treat gonorrhoea infections.” – HP03 “Gonorrhoea is becoming increasingly resistant, and perhaps your study will assist us in tackling this issue.” – KI04 “Definitely it is something to be concerned about, firstly because of its virulence. We have seen some cases of drug-resistant gonorrhoea.” – HP05 “These antimicrobial resistant organisms are everywhere in the world... most countries are worried about antimicrobial resistance and gonorrhoea.” – KI06 “I think so. Definitely. I think the famous phrase, prevention is better than cure.” – HP01 “Patients are receiving multiple antibiotics, even when they don’t need them. This has definitely contributed to the resistance problem.” – HP04
Silent Protection for Vulnerable Women	“From a woman's perspective... them being protected and having access to something else is amazing.” – HCP01 “At least if there's that element of prevention instead of going to the clinic multiple times to treat gonorrhoea because your partner refuses to engage with you.” – HCP01

Other Health	“Vaccines that prevent multiple conditions are more likely to be well-received by people than separate vaccines for each condition.” – KI01 “If it prevents both meningitis and gonorrhoea, it makes a stronger case for inclusion in public immunization programs.” – KI01 “If we emphasize the broader health benefits of this vaccine, such as preventing meningitis alongside gonorrhoea, it would likely be more acceptable.” – KI03
Syndromic Management’s Double-Edged Nature	“The syndromic management approach is both beneficial and problematic. On one hand, it allows for immediate treatment without waiting for lab results.” – KI04 “However, it also contributes to antibiotic misuse and potential resistance, as patients are often treated empirically without confirming the specific pathogen.” – KI04 “We could be essentially over treating the symptom.” – KI06 “Syndromic management presents challenges, as it can lead to over-treatment or under-treatment.” – KI05 “It's sort of a quick fix for the patients. So, they know even if I don't listen, I'll go back, and I will get a quick fix.” – HP02 “A patient may believe they've been treated when, in reality, they had a different infection that wasn’t covered by the given treatment.” – HP03 “Sometimes, the diagnosis is just guessed, and that’s not ideal for managing resistance.” – HP01

Limited Surveillance Capacity	“Our surveillance is currently limited to three facilities, which is not enough. That is why we are expanding microbiological surveillance to other provinces.” – KI06
Anticipated impact on health burden	“I think it would be a game changer. Given the rise in antibiotic resistance, a vaccine could help control gonorrhoea and reduce the burden on our healthcare system.” – HP04 “A vaccine could significantly contribute by reducing overall STI rates and indirectly lowering HIV transmission.” – KI05 “I think a vaccine that would prevent gonorrhoea would reduce the amount of gonorrhoea infections we see at the clinic.” – HP02 “I think a vaccine would definitely be very useful in reducing antibiotic use and slowing down AMR.” – KI02 “If we had a gonorrhoea vaccine, it would sort of combat the threat of antimicrobial resistant gonorrhoea.” – HP05 “People would definitely take it if they knew it protected them from gonorrhoea, especially given the resistance issue.” – KI03 “Even if it’s only partially effective, if we use it in high-incidence populations, it could have big impact.” – HP06
Financial considerations	
Economic impact, costs, value for money, degree of vaccine market challenges	“New vaccine introductions are expensive, and we need to ensure this is the best use of limited funds.” – KI06 “The biggest player in most health systems is the cost. Is it cost-effective, whether you're doing a cost-effectiveness analysis or cost-benefit analysis?” – KI03 “Participants involved in vaccine procurement identified that high initial investment would be required for a new vaccine, in a context of restrictive budget and other health priorities.” – KI04 “STI management is a struggle because there isn’t a dedicated budget for it, yet it is a significant issue.” – KI04 “Financial sustainability was also a major factor. A previous example referenced the suspended distribution of a vaccine, which was discontinued mainly due to economic restrictions.” – HP01 “The reason why they stopped giving the Meningococcal vaccine was due to cost constraints.” – HP01

	“Even though STIs are a major issue, they are not prioritized as highly as HIV. This model involves collaboration with the private sector, social sector, other health programs...” – KI04. “We calculate the budget impact that the introduction of this vaccine might have... If the vaccine is very expensive, we might say, 'Let's start vaccinating key populations first...' – KI03. “It gets down to the socioeconomic impact that the disease has on the community and what you can afford, measured against every other vaccine... which would make the biggest impact in your community and can be afforded” - “Given the impact of STIs, I have made several submissions to National Treasury... A committee would need to assess the efficacy, quantification, and target population... the cost must be determined” – KI04. “You have to weigh up the prioritisation of other vaccines... If money was well-managed, we'd be able to afford prevention... Cost-effectiveness, outcomes, burden—all must be evaluated through an Evidence-to-Recommendation framework” – KI06
Implementation feasibility and broader health system benefits	
Sociocultural & Gender Barriers	“Patients who are physically and emotionally abused cannot advocate for condom use.” – HCP04 “Many young people are scared to visit healthcare centres to get information about STD prevention or treatment once they suspect they might have a condition.” – KI01 “Cultural ideologies also play a role, from a patient or population perspective.” – HP05
Healthcare System and infrastructure	“Our healthcare system is already struggling with human resource shortages. Any new vaccine program must be integrated in a way that does not overwhelm existing services.” – KI05 “Nurses are already overwhelmed due to expanding responsibilities. A two-dose vaccine would require careful planning to avoid overburdening our healthcare staff.” – KI03 “We are dealing with long patient queues and staff shortages. If we introduce a new vaccine, we need to ensure clinics can handle the extra workload.” – HCP06 “Implementation would depend on various factors: approval by SAHPRA, cost-effectiveness assessments, epidemiological considerations, and the perceived public health burden” – KI05.
Major Barriers – Supply Chain, Stigma, Vaccine Hesitancy	“Vaccine supply issues happen all the time. If we roll this out, we must ensure stock levels are stable to maintain trust and adherence.” – HCP02

	“Many people are sceptical about vaccines after COVID-19. We need strong awareness campaigns to counter this.” – KI05 “People might be hesitant to ask for an STI vaccine due to stigma.” – HP03 “The properties of the vaccine... determine how you would roll it out. Whether one or multiple doses... age group... all influence decision-making.” – KI02
Vaccine introduction strategy.	“If resources are limited, we should begin with MSM, sex workers, and adolescents, then expand once more funding and data are available.” – KI04 “If we integrate the gonorrhoea vaccine into existing reproductive health services, it will be easier to implement and more widely accepted.” – HCP06 “Taking the service to the people really does help. With the mobile unit, they don’t have to take a taxi or go far. It makes access much easier.” – HP02 “We have had real success with our HPV program in schools, so there are definitely benefits in vaccinating specific populations where they receive health services.” – KI02 “We should begin with MSM, sex workers, and adolescents first, and then we extend it to the broader public.” – KI05 “Targeting populations, for example, adolescents, sex workers, MSM, immunocompromised groups, were identified as strategies to get government buy-in.” – KI01 “We already know where high-risk groups are. Starting with them helps us manage logistics and evaluate outcomes before national rollout.” – HP01
Potential Use of Existing Infrastructure	“We already have the infrastructure. It might need adaptation, but it's there.” – KI06 “If rural areas were able to manage mass COVID-19 vaccination, we can adapt similar strategies to ensure equitable STI vaccine access.” – KI0
Policy governance and decision making	
Policy governance and decision making	“Government discussions on STI control remain fragmented, with more focus placed on treatment rather than prevention.” – KI01 “We lack a clear national strategy for STI control, making large-scale interventions like vaccination difficult to implement.” – KI04 “I serve on NAGI, the National Advisory Group on Immunisation. This group advises the Minister of Health and the Department on immunisation strategy... We also make recommendations, particularly for new vaccine introductions.” – KI05 “At the global level, I was a member and later chair of SAGE, the WHO’s Strategic Advisory Group of Experts on Immunisation.” – KI05

	“I also chair the African Regional Immunisation Technical Advisory Group... we often take global recommendations and adapt them for regional needs.” – KI05 “As the official responsible for Clinical Health Services, I oversee anything related to clinical health, The HIV and AIDS unit, Primary Healthcare Unit, District Health Units, hospital Services, emergency Medical Services.” - KI03 “With new programs like the HIV/AIDS initiatives, we didn’t adequately consider the capacity on the ground. Nurses often face significant pressure from their expanding responsibilities.” – KI03 “If we introduce new initiatives, we must also introduce the necessary resources to support them.” – KI03 “A vaccine will not be considered if it’s not registered in our country. Then we calculate the budget impact for the introduction of this vaccine to a specific population.”- KI02 “Until the company submits the dossier of evidence to SAHPRA and gets licensure for gonorrhea prevention, it cannot be considered for that use.” – KI06
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5.5 Appendix E: Similarity Report

