Integrating diagnosis in primary health care settings in low- and middle-income countries: What is it, when and how does it work?

Gamuchirai Pamela Gwaza

A thesis submitted for the degree of

Doctor of Philosophy in Evidence-Based Health Care

Kellogg College, Department for Continuing Education

University of Oxford

Hillary Term 2025

Until the lion learns to write, every story will glorify the hunter.

African Proverb

Abstract

Introduction

Diagnosis is the cornerstone of effective healthcare. Yet, it remains the most significant gap in healthcare delivery, especially in primary care settings in low- and middle-income countries. In low-resource settings, making multiple diagnoses during a single visit can bring many benefits. It can lead to early detection of diseases, better use of health system resources, and stronger disease surveillance. It can also improve access to treatment and care, leading to better patient experiences and health outcomes. Despite these advantages, integrated diagnosis interventions are not widely or optimally implemented. This thesis explores the concept of integrated same-day diagnosis, identifying when it is most effective and examining how such interventions are designed and implemented in primary healthcare settings to achieve optimal impact. It focuses on low- and middle-income countries, especially in Africa. The goal is to find practical, evidence-based solutions to improve these interventions. Ultimately, this could lead to better healthcare outcomes and improved patient experiences.

Methods

The thesis uses a structured approach, adopting a mix of methodologies across seven interconnected sub-studies. It begins with a literature review to define integrated diagnosis. This foundation is followed by three studies aimed at identifying barriers to the implementation of integrated diagnosis: a programme evaluation in Lesotho, a scoping review, and a national health policy review. An initial theory of integrated diagnosis implementation is then developed through a realist review, identifying contexts and mechanisms necessary for successful interventions across diverse low-income contexts. This is followed by a Delphi study to prioritise the factors identified in the realist review.

Finally, these prioritised criteria are confirmed through a qualitative case study, capturing the experiences of end users, that is, pregnant women receiving integrated diagnoses during antenatal care at a primary care facility in Zimbabwe.

Results

The findings from these studies highlight the importance of a health system's approach to successful integration, identifying 18 core criteria as critical to its effectiveness. Health systems are complex and characterized by numerous, non-linear, and interdependent relationships, and any change in one aspect will affect the other parts, thus requiring synergistic and coherent innovations. Given that health systems fundamentally serve end-users and are socially constructed, improving patient experiences requires a human-centred problem-solving approach that considers the values and preferences of the patients.

The thesis synthesises these findings into an evidence-informed framework for integrated diagnosis with two broad recommendations for policymakers and funders, and implementers. The recommendations for policymakers and funders are presented as a holistic conceptual framework outlining the core criteria necessary for effective interventions. For implementers, a facility readiness tool to assess the preparedness of primary healthcare facilities for implementing multi-disease diagnostic tools is proposed. This tool is designed to ensure that facilities can effectively support integrated diagnosis, focusing on patient outcomes.

Conclusion

By integrating theoretical insights with practical applications, this thesis delivers actionable guidance and provides a novel and actionable framework and assessment tool to inform decisions on programme design and implementation for effectively integrating diagnosis at the primary care level in low—and middle-income countries.

Personal Statement

Sometimes, I feel like I live between two worlds. I am a Zimbabwean woman who has spent a decade working across Africa—from Zimbabwe to Zambia to Kenya. Then, in 2017, I moved to Geneva, Switzerland, where I began working with global health agencies—this time, on the other side of the table, designing and funding the very interventions we once implemented. That transition gave me a broader perspective on how funding decisions shape programme design and implementation. I have come to realize how rare it is to be equally comfortable in both worlds. But should it be?

This thesis is, in many ways, a product of that duality.

In Geneva, I joined the Foundation for Innovative New Diagnostics (FIND), a global health organisation focused on diagnostics. My role in monitoring and evaluation, however, often felt secondary—more about meeting donor requirements than shaping programmes. This is not unique to FIND; it reflects a broader pattern across global health.

At that time, FIND was working on integrated diagnosis, investing in multi-disease testing platforms like the GeneXpert machine. These tools are meant to maximise diagnostic opportunities, particularly in primary care settings were returning for follow-up care can be challenging. The promise of integrated diagnosis was exciting, but my experiences in Africa made me cautious. I had seen too many well-intentioned interventions fail to deliver on their intended impact. This made me question: What evidence were we using? What if we looked at a different kind of evidence? What if we looked at all kinds of evidence?

An opportunity to visit a health facility in Lesotho became a turning point. In our “beautiful’ reports, integrated diagnosis was reportedly being implemented there, conducting simultaneous HIV and TB testing on the same platform. However, I found two separate GeneXpert machines—one in the main laboratory for TB and another in the maternal ward for infant HIV testing. When I asked why they weren’t using a single platform for both tests,

which could save costs given the low demand, the healthcare worker replied, *"It wouldn't work. The system doesn't work that way."* The facility reported integration because donors expected it. I was sobered.

I realized something I had already experienced in my previous work across African countries: the complicated relationship between the donors and the recipients. Even when the donors- mostly from the Global North - believe they had consulted the local stakeholders -often from the Global South, the power dynamics and historical layers of these relationships make honest conversations difficult.

I wanted to systematically gather evidence to understand these complexities and find practical solutions. I wanted to bring insights from both sides of the table. This motivated me to pursue a DPhil in Evidence-Based Health Care, to examine the challenges of implementing integrated diagnosis interventions—an area I have now worked in for seven years. I returned to Lesotho for a full evaluation of the TB and HIV testing programme, which I explore in Chapter 3 of this thesis.

This thesis is ultimately about bridging the gap between global health strategies and local realities. It is meant to support African health implementers and policymakers in confidently articulating what works in their contexts. At the same time, it urges donors and decision-makers in the Global North to engage with evidence that is rooted in real-world experiences. While it offers practical recommendations, it also seeks to highlight the complexities of change—acknowledging that real transformation requires not just better policies but shifts in power, perception, and behaviour. This is not just an academic exercise for me. It is about ensuring that the work we do is not just well-intentioned but truly effective.

Acknowledgments

I want to express my heartfelt gratitude to my supervisors: Professor Carl Heneghan believed in my potential and provided strategic direction that guided my research journey. Dr. Annette Plüddemann kept me motivated with her constant encouragement and quick feedback. Dr. Marcy McCall MacBain offered practical advice on navigating the DPhil journey and seeing it through to completion.

I am especially grateful to Dr. Sabine Dittrich, a former colleague at FIND and a dear friend who mentored me throughout this journey. She spent countless hours brainstorming with me and discussing the practical implications of my work, and her advice has been invaluable.

I also want to thank Sharon Saacks, a former colleague and friend who generously provided advice on the graphical presentation of my framework, and Dr. Vanessa Fargnoli, who offered valuable insights on qualitative data collection and analysis.

I am also grateful to the 55 experts who participated in the Delphi study, sharing their insights through the questionnaire. My sincere appreciation goes to the men and women who participated in the programme evaluations in Lesotho and Zimbabwe. Their honest conversations about their experiences and the realities of programme implementation deeply enriched this research. I am especially grateful to the pregnant women who shared their stories while waiting for hours for antenatal care—your strength truly inspires me.

I owe special thanks to my brother, Humphrey Chituri, a laboratory scientist who helped me search for study sites in Zimbabwe and introduced me to his colleagues in diagnostics. His patience in explaining diagnostic processes and challenges in public healthcare gave me valuable insights that shaped my research.

To my husband, Dr. Luther Gwaza, thank you for your unwavering support, for listening to countless hours of research discussions, and for providing critical feedback that helped me present my work professionally. Your perspective kept me balanced. To my four children, Anashe, Shane, Shauna, and Anisha, thank you for your patience and understanding as I navigated the demands of this DPhil journey. Finally, my deepest gratitude goes to God, whose strength carried me through the toughest moments and whose grace kept me moving forward.

Statement of Contributions

This doctoral thesis is my independent and original work, for which I am the sole author. I received intellectual guidance on the overall research strategy, thesis structure, analyses, and presentation of results from my academic advisors: Professor Carl Heneghan, Dr. Annette Plüddemann, and Dr. Marcy McCall MacBain.

Several individuals made valuable contributions to specific aspects of this research:

- Dr. Sabine Dittrich provided practical supervision during our time working together at FIND and continued to offer support after moving to THD/DIT University in Germany. She offered advice on the evaluation design in Chapter 4, and giving feedback on the Delphi survey questionnaire in Chapter 7. She also provided feedback on the integrated diagnosis framework and facility readiness checklist in Chapter 9. We co-published parts of the study findings in Chapters 3, 4, and 7.
- Mary Lamy and Rittika Datta from the Asia Pacific Leaders Malaria Alliance in Singapore co-published some of the findings from the scoping review in Chapter 3., provided feedback on the manuscripts, particularly in relation to the barriers to malaria surveillance in Southeast Asia and the Pacific region.
- Nia Roberts, Information Specialist at the University of Oxford's Bodleian Library, provided advice on the search strategy for the scoping review in Chapter 3.
- Kekeletso Kao, a former colleague at FIND, contributed to the organisation of data collection for the evaluation in Lesotho. Monkoe Leqheka, a senior laboratory scientist, and Tsietso Mots'oane, Director of Laboratory Services at the Ministry of Health Department of Laboratory Services in Lesotho, also supported in the organisation of the data collection in Chapter 4.

- Dr. Danai Zhou, a senior lecturer at the University of Zimbabwe, provided advice on the data collection tools and assisted with translating them into Shona for Chapter 8 of the qualitative study in Zimbabwe. Dr. Vanessa Fargnoli, a former colleague and qualitative research expert, also provided advice on the data collection tools in Chapter 8.
- ZimHealth, an organisation based in Geneva, Switzerland, that supports infrastructure development in public health facilities in Zimbabwe, facilitated permissions for the qualitative study at Mabvuku Clinic as part of a broader programme evaluation that I undertook pro bono. Special thanks to Rutendo Kuwana, who helped coordinate these efforts.
- Sharon Saacks provided valuable advice on the presentation of the final integrated diagnosis framework in Chapter 9. Discussions with colleagues at Unitaid also enriched the framework.

I also benefited from attending several methodology short courses at the University of Oxford, Department for Continuing Education, where I incorporated parts of my research into assignments for feedback. Chapter 6 on the realist review was informed by the Realist Review and Evaluation course. Chapter 8 was enhanced by insights from Dr. Anne-Marie Boylan's Qualitative Research Study course and in addition provided advice to respond to peer reviewers for the published manuscript.

Table of Contents

List of Figures

List of Tables

List of Abbreviations

Abbreviation	Meaning
AMR	Anti-microbial resistance
ASSURED	Affordable, Sensitive, Specific, User-friendly, Rapid, robust, and Equipment-free
ASLM	African Society for Laboratory Medicine
CHW	Community Health Workers
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
DI	Diagnostic Imaging
EDL	Essential Diagnostics List
EHP	Essential Health Services
EID	Early Infant Diagnosis
EML	Essential Medicines List
GX	GeneXpert
HCW	Healthcare workers
FIND	Foundation for Innovative Diagnostics
HIV	Human Immunodeficiency Virus
IMCI	Integrated Management of Childhood Illnesses
iCCM	Integrated Community Case Management
LMICs	Low- and Middle-income countries
M&E	Monitoring and Evaluation
MoH	Ministry of Health
MTCT	Mother to child Transmission
MDR-TB	Multi-drug resistant TB
MTB	Mycobacterium tuberculosis

NCD	Non-communicable disease
NHP	National Health Policy
NTDs	Neglected Tropical Diseases
OECD	The Organisation for Economic Co-operation and Development
PALM	Pathology and Laboratory Medicine
PCR	Polymerase Chain Reaction
PHC	Primary Healthcare
POC	Point -of- Care
REASSURED	Real-time connectivity, Ease of specimen collection, Affordable, Sensitive, Specific, user-friendly, Rapid and Robust equipment-free, and Deliverable
RIF	rifampicin
SADC	Southern African Development Community
STIs	Sexually Transmitted Diseases
TAT	Turnaround Time
TB	Tuberculosis
UHC	Universal Health Coverage
UNICEF	United Nations Children's Emergency Fund
WHA	World Health Assembly
WHO	World Health Organisation

Chapter One

Introduction and Background

1. Introduction and Background

1.1 Chapter Aim and Objectives

This chapter provides the background and rationale for the thesis's focus on integrated diagnosis. It outlines the scope of the research and offers an overview of the thesis structure, including the objectives of each chapter, the research questions being addressed, and the methodology employed. It serves as the necessary framework for the entire thesis.

1.2 Scope of the thesis

The thesis focuses on integrated diagnosis interventions at the primary health care (PHC) level in low and middle-income countries (LMICs). The facilities considered at PHC level can differ across LMICs, further explored in Chapter 5. It can range from basic primary care, which includes facilities such as pharmacies, health posts, or similar facilities where no qualified doctor or nurse is available, or advanced primary care, typically delivered at health centres or hospitals staffed by a doctor or nurse. The key distinction is that PHC is more inclusive and serves as the first point of contact, offering comprehensive services, ranging from prevention and diagnosis to treatment and rehabilitation, without the need for referrals, unlike specialized care. [1] As such, secondary care or complex diagnoses requiring complex diagnostic technology in sophisticated laboratories or interventions focusing on sample integration with limited interaction with the patients are excluded. Only diseases that are addressed at the PHC level are in scope.

While diagnosis as a concept is much broader, as will be explained later, most of the literature explored focuses on testing, which is only one element of it, and uses the terms 'testing' and 'diagnosis' interchangeably. In the thesis, a differentiation is made where 'integrated diagnosis' is used to mean the broader definition of the term, and 'integrated testing' where

focus is on the testing and use of diagnostics such as point-of-care (POC) or near-point-of-care tools. These can enable a one-stop-shop approach, allowing patients to be screened, tested, diagnosed, and either treated or referred for additional care—all within a single visit to the health centre.[2] Chapter 2 explores the definition of integrated diagnosis further.

This thesis focuses specifically on same-day integrated diagnosis, where patients receive multiple tests or diagnoses within one visit. Although this approach may not always be feasible in LMIC settings, same-day integrated diagnosis represents an ideal approach for maximising healthcare opportunities, improving early diagnosis and health outcomes by minimising loss to follow-up, optimizing resource use, and in alignment with global health priorities and funders who advocate for integrated patient-centred models.[2-5] The background section below expands on this.

In summary the thesis focuses on same-day integrated diagnosis at PHC level in LMICs in order to contribute to the growing body of evidence supporting integrated care models in resource-limited settings.

1.3 Background and Rationale

Understanding integrated healthcare more broadly is important for contextualizing integrated diagnosis, as diagnosis represents just one component of the broader healthcare cascade. This cascade of care includes screening, diagnosis, treatment, and care or successful management.[6] Integrated healthcare, and by extension, integrated diagnosis, has been advanced through various efforts across different healthcare systems.

1.3.1 Integrated Healthcare

The concept of integrated healthcare has evolved over decades, shaped by multiple drivers and influenced by diverse fields. While Alexander Blount is credited with the first formal mention of the term in 1994[7], while describing a model for integrating mental health services into primary medical care, its foundational discussions and roots trace back much earlier. These roots were influenced by global health movements, the emergence of integrated medicine, and practical challenges in health system design.

Early Foundations: The Primary Healthcare (PHC) Movement: A major precursor to integrated healthcare was the movement for PHC, driven by WHO and UNICEF in the 1970s[8] The Alma-Ata Declaration of 1978 marked a pivotal moment, positioning PHC as the cornerstone of global health systems. It emphasized the need for a person-centred approach, affirming individuals' rights and responsibility to participate in their healthcare planning and implementation.[1]

The Declaration envisioned a comprehensive, community-based model of care that addressed the social, economic, and political determinants of health.[1] This model required intersectoral collaboration, a principle that remains integral to modern integrated healthcare.[9] However, Alma-Ata's vision conflicted with already-established healthcare systems rooted in vertical, targeted interventions. A year later, a narrower concept of "selective PHC" was adopted, focusing on cost-effective, disease-specific, and feasible interventions.[8] A decade later, another PHC conference was held in Burkina Faso to reiterate the initial sentiments and recognise the value of an integrated and multisectoral approach to health systems improvement.[10]. Chapter 5 will delve more into the PHC movement and approach.

Alternative treatment approaches: Parallel to these developments, the rise of alternative

treatment approaches in a discipline called integrated medicine[11], later proposed to be changed to ”integrated health care” to encompass other disciplines outside medicine, also influenced the field. "Integrative medicine" was guided by a philosophy that values a holistic view of the patient, understanding the multifactorial nature of disease, and the importance of combining conventional and non-conventional treatment modalities and alternative views of health into their practices.[11] There was a need for multidisciplinary approaches to healthcare, combining two or more types of treatment modalities, such as allopathic or conventional care, with Chinese medicine or other alternative therapies.

Limitations of vertical programmes: By the early 2000s, the limitations of single-disease programmes became increasingly evident, particularly in the context of achieving the Millennium Development Goals.[8] [12,13] While targeted vertical programmes for diseases such as HIV and AIDS, malaria, and tuberculosis (TB) achieved notable successes, progress toward broader health goals remained slow. This was largely due to weak and fragmented health systems that were unable to deliver the necessary volume and quality of services.[14] [3] In addition, increased funding for these diseases raised concerns about neglecting less well-funded health priorities. Moreover, these previously cost-effective strategies for specific diseases became financially unsustainable within a shifting epidemiological context. [15,16]

As a result, the focus shifted toward strengthening health systems and integrating care delivery to improve outcomes across a broader spectrum of health priorities. Partnerships and person-centred approaches became central, emphasizing care for the individual rather than targeting isolated diseases.[17] This shift has also been driven by concerns over the financial and epidemiological sustainability of vertical programmes amidst changing health needs and resource constraints.[12,13,18] The current debate on integration focuses on identifying the contexts in which vertical or integrated health service delivery models are most appropriate.[3] It also examines how to effectively coordinate these interventions with general

healthcare services to achieve efficiency, continuity of care, patient-centred care, and optimal health outcomes.[3,15,19,20]

Demographic and epidemiological changes: The need for integrated health care was further reinforced by changing demographic and epidemiological trends, particularly in Europe and America. Aging populations and the rising prevalence of chronic diseases highlighted the inefficiencies of fragmented care models.[21] Policymakers prioritized integration efforts for high-need groups, such as the elderly and those with frailty, to enhance the efficiency and effectiveness of care delivery.[22]

Over the past decade, integrated healthcare has become an integral part of health policy reform across Europe. It has been adopted widely in North America and Europe, especially for managing patients with chronic diseases.[23] In 2003, the WHO identified integrated health care as a key pathway to improve primary care.[24] In 2004, the European Commission echoed this sentiment, declaring that integrated care was vital for the sustainability of social protection systems across the continent.[25]

Technological and financial drivers: Emerging technologies and data systems have accelerated the adoption of integrated health care by enabling more coordinated and patient-centred models of care. These innovations have improved information flow, enhanced efficiency, and facilitated the delivery of personalised interventions.[2] Financial considerations have also played a significant role, with integrated care offering cost efficiencies that benefit both consumers and providers seeking sustainable profit models. [22]

1.3.2 Integrated Diagnosis

Diagnosis is a central, often understated component of quality health care, as effective treatment and care depend on timely and accurate diagnosis. [6,26] Although diagnostics usually make up less than 5% of hospital costs, they influence up to 60–70% of healthcare decision-making.[27] Diagnosis involves a range of activities, including taking a clinical history and conducting interviews, performing physical examinations, testing, and consulting with other clinicians.[6] It is inherently collaborative and iterative, aiming to narrow down diagnostic possibilities to understand a person's health problem better.

Integrated diagnosis is a relatively recent concept, particularly at the PHC level, and there is limited literature explicitly using the term. However, its foundations can be traced to secondary care, where diagnostic practices are more established.

Two key diagnostic disciplines—pathology and laboratory medicine (PALM) and diagnostic imaging (DI)—are traditionally associated with secondary care.[6] PALM encompasses areas like biochemistry, microbiology, and immunology. At the same time, DI involves advanced imaging technologies such as Computed Tomography (CT) scans, Magnetic Resonance Imaging (MRI) scans, and Positron Emission Tomography (PET) scans.

Integrated diagnosis is increasingly being recognized as critical at the PHC level, where rapid diagnostic tests, dipstick tests, and basic equipment like glucometers and haemoglobinometers are essential. For example, WHO recommends including ultrasound in antenatal care to enhance diagnostic capabilities at this level.[6]

There are several drivers to integrated diagnosis, including the complexity of diseases, the diagnostic gap, comorbidities, and technological innovations.

Complex Diseases and Predictive Medicine - Addressing complex diseases often requires integrating data from diverse diagnostic investigations. For instance, in oncology, combining advanced imaging techniques with PALM data enables precise tumor staging, disease

progression prediction, and targeted therapy selection.[6] Predictive medicine, which extends beyond cancer, exemplifies the efficiency and efficacy of integrating diagnostic disciplines. Despite these advantages, diagnostic disciplines often function in silos, hindering optimal care delivery.

Coinfections and Antimicrobial Resistance (AMR): Coinfections, such as HIV with TB or hepatitis, present significant diagnostic challenges. Many coinfections remain undiagnosed, exacerbating the disease burden and facilitating further transmission. For instance, TB is the leading cause of death among people living with HIV, and coinfections like hepatitis B and C contribute to increased morbidity.[28] Additionally, AMR poses a growing threat, with approximately 700,000 deaths annually attributed to resistant infections.[2] Better diagnostic programmes can mitigate the overuse of antimicrobials, which is a major driver of AMR.

Diagnostic gap: The Lancet Commission on Diagnostics in 2021 identified diagnosis as the single largest gap in the care cascade for six tracer conditions: diabetes, hypertension, HIV, TB, hepatitis B, and syphilis (in pregnant women).[6] Together, these conditions contribute significantly to the global disease burden and are included in the WHO's primary care testing recommendations for antenatal care. In LMICs, the diagnostic gap—defined as the proportion of individuals with a condition who remain undiagnosed—ranges from 35% to 62%. This gap leads to an estimated 1.1 million preventable premature deaths annually due to delayed or absent diagnostic access.[6] While diagnosis alone cannot reduce the disease burden, it represents a crucial first step.

At the PHC level, where the diagnostic gap is most acute, only 19% of populations in low-income and lower-middle-income countries have access to basic diagnostic tests beyond HIV and malaria.[6] Table 1 shows the availability of the basic tests across different tiers of care. For the top 20 diseases contributing to years of life lost in LMICs, diagnostic tests at the PHC level exist for fewer than 50% of these diseases. To address this gap, it is essential to improve

access to diagnostics at the PHC level and optimise interactions with the health system by enabling the provision of multiple diagnoses during each visit.

Table 1: Availability of basic diagnostics by tier in LMICs

Type pf diagnostic and defiition	**Basic Primary level**	**Advanced primary level**	**Secondary level**
Clinical *Bench assessments made by health workers*	Blood pressure Temperature	Blood pressure Temperature	Blood pressure Temperature
Point of care test *Rapid tests performed near the patient, without laboratory infrastructure*	Malaria HIV Syphilis Pregnancy	Malaria HIV Syphilis Pregnancy	Malaria HIV Syphilis Pregnancy
Laboratory *Tests requiring laboratory equipment or trained personel*		Urine protein Urine glucose Sputum Microscopy	Urine protein Urine glucose Tuberculosis Microscopy Haemoglobin Chemistry analyser Haematology analyser Gram stain
Radiological *Imaging tools used for internal visualization*		Ultrasound	Ultrasound X-ray Computed Tomography (CT) scans

**Information in the table is extracted from the Lancet Commission on Diagnostics (2019), based on data collected from ten LMICs: Namibia, Senegal, Kenya, Haiti, Tanzania, Rwanda, Uganda, Nepal, Malawi, and Bangladesh. The focus is on six priority conditions—diabetes, hypertension, HIV, tuberculosis, hepatitis B, and syphilis. Only diagnostics with at least 50% availability across these countries have been included.*

Global policy efforts: Recent global policy initiatives have amplified momentum toward integrated healthcare and integrated diagnosis. The 2016 WHO Framework on Integrated People-centred Health Services [29] emphasised the importance of organizing services around people's needs rather than around diseases. This approach promotes integrated patient-centred care and linkages with primary health care services.

In May 2023, the World Health Assembly (WHA76.5) adopted a resolution on diagnostics,[30] calling for integrated and coordinated diagnostic interventions as part of universal health coverage (UHC). The resolution urges countries to move away from siloed approaches to guidance, policy, and funding streams and advocate instead for horizontal programmatic approaches that address diagnosis across diseases.

Technology innovation: Advancements in technology have created new opportunities for integration, similar to what was described above for integrated healthcare in general. Innovations such as multiplex devices, that is, devices that can analyse, detect, and measure a number of different analytes from one sample, dual rapid tests, and multi-disease diagnostic platforms promise to make integrated diagnosis more feasible at or near the point-of-care in primary care settings.[2,31,32]

Innovative technology that is highly accurate but also affordable and accessible is needed, meeting the WHO REASSURED (Real-time connectivity, Ease of specimen collection, Affordable, Sensitive, Specific, user-friendly, Rapid and Robust equipment-free, and Deliverable) criteria, especially in LMICs.[27] While no diagnostic device currently meets all the criteria, the rapid emergence of new technology, such as machine-learning-assisted diagnostics, CRISPR-based (Clustered Regularly Interspaced Short Palindromic Repeats) diagnostics, and nanofluidic technology, places such ideals within reach with further research and innovation.[27] Lateral flow assays meet the standards for affordability and accessibility but need to improve their accuracy, while molecular tests already have high accuracy but need to decrease cost and complexity.

Developments in digitalisation, artificial intelligence, mobile technologies, and electronic data transfer have improved diagnostic accuracy and accessibility. Point-of-care testing, patient self-testing, and specimen self-collection address the "last mile problem," bringing diagnostics closer to patients and enhancing convenience. These innovations, coupled with

improved education, workflow organisation, and supply chain management, are transforming diagnostic capabilities in primary care.[2,6]

COVID-19 pandemic: The COVID-19 pandemic brought global attention to the critical importance of diagnostics, highlighting significant gaps in access to diagnostic tests, particularly in LMICs. These gaps, though long acknowledged, became more visible as countries struggled to manage their public health responses during the pandemic.[33] [34] Diagnostics emerged as an indispensable yet overlooked foundation of quality healthcare.[6]

However, despite this increased global momentum and significant technological innovation, integrated diagnosis interventions in LMICs remain fragmented and inconsistent. While some integrated care models have demonstrated feasibility, effectiveness, and acceptability, [3,4,35,36] integrated diagnosis in LMICs at the PHC level is still evolving, with low uptake and persistent barriers[26], such as limited resources, fragmented health systems, and inadequate infrastructure, which will be explored in Chapter 3,4 and 5 . These efforts are often limited to small-scale pilot projects and opportunistic interventions, which limits the ability to compare, evaluate, or replicate across diverse settings. The focus is mainly on immediate outcomes, such as improving service coverage and saving costs. While this is important, emphasis must also be placed on measuring its impact on health outcomes and improving patient care. Optimising integrated diagnosis interventions is, therefore, essential to achieving this impact.

Research on vertical and integrated service delivery over the past three decades provides mixed evidence on the efficiency and effectiveness of integration. There is some evidence of efficiency gains in family planning integration,[37,38] HIV testing within TB and STI services, [39,40] and STI treatment effectiveness as part of integrated HIV control.[41] However, studies have also shown that in certain contexts, vertical programmes outperform fully integrated services for STI treatment, and there is no consistent evidence that integration improves health outcomes across the board. While recent studies have become more rigorous and are

producing higher-quality evidence, further well-designed studies are needed to explore strategies for integration across a wider range of service areas and settings.

1.4 Overview of the thesis

The thesis consists of seven sub-studies to answer the overall research question on what integrated diagnosis is, when, and how it works to achieve impact, as shown in Table 1. The first step of building this thesis involved an extensive literature review to define the concept of integrated health care and integrated diagnosis. This led to the adoption of a specific definition of integrated diagnosis, which centres on maximising the patient's outcome, that is used in this thesis.

Following this, three different studies were conducted to understand the barriers to integrated diagnosis. The first study was a scoping review that examined barriers documented in the literature broadly, with a specific focus on challenges to integrating the diagnosis of febrile illnesses in primary care settings within the Asia-Pacific region. The second study involved a programme evaluation in Lesotho, a country in Southern Africa, where numerous interventions to integrate TB and HIV testing had been implemented. This study, covering 22 health facilities, provided in-depth insights into the practical barriers encountered during HIV and TB testing integration. The third study examined the policy environment as a barrier, a factor identified in both the scoping review and programme evaluation. An analysis of eight national health policies in Southern Africa revealed that except for two countries, diagnostics are not explicitly mentioned or prioritised, despite the broad endorsement of the PHC approach.

Building on these foundational findings, a theoretical framework was developed through a realist review. This realist review analysed the necessary mechanisms and contexts under

which the interventions were successful in improving health outcomes and patient experiences, with two theoretical frameworks being developed for the healthcare workers and the patients or clients, respectively.

The success factors identified in the realist review were prioritised through an online Delphi consensus study, which engaged 55 experts. Eighteen core criteria, spanning the six WHO health systems pillars[42], reached a consensus, with 70% or more strong agreement.

Finally, a qualitative case study was conducted in a primary care setting to incorporate the patient or client perspective and confirm these criteria. The study, conducted in Zimbabwe, examined the experiences of pregnant women accessing integrated diagnostic services as part of antenatal care and the healthcare workers providing these services.

The prioritised criteria were used to develop the integrated diagnosis framework, a major contribution of this thesis to the field. The framework articulates the essential elements necessary for the successful implementation of integrated diagnosis. In applying the framework, policymakers and funders can ensure that all critical success components are considered. For healthcare implementers, a facility readiness assessment tool was developed, another contribution to knowledge and practice in the field. This tool allows health managers to assess the readiness of their PHC facilities to adopt multi-disease diagnostic tools. By identifying existing strengths and pinpointing gaps at the facility level, they can make informed decisions about resource allocation, capacity building, and operational adjustments needed to support the effective use of multiplex tools.

1.5 Research Methodology

The research uses a mix of methodologies that reflects the complexity and challenges of health service delivery in general and integrated diagnosis in particular, the diversity of health

actors, the dynamic environment in LMICs, and the sources and characteristics of health funding in LMICs. The questions are addressed using multiple methods relevant to each research question. These different methods will be explained in each chapter and include different types of reviews, programme evaluations, case studies, and a Delphi expert consensus. In the discussion, Chapter 10, a comparison of these methods is done, highlighting some of the strengths and weaknesses of the methods selected.

The six WHO health systems pillars provide an analytical framework for integrated diagnosis interventions across the various studies in this thesis. These pillars include health service delivery, health workforce, health information systems, access to diagnostics (analogous to essential medicines), financing, and leadership and governance.[42] Even though not explicitly mentioned in the WHO health systems pillars, access to essential diagnostics is considered analogous to access to essential medicines through the Essential Diagnostics List (EDL)—a priority list of medical tests. This was the same apporach taken in the Lancet commission on Diagnostics. In 2019, for the first time, WHO published the latest editions of the Essential Medicine List (EML) and the EDL together. This landmark move underscored the critical importance of aligning diagnostics with treatment to advance the Universal Health Coverage (UHC) agenda. Effective and responsive health systems require both diagnostics and medicines—they are a package deal.[1]

1.5.1 Research Aim and Objectives

1.5.1.1. Aim of the thesis

This thesis explores the design and implementation of integrated diagnosis interventions in PHC settings, focusing on LMICs, particularly in Africa. It aims to explore what integrated diagnosis is, when, and how it works to achieve impact and provide practical, evidence-informed solutions to optimise these interventions so that they can improve health outcomes and patient experiences.

1.5.1.2 Objectives

There were five main research objectives, and six sub-objectives explored in different chapters of the thesis, which are:

1. Define integrated health care and diagnosis
2. Understand the barriers to integrated diagnosis in LMICs
    - Identify the barriers to integrated diagnosis in LMICs, with integrated diagnosis of febrile illnesses as a test case
    - Evaluate an integrated diagnosis intervention to identify the barriers to effective TB and HIV testing integration
    - Review national health policies in Southern Africa to assess how integrated diagnosis and the primary health care approach have been incorporated
3. Synthesise the evidence on the effectiveness of integrated diagnosis
    - Identify the necessary factors and mechanisms for integrated diagnosis to improve patient experiences and health outcomes in PHC settings in LMICs
4. Prioritise the core criteria for successful integrated diagnosis interventions

5. Understand the experiences of healthcare workers and patients/clients using integrated diagnosis services
    - Explore the experiences of pregnant women accessing integrated diagnosis during antenatal care
    - Explore the experiences of healthcare providers delivering integrated diagnosis services.

Table 2: Overview of thesis structure

Main Research Question: What is integrated diagnosis at the primary care level in LMICs, when and how does it work?			
Step 1: Defining integrated diagnosis	**Chapter 1**: Introduction and Background **Research Question**: Why is this thesis important?	**Chapter 2**: Literature review **Research Question**: What is integrated diagnosis? **Research Method**: Literature Review	
Step 2: Understanding the challenge	**Chapter 3:** Barriers to integrated diagnosis **Research Question**: What are the barriers to integrated diagnosis in LMICs? **Research Method**: Scoping Review	**Chapter 4**: Programme Evaluation **Research Question**: How is TB and HIV testing integrated? What are the challenges to integration in Lesotho? **Research Method**: Semi-structured interviews and secondary data analysis	**Chapter 5**: A review of national health policies **Research Question:** To what extent are integrated health care and integrated diagnosis, incorporated in national Health Policies in Southern Africa? **Research Method**: READ approach for Policy review
Step 3: Developing a theory for integrated diagnosis	**Chapter 6**: Integrating diagnosis at the primary care level: A Realist Review **Research Question**: What are the necessary contexts and mechanisms for integrated diagnosis interventions to work well? **Research Method**: Realist methodogy		
Step 4: Prioritising core criteria for integrated diagnosis	**Chapter 7**: Prioritising core criteria **Research Question**: What are the core criteria for effective integrated dignosis interventions? **Research Method**: Delphi Method	**Chapter 8**: Experiences of users accessing integrated diagnosis services **Research Question**: What are the experiences of users accessing integrated diagnosis services and validate some core criteria **Research Method**: Case Study (Qualitative)	
Step 5: Developing an integrated diagnosis framewok	**Chapter 9**: Integrated Diagnosis Framework **Research Question**: How does all the evidence fit together into a framework? **Research method**: Evidence synthesis	**Chapter 10**: Discussion and Conclusion **Research Question**: What does this all mean for integrated diagnosis? What are the implications for policy and practice?	

1.6 Structure of the thesis

The thesis is structured according to the following chapters and focus areas.

1.6.1 Chapter 2. Defining integrated health care and diagnosis

Chapter 2 provides the foundational context for integrated health care and diagnosis, outlining its rationale and the specific gap that this thesis seeks to address. Based on a literature review, the chapter explores various definitions and themes within the field. A tailored definition of integrated diagnosis is proposed to guide the focus of this thesis.

1.6.2 Chapter 3. Barriers to integrated diagnosis

Chapter 3 presents a scoping review of the barriers to integrated diagnosis identified across different LMIC settings at the primary care level. Using the integrated diagnosis of febrile illnesses as a case example, the chapter highlights specific challenges within this context. These barriers are analysed across various components of the health system, structured using the WHO Health Systems Framework.

1.6.3 Chapter 4. Evaluation of TB and HIV testing in Lesotho

Chapter 4 presents a programme evaluation aimed at gaining deeper insights into the implementation of integrated diagnosis in LMICs. The evaluation focuses on TB and HIV testing across 13 health facilities in Lesotho. The evaluation reveals limited integrated testing of HIV and TB on the GeneXpert platform, highlighting critical gaps and areas for improvement in leveraging technology platforms for integrated testing.

1.6.4 Chapter 5. A review of national health policies in Southern Africa

Chapter 5 provides a policy review of national health policies across eight LMICs in Southern Africa, examing the extent of political will and commitment to integrated diagnosis. The review shows that while the primary healthcare approach is broadly valued, except for two policies, there is minimal reference to diagnostic services or their integration. These findings highlight significant policy gaps that must be addressed to strengthen the planning and implementation of integrated diagnostic interventions.

1.6.5 Chapter 6. A realist synthesis of integrated diagnosis interventions

Chapter 6 synthesises integrated diagnosis interventions in LMICs, with a particular focus on Africa. Through a realist review of 25 primary studies and 15 systematic reviews, the chapter develops a programme theory of integrated diagnosis. It identifies key mechanisms and contextual factors essential for the successful implementation of integrated diagnosis interventions, providing a framework for understanding and optimizing these interventions in resource-constrained settings.

1.6.6 Chapter 7. Developing core criteria for integrated diagnosis

Chapter 7 details the development and prioritisation of core criteria derived from the realist review using a Delphi survey methodology. Through two rounds of online surveys involving 55 global experts, 18 core criteria were identified as critical for the effective design and implementation of integrated diagnosis interventions at the PHC level.

1.6.7 Chapter 8. A qualitative study on the experiences of accessing integrated diagnosis

Chapter 8 presents a qualitative study conducted in Zimbabwe to explore the experiences of women and healthcare providers using integrated diagnosis services within antenatal care. Semi-

structured interviews with 22 women and 10 healthcare workers were conducted, providing insights into the practical application of the identified criteria and highlighting contextual factors influencing the delivery and uptake of integrated diagnostic services.

1.6.8 Chapter 9. Integrated diagnosis framework and Facility Readiness Assessment tool

Chapter 9 introduces the integrated diagnosis framework, developed by synthesising evidence and drawing on insights from the studies, to guide policymakers and funders in improving the design and implementation of interventions. It also presents a facility readiness assessment tool for multi-disease diagnostics targeted at implementers and facility managers.

1.6.10 Chapter 10. Discussion and Conclusion

Chapter 10 discusses and synthesises the findings from all studies, highlighting their implications for integrated diagnosis. It evaluates the research's contribution to advancing knowledge and practice in this area while addressing methodological strengths and limitations. The chapter also outlines strategic directions for improving integrated diagnostic interventions, offering actionable insights for policymakers, implementers, and researchers.

1.7 Chapter 1 Summary

This chapter outlines the importance of integrated diagnosis, defines the scope of the thesis, and provides an overview of its structure.

- The thesis focuses on same-day integrated diagnosis at the PHC level in LMICs. While integrated diagnosis is often used interchangeably with integrated testing, this thesis takes a broader view—diagnosis encompasses not just testing but also processes such as

examination, history-taking, and referrals. When referring specifically to testing using diagnostic tools, the term integrated testing will be used.

- To understand integrated diagnosis, it is essential first to understand integrated healthcare, as diagnosis is just one component of a larger system.
- The push for integrated healthcare stems from several factors, including the PHC movement, the need for alternative treatment approaches, limitations of vertical programmes, demographic and epidemiological shifts in Europe, technical innovations, and financial considerations.
- Integrated diagnosis, though a term rarely found in literature—and when it is, mostly in reference to secondary and tertiary care—is important for several reasons. It has the potential to address the complexity of diseases, the rising burden of comorbidities and AMR, and the increasing diagnostic gap.
- There is a growing emphasis in global policy on strengthening diagnostics. The COVID-19 pandemic also elevated the importance of diagnostics on the global agenda.
- The thesis is structured around seven sub-studies, each using different methodologies to address specific research questions. Together, these studies aim to answer the broader question: What is integrated diagnosis, and when and how does it work effectively?

CHAPTER TWO

Defining Integrated Healthcare and Integrated Diagnosis

2. Defining Integrated Healthcare and Integrated Diagnosis

2.1 Chapter Aim and Objectives

This chapter aims to define integrated health care and integrated diagnosis by reviewing relevant literature to identify common themes and key characteristics. Establishing a clear and consistent understanding of these concepts is essential for this thesis, and arguably for effective interventions. Given the considerable variation in how integrated diagnosis is interpreted across different disciplines, the term has become somewhat of a “buzzword” with multiple meanings. This challenge is not unique to integrated diagnosis, as PHC also struggles with conceptual clarity, as discussed in Chapter 5.

The diverse approaches and conceptualisations of integrated healthcare complicate comparisons of interventions, replication, and evaluation of integration models across different settings. This creates knowledge gaps regarding its true impact or the essential elements necessary for successful scale-up.[43-46] Various authors emphasise different aspects of integrated health care, contributing to a lack of conceptual clarity. [47] While some widely accepted definitions exist, none fully capture all contexts in which the concept is applied across different countries.[48]

Although innovative examples of integrated diagnosis exist, many remain confined to the pilot phase and fail to scale up.[45,49-51] Sharing knowledge across these examples can provide valuable insights into scaling, spreading, and sustaining innovation – critical steps for broader health system transformation.[52]

This thesis focuses on primary care. While integrated care and primary health care are closely related and often intersect in practice, they represent distinct concepts. Primary health care refers to the overarching framework and approach to delivering health services at the community level—the first point of contact within the health system. In contrast, integrated care emphasizes the

coordination and continuity of services across different levels and providers within that system. Clarifying this distinction is important when examining the integration of diagnosis in LMIC primary care settings, where the principles of PHC and the strategies of integrated care must align to strengthen service delivery and advance universal health coverage (UHC).

2.2. Methods

A literature review was conducted using a systematic search strategy across several academic databases, including the Cochrane Library, PubMed, Oxford SOLO, and Google Scholar. Targeted searches were also carried out in the *Journal of Integrated Health Care*, as well as on the WHO website for relevant reports and technical guidance. While the search process was systematic in its approach, the review itself was a narrative literature review rather than a formal systematic review. It broadly explored the themes of integrated healthcare and integrated diagnosis without applying specific data extraction tools or predefined inclusion/exclusion criteria, as would be required in a systematic review.[53]

2.2.1 Search strategy

Key search terms included “integrated health care,” AND “primary healthcare,” OR “primary care,” and “integrated diagnosis,” AND “primary healthcare,” OR “primary care.” These were filtered for “definition,” OR “origins of integrated health care,” OR,” “models,” OR “concept.”

2.2.2 Data Analysis

All data were coded deductively using NVivo and analysed according to the themes identified in the provided definitions. As coding progressed, recurring themes emerged across the different definitions. The data collected were coded into categories and presented under appropriate subject headings, reflecting the key themes and tenets of integrated health care or integrated diagnosis.

2.3 Results

2.3.1 Search results

The database search for integrated health care initially identified 111,464 articles. An additional 21 reports and technical guides were sourced from the WHO website. Narrowing the search by adding the term "primary health care" reduced the number of articles to 28,764, which further decreased to 14,040 after removing duplicates. Subsequently, 11,640 articles were excluded based on the absence of specific mentions of integrated health care in their titles.

The abstracts of the remaining 2,400 articles were screened, leading to the exclusion of 2,225 articles due to their lack of focus on integrated healthcare at the primary care level. A detailed review of 175 full-text articles followed, resulting in the exclusion of 134 because they lacked a definition or explanation of integrated health care or contained redundant definitions. Ultimately, 41 papers were included in the review, which analysed twenty-six definitions of integrated health care.

A similar search for "integrated diagnosis" with filters for definitions and primary healthcare yielded fewer papers. Several related terms, such as "integrated management of childhood illness," were also included, as these terms described specific types of integration. Much of the existing literature focused on integrated “diagnostics” at secondary levels of care, such as integrated point-of-care molecular devices.

The search for integrated diagnosis, based on the defined criteria, identified 395 articles. These were further filtered by relevance and their provision of a definition of integrated diagnosis at the primary care level. This process resulted in 21 relevant articles, including nine peer-reviewed papers and 12 reports from global health organisations such as WHO, Unitaid, and the Foundation for Innovative New Diagnostics (FIND).

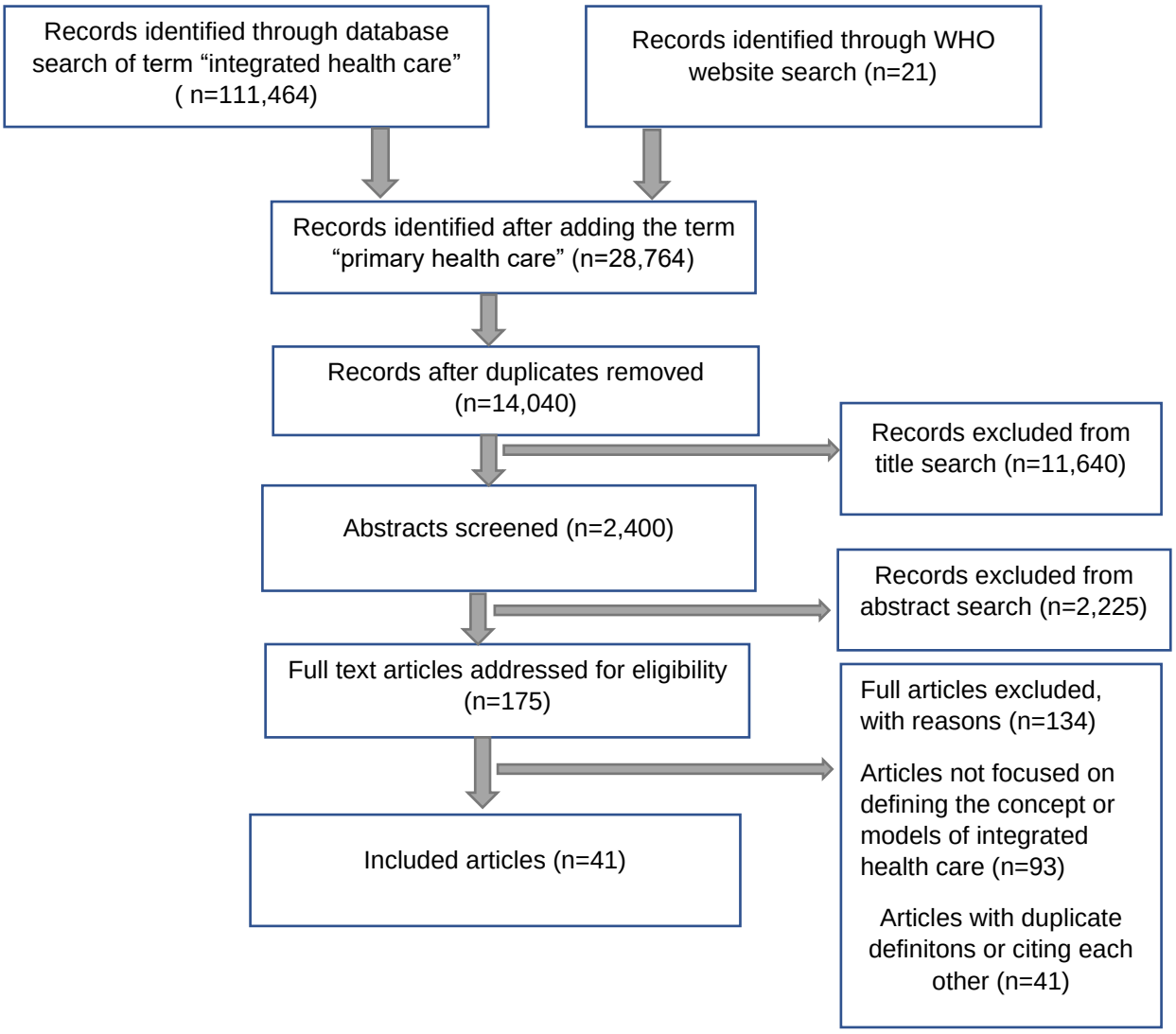


Figure 1: Prisma diagram for literature review on definition of integrated healthcare

2.3.1 Integrated Healthcare

There is no single, universally accepted definition of integrated health care. A literature review by Frisch[11] concluded no firm definition exists. However, several common themes emerge across the literature, including collaboration, coordination, continuity, comprehensiveness, and patient-centredness. Appendix 1 presents the 26 different definitions from the literature, which reflect these recurring themes.

Collaboration

Collaboration is one of the earliest and most widely discussed aspects of integrated healthcare.[22,47,54,55] It is often described using synonyms, such as 'bringing together [45,56-58] or multidisciplinary.[59] Early proponents of the concept[7], argued that collaborative conversations are central to creating an integrated system. This typically involves interdisciplinary professionals working together to address a patient's needs. However, implementing collaboration has proven challenging, as it requires additional time with each patient, and financial pressures often take precedence.

Dawda [22] emphasises that integrated healthcare must always be a collaborative effort supported by strong relationships at multiple levels: macro (policy and governance), meso (organisational structures), and micro (individual care teams). Unlike hierarchical teams in surgical settings or distributed team structures where care is provided separately through referrals (e.g., physical therapy, radiology), collaborative teams maintain professional autonomy while coordinating care. A designated coordinator may intervene if challenges arise.

The WHO's definition of integrated health care has evolved since its 1996 formulation, with later definitions, removing the phrase "bringing together". However, collaboration remains a core principle of integrated healthcare.

Continuity of Care

Continuity of care is another defining feature of integrated healthcare [3,29,60]. The literature describes it using terms such as seamless**,**[25,61], coherent [47,62,63], smooth [64], aligned [47]and non-fragmented.[52,65] Linkages among services are essential to ensure continuity of care.[44]

Improved information exchange plays a crucial role in enhancing continuity. It saves time for both

patients and healthcare providers, reduces duplication of tests and treatments, and facilitates a holistic approach to patient care.[46] According to WHO[29], integrated healthcare ensures that services are managed and delivered in a way that ensures people receive a continuum of health services across different levels and sites of care within the health system and tailored to individuals' needs throughout their lives. This patient-centred approach minimises the number of appointments and healthcare visits required while making navigation of the system more seamless.[3]

Goodwin argues that integrated healthcare is fundamentally about addressing care fragmentation.[52] WHO reinforces this by stating that integration occurs when policies, financing, regulation, and service delivery decisions are not arbitrarily compartmentalised at the macro level[3]. However, Gray (2020) suggests a pragmatic approach, acknowledging that no system is immune to fragmentation.[66] Even the most well-designed health systems experience discontinuities, requiring ongoing innovation to address challenges.

Connectivity

Connectivity between different services is another vital element of integration.[21,47,62] Effective referral systems ensure seamless transitions between healthcare services.[54] Connectivity also includes improved information sharing, reducing redundancies in diagnosis and treatment.

Coordination

Coordination is often distinguished from collaboration. While collaboration involves professionals working together, coordination focuses on joint planning.[67,68] The WHO empasises coordination as a core principle of integration, ensuring that services are provided, managed, financed, and evaluated in a closely aligned manner.[29] Effective coordination minimises inefficiencies, streamlining healthcare delivery.

Comprehensiveness

Although not always explicitly highlighted in definitions, comprehensiveness is a recognized goal of integrated healthcare. The WHO defines comprehensiveness as delivering care tailored to evolving health needs while promoting Universal Health Coverage (UHC).[29] Integration should be seen as a step toward making health systems more complete.[52] Some scholars advocate for comprehensive primary health care services that ensure continuity of care through efficient referral systems and feedback mechanisms between primary, secondary and tertiary levels.[69]

Combination of Services

A common feature of integration is the combination of multiple healthcare services.[7,11,67,70] This often involves creating care packages or bundles of care.[71] However, Druetz [72] argues that merely juxtaposing different tasks—such as training community health workers to manage multiple diseases—does not constitute true integration. Instead, effective integration extends beyond simply merging services; it requires coordination and systemic alignment. Integrated services do not necessarily mean everything must be combined into a single package but rather that care should be coherent, patient-centred, and well-coordinated.[3]

Co-location

Co-location refers to centralising multiple healthcare services within a single facility.[54] It allows patients to access general medical care, diagnosis, physiotherapy, radiology, and pharmacy services and other specialities in one location, often described as a “one-stop-shop”.[73] This model enhances convenience and accessibility, particularly in resource-limited settings. In South Africa, for example, the “supermarket” or “one-stop-shop” model has been widely implemented as a foundation for integrated primary care.[19]

2.3.2. Integrated Diagnosis

Integrated diagnosis is a crucial element of integrated healthcare, extending its principles to diagnostic services. In the context of this study, the integration of diagnostics into primary care includes four main categories: clinical diagnostics (e.g., blood pressure measurement), point-of-care tests (e.g., malaria RDTs), laboratory-based investigations (e.g., hemoglobin testing), and radiological imaging (e.g., obstetric ultrasound). These diagnostic modalities serve different functions and levels of care but are all critical for timely diagnosis and management of both communicable and non-communicable diseases.

Similar to integrated healthcare, integrated diagnosis aims to enhance patient-centred care, improve efficiency, and optimise health system performance by addressing fragmentation in diagnostic services. The literature conceptualises integrated diagnosis in different ways, depending on **who** delivers the services, **where** and **how** they are integrated, and **why** integration is pursued (Figure 2).

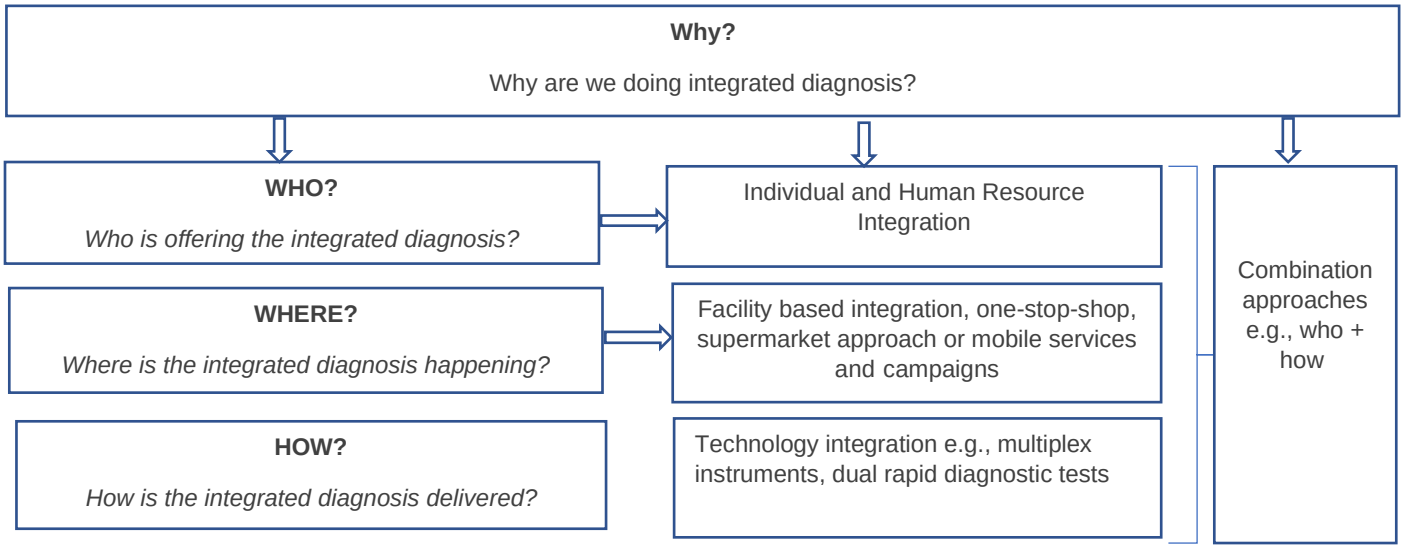


Figure 2: Ways in which integrated diagnosis was conceptualised

While integrated diagnosis is often equated with multi-disease testing, its scope extends beyond testing alone. It encompasses broader diagnostic service delivery models that align with key themes of integrated healthcare, such as co-location, coordination, continuity, and comprehensiveness. Various forms of integrated diagnosis exist, each reflecting different integration strategies.

Facility-Based Integration

Facility integration aligns with the co-location and coordination principles of integrated health care. This approach consolidates diagnostic services for multiple conditions within a single physical location, often described as the "supermarket approach" or "one-stop shop".[43,74-81] Integration may occur within the same building or through coordinated referrals between different units. Examples include TB and HIV integrated testing[78], Non-communicable disease (NCD) and HIV testing[76] and a Chronic Care models.[82]

Facility integration is particularly useful for interventions that were traditionally delivered through "vertical programmes", such as TB or HIV services. Global health organisations such as UNAIDS advocate for integrating these services to maximise health outcomes.[28,83] In addition, integrating diagnosis into healthcare touchpoints- such as maternal health services for pregnant women – presents a strategic opportunity. Routine visits for antenatal care provide an efficient platform for integrating screening of sexually transmitted infections (STIs), cervical cancer, and hypertension.[74,75,80,81,84] This approach also improves testing coverage among key populations, particularly where co-infections are common, such as HIV and TB.[85]

Individual (Human Resource) Integration

Aligned with the continuity of care principle, individual integration involves a single healthcare provider delivering multiple diagnostic services within a single visit.[77,86-92] Unlike facility integration, where multiple professionals can coordinate care, individual integration streamlines diagnosis within a single consultation. Examples include case management approaches such as the

Integrated Management of Childhood Illnesses (IMCI) model or symptomatic diagnoses conducted by primary care providers.[89,93]

Mobile and Campaign-Based Integration:

Mobile and campaign-based models extend facility-based integration to community settings, ensuring diagnostic services reach underserved populations.[94-97] Examples include mobile clinics offering integrated HIV and NCD testing [82,95] or child health campaigns incorporating multi-disease testing.[96]

However, a significant challenge with mobile or campaign-based models is the high rate of loss to follow-up. While initial testing coverage is often high, many individuals do not proceed to treatment and ongoing care. For instance, in a mobile HIV screening initiative in Lesotho, only 36.6% of individuals who tested positive for HIV enrolled in further care HIV care.[43]

Technology Integration

Technology plays an increasing role in enabling integrated diagnosis, particularly through multi-disease testing platforms. Examples include GeneXpert platforms for TB and HIV testing in Zimbabwe and Malawi [98,99], with digital health solutions improving turnaround time and optimising laboratory capacity.[100] While technology-driven integration enhances efficiency, there is a risk of instrument-centred approaches that prioritise diagnostics over patient-centred experiences. Maintaining a balance between technological advancement and comprehensive, holistic care is essential.

Combination Approaches

Some models blend multiple integration strategies, such as combining facility-based and individual integration. For example, a single provider diagnosing both HIV and TB within a co-located facility ensures rapid diagnosis and faster treatment initiation.[101]

The Patient Perspective on Integrated Diagnosis

From the patient's perspective, integrated diagnosis involves both accessible and continuous diagnostic services.[86,90,102,103] Patients commonly define integration in two ways:

1. **Single-Provider care:** Patients prefer receiving comprehensive care from one provider rather than consulting multiple specialists for different conditions. A study in South Africa found that patients with comorbidities perceived their conditions not as separate diseases but a collective experience of chronic suffering.[104] They preferred a holistic approach delivered by a single healthcare professional rather than fragmented care.
2. **Convenient Access to Multiple Services:** Some patients define integration based on service availability within the same facility, even if services are provided on different days.[105] In that sense, vertical programmes housed within the same location may still be perceived as integrated, despite lacking structural or functional integration.

Linking Integrated Healthcare and Integrated Diagnosis: Intended Outcomes

Integrated healthcare and integrated diagnosis share a common goal: optimising health system performance while improving patient experiences and health outcomes.

Key objectives include:

- Breaking down professional and departmental silos through multi-professional collaboration (horizontal integration).[46]
- Strengthening linkages between primary, secondary, and tertiary care (vertical integration).[69]
- Enhancing patient-centred care and improving client satisfaction.[21], [62]
- Improving health outcomes and quality of care.[106]

A critical distinction exists between integration as a structural reform and integrated care as an outcome-oriented approach.[62] While integration focuses on system-level structures and processes, integrated healthcare emphasises patient experiences and results. Different health

system integration models target different desired outcomes:

- System-level integration focuses on organisational efficiency.[107 25 62]
- Programme-level integration aims to improve patient outcomes and service coordination.[108]
- Progressive integration models view healthcare as a continuous improvement process, adapting to evolving healthcare needs.[108]

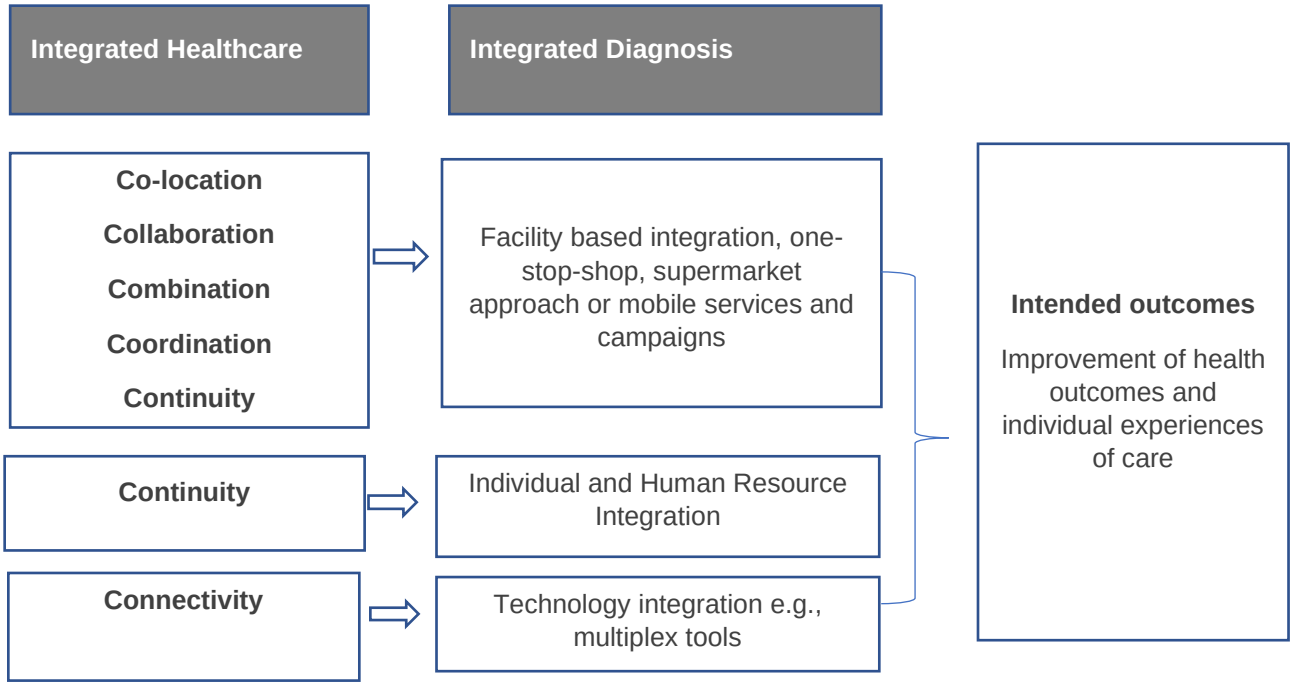


Figure 3: Common themes between integrated healthcare and integrated diagnosis

Ultimately, integration is a means to an end**,** not the goal itself. The true measure of success lies in how well it improves patient care, streamlines service delivery, and improves overall health system performance.[3]

2.4 Discussion

Despite variations in definitions across the literature, integrated healthcare consistently emphasises collaboration, continuity of care, and co-location of services. Patients particularly value services that are continuous, easily accessible, and delivered within a one-stop-shop model. While coordination is often viewed as a means to achieving integration, comprehensiveness is regarded as the ideal end goal. However, the relative importance of these elements differs across stakeholders, and there remains a gap in understanding how patients prioritise and define integration.[109] Most existing integration frameworks have been developed from the perspectives of service providers and organisations, with limited input from patients.[73]

Integrated diagnosis builds on the core principles of integrated healthcare, applying them specifically to diagnostic services. It focuses on:

- Collaboration: Interdisciplinary teamwork facilitates a comprehensive understanding of patients' conditions, leading to more accurate and efficient diagnoses.
- Continuity of Care: Ensuring that diagnostic services are consistent and well-coordinated, reducing fragmentation and improving patient follow-up.
- Co-location of Services: Providing multiple diagnostic services within a single facility enhances convenience, reduces patient burden, and improves healthcare access.

These elements align with patients' preferences for comprehensive, accessible, and continuous healthcare services.

To strengthen integration, decision-makers should prioritise research that establishes clear evaluation standards for integrated health systems. Additionally, documenting case studies that explore implementation processes, challenges, and stakeholder roles across different contexts is essential.[108] Integration in healthcare is inherently shaped by the local healthcare landscape, requiring context-specific approaches.[19] Effective management of integrated healthcare relies on evidence-based practices to guide decision making, feedback loops for continuous improvement

and a balance between system efficiencies and patient-centred care. A holistic approach should be central to integration efforts, ensuring that care is tailored to patients' unique needs, ultimately leading to more personalised and effective healthcare delivery.

Innovations over the past decade have created new opportunities to improve access to diagnostics. Advances in digital technologies, artificial intelligence (AI), electronic data transfer, and mobile health—alongside progress in education, training, workflow design, and supply chain management—are transforming how diagnostics are delivered. Notably, developments such as point-of-care testing, patient self-testing, self-collection of specimens, and remote or digital interpretations of radiological results, are beginning to address a long-standing barrier; the need for diagnostic services to be available close to the patient and making integration possible.

A working definition for this thesis proposed is: **"**Integrated diagnosis is the provision of comprehensive services to identify multiple conditions or diseases during a single visit, ensuring ease of access, same-day diagnosis, and continuity of care, with the intended aim of improving patient experiences and health outcomes." This definition focuses particularly on primary care settings in LMICs.

2.5 Limitations

Most of the existing literature on integrated healthcare is based on high-income countries, where resource constraints and access challenges differ significantly.[56] In LMICs, the PHC system often faces inadequate funding, fragmentation, and poor governance, making integration more difficult.[110] Consequently, findings from high-income countries require careful adaptation to be relevant in LMIC contexts. The evidence base for integrated care remains underdeveloped, with many promising innovations failing to progress beyond pilot phases or temporary funding initiatives.[49] To bridge this gap, further research is needed to identify, adapt, and refine integration

strategies that are both sustainable and effective in LMICs.

2.6 Chapter 2 Summary

This chapter explores the concepts of integrated health care and integrated diagnosis, identifying key themes and characteristics through a literature review.

- While there is no singular definition of integrated health care, common elements include collaboration, continuity of care, coordination, co-location, and comprehensiveness. Integration is often seen as a way to improve system efficiency and patient-centred care, with goals such as enhancing health outcomes, improving service delivery, and reducing fragmentation.
- However, most existing integration frameworks are shaped by service providers and policymakers, with limited input from patients, whose perspectives emphasise ease of access, convenience, and continuity of care.
- Different models of integrated diagnosis were discussed, including facility-based integration, individual-provider integration, mobile and campaign-based integration, and technology-driven integration.
- Most of the existing literature on integrated health care comes from high-income countries, making it essential to adapt and refine integration strategies for LMIC contexts.
- The lack of a strong evidence base and the failure of many pilot programmes to scale further highlight the need for sustainable, context-specific solutions. To address these challenges, research should focus on establishing clear evaluation standards, documenting implementation processes, and understanding the roles of key stakeholders.
- A working definition of integrated diagnosis is proposed for this thesis: *"Integrated diagnosis is the provision of comprehensive diagnostic services to identify multiple conditions or diseases during a single visit, ensuring ease of access, same-day diagnosis, and continuity of care, with the goal of improving patient experiences and health outcomes."* This is aimed

at primary care settings in LMICs.

- By aligning the principles of integrated health care with patient-centred diagnostic strategies, integrated diagnosis has the potential to strengthen health systems, enhance service delivery, and improve health outcomes in resource-limited settings.

Chapter Three

Barriers to Integrated Diagnosis with a focus on integrating diagnostic services for febrile Illness in the Asia-Pacific region.

3. Barriers to Integrated Diagnosis in LMICs: A Scoping Review with a focus on integrating diagnostic services for febrile Illness in the Asia-Pacific region.

Publication Statement

Results of this chapter are published in the following peer reviewed journal:

Gwaza, G. P., Lamy, M., Datta, R., & Dittrich, S. (2022). Barriers to integrating diagnostic services for febrile illness to support surveillance and patient management in Asia-Pacific. Asia & the Pacific Policy Studies, 9(2), 196–212. https://doi.org/10.1002/app5.353

3.1 Chapter Aim and Objectives

This chapter identifies the key barriers to integrated diagnosis in LMICs and how they impact implementation. By examining these barriers, this chapter aims to provide a foundation for addressing them and developing tailored solutions to improve health outcomes and patient experiences. It provides a broad overview across LMICs in Africa, Asia, and the Pacific to show some of the similarities in the challenges, even though there are some region-specific factors explored for the Southeast Asia and Pacific region when it comes to integrating the diagnosis of febrile illnesses in the context of declining malaria cases.

3.2 Integrating diagnosis for febrile illnesses

As malaria cases decline in Asia and the probability that a febrile patient has malaria dwindles, the malaria-only programmes' perceived value declines.[111] To address this shift, community

health workers must be equipped with appropriate tools and training to integrate diagnosis of other illnesses when febrile patients test negative for malaria.

Integrated diagnosis for surveillance has been identified as a valuable next step in many regional malaria elimination strategies, including those of Lao PDR and Cambodia. Both countries aim to integrate dedicated malaria services into the wider health care landscape to make them sustainable and keep the momentum towards malaria elimination.[112-114] However, these efforts have faced challenges, partly due to the structure of funding mechanisms and the high prevalence of malaria among the mobile populations.[115,116] The importance of integrated diagnosis has become even more relevant as the region, along with the rest of the LMICs, navigates challenges posed by the COVID-19 pandemic.

Integrated diagnosis is already a core component of the Integrated Community Case Management (iCCM) guidelines, which focus on improving child health outcomes. iCCM is a strategy designed to train, equip, and support community health workers to provide diagnostic, treatment, and referral services for three common, treatable, and curable childhood illnesses: malaria, pneumonia, and diarrhoea. Since fever is one of the defining symptoms in most malaria testing guidelines, it is essential to provide differential diagnostic, treatment, and care protocols for patients who test negative for malaria.

A recent systematic review of the causes of non-malarial fevers in the Asia region showed that many fevers were attributed to dengue, typhoid, and other vector-borne diseases.[117] This diversity of fever aetiologies underlines the need to integrate malaria surveillance with other febrile illnesses endemic to the region, especially in settings where febrile illness is frequently misattributed to malaria due to the historical dominance of the disease in public health agendas. Integrated diagnosis is ever more urgent to ensure that no malaria and fever cases are missed and for the malaria health workers to continue contributing to broader infectious disease control

efforts. Without access to diagnostic tools that can differentiate between causes such as dengue and bacterial infections like typhoid or leptospirosis, febrile patients are often treated with antimalarials or antibiotics, contributing to both mismanagement and antimicrobial resistance. However, despite its perceived merit, implementing integrated diagnosis in practice remains challenging due to several systemic barriers that will be described in this chapter.

3.3 Methods

A scoping review was conducted following published guidance to map the existing literature and understand the barriers to integrated diagnosis.[118] The review included a range of primary and secondary data sources, such as peer-reviewed articles, expert opinion pieces, technical guides, and reports. Literature searches and bibliography reviews to identify relevant publications were done using PubMed, Cochrane Database for systematic reviews, and grey literature sources through Google and Google Scholar. Key terms used in the search strategy included “integrated health care”, "integration of health care diagnosis," integration of surveillance for febrile illnesses," "challenges or barriers," malaria", and "Asia Pacific” added as filters. The search was limited to English-language publications focusing on LMICs. It was also limited to infectious disease examples to maintain validity in applying outcomes to most LMICs contexts. Papers included reported implementation or evaluations of integrated diagnostic interventions with implementation challenges, barriers, and successes clearly stated.

The search with filters yielded 84 peer-reviewed publications, and 24 were found to be relevant and included in the review. Further, a snowballing technique was used to identify more literature based on the bibliographies of relevant papers. An additional 13 papers were identified in this way. In total, 37 papers were included in this scoping review.

All the papers and reports were analysed and coded inductively using NVivo. This meant that

each paper was coded on the specific barriers and challenges presented rather than having predefined themes. These were later categorized using the WHO "Framework for Action" on health systems, which describes six clearly defined Health system building blocks or pillars that together constitute a complete system.[42]

3.4 Results

Based on the reviewed literature, the main barriers to implementing integrated diagnosis interventions were structured using the six WHO health system pillars: service delivery, health workforce, health information, medical technologies, health financing, and leadership**/**governance.[42] These building blocks are interconnected, and require a holistic understanding of their dynamic interactions and synergies to address systemic challenges effectively[119]. Evidence from high-income countries shows how these structural elements shape PHC outcomes.[120] Brief overviews of the relevant studies identified are presented in Table 2.

Table 3: Summary of key literature identified in the scoping review on barriers to integrated diagnosis

Author	**Title**	**Building block**	**Key challenges identified and *focus area***
Rahi et al., 2021	India can consider integrating three eliminable disease control programmes on malaria, lymphatic filariasis, and visceral leishmaniasis.	Leadership/Governance Financing	Vertical structure of malaria programme *Focus: Integrating febrile illness*
Aung et al., 2020	Challenges in early phase of implementing surveillance and response approach in malaria elimination setting: a field study from Myanmar	Health Information systems	Integration of data *Focus: Integrating febrile illness*
Burkot et al., 2019	Integrated malaria vector surveillance and control activities	Health Information systems	Integration of data; Data utilisation *Focus: Integrating febrile illness*

Nagpal et al., 2018	Integrated control of vector-borne diseases	Health Information systems, Health workforce, Financing, Leadership/Governance	Data management and utilisation; lack of skilled human resources, sustainable funding, and internal co-ordination *Focus: Integrating febrile illness*
Tham et al., 2018	Integrated health care systems in Asia: an urgent necessity	Health Information systems	Lack of Information technology infrastructure and high-quality data *Focus: Integrating diagnosis in general*
Druetz, 2018	Integrated primary health care in low- and middle-income countries: a double challenge.	Financing, Leadership/Governance	Fragmentation of efforts; poor co-ordination *Focus: Integrating diagnosis in general*
Tambo et al., 2016	Integrated dengue early warning surveillance and related vector-borne diseases	Health Information systems, Leadership/Governance	Lack of sustained monitoring and evaluation systems and co-ordination Focus: *Integrating febrile illness*
de Jongh et al., 2016	Barriers and enablers to integrating maternal and child health services to antenatal care in low and middle-income	Leadership/Governance; Service delivery; Health workforce, medical technologies, Financing, Health Information systems	Lack of training and guidelines, staff shortages, country's legal framework and policies; *Focus: Integrating diagnosis in general*
Fowkes et al, 2016	Achieving development goals for HIV, tuberculosis and malaria in sub-Saharan Africa through integrated antenatal care: barriers and challenges.	Leadership/governance, service delivery, health financing, health workforce	Limited policies; infrastructure challenges, staff shortages *Focus: Integrating diagnosis in general*
Brieger W, 2010	Integrating public health programmes with malaria control	Service delivery; Health workforce	Attitudinal barriers such as motivation for supervision affect the quality of implementation. *Focus: Integrating diagnosis in general*
Kabatereine et al, 2010	How to (or not to) integrate vertical programmes for the control of major	Health financing	Limited funding

	neglected tropical diseases in sub-Saharan Africa.		*Focus: Integrating diagnosis in general*
Shiff, 2002	Integrated Approach to Malaria Control	Leadership/Governance; Health workforce	Lack of national implementation strategies; regular change of personnel; *Focus: Integrating febrile illness*

3.4.1 Leadership and Governance

Leadership or governance plays a pivotal role in shaping health system design by ensuring the use of strategic policy frameworks, effective oversight, accountability, regulations, and incentives.[119] At the political level, integrated diagnosis depends on the commitment and responsibility of key stakeholders to ensure ownership and consistency with overall health systems development goals.[71] Political will is evident globally, with initiatives such as the WHO resolution on diagnostics and guidelines for integrating care,[30] including guidelines for integrating TB and HIV services,[4] NCDs[121,122], and integrated antenatal care.[123] Similarly, in the Asia-Pacific region, there is significant political will to prioritise malaria elimination, as evidenced by statements at the East Asia Summit.[124]

However, transforming global commitments and policies into national policies requires strong advocacy and oversight from senior officials within ministries of health, who can drive governance reforms at national, district, and facility levels. A WHO report suggests that integration is most successful when managed at a sub-national or facility level where implementation takes place.[125] A lack of leadership and governance can severely hinder the adoption of integrated health systems. For example, a study examining malaria-in-pregnancy policies across five sub-Saharan African countries found major inconsistencies within and between national policies and training documents.[110] Outdated, inconsistent, or unclear guidelines can lead to poor adherence, incorrect implementation of care strategies, and low coverage of essential interventions for malaria, HIV, and TB.[123,126] Integration of services should be done according to clear strategies and guidelines

to avoid gaps in access to services or key commodities.[125] For febrile illness, in many cases, there is a lack of national strategies for other febrile illnesses (besides malaria) endemic to the area, such as dengue, leading to disjointed programmes run by non-governmental organisations with varying agendas.[127] Integration of pulse oximeters in PHC facilities in low-income settings, for example, has been hindered largely due to its absence in national health policies, medical device lists and clinical guidelines.[128]

Without clear national guidelines, service provision may become sub-optimal.[129] In their review of integration efforts for maternal health care in HIV, TB, malaria, syphilis, or nutrition services with antenatal care in Asia, Africa, and the Pacific, Jongh et al. (2016) [54] noted uncertainty about the care pathways. In Tanzania, fear of harming patients resulted in healthcare providers opting for "doing nothing" rather than risk errors.[54] Similarly, uncertainty about how to deliver intermittent preventative treatment for malaria in pregnancy for specific cases (such as HIV-positive women), led to confusion about addressing potential side effects.[129]

In countries with disease-specific control programmes, integration may involve combining the roles and responsibilities of multiple programme managers into a single leadership position. While this consolidation could streamline efforts, it also risks redundancies and may provoke resistance from managers of previously disease-specific programmes. In some cases, resentment can lead to obstruction or challenges in managing the transition process.[71] Clear leadership and governance are essential to overcoming these structural and interpersonal challenges and ensuring the successful integration of services.

Another leadership and governance issue that affects LMICs is poor coordination of partners and funding, where health budgets often rely heavily on external donors. Health financing is further explored below. An example is the donations of diagnostic equipment, which can be both a barrier and enabler to integrated diagnosis. While these donations are intended to improve access, they

can inadvertently exacerbate systemic issues as they are not fit- for-purpose. For instance, estimates suggest that 40–96% of donated medical equipment is out of service at any given time, partly due to inconsistent power supplies and maintenance difficulties.[6] A systematic review highlighted that only 39.1% of hospitals in sub-Saharan Africa had reliable electricity, compared to 58.1% in 21 countries with available data.[6]

Uncoordinated equipment donations exacerbate these challenges at both the facility and systemic levels. Donors often fail to assess recipients' immediate and long-term needs, leading to equipment incompatibility and fragmented procurement programmes requiring support for multiple supply chains. Without coordinated efforts among donors, recipients, and governments, these donations risk hindering rather than advancing progress. Consequently, these financing inefficiencies and the prevalence of ‘equipment graveyards' render integrated diagnosis interventions suboptimal and fail to achieve their intended impact.

3.4.2 Health Financing

A significant barrier to the integration of health services lies in disproportionate investment across diseases requiring integration. One of the concerns raised at the PHC conference in Africa in Burkina Faso was that much funding to African countries comes from global initiatives.[10] These initiatives tend to undermine the comprehensive approach to health care since they do not address the underlying factors.[10]

Integration efforts often involve incorporating underfunded diseases into programmes with more robust funding, such as HIV programmes. However, diseases with limited resources, such as neglected tropical diseases (NTDs), are at risk of being deprioritised, which hinders effective integration.[71] Without sufficient additional funding, integration efforts cannot cohesively and effectively address the diverse health needs, as seen in the limited resources for integrating malaria treatment and prevention into antenatal care.[123]

In the case of malaria, funding challenges are multifaceted, involving declining investments, disproportionate funding relative to the disease burden, and a lack of resources for other febrile illnesses endemic to affected regions. Adequate funding is essential to ensure the availability and accessibility of services and protect populations from financial hardships associated with out-of-pocket payments.[119] Historically, malaria control and elimination have been operated as standalone programmes with dedicated funding streams. In the Asia-Pacific region, nearly 50% of the total malaria funding in 2016 came from the Global Fund.[130] For example, in Papua New Guinea, the Global Fund was the sole donor providing funding for malaria case management, including rapid diagnostic tools and treatment. Similarly, 70% of malaria control funding in Cambodia came from the Global Fund. When funding was halted between 2015 and 2016 due to accountability concerns, core malaria activities were disrupted, showcasing the vulnerability of vertical funding structures.[116] Many LMICs face a significant knowledge gap in consolidating existing vertical programmes and operationalising integrated PHC services.[131]

In contrast, other febrile illnesses, such as dengue, receive lesser funding even if they have a significant economic burden in some countries. In Southeast Asia, the annual economic burden of dengue fever was estimated to be between $ 610 and $ 1,384 million, with a per capita cost of $ 1.06 to $ 2.41. In comparison, malaria control's annual per capita cost ranged from $ 0.11 to $ 39.06, and for elimination, from $ 0.18 to $ 27.[132]

On the patient side, integration often means an increase in out-of-pocket costs, resulting in low service uptake. An example is the integration in PHC facilities for diagnosis on hypoxemia, which led to an increase in costs of services in many countries.[128]

Limitations in other health system pillars, such as information systems, further compound funding challenges. Weak data collection and impact evaluation systems hinder the ability to demonstrate

the benefits of integrated programmes, which in turn weakens the investment case and decision-making quality.[133] Generating robust impact data is vital to ensure sustained investment in integrated diagnosis efforts.[134]

3.4.3 Health Information

The health information system pillar includes the production, analysis, dissemination, and use of reliable and timely information on health determinants, system performance, and health status.[119] High-quality and robust evidence is required to support stakeholders in making informed decisions about designing and implementing integrated diagnosis interventions.

A critical gap identified in the literature is the absence of monitoring and evaluation (M&E) systems to measure the performance of integrated programmes, resulting in erratic and inconsistent interventions.[106] For example, although integration is intended to increase efficiency compared to standalone programmes, there is little empirical evidence demonstrating how or whether this efficiency is achieved.[71] A review of Integrated Management of Childhood Illness (IMCI) interventions across 29 countries in Asia and sub-Saharan Africa revealed that more than half of these countries showed no significant improvement in health outcomes or service coverage. The availability of services often depended on demand frequency, the complexity of delivery, and donor agency preferences.[133]

Effective integration requires appropriate process, outcome, and impact metrics that can provide actionable insights for decision-making.[123] In addition, improved indicators are needed at the local, regional, and global levels to assess endemicity, disease burden, and the progress of disease surveillance efforts.[126]

Existing funding often prioritises intervention delivery rather than in-depth M&E, creating a weak

evidence base for integrated diagnostic and surveillance efforts, especially for febrile illnesses.[71] For instance, while community health worker programmes have proven effective in reducing morbidity and mortality from acute respiratory infections and diarrheal diseases, there is relatively limited evidence of their efficacy in malaria control and their impact on community uptake in malaria elimination contexts.[111] Moreover, a survey by the Asia Pacific Malaria Elimination Network found that most countries lacked robust M&E systems for interventions targeting high-risk populations. Challenges such as mobility and porous borders further complicate M&E efforts, as reported by Bhutan, Nepal, and Vanuatu.[135] This has resulted in a weak evidence base for programming among high-risk populations and for integrating diagnostic surveillance efforts across diseases.[135]

Another challenge with information systems in LMICs is that even when there are M&E systems, the indicators and data requirements are not standardised to allow for more efficient data sharing and reporting.[136] This is partly because many integrated diagnosis efforts are supported by research institutions and non-governmental organisations, and coordination gaps remain. An integrated data reporting system is necessary, which provides a view of the combined disease burden. However, information technology infrastructure and literacy in many LMICs remain inconsistent [23] and require coordinated support from various stakeholders.

The disparity between national health management information systems and the heavily funded vertical programmes often discourages integration. Vertical programmes, with their often robust monitoring and transparent governance mechanisms, tend to outperform under-resourced public health systems.[137] For example, Thailand's attempt to integrate malaria programmes into the public health system faced challenges due to systemic vulnerabilities, incomplete transfer of responsibilities to public health departments, and socio-ecological factors.[138] Similarly, parallel systems in African countries, such as the Global Fund-funded malaria programmes, have created separate planning, functioning, and reporting systems. These fragmented systems often divert

and deflect the efforts of policymakers from strengthening unified health systems.[137]

Even when routine monitoring data is collected, its use in evidence-based decision-making remains a challenge. For instance, in integrated vector control programmes, 89% of countries collected surveillance data for at least one of eight priority vector indicators, yet only 64% of these countries used this data for programme decisions.[139] For example, more accurate estimates of the dengue disease burden, or other neglected tropical diseases, could inform economic and impact analyses of integration efforts and advocate for more coordinated funding to achieve adequate coverage.[126]

3.4.4 Service delivery

Service delivery as a health system building block includes the provision of effective, safe, and high-quality health interventions to those in need, when and where needed (including infrastructure), using minimal resources.[119] However, integration alone cannot resolve the challenges of inadequate resources or dysfunctional systems.[3]

Integrating health services may lead to some cost savings but incorporating new activities into an existing system can cause severe strains. For example, health workers cannot be expected to continuously absorb additional responsibilities without a corresponding expansion of the workforce. A case in point is Tanzania, where integrating malaria services into antenatal care faced significant challenges due to a lack of additional resources and funding.[129]

The lack of infrastructure, geographic access, and targeted support are significant barriers to effective service integration. In the Asia Pacific region, high-risk populations for malaria are often marginalized groups such as mobile ethnic groups, rural indigenous communities, displaced individuals, and those living in border areas, such as the Laos–Cambodia, Vietnam–Cambodia,

and Thailand–Myanmar borders. These populations usually have limited access to health facilities and prevention programmes.[115,135,140,141]Similarly, cross-border movement and mobile and migrant populations in Nepal, who face a higher risk of imported malaria from India, often evade routine surveillance due to their frequent movement and low use of public health services.[117] Targeted interventions, such as integrated screening and diagnosis interventions at borders, may effectively address specific diseases in these populations. However, the need for such tailored approaches can act as a disincentive to integration because they may not be cost-effective or optimal in broader health system contexts.

Effective integration of HIV, TB, and malaria interventions into antenatal services requires improved physical and technical infrastructure. For example, services provided at separate locations, such as, consulting rooms or laboratories in different facilities or on different days create logistical challenges that hinder integration.[123]

On the patient side, cultural and social barriers further complicate service delivery of integrated interventions. For instance, a systematic review found that many women lacked awareness about intermittent preventive treatment of malaria during pregnancy's benefits, safety, or regimen, which undermined its implementation through antenatal services. Additionally, the social context of diseases, including stigma and cultural perceptions, also poses challenges for integrated service delivery. In rural Kenya, studies found that while 82% of HIV-infected women preferred integrated HIV and antenatal services, some pregnant women feared they would be tested for HIV without consent during antenatal visits. This fear discouraged antenatal attendance and hampered the delivery of other interventions.[123] In Malawi, stigma associated with TB—linked to both the fear of infection and its perceived association with HIV—was reported as a barrier to integrated antenatal services. Patients frequently viewed new TB cases as indicative of HIV, creating significant concerns about being labeled as AIDS patients.[123] Similarly, the co-occurrence of HIV with TB has been identified as a deterrent to care-seeking behaviour in integrated diagnosis settings.

Despite these challenges, some studies highlight positive outcomes from integration. For example, in rural Kenya, HIV-negative women reported high levels of satisfaction with integrated HIV and antenatal services, likely due to the non-discriminatory nature of care.[86] Nonetheless, cultural and social barriers, including stigma, fear of diagnosis, and a lack of trust, underscore the need for operational and implementation research to identify ways to reduce these barriers effectively.

3.4.5 Medical technologies

Health technologies, equipment, and supply chains represent a critical pillar of health systems, directly influencing the availability and quality of service delivery.[119] While advances have been made in POC or near POC technologies for diseases like HIV, malaria, and TB, significant gaps remain for other diseases prevalent in LMICs. Despite the existing demand for low-cost POC diagnostics in LMICs, the commercialisation mechanisms necessary to ensure their distribution and sustainability are often inefficient or entirely absent.[142] Addressing these gaps is crucial to enabling effective integrated diagnostic interventions across a wider range of diseases.

The procurement and supply of testing kits, essential medicines, and consumables remain significant barriers to effective service integration both in the public and private healthcare sectors in LMICs. Inadequate procurement and distribution systems have been highlighted as critical barriers to the success of integrated HIV and malaria services.[123] Unavailability of commodities and irregular supplies of essential drugs have been identified as major challenges, hindering effective same-day test and treat interventions. For example, the uptake of integrated HIV, syphilis, and malaria services was severely hindered by frequent stockouts and inconsistencies in the supply chain.[129] Without reliable access to essential diagnostics and treatments, the potential benefits of integration efforts are undermined, leading to missed opportunities for improving health outcomes.

LMICs also rely on donated medical equipment, which has sometimes not been incompatible with health facilities, and broken down due to lack of maintenance as donations usually cover just purchase of equipment with no funding for consumables and operational costs, resulting in equipment graveyards and poor service delivery.[128]

3.4.6 Health Workforce

The success of integrated diagnosis interventions relies heavily on the skills, motivation, and compliance of health workers.[143] A responsive, fair, and efficient health workforce, available in sufficient numbers, is critical to delivering effective, high-quality care[119]. Ultimately human resources determine how services are provided and what interventions can be implemented.

However, capacity constraints in the health workforce remain a significant barrier to integrating diagnostic and treatment services, especially in resource-limited settings like sub-Saharan Africa. Staff shortages, overburdened workloads, and frequent workforce reallocations often hinder the integration of diseases such as HIV, TB, and malaria into routine antenatal care. These challenges are compounded by inadequate training, high turnover, and insufficient supervision—all of which undermine motivation and reduce buy-in from staff tasked with implementing integrated services.[123] For integration to succeed, staff at all levels must acquire knowledge about the additional diseases they are expected to address.[71] Ongoing supervision and mentorship are crucial with opportunities to practice what they have been taught.[128]

The delivery of diagnostic services in LMICs also involves a wide range of healthcare workers with diverse roles, training, and accreditation. At the primary care level, nurses, clinical officers, and community health workers (CHWs) often conduct clinical assessments and administer point-of-care (POC) tests, such as malaria rapid diagnostic tests or glucose monitoring. Their training typically includes short courses, in-service instruction, and national certification programs, though

these vary in quality and depth across countries.

More complex diagnostics, such as microscopy, hematology, or imaging procedures, are typically handled by laboratory technicians, technologists, and radiology staff who receive diploma- or degree-level training and accreditation through national regulatory bodies. At secondary and tertiary levels, diagnostic responsibilities fall to specialists such as radiologists and pathologists, who undergo university-based education and postgraduate training in their respective fields. Despite these formal structures, gaps in interpreting test results and adhering to diagnostic protocols persist.

Integration also places increased demands on frontline workers, often expanding their responsibilities beyond initial training.[129] For instance, while community health workers play a crucial role in malaria diagnosis and management in remote areas, they may lack the training to identify and respond to other febrile illnesses.[144] Policymakers express concern about relying on these workers to differentiate between non-malaria fevers, leading to frequent referrals to higher-level facilities and missed opportunities for local diagnosis.

A systematic review of barriers and facilitators to lay health worker programmes found that although the communities generally trust community health workers, the care they provide is sometimes perceived as 'insufficient', particularly when workers lack access to medicines and essential equipment.[144] In Thailand, for example, community members expressed mixed feelings: they appreciated the convenience of receiving care locally but believed nurses in local facilities delivered lower-quality care compared to hospitals.

To support the delivery of integrated diagnostics, frontline workers must be trained to distinguish between various febrile illnesses and deliver appropriate care packages. Additionally, community healthcare workers need supportive clinical supervision to ensure quality service delivery, build

skills and confidence, and ensure proper documentation.[145] However, supervision and monitoring are significant cost drivers for community health workers' programmes, particularly in hard-to-reach areas where mobile health teams provide support.[146]

Low motivation and a perceived lack of capacity among health workers can weaken surveillance and service delivery for unfamiliar diseases, causing them to focus on more routine or easier tasks. Studies globally have shown that individual benefits, such as allowances, are important for recruitment. Still, professional benefits, including relationships and opportunities, are more important for retention. However, what incentives work will vary considerably among health service delivery contexts and models of care, within health systems, and between individual workers.[110]

3.5 Discussion

The scoping review highlighted some key barriers to integrated diagnosis programmes, ranging from strategic challenges, such as leadership and governance to operational issues, such as service delivery and healthcare workers' capacity. While the review does not address which diseases or conditions to integrate, it underscores that these decisions should be guided by evidence rather than intuition.[71]

As comorbidities increase and traditional diseases like malaria continue to decline in many regions, the need for integrated service delivery is becoming more urgent. For example, in Asia and globally, the continued monitoring of diseases like malaria remains critical, even as HIV-positive individuals live longer and face the dual burden of chronic illnesses. Addressing integration challenges requires a health systems approach that acknowledges the interdependence of various components.

Systemic barriers to integration are consistent across LMICs, indicating that solutions must be informed by shared experiences and tailored to local contexts. A lack of systematically assembled knowledge about effective integration strategies poses a significant obstacle for health system planners. There is an urgent need to identify evidence-based implementation strategies, prioritise evidence gaps, and direct future research to address these challenges effectively.

Integration efforts should be customised to individual countries, factoring in existing infrastructure, health needs, and operational feasibility. This includes deciding which diseases, for example, vector-borne diseases like malaria or syndromes, respiratory or undifferentiated fevers are best suited for integration. Beyond operational considerations, political and economic interests play a significant role in advancing integrated diagnosis programmes.

Finally, the review emphasises the importance of further research to understand the drivers of success and failure at different levels of the health system. Additionally, the development of fit-for-purpose M&E systems is critical to track progress and ensure the sustainability of integrated diagnosis programmes. Building on existing knowledge and tailoring integration strategies to country-specific contexts will be key to overcoming barriers and advancing health outcomes in LMICs.

3.6 Chapter 3 Summary

This chapter examined the barriers to integrated diagnosis programmes in LMICs, identifying challenges that span strategic, operational, and systemic dimensions of health systems.

- Strategic barriers include weak leadership, governance, and the lack of evidence-based decision-making for integration.

- Operational challenges are rooted in workforce capacity, with health worker shortages, insufficient training, and overburdened staff limiting the success of integrated programmes.
- Gaps in infrastructure, irregular supply chains for diagnostic tools and medicines, and insufficient M&E systems further constrain service delivery.
- Future integration efforts must prioritise evidence-based strategies, address resource and capacity constraints, and focus on building sustainable systems that meet the unique needs of each country

Chapter Four

Integrated TB and HIV Testing in Lesotho: A Programme Evaluation

4. Integrated TB and HIV Testing in Lesotho: A programme evaluation

Publication Statement

Results of this chapter are published in the following peer reviewed journal:

Gwaza GP, Leqheka M, Mots'oane T, Dittrich S, Kao K. Missed opportunities for integrated testing of HIV and tuberculosis on the GeneXpert platform in Lesotho. African Journal of Laboratory Medicine. 2023;12(1), a2132, https://ajlmonline.org/index.php/ajlm/article/view/2132

4.1 Chapter Aim and Objectives

This chapter evaluates the implementation of integrated testing of TB and HIV in Lesotho, an LMIC in Southern Africa, to assess the extent of integration and identify practical barriers and enablers to effective implementation. The evaluation is guided by the definition of integrated diagnosis established in Chapter 2, which refers to the provision of comprehensive diagnostic services to identify multiple conditions or diseases during a single visit, with ease of access, same-day results, and continuity of care, ultimately improving patient experiences and health outcomes. While the previous chapter explored barriers to implementation more broadly, this chapter delves into the specific challenges and facilitating factors affecting integrated HIV and TB testing in Lesotho, offering a practical understanding of real-world implementation dynamics.

Lesotho was also chosen as a focus for this study because a visit to one of its healthcare facilities was a key inspiration for embarking on this DPhil journey, as explained in the personal statement.

4.2 Background

TB and HIV remain major public health challenges in many resource-limited settings, including Lesotho. Integrated approaches to diagnosis, treatment, and care have been identified as key strategies to address the dual burden of TB and HIV [4,147] with potential benefits such as improved health outcomes, cost savings, and enhanced patient experiences.[5,50,148,149]

TB is the leading cause of death among people living with HIV, who are 18 times more likely to develop TB compared to the general population.[150] In 2020, 9% of individuals diagnosed with TB were also living with HIV.[151] Despite the well-established co-morbidities between these diseases, the implementation of integrated TB and HIV diagnostic services remains suboptimal. A previous scoping review identified several barriers to effective integration, including resource constraints, a lack of clarity on optimal integration models, and insufficient coordination between TB and HIV programmes.[152]

In 2010, the WHO recommended the use of the Xpert MTB/RIF assay, based on the GeneXpert (GX) multi-disease platform, for TB diagnosis. The Xpert MTB/RIF is a specific assay (test cartridge) used with the GeneXpert system, designed to detect Mycobacterium tuberculosis (MTB) – the bacteria that causes TB, and detect rifampicin (RIF) resistance – which is a strong indicator of multi-drug resistant TB (MDR-TB). The GeneXpert is a molecular diagnostic system developed by Cepheid that uses real-time PCR (polymerase chain reaction) technology to detect the genetic material of pathogens directly from clinical samples. Each test uses a disposable, self-contained cartridge that includes all necessary reagents. This molecular test is simple, robust, and feasible for use in peripheral laboratories and clinics, even by individuals with limited or no laboratory training.[153-155]

In 2016, WHO further approved several point-of-care (POC) assays for HIV diagnostics, including the Xpert HIV-1 Qual for HIV qualitative testing for Early Infant Diagnosis (EID) using whole blood or dried blood spots (DBS), which also operates on the GX platform.[156] EID refers to testing infants

born to HIV-positive mothers to detect HIV infection as early as possible, because maternal antibodies cross the placenta and can make routine antibody tests unreliable up to 18 months of age. Tests included in EID are i) Virological tests (mainstay for EID): HIV DNA PCR – detects proviral DNA integrated in infant cells; HIV RNA PCR (viral load test) – detects viral RNA in plasma, and Xpert HIV-1 Qual assay (GeneXpert platform).

POC testing offers significant advantages, including reduced turnaround times, same-day diagnosis, minimised patient loss along the HIV testing cascade, reduced infant mortality, and the ability to shift diagnostic tasks to lower-level health workers in decentralised facilities.[157] [158,159]

The GX platform's versatility allows for the simultaneous testing of multiple pathogens, including TB and HIV, using different cartridges within the same instrument, including HIV viral load monitoring, Hepatitis virus, and sexually transmitted infections such as chlamydia and gonorrhea. More recently, this platform has also been adapted for COVID-19 testing.[160] Given its ability to support multi-pathogen diagnostics, GX has the potential to enhance service delivery efficiency and reduce patient costs by integrating TB and HIV testing.[161]

Despite advancements in diagnostic technologies, Lesotho continues to face a high dual burden of TB and HIV.[160] The introduction of POC EID tests, such as the GeneXpert HIV-1 Qual and m-PIMA HIV-1/2 Detect/Alere q, has strengthened efforts to reduce mother-to-child transmission (MTCT) of HIV.[158,162] However, Lesotho remains one of the 30 high TB-burden countries, with an estimated incidence rate of 654 cases per 100,000 people—the highest globally.[160] Since 2016, the Foundation for New Innovative Diagnostics (FIND) has supported the Ministry of Health (MOH) in expanding TB testing on the GX platform. Investments in molecular TB and HIV testing have progressively increased. In 2020, Lesotho had 42 GX instruments, each with four testing modules, across 21 health facilities, which could be leveraged for integrated TB and HIV testing. Additionally, the country has deployed 15 Alere Q instruments in 15 health facilities for HIV POC testing.[163]

Given the high rates of TB and HIV co-infection, Lesotho has adopted a policy of using Xpert MTB/RIF as the primary diagnostic test for individuals with presumptive TB to improve detection rates.[163] The country also provides HIV viral load testing for all HIV-positive individuals in accordance with WHO HIV treatment guidelines,[162] and offers POC HIV EID testing to minimise loss to follow-up.

The MOH guidelines for HIV EID testing align with WHO recommendations, which advise conducting the first virological test for HIV-exposed infants at around six weeks of age, followed by a second test after weaning. Additionally, all infants diagnosed with HIV should be initiated on antiretroviral therapy (ART) immediately, regardless of CD4 count.[164] In line with WHO recommendations, Xpert MTB/RIF is also used as the initial diagnostic test for individuals suspected of multidrug-resistant TB (MDR-TB) or HIV-associated TB.[165]

FIND has supported efforts to integrate TB and HIV testing by conducting diagnostic network optimisation activities in Lesotho.[166,167] This evaluation aims to assess the extent of implementation and integration of TB and HIV testing on the GX platform. Throughout this report, the Cepheid Xpert® MTB/RIF platform is referred to as the GeneXpert instrument or GX.

4.3 Methods

The objectives of the programme evaluation were to assess the:

- implementation of integrated testing of TB and HIV in Lesotho,
- identify barriers and enablers to effective implementation.

This programme evaluation employed a mixed-methods approach, integrating both quantitative (for the implementation) and qualitative (for the barriers and enablers) data collection methods[168] to assess defined processes and outcome indicators. The process indicators included number of instruments, date of installation, training received, number of tests conducted for both HIV and

TB, data connectivity, quality assurance measures and storage issues. The outcome indicators included testing capacity, costs of services, and treatment linkages and care.

The evaluation consisted of two main components: secondary data analysis and primary data collection through interviews.

Secondary data analysis: A retrospective secondary data analysis of laboratory records of tests conducted from the previous three years 2017 to 2020 was conducted to see the extent of simultaneous HIV EID and TB testing on the GX machines. However, only data from 2017 and 2019 was used in the analysis as it had more complete and accurate records across the diseases and the health facilities and could be used for comparisons. Complete data meant that the data included the day the test was taken, time started, time finished, result of the state, and error rates.

Semi-structured interviews: Two semi-structured questionnaires were developed to guide the interviews, targeting laboratory and clinical staff involved in TB and HIV testing and care. (i) **Laboratory questionnaire**- Focused on aspects related to GX instrument installation, staff training, instrument maintenance, quality management, data reporting, testing rates, associated costs, and challenges in implementing TB and HIV testing.

(ii) **Clinical questionnaire**- focused on patient profiles, economic costs, staff training, testing rates, linkage to treatment, health outcomes, and challenges related to TB and HIV integration. Additionally, it explored healthcare workers' experiences and their perceptions of patients' experiences with integrated testing.

The development of these questionnaires was informed by the monitoring metrics used by FIND during the implementation of GX testing in Lesotho prior to 2016[166]. Since these tools had been previously piloted and tested in similar contexts, they were considered appropriate for this evaluation. The full questionnaires are provided in the Appendix to Chapter 4.

Two groups of healthcare professionals were interviewed, each corresponding to one of the questionnaires:

- **Laboratory Professionals** – Individuals responsible for conducting GX testing daily.
- **Clinical Staff** – Healthcare providers responsible for screening, referrals, management, care, and treatment of TB and HIV patients within the facility. This group primarily included nurses working in TB departments or maternal health wards, where most screening and GX machines for HIV EID testing were located.

At each site, two healthcare professionals were interviewed—one responding to the laboratory questionnaire and the other to the clinical questionnaire—ensuring a comprehensive understanding of both diagnostic and clinical perspectives on integrated TB and HIV testing.

4.3.1 Sampling Strategy

Lesotho utilises a hub-and-spoke model for sample referrals, where hubs- typically laboratories located in district or regional hospitals- are equipped with GX instruments for diagnostic testing.[163] Samples are collected at "spokes" sites, which include primary healthcare facilities such as clinics and health centres, and then transported to hub laboratories for testing.[169] Hubs in peri-urban areas generally cover larger catchment areas and receive samples from multiple spoke sites.

For this evaluation, GX testing sites were selected across rural, urban, and peri-urban areas to ensure diversity in facility type and geographic representation. The selection was conducted in consultation with the Ministry of Health (MOH) and followed a purposive sampling approach to capture variations in healthcare infrastructure and service delivery. The sample included regional, district, and local hospitals, primary healthcare facilities, and district hospitals that serve as the first point of care for many patients, particularly in rural areas.

A key criterion for inclusion was the presence of at least one GX instrument used for TB or HIV testing. In some facilities, GX was used exclusively for TB testing, while Alere Q (AQ) was used for HIV Early Infant Diagnosis (EID). These sites were still included in the evaluation, though AQ-generated data were later excluded from the final analysis to ensure comparability of integrated diagnosis outcomes. However, these facilities still provided valuable insights into the broader landscape of diagnostic integration across different technological platforms.

4.3.2 Data Analysis

The data were analysed using Microsoft Excel, focusing on the utilization rate for the GX instrument and turnaround times for diagnostic testing.

Utilisation Rate Calculation

The utilisation rate of the GX instrument was determined by calculating the proportion of actual tests performed at each site per year, for a given disease, relative to the maximum possible number of tests that could be conducted. According to WHO guidelines, the theoretical maximum capacity of a four-module GX instrument is 20 specimens per day.[165] However, the recent Global Laboratory Initiative (GLI) recommends that a single technician can realistically perform at least 12 Xpert MTB/RIF tests per day.[170]

For this evaluation, a maximum testing capacity of 12 specimens per day per four-module GX instrument (GXIV) was assumed, considering three two-hour runs per day. Additionally, the analysis accounted for an annual testing period of 264 days, based on the recorded operational schedule of 22 testing days per month across study sites. Using this assumption, the maximum annual capacity per GXIV instrument was calculated as:

12 specimens/day×264 testing days/year=3,168 specimens/year

Turnaround Time (TAT) Measurement

The standard turnaround time (TAT) was defined in two distinct ways:

1. Sample-to-laboratory TAT – The time from sample collection to when the test results were received in the laboratory.
2. Sample-to-patient TAT – The time from sample collection to when the patient received their results.

Since TAT varies across countries and sites based on infrastructure and logistical factors, data on turnaround times were primarily collected through interviews with healthcare staff. Laboratory records provided timestamps for sample receipt and test completion but often lacked data on when patients collected their results. During the interviews, staff were asked, '*approximately how long does it take from the time the sample is collected and when the patient receives their results*?" Where possible, interviewees were also requested to break down the turnaround time into the two stages defined above.

4.3.4 Ethical considerations

This evaluation was conducted as part of the researcher's role as a Monitoring and Evaluation Manager at FIND, an organisation providing technical support for the rollout of GX machines in collaboration with the MoH. Since the study was part of a routine programme evaluation already agreed upon with the MoH and with the officials from the MoH as part of the evaluation team, formal ethical approval was not required. A confirmation letter of the study from FIND is included as Appendix 1 of this Chapter. Permission to conduct the evaluation was obtained from the MoH, Department of Research and Laboratory Services. A representative from this department was also part of the evaluation team.

Several ethical measures were implemented to protect data and maintain participant confidentiality. All interview responses were anonymized, and only aggregate test numbers were reported to prevent the identification of specific sites or individuals. Interviews were conducted in a private setting to ensure confidentiality. No patients were interviewed as part of this evaluation.

4.4 Results

4.4.1 Demographics

A total of 44 individuals were interviewed, including 24 participants involved in TB diagnostics, 18 in HIV diagnostics, and 2 from the MoH. On average, two people were interviewed per health facility, with an additional two participants from the central MoH offices. A total of 42 questionnaires were completed, comprising 24 for TB and 18 for HIV. Half of these focused on clinical aspects, while the other half covered laboratory-related topics.

Thirteen health facilities were included in the evaluation. Twelve of these facilities conducted TB testing using the GX instrument, while one site, Thamae Health Centre, did not offer TB testing. Collectively, these 12 sites served 137 spoke sites. Nearly half of the hospitals (46%; 6 out of 13) had more than one four-module GX instrument (GXIV), including Mafeteng (3), Berea (2), Motebang (2), Ntshekhe (2), Partners in Health (PIH) Clinic (2), and Scott Hospital (2).

Nine health facilities had a GXIV for HIV EID testing, serving a total of 73 spoke sites. Among these, three were primary care facilities, while the remaining sites were secondary-level hospitals. However, many individuals in the surrounding areas used these secondary facilities as their first point of care, showing how the definitions of PHC can vary in contexts where a district hospital is the only accessible health facility.

None of the 13 facilities conducted simultaneous TB and HIV EID testing on the same instrument. Instead, testing for TB and HIV was performed separately, in different rooms, by different personnel, and using different instruments.

Table 4: Location of health facilities sampled for the evaluation

Health Facility (*Hubs)	Level of facility	District	Setting	No. of four-module GX instruments		No. of spoke sites	
				TB	HIV EID	TB	HIV EID
1. Berea Hospital*	Secondary care	Berea	Peri-urban	2	1	12	12
2. Maluti Hospital*	Secondary care	Berea	Rural	1	1	7	7
3. Mafeteng Hospital*	Secondary care	Mafeteng	Peri-urban	3	1	9	12
4. Maputsoe Filter Clinic	Primary care	Leribe	Peri-urban	1	Alere Q	0	Alere Q
5. Motebang Regional Hospital*	Secondary care	Leribe	Peri-urban	2	1	31	9
6. Seboche Hospital*	Secondary care	Leribe	Rural	1	1	5	5
7. Ntshekhe Hospital*	Secondary care	Mohale's Hoek	Peri-urban	2	1	25	8
8. Paray Hospital*	Secondary care	Thaba Tseka	Rural	1	1	11	8
9. Partners in Health (PIH) Lab*	Primary care	Maseru	Urban	2	Alere Q	7	Alere Q
10. Scott Hospital*	Secondary care	Maseru	Peri-urban	2	1	15	10
11. Thamae Health centre*	Primary care	Maseru	Urban	No	1		2

12. St James Hospital*	Secondary care	Mokhotlong	Rural	1	Alere Q	7	Alere Q
13. St Joseph's Hospital*	Secondary care	Roma	Peri-Urban	1	Alere Q	8	Alere Q
TOTAL				**19**	**9**	**137**	**73**

4.4.2 Number of tests conducted for TB and HIV EID

In 2017, there were 32,037 TB tests conducted on 16 GXIV instruments across the 12 facilities Seven GX instruments designated for EID testing were installed that year, with data available from three of the sites, where a total of 2,297 EID tests were performed.

By 2019, the number of GXIV instruments used for TB testing had increased to 19 across the same 12 sites, with a total of 37,347 TB tests conducted. Nine GXIV instruments were in use across nine sites, and 6,977 EID tests were performed.

Table 5: Number of tests conducted on the GX instrument, based on the data recorded in lab registers and hospital files

Health Facility	2017					2019				
	TB	EID	Total	Maximum annual capacity†	Utilisation rate	TB	EID	Total	Maximum annual capacity	Utilisation rate
Berea Hospital	2565	n/a				2553	846	3399	6336	54%
Maluti hospital	1849	442	2291	3168	72%	2948	690	3638	3168	115%

Mafeteng hospital	4347	1321	5668	9504	60%	4565	1033	5598	9504	59%
Maputsoe FC	n/a	n/a				44*	381			
Motebang Regional Hospital	5959	n/a				8573	835	9408	6336	148%
Seboche Hospital	1054	n/a				1476	340	1816	3168	57%
Nshekhe Hospital	3038	n/a				3834	834	4668	6336	74%
Paray Hospital	1165	534	1699	3168	54%	1699	549	2248	3168	71%
PIH Lab	6061	n/a				4883	n/a			
Scott Hospital	3710	n/a				3974	703	4677	3168	148%
Thamae Health centre	n/a	n/a				766	766			
St James Hospital	664	n/a				644	AQ			

St Joseph's Hospital	1625	n/a				1432	AQ			
Total	32037	2297				37347	6977			

*†Maximum capacity for the GXIV was calculated based on the assumption that 12 specimens were run per day, given three two-hour runs in a day. In addition, 264 days of testing per annum were used, based on 22 days per month recorded during data collection at the sites, was used. i.e., 264 *12=3168 tests per year for one instrument. This was multiplied by 2, 3 or 4 depending on the number of GXIV modules available at the facility.*

**December only data, excluded from the addition as it is not complete*

AQ-Tests conducted on Alere Q instrument

Calculation of utilisation rate: Total of TB + EID Tests Conducted)/Maximum Capacity 100%. For facilities with more than one GX instrument, the number of tests performed per year was divided by the number of instruments to get an estimate of the utilisation rate of one instrument. The percentage is rounded off to the nearest 100.*

n/a- data not available either because the GX was not available to do the HIV EID tests or, in some cases, TB or HIV EID tests were not conducted at the facility

4.4.3 Turnaround time (TAT)

The turnaround time for performing tests and generating results in the laboratory using the GX instrument was approximately two hours. However, the time taken for patients at the hub sites to receive their results varied between two and twenty-four hours for both TB and HIV testing.

For patients at spoke sites, the time to receive results varied significantly across facilities, ranging from two to seven days. This variation was primarily due to logistical challenges in sample transportation and result dissemination.

At health facilities equipped with a GX instrument, same-day integrated diagnosis was technically possible, allowing patients to receive their results within the same day. However, at primary care facilities—typically satellite sites without a GX instrument—integrated TB and HIV same-day diagnosis was not feasible, as testing was conducted off-site, leading to delays in result availability.

Table 6: Turnaround time for TB and EID tests at hub and spoke sites based on interviews with health workers

Name of Health Facility	Time (Hours)		Satellite sites	
	TB	EID	TB	EID
Berea Hospital	3	2	48	48
Maluti hospital	2	2	168	168
Mafeteng hospital	2	2	48	48
Maputsoe FC	2	AQ	n/a	n/a
Motebang Regional Hospital	2	2	48	168
Seboche Hospital	2.5	2	120	120
Nshekhe Hospital	3	1.5	48	48
Paray Hospital	2	2	48	48
PIH Lab	2	n/a	120	n/a

Scott Hospital	24	24	168	168
Thamae Health centre	n/a	2	n/a	48
St James Hospital	2	2	48	48
St Joseph's Hospital	24	AQ	48	AQ

n/a shows tests not conducted at the facility

AQ shows tests conducted on the Alere Q instrument

4.4.4 Staff Capacity

The number of staff trained to operate the GX instrument varied across sites and between TB and HIV testing. On average, four staff members were trained for TB testing, while three were trained for HIV EID testing.

For TB testing, trained personnel typically included laboratory technicians, microscopists, or health technologists. Testing was conducted within the health facility's central laboratory, where staff primarily handled samples rather than interacting directly with patients due to the infectious nature of the disease.

In contrast, HIV EID testing was performed at the point of care within the maternal wing of the health facility. Nurses, healthcare professionals, and lay counselors were trained to operate the GX instrument for this purpose. As a result, staff conducting HIV testing had direct interactions with patients, unlike those performing TB testing, who primarily engaged with other hospital staff rather than patients.

Table 7: Staff trained at the sites to operate the GX instrument for testing. Data based on interviews

Name of Health Facility		
	TB	EID
Berea Hospital	7	2
Maluti hospital	2	3
Mafeteng hospital	4	6
Maputsoe FC	1	AQ
Motebang Regional Hospital	4	3
Seboche Hospital	3	3
Nshekhe Hospital	3	4
Paray Hospital	3	2
PIH Lab	6	n/a
Scott Hospital	6	2
Thamae Health centre	n/a	4
St James Hospital	4	AQ
St Joseph’s Hospital	6	AQ

4.4.5 Linkage to Treatment

At all HIV EID sites, same-day initiation of treatment was implemented, with 100% of those testing positive promptly started on ART. The proportion of infants remaining on treatment for at least twelve months was also very high (100%) across six sites.

For HIV treatment at other sites, five out of the nine facilities (St Joseph's, Scott, Motebang, Thamae) implemented same-day ART initiation. However, treatment initiation was delayed at some sites: Paray took two days, Berea required four days, and Maluti Hospital could take up to ten days.

For TB treatment, care cascade and linkage to treatment data were incomplete or unavailable for more than half of the TB-testing facilities (7 out of 12).

Table 8: Table 5: Linkage to treatment for HIV EID. Data is based on interviews.

Name of Health Facility	Average time between testing and initiating anti-retroviral therapy (ART) in days (Onsite)		Percentage of those on ART who remain on ART for at least 12 months
	Hub	Satellite	
Berea Hospital	Same day	4 days	100%
Maluti hospital	Same day	10 days	100%
Mafeteng hospital	Same day	2 days	100%
Maputsoe FC	AQ	n/a	n/a
Motebang Regional Hospital	Same day	Same day	100%

Seboche Hospital	Same day	Same day	100%
Ntshekhe Hospital	Same day	Same day	n/a
Paray Hospital	Same day	2 days	n/a
PIH Lab	n/a	n/a	n/a
Scott Hospital	Same day	Same day	80%
Thamae Health centre	Same day	Same day	100%
St James Hospital	AQ	n/a	n/a
St Joseph's Hospital	AQ	n/a	n/a

n/a means no data available, or Alere Q instrument used, so data not included

4.4.6 Barriers to integrated TB and HIV testing

Interviews with laboratory and clinical staff revealed several barriers to achieving same-day integrated TB and HIV testing at the facilities.

4.4.6.1 Resources

The lack of resources—human, financial, and time—was a significant barrier to integrated testing. A key concern raised during the interviews was that staff trained to conduct HIV testing had minimal experience with TB testing and vice versa. Although some staff had received training in the past, many had not yet had the opportunity to apply their knowledge in practice, necessitating additional training before they could effectively conduct both tests. As a result, simultaneous TB

and HIV testing on the same platform was often not feasible, even when the infrastructure allowed for it.

Even though the facilities were co-located, it was theoretically possible to refer patients between departments for TB and HIV testing. However, clinical staff reported that, depending on workload, it was often difficult to obtain same-day TB test results. While HIV testing was generally prioritised as more urgent, delays in receiving TB results were common, which posed challenges for timely diagnosis and treatment. Furthermore, increasing the volume of testing—particularly at sites with higher utilisation rates—was seen as a potential source of further time constraints.

Another resource-related barrier stemmed from the differing sources of funding for TB and HIV programmes. Each disease programme was often supported by separate funding partners, with each partner purchasing its own equipment with different reporting requirements. This affected how the two disease programmes were structured at the facilities. These discrepancies made it difficult to align testing workflows and integration efforts, even when the testing equipment was located in adjacent rooms. Moreover, the diagnostic algorithms and timelines for TB and HIV were often not coordinated, hindering integration at the facility level.

4.4.6.2 Health Information Systems

Another key barrier was a functional data connectivity system. Staff reported that the lack of electronic data transmission capabilities made it difficult to coordinate and manage testing processes. Some sites still relied on paper-based systems or were in the process of transitioning to digital systems. Most GX instruments were no longer linked to electronic reporting systems, meaning that results had to be manually entered by staff. This added extra workload and increased the risk of errors.

Implementing better data connectivity could have facilitated coordination, particularly for primary care facilities, by allowing them to receive test results electronically from hub sites where the GX machines were located. This would have streamlined communication and potentially improved turnaround times.

4.5 Discussion

This evaluation of integrated TB and HIV testing on the GX platform highlights several important challenges and potential opportunities for improving integrated testing. None of the sites visited were able to perform simultaneous TB and HIV testing on the same instrument, and the GX machines were not operating at maximum capacity. Although theoretically possible based on the timelines of the instruments, same-day testing for both TB and HIV was not consistently achieved across the sites. This issue is not unique to Lesotho; similar barriers to integrated testing have been observed globally, including in Europe. Despite efforts to integrate TB and HIV programmes in the WHO European region, the integration has had limited impact, primarily due to the dependence on disease-specific donor funding that is often siloed and project-focused, hindering the integration of these programmes.[155]

In 2004, the WHO defined the ASSURED criteria (affordable, sensitive, specific, user-friendly, rapid, robust, and equipment-free) for POC diagnostics. In 2019, these were updated to include the REASSURED criteria, emphasizing the need for real-time connectivity and ease of specimen collection.[27] While the GX platform fulfills many of these criteria, connectivity emerged as a significant challenge in Lesotho. This gap in connectivity fell short of the REASSURED criteria, limiting the ability to leverage the benefits of POC diagnostics fully.

POC diagnostics offer notable advantages, such as patient-centredness, rapid results, reduced hospital visits, and avoidance of transport issues. However, their reliability can be compromised, depending not only on the performance of the test but also on factors like sample collection, result

interpretation, and communication. These elements require adequate staff training, ongoing access to quality control materials, and regular technical support. As such, integrating quality assurance and quality control into point-of-care testing protocols is essential. Furthermore, these diagnostics should only be used where referral pathways exist and where there is buy-in from healthcare providers and trust from patients.

The utilisation rates observed in this study align with findings from a 2017 diagnostic network mapping exercise in Lesotho, which showed low utilisation of GX instruments, with 19 out of 24 facilities using them at less than 50% capacity.[166] This underutilisation is consistent with trends observed in other countries, such as in a 22-country analysis of TB high-burden nations, where only 37% of countries used GX instruments for multiple tests, including TB, HIV, and hepatitis C (28). Similarly, in Zimbabwe, the daily utilisation rate of point-of-care EID instruments was only 1.51 tests/day in 2019.[171] A later study (2020) in Lesotho confirmed that the GX instruments are largely underutilised, and relocation of instruments will deliver equivalent access to services compared to procuring new instruments.[167]

The relatively low utilisation rate at many of the sites evaluated in this study suggests there is potential for integrated testing in the future, purely based on capacity. For instance, in 2017, three sites that installed new GX instruments could have integrated HIV EID tests with the available TB testing capacity. At Mafeteng, for example, two machines used for TB testing could have conducted 5,668 tests (4,347 for TB and 1,321 for HIV EID), achieving 89% of maximum capacity. Similar opportunities existed at other sites, with the potential to integrate testing without exceeding the instruments' capacity. Despite this, some sites still did not utilise the full potential of their GX machines, with capacity being underutilised for both TB and HIV testing.

Similarly, in Maluti, 2291 tests (1849 TB and 442 EID) could have been conducted on one instrument with a 72% utilisation rate. In Paray, 1699 (1165 TB; 534 EID) tests could have been undertaken at a 53,6% utilisation rate. In 2019, had all the EID tests been integrated or conducted on the GX instruments used for TB testing, five sites would still not have used the maximum

capacity. Only three of the sites would not have been able to handle both tests without an additional machine.

The successful integration of diagnostics for multiple diseases can improve resource use in developing countries.[172] In Zimbabwe, a study demonstrated the feasibility of using the GX platform for TB, rifampicin resistance testing, HIV EID, and viral load testing, highlighting the potential for broader integration.[99] In Lesotho, this integration is already supported within the country's U.S. President's Emergency Plan for AIDS Relief (PEPFAR) framework, which includes a tiered laboratory network.[162] However, significant barriers remain to fully operationalising integrated testing in Lesotho, as also observed in other countries. One such barrier is staff capacity. Similar challenges were identified in Uganda in 2009, where health workers were trained on either TB or HIV but lacked training on integrated TB and HIV testing.[152] Inadequate follow-up supervision further compounded this issue.

In this evaluation, TAT for both TB and HIV testing at hub sites was under four hours, which aligns with best practices for point-of-care diagnostics. These results are consistent with similar studies showing that same-day test results were available at testing sites and that TATs at spoke sites were reduced to five days, a notable improvement compared to the conventional model of 61.7 days.[169] Notably, the TAT in this evaluation was a reduction from a 2019 study in eight African countries, where TAT at spoke sites was as high as nine days.[158] This improvement may be attributed to a country review of the joint TB and HIV programme, which highlighted the need to address TAT delays at spoke sites.[172] Reducing TAT can increase the testing rates for TB and HIV as it will cut down on travel time and costs, especially in rural areas, which may be a significant burden for some people.

Reducing TAT can have a significant impact on testing rates, especially in rural areas where long travel times and costs pose barriers to care. However, interviews with laboratory staff revealed that, despite the potential for same-day results at the hubs, patients often had to wait at least a day to receive their results. This delay was due to workload pressures on laboratory staff, who

were hesitant to have patients waiting for results while managing samples from spoke sites. Additionally, the time commitment required by patients—particularly those who needed to stay at the hub for results—imposed an economic burden, as it prevented patients and their families from engaging in paid work or caregiving.

4.8 Limitations

Access to data was a challenge at some sites, which impacted the completeness of the analysis. The evaluation focused on data from 2017 and 2019, as these were the most comprehensive years available. Additionally, due to limited variation in cost data across sites, a cost-effectiveness analysis could not be conducted. These limitations highlight the need for improved data collection and management systems to enable more robust evaluations of diagnostic integration in the future.

4.9 Policy Implications

This evaluation highlights areas that need more focus and more detailed diagnostic network optimisation exercises to improve service delivery and allocate stocks, staff, equipment, and training. Better coordination of donor support or increased flexibility in reporting of use will be essential to maximise the use of resources, where integration may be more effective than purchasing new equipment. Monitoring and evaluation should be a routine part of the implementation and should be budgeted and demanded by policymakers and donors. Health facilities may require additional resources and technical support to improve data collection, analysis, and dissemination.

4.10 Conclusion

Previous studies have demonstrated that integrated testing is feasible and can improve health outcomes and patient experiences. The findings from this evaluation confirm that while there is

potential for integrating TB and HIV testing on the GX platform in Lesotho, several operational challenges persist. These challenges include limited staff capacity, underutilisation of existing resources, and difficulties with data connectivity. Addressing these barriers through targeted interventions—such as improved training, better resource allocation, and enhanced coordination between funding streams and disease programmes—could help maximise the potential of multi-disease testing platforms. Further research into the contexts in which integrated testing models work best will be crucial for developing effective strategies to expand testing coverage and optimise health system efficiency. This topic is explored in detail in Chapter 6 of the realist review.

4.11 Chapter 4 Summary

This chapter focused on a programme evaluation of TB and HIV testing in Lesotho at 13 healthcare facilities. Three of these were small PHC centres, and the other ten were secondary facilities, even though many people used four of these facilities in the rural areas as their first point of contact.

- The overall average utilisation rate was 90.7%, with three facilities exceeding their average capacity and 2 facilities having just over 50% utilisation rates for both TB and HIV testing on the platforms.
- The low average utilisation rate suggests there is potential to optimise testing through integration on the same platform.
- At the hub sites, the same-day testing is possible as the GX machine has a fast TAT for both diseases.
- Some key barriers to integrated TB and HIV testing identified include the lack of resources in terms of trained human resources to conduct both tests, workload issues, and the financing arrangements of different donors, which required different reporting requirements, as well as the structural setup of the TB and HIV programmes at the facility.

4.12 Personal Reflections

The programme evaluation in Lesotho played a key role in shaping some of my initial assumptions at the start of the DPhil journey, regarding the structural and implementation challenges of donor-funded programmes. It also reinforced my earlier thinking on the complex relationship between donors and recipients.

Before conducting the evaluation, while still in Geneva, discussions with the MoH and existing reports led us to believe that TB and HIV testing were fully integrated on the same GX platform. However, this was not the case. The MoH interpreted “integration” to mean that both tests used similar platforms rather than simultaneous testing.

I presented the evaluation findings to MoH representatives in Lesotho, who acknowledged the challenges of implementing same-day integrated HIV and TB testing and the practical constraints on the ground. I also shared the results with colleagues at FIND in Geneva, helping them better understand these implementation hurdles. As a result, they incorporated some of the recommendations into their access strategy. They are yet to be implemented at the time of the study.

Beyond the publication mentioned earlier in this chapter, the findings were also presented as a poster at the 23rd International Conference on Integrated Care (ICIC23) (see Appendix 4). A key outcome of this presentation—and the networking opportunities it created—was a meeting with Prof. Yeuk Fan from Singapore. He pioneered the *Health System Transformation Playbook*, a methodology designed to transition health systems toward people-centred, integrated, and value-driven systems[173] . He successfully applied this approach to transform several health facilities at Yishun Health into integrated healthcare centres. His perspective influenced the design and approach of the qualitative case study in Chapter 8, which explored the views and experiences of end-users of integrated diagnosis in Zimbabwe. It reinforced the idea that health system

improvements—such as enhancing diagnostic capacity—require synergistic, well-coordinated innovations. This insight was particularly important given the challenges observed in facilities where GX platforms were introduced without sufficient consideration of the broader system interactions necessary for effective health system improvement.

Prof. Yeuk Fan, along with several European experts with experience in LMICs, contributed as experts to the Delphi study in Chapter 7.

Chapter 5

The Primary health care approach and integrated diagnosis: A review of national health policies in Southern Africa

5. The primary health care approach and integrated diagnosis: - A review of National Health Policies in Southern Africa

Publication Statement

Results of this chapter are published in the following peer reviewed journal:

Gwaza GP, McCall M, T, Plüddemann A, Heneghan C, 2023, The Primary Health Care Approach: Rhetoric or Policy? - A Review of National Health Policies in 8 Countries in Southern Africa, Global Journal of Health Sciences, Vol 15, No. 12, URL: https://doi.org/10.5539/gjhs.v15n12p1

5.1 Chapter Aim and Objectives

This chapter examines the policy framework supporting PHC, integrated healthcare, and integrated diagnosis, focusing on how these components are reflected in National Health Policies (NHPs) across the Southern African Development Community (SADC) countries. The initial research for this chapter was conducted in 2022 with an update in February 2025 to ensure the data remains relevant and to account for changes in policies. Eswatini showed the most significant updates, as its 2016 policy addressed many of the gaps identified in the 2007 version. The specific updates are highlighted in the relevant sections.

One key barrier to implementing integrated diagnosis, as identified in Chapter 3, is the absence of multi-disease policies and clear policy guidance. Globally, access to diagnostics remains limited, particularly in LMICs, further exacerbated by the lack of diagnostics in NHPs and health strategies. [6]. As discussed in Chapter 4, Lesotho's enabling policies and guidelines on integrated TB and HIV testing have facilitated implementation, linkages, and referrals across the two disease programmes.

The PHC approach is fundamental to advancing integrated healthcare by providing a comprehensive range of prevention, diagnosis, treatment, and support services, thereby contributing to universal health coverage (UHC). However, the implementation of PHC in Africa remains suboptimal.[12]

National governments are responsible for developing and implementing health policies, and assessing the integration of PHC into NHPs serves as a measure of political commitment. These policies guide implementation and act as reference documents for organisations working with governments to deliver health services.

Regular updates to NHPs are essential to reflect emerging evidence and best practices. Despite the recognized importance of integrated healthcare in achieving UHC, its absence from many NHPs highlights a significant gap in policy alignment. This chapter explores these gaps and examines how policy frameworks can either support or hinder the implementation of integrated diagnosis in the SADC region. There is also an abundance of guidance manuals and scholarly output on developing policy and evaluating its implementation.[174-178] However, once a policy has been developed, minimal guidance is available on how to assess the processes and content issues that are likely to lead to its success.[179] Evaluation of a policy document from both a process and content perspective can determine its value, worth, feasibility, and likelihood of success.[179] This paper contributes to knowledge by providing an adapted checklist for evaluating the content of health policies in accordance with the PHC approach.

5.2 Background

The terms “primary care” and “primary healthcare” are often used interchangeably, but they originate from different concepts and carry distinct connotations. The term “primary care” emerged in the United Kingdom in 1920, initially referring to the regionalisation of health services. Over time, it evolved to denote first-point medical care.[180]

In contrast, primary healthcare was shaped by global developments in the late 1960s. Doubts about the effectiveness of vertical programmes emerged, particularly following the failure of malaria eradication efforts led by United States agencies and the WHO in the late 1950s.[8] At the same time, new research on community health revealed that despite medical advances, persistent health challenges remain. These studies highlighted the connection between population health, standards of living, and nutrition.[8]

The political landscape was also shifting. The Cold War was shaping global policies, and many African countries were gaining independence. In 1974, the United Nations passed a resolution calling for a "new international economic order" to improve social conditions in underdeveloped countries. In response, the WHO and United Nations Children's Emergency Fund (UNICEF) convened the first international conference on PHC in 1978, in Alma Ata, where the PHC approach was formally adopted as a key strategy for attaining "Health for All"[8]. PHC was further endorsed at the 1981 World Health Conference, prompting many African countries to develop or update their NHPs and national development plans to align with this approach.[181,182]

Thirty years later, in 2008, the International Conference on Primary Health Care and Health Systems in Africa was held in Ouagadougou, Burkina Faso.[10] The meeting reaffirmed the principles of the Alma-Ata Declaration and emphasized the urgent need for African governments to strengthen health systems and revitalise PHC as the primary strategy for improving health outcomes. In response, many countries updated their NHPs and developed PHC revitalisation plans.[183]

A decade later, in 2018, the second international PHC conference, was held in Astana to review progress and redefine the PHC for modern health challenges.[1] PHC was redefined as a "*whole-of-society approach to health that aims equitably to maximise the level and distribution of health and wellbeing by focusing on people's needs and preferences (both as individuals and communities) as early as possible along the continuum from health promotion and disease*

prevention to treatment, rehabilitation and palliative care, and as close as feasible to people's everyday environment."[1]

The conference identified three core elements of PHC:

(1) meeting people's health needs,

(2) systematically addressing the broader determinants of health, and

(3) empowering individuals, families, and communities to take charge of their health.

Furthermore, PHC was characterised as being accessible, equitable, safe, high quality, comprehensive, efficient, acceptable, available, and affordable. It was designed to deliver continuous, integrated, people-centred, and gender-sensitive healthcare services.[17]

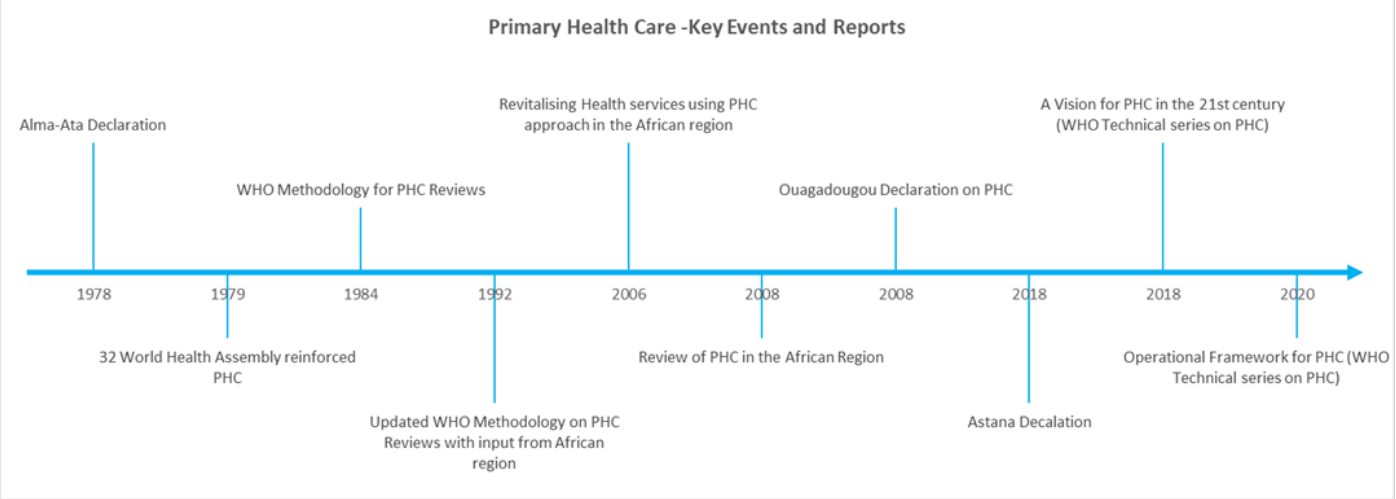


Figure 4: A Timeline of key events in the PHC movement

The PHC approach serves both as a philosophy and a framework for health service delivery.[110,184] It is widely regarded as the most inclusive, effective, and efficient strategy for improving health outcomes and strengthening health systems, particularly in developing countries.[1] In addition, PHC forms the foundation for achieving UHC by promoting country-focused, integrated, people-centred health services.[17] Governments have committed to integrating the PHC vision into their

national health strategies. In 2023, the Lusaka agenda also called for global health initiatives to strengthen PHC by effectively strengthening health systems in LMICs aligned with one national plan.[185]

However, despite decades of commitment, many African countries continue to face challenges in fully implementing PHC models due to economic, human resource, and institutional constraints.[12,182] Some countries, such as Malawi, have shifted their focus to the Essential Health Package (EHP) after recognizing that PHC as a strategy for achieving health for all was unclear, unfocused, and too general to be attained.[186] Over time, most initial NHPs have been revised to address these challenges. However, all current policies pre-date the Astana Conference in 2018 and may not incorporate the new understanding of PHC.

There is also an abundance of guidance manuals and scholarly literature on policy development and implementation evaluation.[174-178] However, once a policy is developed, limited guidance exists on assessing the processes and content factors that influence its success.[179] Evaluating a policy document from both a process and content perspective is essential in determining its value, feasibility, and likelihood of success.[179]

5.3 Methods

5.3.1 Study design

A document analysis was performed using the READ approach[187] (**R**eady your materials, **E**xtract data, **A**nalyse data and **D**istill your findings). Document analysis is a systematic procedure for reviewing or evaluating documents, which can be used to provide context, generate questions, supplement other types of research data, track change over time, and corroborate other sources.[188] It is a common approach in health policy analysis, media studies, cultural studies, and literary theory, all disciplines that recognize documents as social facts that are created,

consumed, shared, and utilised in socially organised ways. It can be used as a standalone method or in combination with other methods such as interviews.[187]

The following steps were taken in line with the READ approach.

Table 9: Steps taken in the READ Approach to Document Analysis

Steps	Description
Step 1: Ready your material	This included setting the parameters for the documents to be included in the analysis. The inclusion and exclusion criteria listed below show these boundaries and definition of the NHPs.
Step 2: Extract your data	An Excel spreadsheet was used to extract data, as detailed in the data analysis section below. Each row was a policy document, and each column was a category of information based on the checklist developed for the study. Basic data such as the document title, date published, and contributors acknowledged were also extracted.
Step 3: Analyse data	The data extraction tool used thematic analysis along the pre-identified themes or areas of interest. Ratings were applied as described in the data analysis section. Patterns forming were also interrogated.
Step 4: Distill your findings	The analysis results were distilled into buckets, and conclusions were made, which were included in the study report.

In addition, a word frequency analysis was conducted as part of the document analysis to assess the emphasis on specific terms, such as "integrated" and "diagnosis."

Data were extracted using a checklist adapted from the WHO checklist for evaluating mental health policies.[179] This was used as a tool that could be applied to assessing the content of policy documents. While originally designed to assess the content and processes of mental health policies, this approach can be broadly applied to other health policies and plans.[179] Although achieving a completely objective policy assessment is challenging, a systematic evaluation can identify areas for improvement or necessitate significant changes, potentially leading to substantial resource savings.

The WHO mental health policy checklist is divided into two sections - Process and Content Issues – comprising 28 questions rated on a four-point scale (1=yes/to a great degree, 2=to some degree, 3=no/not at all, 4=unknown). For this study, seven questions, covering 12 items, were included in the extraction tool, as they were deemed directly relevant to PHC and could be reworded to align with PHC elements described in the definition above. Process-related questions were excluded since this review focused solely on policy content. The rating scale used in the analysis retained three points from the WHO scale, excluding the fourth category (4 = Unknown). Any element not mentioned in the policy was rated as 3 (Not mentioned).

5.3.2 Inclusion and exclusion criteria

This review included countries within the SADC that have a publicly available NHP. SADC is a regional economic community with a shared vision for its future.[189] For practical reasons, only policies written in English were included.

The study adopted the WHO definition of health policy, which describes it as a formal, overarching statement of intent outlining a country's vision, goals, and broad policy directions and priorities.[190] In contrast, strategic health plans and other frameworks typically focus on the measures and instruments for implementing or operationalizing the policy. Therefore, only NHPs were included

in this review. Disease-specific policies, such as those addressing HIV, and health strategies were excluded to ensure comparability across similar policy documents.

5.3.3 Document Search and Selection

The published NHPs of the included SADC countries were identified through an internet-based search. The initial search was conducted using Google to locate the official websites of each country's Ministry of Health. If an NHP was not available on the official government site, the WHO Country Planning Cycle database[190] (2022) was used to retrieve the document. Only policy documents that met the WHO definition of a health policy and were explicitly labeled as an NHP were included. Consequently, national health strategies from South Africa and Zimbabwe were excluded.

Additionally, a search for relevant publications on policy analysis and the PHC approach in Africa was conducted using the WHO Regional Office for Africa website (2022) and Google Scholar. Articles were screened based on their titles to identify those focusing on NHPs in SADC countries, rather than disease- or age-specific policies. The selected articles were stored and managed using EndNote referencing software.

5.3.4 Data analysis

As part of the READ approach to document analysis, relevant data were extracted from the checklist into an Excel document, as described in the study design, and then summarised. The WHO checklist rating scale was applied as follows:

- **1 = Yes / To a great degree** – Assigned when a concept or issue was both mentioned and clearly described.

- **2 = To some degree** – Assigned when a concept or issue was mentioned but lacked further explanation.
- **3 = No / Not at all** – Assigned when a concept or issue was either not mentioned or was too vague to be clearly interpreted.

A comparison was conducted across the countries for each question, and findings were summarized with explanatory comments to justify the ratings. Additionally, a word frequency analysis was performed to assess how often certain terms and phrases appeared. The words and phrases analysed were aligned with key elements of PHC as outlined in the Astana Declaration, including "integrated," "community," "multisectoral," "intersectoral," "people-centred care," "gender," and "community health workers."

Table 10: Checklist for evaluating an NHP for alignment with the PHC approach

	Question
1.	Is primary health care mentioned as a general approach to care
2.	Do the values, principles and objectives in the policy promote key PHC elements such as: a. Integrated care
	b. Community participation
	c. Multisectoral collaboration
	d. People-centred care
	e. Comprehensive care
3.	Is Universal Health Coverage mentioned addressing? a. Access
	b. Affordability
4.	Is an Essential Health Package (EHP) clearly described?
5.	Does the policy establish a coordinating body to oversee major decisions in PHC?
6.	Does the policy address an integrated national health information system from the primary level?
7.	Does the policy address advocacy for community health workers and other staff at the primary level?

Ethical Considerations: All data was based on publicly available and published government policies or peer-reviewed papers

5.4 Results

The SADC region consists of sixteen countries: Angola, Botswana, Comoros, Democratic Republic of Congo (DRC), Eswatini (formerly Swaziland), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Tanzania, Zambia, and Zimbabwe.[189]

During the search conducted in 2022, five countries - Angola, Comoros, DRC, Madagascar, and Mozambique, were excluded because their policies were not available in English. No NHPs could be located for Zimbabwe, South Africa and Mauritius; only their national health sector strategies were available, leading to their exclusion. Ultimately, eight NHPs, available as PDFs, were selected from Botswana, Eswatini, Lesotho, Malawi, Namibia, Seychelles, Tanzania, and Zambia. Notably, Eswatini was referred to as Swaziland in its NHP, but since the country officially changed its name in 2018, this chapter refers to it as Eswatini. A follow-up search conducted in February 2025 resulted in updates based on newly available national health policies. Eswatini and Lesotho had updated policies.

The WHA in 1977 and 1981, along with the Alma Ata declaration in 1978, played a key role in stimulating health policy formulation across Africa.[181] Among the NHPs reviewed, six were second revised versions following these global events: Botswana, Eswatini, Lesotho, Namibia, Tanzania, and Zambia. With the exception of Namibia, Seychelles, and Eswatini, five of the selected countries had separate, standalone policies and strategies specifically dedicated to PHC. Tanzania had a more recent NHP revised in 2007, but as it was only available in Swahili, the English version from 2003 was used for this analysis. It was unclear from the literature search whether Seychelles' NHP was its first policy or if an earlier version had existed.

Table 11: List of countries and NHPs reviewed

Country	**First NHP published**	**NHP reviewed**	**Link to the source (accessed 28 April 2022)**	Link to sources (accessed 18 February 2025)
Botswana	1995	National Health Policy 2011 (revised)	https://p4h.world/en/documents/national-health-policy-towards-a-healthier-botswana/	
Eswatini	1983	National Health Policy 2007 The National Health Sector Policy, Version 3, 2016 – 2026	https://extranet.who.int/countryplanningcycles/sites/default/files/planning_cycle_repository/swaziland/ministry_of_health_-_national_policy.pdf	https://p4h.world/app/uploads/2024/06/National-Health-sector-Policy-Final.x23411.pdf
Lesotho	2004	National Health Policy 2011 Final draft National Health Policy (NHP 2017)	https://extranet.who.int/countryplanningcycles/sites/default/files/planning_cycle_repository/lesotho/health_sector_policy_2011-22_2_3.pdf	https://extranet.who.int/countryplanningcycles/sites/default/files/public_file_rep/LSO_Lesotho_National-Health-Policy_2017.pdf
Malawi	2017	National Health Policy 2018- 2030	https://p4h.world/app/uploads/2024/04/National-Health-Policy_2020.x23411.pdf	
Namibia	1998	National Health Policy Framework 2010-2020	https://extranet.who.int/countryplanningcycles/sites/default/files/planning_cycle_repository/namibia/namibia_policy_framework_2010-2020.pdf	
Seychelles	Undetermined	National Health Policy 2016	National-Health-Policy-2015.pdf	
Tanzania	1990	National Health Policy 2003 (also 2007 in Swahili)	Microsoft Word - nhp_finaldraft_24.10.03.doc	
Zambia	1991	National Health Policy 2011	https://extranet.who.int/countryplanningcycles/sites/default/files/planning_cycle_repository/zambia/nhp_prepared_23_january_2012.pdf	

The results are presented in two sections. First, the situation assessment outlines the economic and socio-political context of the countries as described in their NHPs. Second, the key elements of the PHC approach, as defined in the Astana Declaration[1], are presented.

5.4.1 Overview of the countries

Optimal PHC implementation requires a conducive economic and socio-political environment, which is lacking in much of Africa, affecting its execution.[12] Of the countries under review, three are low-income, four are middle-income, and one is high-income. These countries have relatively small populations, with Seychelles, Botswana, Lesotho, Eswatini, and Namibia having populations of fewer than three million people.[191] Tanzania has the largest population, with an estimated 59 million people, while Malawi and Zambia have populations of 19 and 18 million, respectively. All eight countries have relatively young populations, with 50% (4/8) having more than 40% of their populations under the age of 15. Malawi has the highest dependency rate, with 64% of its population under 15 years old, while Seychelles has the lowest, with only 22% under 15 years old.[191]

These eight countries share a colonial history, which influenced their adoption of the PHC approach, even before it was formally established in 1978.[12,192,193] Colonial health systems were often fragmented, discriminatory, and urban-focused, primarily delivering services.[192] After gaining independence, governments were committed to ensuring universal access, equity, and social justice—key principles of PHC.[194] For example, Botswana, which gained independence in 1966, incorporated community participation, intersectoral collaboration, and preventive health care as central to its health care system during the late 1960s and early 1970s.[195] Similarly, Tanzania's 1967 Arusha declaration aimed to make basic health services more accessible to the population.[196] Countries that gained independence later, such as Namibia in 1990—more than a

decade after the Alma Ata Declaration—adopted the PHC approach in the same year.[12] This was Malawi's first national health policy.

5.4.2 Primary Health Care Approach

There are two perspectives on PHC. The first defines PHC as *primary care*, referring to the first level of health service delivery. This definition is clearly outlined in all eight NHPs. The second perspective, which is the focus of this analysis, views PHC as a philosophy and strategy for health service delivery. This approach emphasizes community involvement, participation, and empowerment in health development while addressing the interrelationships among health determinants.[182] Table 12 shows how each country defines and describes PHC within the NHP.

PHC is generally understood as essential healthcare delivered as close to the community as possible, integrating prevention, treatment, rehabilitation, and care. However, explicit recognition of PHC as a comprehensive approach or strategy to health service delivery is mentioned in only six NHPs:

- Tanzania explicitly states that PHC is the cornerstone of its healthcare system.
- Namibia identifies PHC as a *policy goal*.
- Lesotho, Malawi, and Zambia include PHC as a key principle in their NHPs. The updated Lesotho NHP further integrates PHC into its mission statement.
- Eswatini initially did not reference PHC and was rated 3. However, in the updated NHP, PHC is now included as a key principle, along with plans to establish health posts to bring services closer to communities. This update improved its rating to 1.

Botswana and Seychelles do not mention the PHC approach in their current NHPs and remain rated 3. Botswana's NHP has undergone reforms since 1995, aligning with PHC principles in

earlier versions. However, there is no explanation in the current NHP for why PHC is no longer highlighted as a key strategy.

Table 12:: Definition of PHC used in the NHPs

Botswana	A main health care delivery model at the 2nd and 3rd levels of the five-tier system comprising individual/family, primary health clinics/centres, primary hospitals, district/secondary hospitals, and referral hospitals. Primary care is provided through a network of clinics, health posts and mobile stops, and community-based preventive and promotive services.
Eswatini	The first level of care provides health education, promotes food supply and proper nutrition, improves access to clean water and basic sanitation, promotes maternal and child health (including family planning, immunisation, prevention, and control of endemic diseases), improves treatment of common diseases and injuries, and provide essential drugs.
Lesotho	Basic health care services available nearest to the population at the community level. Basic primary healthcare services are safe, effective, well organised, patient-centred, culturally appropriate, tailored to the particular needs of each community and prioritised to support vulnerable populations (in updated NHP).
Malawi	Essential basic health care based on practical, scientifically sound, and socially acceptable methods and technology; universally accessible to all in the community through their full participation; at an affordable cost; and geared toward self-reliance and self-determination (adopted from WHO 1978).
Namibia	Care that embodies these key principles: people-centred care, health equity, solidarity and social inclusion, health authorities that can be relied on and communities where health is promoted and protected. Orientation of social services from curative and remedial social work to a developmental approach emphasising the prevention of social ills and empowerment of individuals, groups, and communities.

Seychelles	Care delivered through a network of community-based facilities offering a well-defined, cost-effective health intervention package centred on disease prevention, health promotion, multisectoral collaboration and each individual, family and community taking responsibility for its health. Essential health care model to achieve universal health coverage.
Tanzania	Essential health care that emphasises community involvement and ownership, multisectoral collaboration, equity and accessibility to health care, empowerment through decentralisation of health services and providing promotive, preventive, curative, and rehabilitative interventions.
Zambia	Essential health care based on practical, scientifically sound, and socially acceptable methods and technology made universally accessible to individuals, families, and communities at a cost that the community and the country can afford to maintain (adopted from WHO 1978)

5.4.3 Elements of PHC

The Astana declaration (2018) provides elements of the PHC to build a sustainable primary health care system. Below are the key elements of the PHC approach. These criteria are not provided in any hierarchy of importance.

a. Integrated healthcare

PHC aims to prevent the fragmentation of services by ensuring strong linkages and referral systems between primary and higher levels of care.[17] However, referral systems are not always well-defined or fully functional, which can limit their effectiveness in guiding patients to appropiate levels of care.[202,203] Strengthening referral systems across all levels is a critical policy action to ensure patients receive care at the right level without overburdening the health system.

NHPs address integrated care at varying levels and across different health conditions. Table 13 outlines how each country defines and describes integrated care within its NHP.

Countries rated 1 (criterion fully met)

Zambia, Lesotho, Namibia, Tanzania, and Eswatini explicitly mention integrated care and provide specific examples of integrated services.

- Zambia focuses on integrating reproductive health services, mental health, preventive chemotherapy for neglected tropical diseases, and mass immunisation.
- Lesotho takes a holistic approach, integrating acute nutrition management, hygiene, and healthy lifestyles at the primary level. It is also one of the few countries that explicitly emphasise early diagnosis and strengthening diagnostic systems, particularly for TB and HIV test-and-treat services.
- Namibia prioritises preventing mother-to-child transmission of HIV, maternal and neonatal health (PMTCT), and integrated management of newborn and childhood illnesses (IMNCI).
- Tanzania defines integrated care within its Essential Health Package (EHP) framework.
- While Eswatini's initial policy did not mention integrated healthcare, the updated policy includes provisions for integrated prevention and control of NCDs. Additionally, the updated policy highlights integrated diagnostic services as a policy direction.

Countries rated 2 (criterion partially met):

- Malawi, Seychelles, and Botswana mention integrated care but provide limited details.
- Malawi identifies integrated service delivery as a policy priority.
- Seychelles includes integrated healthcare as a policy objective but does not elaborate.
- Botswana references an Integrated National Health Services Plan without specifics and mentions integrating health services—such as substance abuse education—into the

school curriculum. Health promotion is a key focus of Botswana's NHP, with integration across several diseases, though details are lacking.

Table 13: Definition of Integrated Care based on the NHPs

Botswana	Attainment of universal coverage of a high-quality package of essential health services (EHSP) (as stated in the Integrated Health Services Plan (2010) referenced in the NHP
Eswatini	Services provided in a multi-disciplinary, multi-sectoral, and integrated approach
Lesotho	The health service provision which approaches health issues holistically such that treatment of diseases will be coupled with aspects of nutrition, hygiene, and promotion of healthy lifestyles
Malawi	Essential health services package
Namibia	Not clearly defined. Examples are provided of IMNCI, PMTCT integrated into maternal and newborn PHC services.
Seychelles	A strong health system capable of responding adequately to present and future health challenges. Through an optimal national primary health care, quality three-tier national referral system, collaboration with the private sector, and support of effective complementary health care services.
Tanzania	Essential health services package
Zambia	Service that is coordinated and streamlined to take advantage of similar functions, skills, resources, and targeted populations. This is particularly related to the Integrated Disease Surveillance and Response Strategy (IDSR) that Zambia adopted from WHO-AFRO to monitor, prevent, and control priority

	notifiable infectious diseases in the country. Other examples given are the Integrated Reproductive Health.

The EHP is mentioned in detail in three countries - Tanzania, Botswana, and Malawi - where it serves as the primary service delivery model. Eswatini, Lesotho, and Zambia were rated a 2, which means they met the criteria to some extent, as they briefly mention the EHP but do not provide details on its components. However, Eswatini's 2016 updated NHP included the EHP, improving its rating to 1. Namibia and Seychelles were rated 3, meaning they do not mention the EHP in their NHPs.

b. Community participation

Community involvement in health services empowers individuals, families, and communities to actively participate in optimising their health outcomes.[17] Health systems are structured with the community as the first level of service delivery, making community participation essential to leadership and governance—one of the key WHO Health systems pillars.[42]

All the NHPs reviewed mention community involvement and participation, earning a rating of 1, which means they fully met this criterion. Lesotho, Tanzania, Zambia, Malawi, Namibia, and Botswana emphasise community involvement as a guiding principle and core value, integrating it across various policy measures and initiatives. Malawi, under its Leadership and Governance section, identifies community empowerment as a policy priority. In Eswatini, strengthening community action and involving service beneficiaries is a guiding principles. The Seychelles NHP, highlights community participation as part of its healthcare organisation and service delivery structure. Tanzania references community involvement most frequently (n=7), including contributing to the PHC budget through in-kind labour or resource donations.[199]

Decentralisation—a major public reform policy in Africa—plays a key role in community involvement by shifting decision-making authority to lower levels of governance.[110] Malawi, Zambia and Eswatini have adopted a decentralisation policy, while Lesotho has developed a decentralisation plan. Namibia, Botswana, Tanzania, and Seychelles also reference decentralisation, albeit with less detail. In Seychelles and Namibia, power has been devolved to the regional level. In contrast, in Tanzania, Zambia, Botswana, Lesotho, and Malawi, decision-making authority extends to the district level, which oversees community-level healthcare. Lesotho's NHP provides the most comprehensive details on its decentralisation strategy, including the establishment of district health management teams to oversee PHC services. In Eswatini, power has been devolved to chiefdoms, urban government, and regional levels.

Lesotho and Malawi are the only countries that mention establishing a coordinating body to oversee major PHC and other health service decisions, one of the key checklist criteria. The remaining six countries do not reference any PHC coordinating body in their NHPs.

Advocacy for community healthcare workers (CHWs): Community participation in healthcare also extends to CHWs, who serve as frontline providers, particularly in rural and remote areas, performing various health-related tasks.[200]

Among the NHPs reviewed, only Lesotho explicitly advocates for community or village health workers, earning a rating of 1, indicating full compliance with this criterion. Tanzania's NHP briefly mentions community health workers but lacks details on advocacy, resulting in a rating of 2, meaning the criterion is only partially met. The remaining six NHPs do not mention community health workers at all and are rated 3, indicating they did not meet criteria.

c. Multisectoral collaboration

While the Ministry of Health (MoH) holds the legal mandate to formulate policies, regulations, standards and guidelines for health services, it is not the sole provider of health interventions.[201] Many other sectors—such as education, agriculture, housing, and water—play a crucial role in

shaping health outcomes, particularly in the context of PHC, which emphasises preventive measures. In Africa, healthcare delivery is highly pluralistic, relying on numerous international and national civil society organisations. Additionally, faith-based institutions, such as the church, are key healthcare stakeholders in countries like Lesotho, Malawi, and Zambia.

The PHC approach recognises the importance of multisectoral collaboration in achieving positive health outcomes and aligns with the *Health in All Policies* approach, introduced at the 1978 World Health Assembly. Among the core components of PHC, intersectoral collaboration is the only one explicitly acknowledged and integrated into all NHPs, particularly concerning prevention, health promotion, and addressing social determinants of health. As a result, all NHPs received a rating of 1, indicating they fully met this criterion.

Seychelles explicitly mentions the *Health in All Policies* approach. Malawi and Namibia emphasise an intersectoral approach through their health sector working groups. Botswana has established a national health council involving various ministries. In Zambia, multisectoral collaboration is a key objective, while in Tanzania, it serves as a core strategy for achieving NHP goals. In Lesotho and Eswatini, the participation of other sectors in health planning, funding, implementation, and M&E is a guiding principle.

d. People-centred care

People-centred care ensures that people have access to health services that are responsive to their life course needs and preferences, coordinated across the continuum of care, and meet standards of safety, effectiveness, timeliness, efficiency, and quality.[125] As a key component of the PHC approach, people-centred care intersects with and reinforces other strategic areas. It focuses on health interventions that address people's legitimate needs and expectations, reaching the underserved, marginalised, and vulnerable populations. Addressing equity concerns and ensuring gender sensitivity are key principles of the PHC approach.

NHPs in Botswana, Tanzania, and Zambia mentioned adopting a client or patient charter and were rated a 1, which means they fully met this criterion. These charters outline patient's rights and responsibilities to safe, timely, quality care, promoting accountability of the health facilities and health workers to the patients. Similarly, Seychelles, Lesotho, and Malawi were also rated 1, as their monitoring frameworks include client satisfaction indicators and outcomes. Notably, Lesotho's updated NHP prioritises patient-centric models, while Malawi identifies client care and satisfaction as one of the three primary health goals of its health system. Patient-centred care is also a core value in the Seychelles' NHP. Moreover, these six countries explicitly recognise gender sensitivity as a guiding principle. A word frequency analysis revealed that Malawi and Zambia reference gender most frequently, 19 and 14 times, respectively, both as a principle and as a cross-cutting element in various policy initiatives and strategies.

Namibia's NHP does not explicitly mention people-centred care but includes gender as a guiding principle. It was rated a 2, indicating partial fulfillment of the criterion. Eswatini's 2007 NHP initially did not reference people-centred care or gender and was rated a 3, meaning the criterion was not met. However, in the updated NHP, patient-centred care became a key principle, leading to a revised rating of 1.[197,198]

e. Comprehensive Care

Six NHPs provide detailed discussions on comprehensive healthcare and describe the range of health services offered. These countries—Namibia, Zambia, Lesotho, Botswana, Seychelles, and Eswatini—were rated 1, indicating full compliance with this criterion.

- Namibia addresses comprehensive care in the context of prevention and emergency obstetric care.
- Zambia includes mental health, medical rehabilitation services, and palliative care as part of its comprehensive care framework.

- Lesotho offers comprehensive services for victims and survivors of gender-based violence, as well as occupational health and hazard management.
- Botswana prioritizes defining a *Comprehensive Essential Health Package*, with a particular focus on health promotion and preventive care.
- Seychelles incorporates comprehensive care as both an objective and a guiding principle in its NHP.
- Eswatini's updated NHP includes comprehensive care as a key principle, improving its rating to 1 from 3.

Tanzania mentions that dispensaries provide comprehensive PHC services but does not elaborate on what these services include. It was rated a 2, partially meeting the criterion.

Malawi does not explicitly mention comprehensive care and was rated a 3, which means they did not fulfill the criteria.

Universal Health Coverage (UHC)

UHC focuses on ensuring access to and affordability of healthcare services.[204] PHC serves as a key strategy to achieving UHC. [205] As part of health system restructuring, many countries have aimed to provide healthcare facilities within a specified geographical reach, often organised into two-, three-, or four-tier systems.[12] While some countries, like Zambia, may not explicitly use the term *UHC*, they address its core principles.

Access to Health Services: All NHPs prioritize access to healthcare, integrating it as a key principle across various policy focus areas. As a result, all countries were rated 1, indicating full compliance with this criterion.

- Seychelles: 86% of the population can reach a health facility within 30 minutes, primarily by public transport or walking.
- Lesotho: 79.5% of people live within a two-hour walking distance of a fixed health facility.

- Malawi: A key policy outcome is increasing the proportion of the population with access to a 24-hour quality EHP facility within an 8 km radius.
- Zambia: Policy measures include ensuring health posts are established within a 5 km radius in sparsely populated areas.
- Botswana, Namibia, Eswatini, and Tanzania do not specify distances to healthcare facilities in their NHPs.

Affordability of Health Services: Affordability is also addressed in all NHPs, appearing in their missions, objectives, or guiding principles. All countries were rated 1 for meeting this criterion.

- Seychelles and Zambia provide free public healthcare, with Zambia having removed user fees.
- Botswana, Lesotho, and Malawi ensure that the Essential Health Package is either free or highly subsidised.
- Eswatini offers free public healthcare for specific vulnerable groups.
- Tanzania plans to establish a Community Health Fund to assist with user fees.
- Namibia will consider implementing universal health insurance if out-of-pocket expenses rise.

Integrated Health Information Systems

Integrated health information systems, including disease surveillance, are explicitly mentioned in the NHPs of Seychelles, Tanzania, Lesotho, Namibia, Botswana, and Eswatini. These countries were rated 1, indicating they fully met this criterion.

- Namibia emphasises integrating parallel resource programmes into the mainstream health information system.
- The other four countries (Seychelles, Tanzania, Lesotho, and Botswana) reference integrated health information systems more generally across all levels of healthcare.

- Eswatini initially did not reference integrated health information systems, but in its updated NHP, integrated data architecture is included as a policy direction, improving its rating to 1.

Zambia mentions an integrated financial management information system, which may include disease surveillance but lacks further details, so it was rated a 2 for partial compliance to criterion.

Malawi refers to aligning information management systems but does not specifically mention integration, and was rated a 3, meaning the criteria was not met.

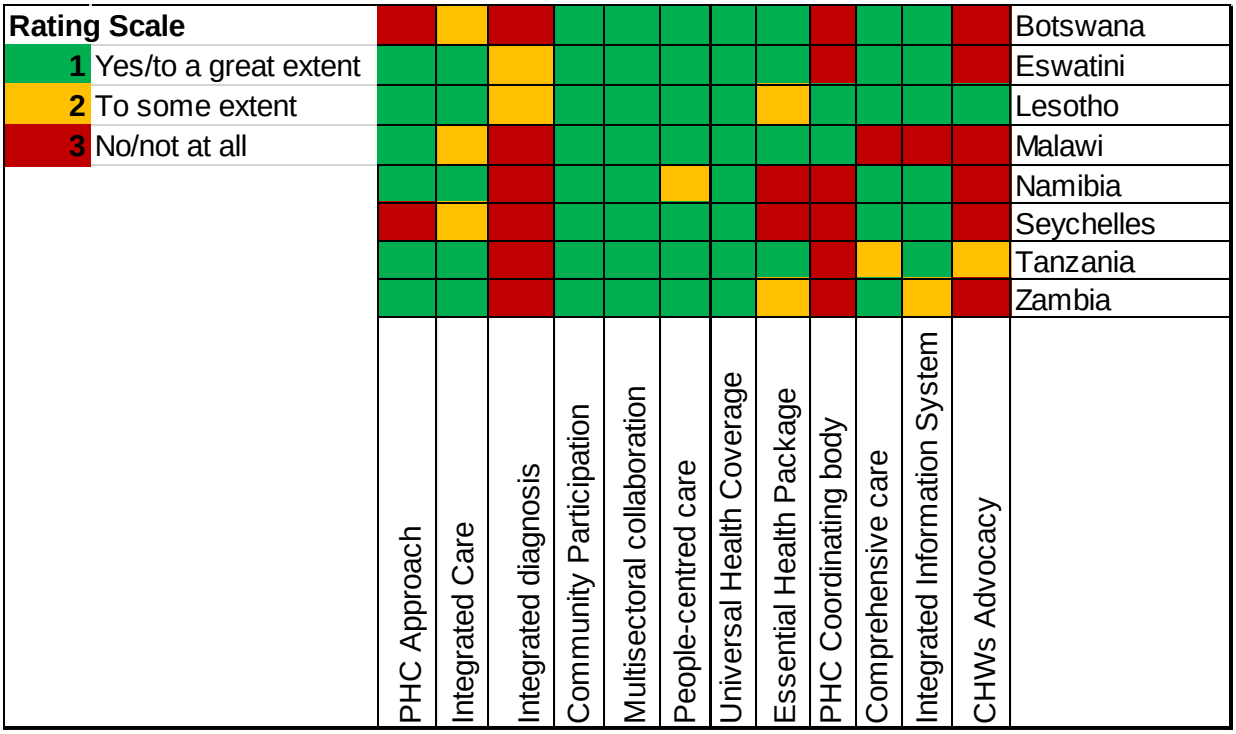


Figure 5: Results from the checklist on NHPs alignment with the PHC approach

All eight countries` NHPs reviewed have integrated at least 50% of the PHC elements on the 12-point checklist. Lesotho NHP included most elements of the PHC approach. Overall, the frequency of NHPs being rated 1 on the 12-point checklist were Lesotho (n=10), Eswatini (n=9),

Tanzania (n=8), Botswana (n=7), Malawi (n=7), Namibia (n=7), Zambia (n=7), and Seychelles (n=6). The NHPs fully addressed community participation, multisectoral collaboration, and UHC.

5.5 Discussion

There is considerable variation in how the PHC approach is defined and understood across different countries. One challenge noted during the Health for All 2000 strategy at the PHC conference in Africa was that each country was left to decide independently how to implement PHC, resulting in different interpretations and approaches.[10]

It appears there is general agreement that PHC should provide essential or basic services, whether at the first level (clinics or community care) or second level (hospitals). For example, in Botswana, primary hospitals offer essential services. Similarly, Malawi and Zambia have adopted the WHO's 1978 definition of PHC in their policies. Six countries explicitly mention the PHC approach as a cornerstone or underlying principle of their healthcare system. These include Tanzania, Malawi, Lesotho, Eswatini, and Zambia. However, Seychelles and Botswana do not refer to it in their policies.

This variation may correlate with a country's income level. The PHC approach is often seen as the most logical way to organise the healthcare system in low-income countries where issues of access and affordability are critical. On the other hand, high- and upper-middle-income countries, like Seychelles and Botswana, tend not to emphasise the PHC approach. However, Namibia, an upper-middle-income country, includes PHC as a policy goal.

Several contextual factors, such as economic conditions, political climate, population size, and health system structure, might also explain these discrepancies. While this paper does not explore these contextual factors in depth, it focuses on the self-reported content of the NHPs.

Integrated care is understood and described differently across the NHPs. In Botswana, Malawi, and Tanzania, integrated healthcare is commonly equated with the EHP, which is provided at

both primary and secondary care levels. The EHP is a prioritised, limited set of basic and cost-effective health services that are selected based on their potential impact on public health and the available resources.[206] However, just because these services are part of the EHP does not necessarily mean they are delivered in an integrated manner.

Priorities within the EHP vary across countries. For example, Botswana prioritises maternal health, Lesotho focuses on acute malnutrition, and Tanzania includes the IMCI guidelines. While some of these services may be integrated, they often exist as separate service bundles within the same facility, potentially leading to disjointed care. Donor priorities often influence these bundles of health services in low-income countries.[207] As a result, vertically integrated programmes can run in parallel, each targeting different components of PHC but with weak coordination. This parallel programme structure can lead to missed opportunities for comprehensive and quality PHC. The Lusaka agenda calls for donors to expand from programmatically focused funding to broader health systems and PHC-oriented funding.[185]

While the EHP supports the PHC approach, it risks perpetuating vertical projects and further fragmenting PHC programmes across Africa. For UHC to be achieved, it is crucial to integrate or coordinate these separate vertical programmes into a unified primary care model. Access to a broad range of services should be equitable, not just limited to a few privileged programmes.[208] Upper-middle-income countries, such as Seychelles, are now prepared to take on more financial responsibility for their health and focus on more comprehensive services.[139]

Although the EHP can be seen as a form of integrated care, the term "integrated care" itself is mentioned relatively infrequently in the NHPs—only in 5 out of the 8 countries. Yet, it remains a key component of the PHC approach and strategy for achieving UHC. A systematic review of integrated models in LMICs suggests that "adding on" services or creating linkages between services can improve healthcare utilisation and outcomes. However, there is limited evidence to show that a fully integrated system improves healthcare delivery or health outcomes in these settings.[45]

Data utilisation for decision-making remains limited, despite policymakers developing numerous health indicators to measure health outcomes.[139] The NHPs demonstrate that, regardless of income levels and population density, most countries have made significant progress in making primary health services geographically accessible to all.

Only Lesotho explicitly mentions advocacy for community health workers, who play a crucial role at the frontline of community health services, particularly in countries with large rural populations. Additionally, there is minimal mention of a coordinating body for PHC—only Lesotho and Malawi refer to this. A coordinating body could serve as a strong advocate for PHC services. However, it is possible that this role is not captured in national policy documents but addressed in more specific policy frameworks.

5.6 Limitations of the research

This review focused solely on NHPs in English, which could introduce bias, as contextual differences across countries may not be fully captured. A more comprehensive study that includes NHPs in other languages could provide a more holistic understanding. The unit of analysis in this study is the NHP, and there is a risk of over interpreting the results. Richer insights could have been gained by combining both secondary (document analysis) and primary (interviews) data sources. However, for this study, a pragmatic decision was made to rely exclusively on documentary evidence from national policy documents due to challenges in accessing the policymakers. Additionally, some aspects of primary care that may be missing in these policies could be addressed in other specific policy documents, which fall outside the scope of this research.

5.7 Implications for Policy

A key policy challenge is the limited recognition of diagnostics as a core component of health systems, leading to significant underfunding and resource shortages across all levels. Strong,

sustained advocacy is needed to highlight the importance of diagnostics and integrated diagnosis. Elevating their role in achieving UHC and ensuring greater visibility within the UHC agenda is crucial for securing the necessary policy attention and investment.

The implications for PHC are significant, particularly in how it is understood and integrated within NHPs. These policies guide national health priorities and influence decisions on health investments. Therefore, the moderate alignment between many NHPs and key PHC elements from the WHO Astana Declaration should raise concern for policymakers and international health organisations. NHPS need to be updated to reflect this revised understanding of PHC.

The variations in how PHC and integrated healthcare are defined affect their implementation and measurement of success, which can lead to a disconnect between policy and practice. This review contributes to the literature by comparing NHPs across Southern African countries and can help inform efforts to standardise and measure PHC in the region. Clear definitions and policies around integrated, people-centred healthcare are essential to avoid implementation gaps.

The PHC approach remains the most effective vehicle for achieving health goals in LMICs. Achieving meaningful health outcomes and positive patient experiences will require sustained and effective implementation of the PHC approach, with continued commitment, prioritisation, and integration into updated NHPs. There are still many policy questions regarding how to define and operationalise key PHC elements, such as integrated, patient-centred, and comprehensive care models. To strengthen PHC policy and practice, more funding is needed for both qualitative and quantitative research in this area to expand the evidence base.

5.8 Conclusion

In conclusion, the priorities outlined in NHPs must be understood in light of each country's unique context. Improving health outcomes in Africa will require strong political commitment and the implementation of evidence-informed healthcare approaches. The PHC approach remains the

most effective strategy for achieving health goals in LMICs. To achieve meaningful health outcomes and positive patient experiences, sustained and optimal implementation of the PHC approach is essential, along with continued commitment, prioritisation, and integration into updated NHPs.

However, significant policy questions remain regarding the definition and operationalisation of key PHC elements, such as the most effective healthcare delivery models for integrated, patient-centred, and comprehensive care. Increased funding for both qualitative and quantitative research on integrated patient-centred care within primary care in Africa is crucial to expanding the evidence base and guiding future policy and practice.

5.9 Chapter 5 Summary

- The PHC approach is widely understood and mentioned in NHPs both as a philosophy and main approach for delivering health services.
- Some key tenets of the PHC approach, such as people-centredness, community involvement, and multisectoral collaboration, are explicitly mentioned. However, community health workers are mentioned in only one NHP, even though they are a crucial part of the health workforce for delivering primary healthcare services.
- Only 5 of the 8 NHPs reviewed explicitly mention integrated health care as well as integrated health systems. Integrated diagnosis as a concept is not mentioned, and only two NHPs mention diagnosis in different capacities, Lesotho and Eswatini. Otherwise, the other NHPs are silent on diagnosis as a critical step.
- Six NHPs mentioned comprehensive care. The UHC is mentioned across all NHPs with access and affordability as key areas of concern.

5.10 Personal Reflections

Through my work with global health agencies, I have observed the significant emphasis placed on national health policies. Partners seeking investment are expected to demonstrate how their work aligns with these policies, which are intended to reflect a country's shared health priorities. However, in my experience working in Zimbabwe and other African countries, the perceived value of NHPs can vary among local actors. While these policies serve as important guiding frameworks, some stakeholders feel they do not fully capture the diverse priorities and realities on the ground. As a result, policy documents may sometimes be viewed as administrative requirements rather than actively used tools for shaping health systems.

Even when international NGOs are required to align their proposals with national policies, these documents are often developed by teams based in the Global North, relying primarily on written policies rather than extensive engagement with local stakeholders. This trend is also reflected in the eight NHPs reviewed here, with at least five acknowledging technical assistance from international partners for their development. Notably, Seychelles—a high-income country—does not include such acknowledgments in its NHP, highlighting a potential difference in how external support influences policy development across income levels. Many partner reports highlight technical support as a key focus—helping countries draft and refine their national health policies. While this support can be valuable, it raises important questions about the extent to which policies remain homegrown versus influenced by external priorities.

Given that global health funding often shapes national health priorities, there is an opportunity to explore more locally driven approaches to policy development. Strengthening mechanisms for inclusive, ground-up policymaking—while still leveraging technical expertise—could help ensure that policies more accurately reflect the needs and aspirations of the populations they are designed to serve.

Chapter Six

Integrated diagnosis in Africa's low- and middle-income countries: What is it, what works, and for whom? A Realist Synthesis

6. Integrated diagnosis at the primary care level in Africa's low- and middle-income countries: What is it, what works, and for whom? A Realist Synthesis

Publication Statement

Results of this chapter have been published in the International Journal of Integrated Care

Gwaza G, Plüddemann A, McCall M, Heneghan C. Integrated Diagnosis in Africa's Low- and Middle-Income Countries: What Is It, What Works, and for Whom? A Realist Synthesis. International Journal of Integrated Care, 2024; 24(3): 20, 1–14. DOI: https://doi.org/10.5334/ijic.7788

The findings of this review were presented in poster format at the African Society for Laboratory Medicine (ASLM) conference held in December 2023 in South Africa.

6.1 Chapter Aim and Objectives

The previous chapters have identified key barriers to implementing integrated diagnosis from a literature search, practical settings, and policy level. A fundamental issue is the lack of systematically assembled knowledge about prerequisites and effective approaches for integration. Without a clear understanding of the factors necessary for success (correlational) and the mechanisms that drive effective implementation (causal), progress toward integrated diagnosis may remain stalled.

Despite these challenges, integrated diagnosis has the potential to improve health outcomes and patient experiences by enabling early detection and identifying cases that might otherwise be overlooked. While existing studies demonstrate the feasibility of integrated diagnosis across various conditions, a critical research gap remains in establishing a link between integrated diagnosis at the primary care level and measurable improvements in patient experiences and

health outcomes. Understanding the necessary contexts and mechanisms for effective integrated diagnosis is essential for developing a robust theory of change.

This chapter employs a realist methodology to synthesise existing evidence on integrated diagnosis, refining and testing an evolving theoretical framework. The success of integrated diagnosis is not a one-size-fits-all approach—local contexts must inform decisions about its implementation, including the conditions and timing of integration, to ensure sustainable outcomes.

6.2 Background

Africa still has the highest disease burden for many communicable and non-communicable diseases (NCDs).[209] Failure to control communicable diseases is, in part, due to challenges in correctly diagnosing and treating cases, especially at primary care facilities. For instance, a significant number of new TB cases and people living with HIV remain undiagnosed, missing opportunities for early intervention and prevention.[6,33] Many adults are unaware of their NCD status [76]. As life expectancy improves for individuals with HIV due to treatment, there is an increasing risk of comorbidity with NCDs.[104] It is estimated that reducing the diagnostic gap for the six tracer conditions for general health system performance, i.e. HIV, TB, diabetes, hypertension, syphilis, and hepatitis B virus infection, could significantly reduce premature deaths and disability-adjusted life-years in LMICs.[6] As such, improved healthcare delivery models are needed to ensure that patients are not missed or lost to follow-up.

There is an increasing level of political recognition of the importance of an integrated approach to healthcare delivery.[35] The Organisation for Economic Cooperation and Development (OECD) sees integration as a quality indicator.[44] In 2016, WHO developed integrated healthcare guidelines, which encompass various healthcare processes, including integrated diagnosis.[210] In

2019, WHO recommended the development of integrated testing services and policies, and there have been policy guidelines for integrating conditions like TB, HIV, and NCDs, where integrated diagnosis can be beneficial.[4,122,211] However, a growing body of literature indicates that the policy focus on integration may not align with the complex realities of service delivery in LMICs.[212]

The primary objective of this review is to explore the specific contexts and mechanisms necessary for the successful implementation of integrated diagnosis interventions. In this context, success is defined by the achievement of intended outcomes, that is, improved patient experiences and health outcomes at the primary care level in LMICs.

6.3 Methods

6.3.1 Rationale for using the Realist method

Several reviews have assessed the effects of integrating health service delivery at the primary care level in LMICs. While these studies do not specifically focus on integrating diagnosis, they serve as a relevant proxy for understanding integrated diagnosis in healthcare delivery. A systematic review by Dudley et al.[45] concluded that integrating health service delivery results in improved service uptake. Still, there was limited evidence of the efficacy of integration in improving patient experiences and health outcomes.[45] Another review by Legido-Quigley et al. (2013) on TB and HIV integration identified various integration models with improved health outcomes.[213] However, the models were not compared across contexts, and there was little information on the effect of integration on patient experiences. In addition to missing patient experiences, these reviews do not explain how the interventions were delivered and received or the mechanisms of change, making it difficult to understand the complexity of programmes or replicate their success.

The realist approach can provide tools for synthesising complex, difficult-to-interpret evidence from interventions.[214] The realist approach applies realist philosophy or scientific realism.[215] Realist philosophy borrows and builds on both the positivist and constructivist paradigms. On the one hand, like positivism, realism believes we can objectively measure and observe the real world. However, like constructivism, we interpret our reality through a subjective lens, such as culture, and therefore, we can only measure it indirectly. Based on these two opposed approaches, realism is based on the principle that, though human agency is involved, individuals are likely, though not always certain, to make similar choices about which resources they will use in specific contexts or situations. In other words, particular contexts influence human choice in such a way that semi-predictable patterns of behaviour occur. The realist review seeks to uncover these patterns by critically scrutinising the interaction between context, mechanism, and outcomes. Mechanisms are underlying entities, processes, or social structures that operate in specific contexts to generate results of interest.[216] They describe how the 'human components' use the available resources. The realist review uses systematic, theory-driven interpretative techniques to help make sense of heterogeneous evidence about complex interventions applied in diverse contexts in a way that informs policy.[216,217] To that end, this review seeks to gain insights and explanations that would be transferable across different types of integrated diagnoses interventions.

Four critical steps were followed in line with realist review methods.[214,218] These included i) background and familiarization search, ii) developing a programme theory, iii) searching for empirical evidence to refine programme theory and iv) synthesis and report writing. While the steps are presented linearly, the process was iterative, with new programme theories surfacing and being tested, inclusion criteria and the review questions being reviewed. For example, during the initial scoping, very few primary studies explicitly focused on integrated diagnosis. To capture relevant insights, the inclusion criteria was broadened to encompass studies on integrated healthcare interventions that, while primarily addressing service delivery, also included references

to diagnostic activities such as testing or screening. This allowed for an analysis of the diagnostic component within broader healthcare integration efforts.

6.3.2 The Context–Mechanism–Outcome (CMO) Approach

The CMO framework provides the analytic building blocks for understanding the relationships or what works, for whom, in what circumstances and why. Context (C) refers to the conditions or circumstances in which an intervention is implemented. It includes social, cultural, institutional, economic, or policy environments, as well as local infrastructure, resources, and workforce. In LMIC diagnostic integration, for example, context could include limited laboratory infrastructure, fragmented health systems, donor-driven programs, or strong community health worker networks. Context does not simply “enable” or “block” interventions; it shapes whether mechanisms can be triggered.

Mechanism (M) are not just the resources provided by an intervention such as, training or new technology, but also the reasoning and responses they generate in people.[216] Mechanisms explain how and why a program works in a given context. For example, providing training (resource) may trigger confidence and competence in health workers (reasoning), leading to better diagnostic accuracy. However, if training occurs without supportive supervision, the mechanism of “confidence” may not be sustained.

Outcome (O) are the observed effects (intended or unintended) that result from mechanisms being triggered in a given context. They can be positive, negative, or neutral. For example, in the presence of strong supply chains and supervision, integrated use of RDTs may lead to improved diagnostic accuracy and timely treatment. In weak contexts, the same intervention may lead to stockouts and misdiagnosis.

The explanatory power of realist synthesis lies in linking contexts, mechanisms, and outcomes into configurations.

6.3.3 Scoping the Literature

A rapid literature review was conducted to develop the theoretical framework to guide the analysis, focusing on broad areas of integrated health care. The framework was used as a discussion guide with individual experts from global health organisations and academia to define a subset of themes relevant to integrated diagnosis interventions in LMICs.

Initially, three prominent themes surfaced: (1) the presence of a multi-disease policy framework, (2) targeted funding and, (3) monitoring and reporting tools as necessary contexts in designing interventions to ensure health workers are motivated and confident to conduct the diagnosis. The term healthcare worker (HCW) has been used in this study in its broadest term, defined by WHO as "people whose job it is to protect and improve the health of their communities."[24] This includes all cadre of health workers trained to deliver testing services, such as doctors, nurses, laboratory specialists and community health workers.

6.3.4 Searching Process

The literature search was iterative and ongoing throughout the review process. An initial investigation of various academic databases was conducted, including PubMed, Oxford SOLO database, Google Scholar, and the Cochrane database of systematic reviews. In addition, the websites of selected international global health organisations active in Africa with a focus on diagnostics were searched for evaluation or programme reports, including FIND, WHO, Elizabeth Glacier Foundation (EGPAF), Médecins Sans Frontières (MSF), Clinton Health Access Initiative (CHAI), Gates Foundation and Global Fund. Search terms included integrated diagnosis,

integrated health care, and integrated care, with MESH words and other variations of the term integration, such as collaboration and multi-disease testing. Additional searches on common types of integration, such as TB and HIV and HIV and NCDs, were also included.

Studies were included if they reported on the diagnosis or screening of two or more diseases or conditions, whether through point-of-care testing, syndromic diagnosis or other screening tools at the primary care level and within LMICs as defined by the World Bank economic rankings. [191]. As there are various entry points for patients, this could mean, for example, that a person already has an HIV diagnosis. Nevertheless, for the study to be included, they needed to receive a diagnosis or screening of an additional two or more conditions or diseases, such as hypertension and diabetes. The studies were in English due to cost considerations for translation. All study designs and publications, including grey literature, were included. All diseases and conditions relevant to primary care settings were included.

Studies were excluded if the studies did not have a screening, testing, or diagnosis element; focused on the integration of diagnosis for just one condition with health services for another condition such as treatment or prevention, for example, vaccination, counseling, diabetes screening with HIV treatment; the study was conducted at secondary levels of care such as regional hospitals or laboratory-based diagnosis in central or reference laboratories.

Integrated health care between specialist services in high-income countries or for ageing people with complex needs with highly sophisticated levels of care may have similar goals to integration in LMICs. However, the context is very different from that of poorer countries, and therefore, the findings of studies evaluating these programmes may not be applicable in poorer settings. This review consequently excluded studies conducted in high-income countries.[191]

6.3.5 Selection and appraisal of documents

A single reviewer selected the articles. To narrow the scope, an initial broad search on integrated health was conducted, filtered by geographical location for LMICs in the African region. An Excel-based identification tool was developed to appraise documents for inclusion. The tool consisted of four questions: the focus of the study, diseases integrated, diagnostic element, and outcomes of the study.

6.3.6 Data Extraction

Information was gathered on the intervention, the context, and the actual 'working of the intervention' or the mechanism to identify key elements of importance to the success or failure of integrated diagnosis interventions. In addition, information on other demographic data points was extracted, such as study type, sample size, health system level, diseases or conditions addressed, and country of study. The NVivo qualitative software (Version 12) was used to index the data as a context, mechanism, or outcome (C-M-O) and link relevant sections of the text of included articles to the emerging analytic framework. As each paper was read and reread, new codes were created and iteratively revised to capture themes or concepts that might contribute to theory testing.[217,218]

6.3.7 Analysis and Synthesis Process

A single researcher undertook data synthesis, and results were shared with methodological and subject experts to ensure the validity and consistency of inferences made. This process involved interrogating potential theories to explain the data reported in empirical studies, especially concerning any prominent patterns encountered. The sections of texts from the included studies, coded and captured within NVivo, formed the raw materials for the interpretations. These sections of texts were used to assess if they could confirm, refute, or refine the potential theories. The data

was synthesised in terms of the generative explanation for causation, that is, an outcome (O) of interest was generated by relevant mechanism(s) (M) being triggered in a particular context (C).[214,219]

Specifically, recurrent patterns were identified, which might act as barriers or enablers to integrated diagnosis and used to test the explanatory powers of the initial programme theories. Where programme theories failed to explain the data, new ones were sought. Data refuting the initial programme theory was deliberately sought throughout this process.

6.4 Results

6.4.1 Document flow diagram

The initial broad search on integrated health care identified 457,687 publications across four databases: PubMed, Oxford SOLO database, Google Scholar, and the Cochrane database of systematic reviews. 36,769 records remained after duplications were removed. Another targeted search of six global health organisations' websites resulted in an additional 22 articles. When filtered by LMICs in the African region and focused on integrated diagnosis or multi-disease testing, 395 articles were identified, which had full texts extracted and filtered by the inclusion and exclusion criteria. From these, 257 articles were excluded as they did not meet inclusion criteria and 110 articles were found to be of low relevance. An iterative reference search of citations in these articles and references from expert opinions added 12 new papers to the review. In total, 40 articles were used, 25 primary studies and 15 systematic reviews to support the emerging programme theories in the review. The PRISMA diagram (see Figure 7) illustrates the screening and selection process.

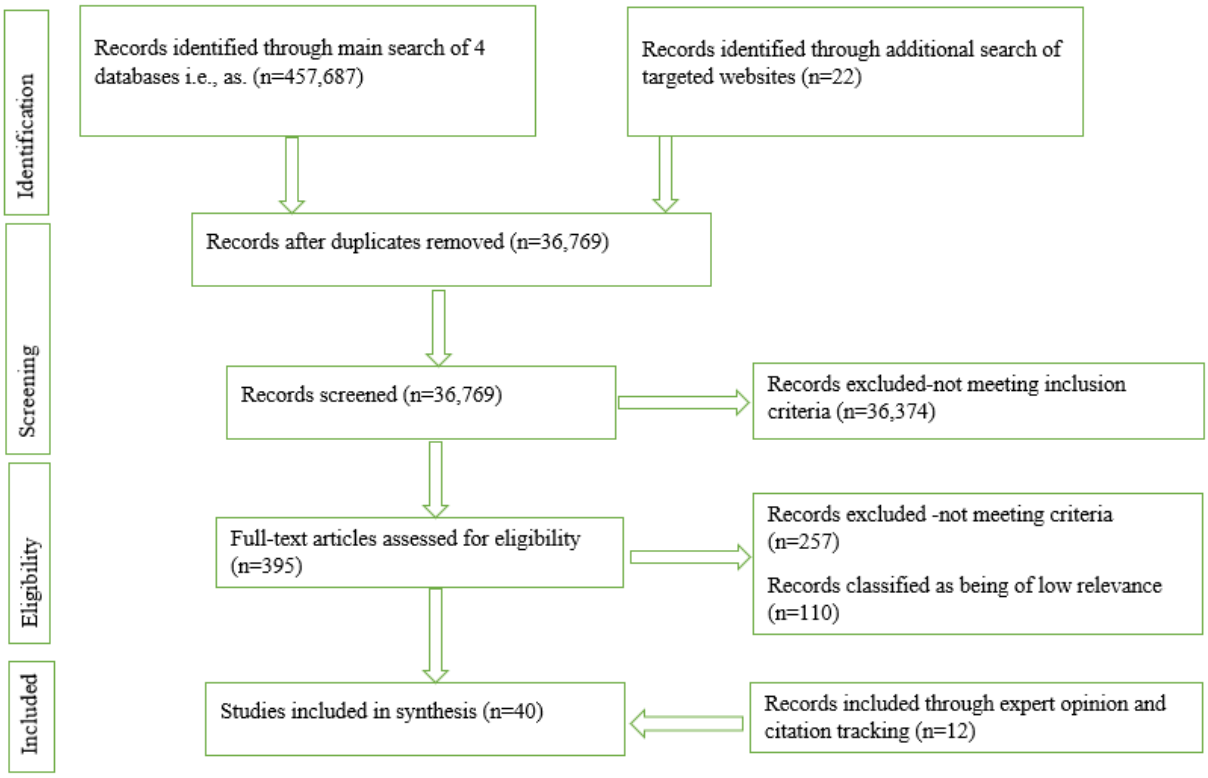


Figure 6: Prisma diagram

6.4.2 Document characteristics

Based on the search criteria described above, 25 primary studies published between 1984 and 2022 were analysed (See Appendix 5). Overall, seven studies were implementation research [74,75,80,98,99,220,221], five were qualitative studies [86,90,91,102,222], three were programme evaluations [72,87,223], two were observational studies [88,224] and two were retrospective studies, one cohort and the other longitudinal [82,95]. The remaining six studies had different study designs: a cross-sectional study [76], longitudinal [225], comparative case study [212], cluster randomized controlled trial [78], non-randomized controlled trial [77] and the design was not clear.[104] Overall, 19 of the 25 studies (76%) had HIV as one of the diseases integrated.

In addition, fifteen systematic reviews were included: two reviews on general health service integration;[18,45] two on patient experiences of integrated care;[226,227] one focusing on TB and HIV integration;[213] one on IMCI;[89] six on HIV and NCDs such as diabetes and hypertension;[35,43,51,94,228,229] one on HIV and SRH;[230] one on antenatal health services;[231] and one on NCDs and reproductive, maternal, newborn, and child health.[84] See Appendix 6 for the list of systematic reviews included.

6.4.5 Contexts and Mechanisms necessary for effective interventions

The review aimed to explore the contexts and mechanisms essential for the success of integrated diagnosis interventions. Integrated diagnosis is a complex healthcare process, and understanding its success factors requires a health systems approach. In addition, HCWs and patients have distinct perspectives and motivations regarding healthcare, so separate theories or C-M-O models were developed to reflect their roles and participation in the diagnostic process.

A. Health Care Workers (HCWs)

The WHO Health Systems building blocks served as an analytical framework to identify the various contexts required for successful implementation.[42] These building blocks include service delivery, health workforce, health information systems, access to essential medicines, health financing, and leadership and governance. Prioritising these elements allows healthcare systems to strive for equitable, affordable, and high-quality care for all. Figure 8 summarises the contextual factors from the studies that align with the six WHO building blocks for health systems.

1. Leadership and Governance

This building block focuses on the establishment of strategic policy frameworks, effective oversight, accountability, regulations, and incentives.[42]

Multi-disease policy: The presence of global or national multi-disease policies or guidelines is an important step to facilitate the successful design of integrated healthcare interventions.[78] Most LMICs rely on guidance from the WHO to inform their national policies and donor priorities. For example, the WHO guidelines on NCD integration influenced changes in NCD prioritisation within national policies and frameworks,[228] leading to increased funding for these interventions. In certain cases, integrated diagnosis interventions were introduced before formal policy formulation. For example, studies on cervical cancer integration proceeded without a national cancer strategy or policy in place.[74] The availability of funding resources and training played pivotal roles in motivating healthcare workers in such instances.

Diagnostic Algorithms and screening protocols: The operationalisation of multi-disease policies is crucial for effective implementation. For example, the successful integration of HIV and TB in many LMICs is attributed to the presence of WHO guidelines, national policies, operational plans, healthcare worker training, and donor funding to support these efforts.[213] When policies are not effectively operationalised, implementation can be suboptimal.

A lack of operationalisation can lead to inconsistent healthcare practices. For instance, in Botswana, prior to 2016, there were no national clinical guidelines for NCDs. As a result, adults seeking care for major NCDs like diabetes, hypertension, cardiovascular disease, chronic respiratory disease, and cancer received inconsistent management and referrals depending on HCW's training.[232] Even when there is a commitment to integrate services, such as HIV and SRH, in national health policies, significant service gaps and mismatches between claimed and

available services are reported due to a lack of standardisation.[230] In the absence of simple screening or diagnostic checklists or algorithms, healthcare workers may be reluctant to intervene or take action, fearing errors in diagnostic or treatment pathways and potential harm.[231]

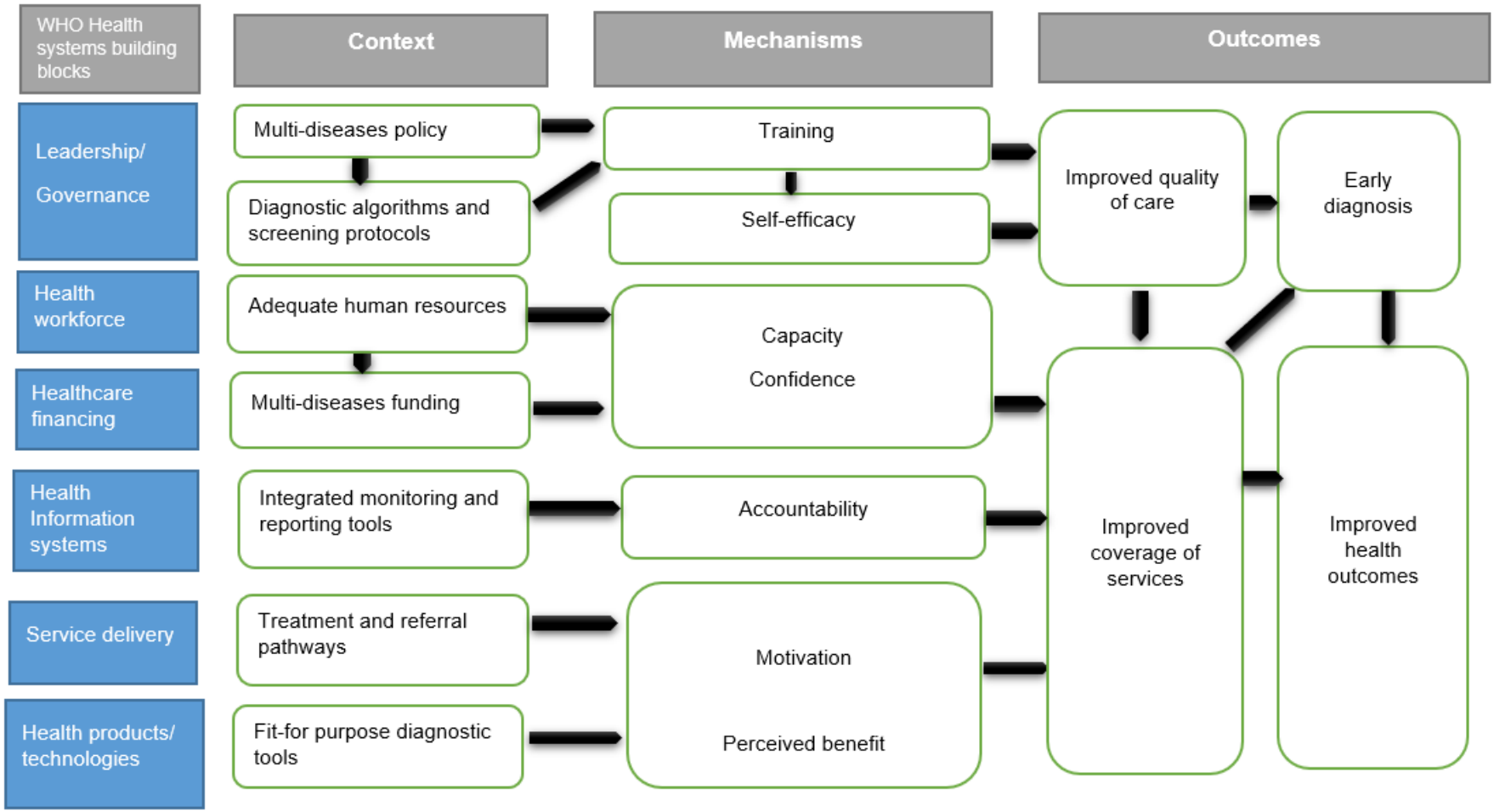


Figure 7: C-M-O for healthcare workers

Training: Training is a crucial mechanism to ensure the effective utilisation of policies, guidelines, and resources. Guidelines alone are insufficient if HCWs are not adequately trained. Training has been shown to positively influence the self-efficacy and engagement of HCWs, enhancing their ability to provide holistic care.[233] Examples from Mozambique and Kenya highlight how training can lead to increased job satisfaction, effectiveness, and motivation among HCWs working in integrated healthcare settings, especially when dealing with maternal and child health services and HIV-infected infants.[231] Evidence on in-service training and continuous professional development suggests that education is most effective when it is practice-based, spaced over time, and reinforced through repetition.[128] In Tanzania, training HCWs, particularly in IMCI, has been linked to improved quality of care, with children managed by trained HCWs receiving better assessments and more appropriate treatment.[89]

Training should focus on all aspects, including the technical diagnosis of diseases, interpersonal relationships, and patient-centred care. Technical diagnosis should be competency based ensuring that health workers, at different levels, not only understand how to perform tests for key diseases such as HIV, TB, malaria and other NCDs like cervical cancer, diabetes, but are also trained to recognize test limitations, such as senitivity, specificity, and contextual factors such as co-infctions or prevalence tates that affect predictive value.Interprofessional tensions can hinder the smooth continuum of care, especially when HCWs feel others are not fully contributing to integrated interventions.[212] Interprofessional collaboration and teamwork are crucial elements in facility-based integration, ensuring coordination among different HCWs, nonprofessional caregivers, and patients. [234]

In LMICs, the training requirements and level of accreditation needed vary substantially across diagnostic modalities, which has important implications for integrated diagnostic delivery. Laboratory-based tests generally require formal laboratory science training, ongoing quality

assurance, and in some settings, formal accreditation or licensing of technicians. Radiology and imaging demand higher levels of technical and interpretive expertise, though portable ultrasound has shown promise where task-shifting to midwives or clinical officers is supported by focused, competency-based training. Point-of-care diagnostics, by contrast, can be implemented with shorter training modules, often delivered to nurses, midwives, pharmacists, and community health workers, though maintaining quality control and refresher training is essential. Clinical assessment tools, such as IMCI/iCCM algorithms and digital decision-support, remain foundational at the primary care and community level; here, effective training and supportive supervision rather than formal accreditation are often the key determinants of diagnostic accuracy. As the Table 14 highlights, accreditation and supervision structures need to be tailored to the complexity of the test, the cadre performing it, and the health system's capacity to sustain quality and accountability.

While training is essential, it can be resource-intensive, particularly during programme start-up, and may require ongoing mentoring support. Furthermore, if the disease burden is low, HCWs might stop testing, leading to a loss of competencies that need regular practice. Additionally, removing HCWs from frontline services for training can strain already limited resources and may result in longer waiting times and reduced consultation time, potentially compromising service quality.[122,231]

Table 14: Categories of diagnostic tests/technologies, training requirements, and health worker cadres in LMICs

Category	Examples	Relevance / Challenges in LMICs	Training Requirements	Typical Cadres in LMICs
Point-of-care diagnostics (POC)	Rapid diagnostic tests (HIV, malaria, syphilis, COVID-19), glucometers, hemoglobinometers, multiplex assays	Highly feasible in community and primary care; support immediate treatment decisions; quality control is key.	Short structured training on correct use, biosafety, result interpretation, and record-keeping, on average one week training. Refresher training essential.	Community health workers, nurses, midwives, clinical officers, pharmacists.
Laboratory-based tests	Microscopy, GeneXpert/NAAT platforms, basic hematology/chemistry analyzers	Critical for TB, HIV, malaria, NCDs; constrained by infrastructure and turnaround times.	Competency-based laboratory training on sample collection, processing, QA/QC, and interpretation limits. Periodic re-accreditation required.	Laboratory technicians, biomedical scientists, sometimes nurses/clinical officers (for sample collection).
Radiology & Imaging	Chest X-ray, ultrasound, digital X-ray	Essential for TB, pneumonia, maternal health; barriers include equipment costs, power supply, and skilled staff.	Technical training on imaging acquisition, plus interpretation skills. For ultrasound, short focused courses can enable task-shifting.	Radiographers, radiologists, trained physicians; portable ultrasound often used by midwives, clinical officers, and general practitioners.
Clinical assessment tools	IMCI/iCCM algorithms, digital decision-support tools, structured physical exam skills, pulse oximetry	Foundational where lab/imaging is absent; critical for childhood illness and emergency triage.	Training in use of algorithms, recognition of danger signs, device handling (e.g., oximeters). Requires supportive supervision.	Community health workers, nurses, midwives, primary care doctors.

2. Health workforce

The availability of sufficient and responsive health workforce is crucial as it directly influences the quality and delivery of healthcare services.[42] It's imperative to assess the material and human resource capacity to ensure that the integration does not have a negative impact on the staff or patients.[83]

Adequate human resources: The fear of increased workload and pressure was a concern among many HCWs when it came to integrating routine HIV testing or TB screening into their existing responsibilities.[102,231] Taking on extra tasks without additional compensation can be challenging unless these additional services become part of routine standard care.

To address staff workloads in the Integra initiative in Kenya and Swaziland, deliberate human resources planning was carried out to prevent staff from becoming overwhelmed. Specific days were allocated for different population target groups. For instance, pregnant women were scheduled to be seen only on Wednesdays, and HIV patients with comorbid conditions like hypertension or diabetes visited the clinic during a designated weekly 'dual diagnosis day'.[94] However, it's worth noting that integrated sites didn't consistently yield better health outcomes; results were often mixed.[212]

In the case of the Epako clinic in Namibia, the previous practice of setting aside specific days for the ARV clinic led to participants feeling stigmatised, as it became widely known who was HIV positive.[224] This issue was resolved through integration, allowing all health services to be provided daily, thus reducing stigma.

3. Healthcare financing

Adequate health financing is a vital building block of the healthcare system, ensuring the availability and accessibility of services while offering financial protection to individuals, shielding them from financial hardship associated with the cost of healthcare services.[42] Multi-disease funding is crucial for the success of integrated diagnosis interventions, but it needs to be managed and coordinated effectively to prevent negative consequences. The lack of coordination and alignment of funding can hinder the implementation of integrated activities, as demonstrated in the example of TB and HIV testing in Lesotho, where different donors funded these programmes with varying reporting requirements.[235]

Multi-disease funding: Most LMICs rely on donor support to fund their health programmes. Donor funding often focuses on specific diseases or conditions that are considered priorities. This can create a situation where only targeted diseases receive funding and attention, such as the HIV programme, while other diseases may be neglected.[94,230] Lack of funding can be a significant barrier to integration, even when there is a recognised need for such, for example with mental health integration.[236]

When certain diseases receive more funding and incentives compared to others, it can create disincentives for HCWs. For example, in the case of HIV, nurses who receive incentives may become overloaded with work, as their colleagues may avoid responsibilities related to HIV care. This imbalance in incentives and workload can lead to inefficiencies and dissatisfaction among HCWs. Unbalanced funding can also affect the delivery and sustainability of health programmes. If incentives are withdrawn or reduced, HCWs may be less motivated to provide services.[96,233]

In some cases, patients are provided with incentives to encourage them to participate in health services, such as testing or screening for HIV and NCDs in chronic mobile clinics in South Africa.[95] This can be effective in promoting early diagnosis and care-seeking behaviour, especially for

conditions that may have stigmas or barriers to access. To address funding gaps, some health programmes charge user fees for additional diagnoses. However, this approach may limit the uptake of these services, especially among populations with limited financial resources.[212] Integrating services may also lead to increased out-of-pocket costs for services that are shifted to the patients, as seen when pulse oximeters are included to diagnose hypoxemia.[128]

4. Health InformationSystems

The health information system building block includes the production, analysis, dissemination, and use of reliable and timely health information.[42] To make informed decisions about developing and implementing interventions, it is essential to have access to high-quality and strong evidence.[237]

Integrated Monitoring and Reporting Tools: Standard templates, registers, forms, and booklets that encompass all targeted diseases are essential for facilitating successful integrated diagnosis interventions. These tools help ensure that HCWs remain accountable for their work and responsibilities. Using integrated reporting tools that encompass multiple diseases can serve as a mechanism to remind HCWs of their responsibilities, encouraging a holistic approach to healthcare. In the integration of HIV and SRH, the lack of integrated indicators for reporting resulted in separate monitoring and reporting systems. Weak monitoring and reporting tools for SRH services compounded this issue.[83,92]

Keeping reporting tools simple is crucial to ensure that HCWs are willing to invest the time required to complete them. Overly complex forms can overwhelm HCWs and negatively impact programme results.[94] Digital tools and innovations can reduce paperwork and streamline reporting processes, allowing healthcare workers to focus more on their actual tasks. Various provider job aids, such as screening tools and flipcharts, have been found effective in supporting integrated

diagnosis activities.[77]

5. Service delivery

Service delivery is a fundamental component of the healthcare system, characterised by the provision of effective, safe, and high-quality health interventions, which include the necessary infrastructure. Health services should be available to those in need when and where required, all while efficiently using available resources.[42] Successful service delivery relies on the effective collaboration of all pillars within the healthcare system. As the first step in the care cascade, diagnosis is only effective when it is seamlessly linked to treatment and follow-up care. Additionally, the experience and perception of patients in accessing these services play a crucial role in determining their overall success.

Treatment and Referral pathways

The success of integrated diagnosis interventions is not just about diagnosing conditions but also about considering the feasibility and complexity of treatment and care once a diagnosis is made. Having well-defined treatment pathways, disease management strategies and referral mechanisms plays a significant role in HCW perception and service uptake. It enhances HCW engagement and motivation and instils confidence and trust in patients that their healthcare needs will be met. The availability of treatment for specific conditions, such as HIV or other STIs, influenced testing uptake in Kenya.[77] In another case of NCD integration, treatment capacity was unavailable and could not be sustained, affecting the continuation of diagnosis.[43,79] However, HCW motivation declines when they are unable to act on a diagnosed condition—such as identifying hypoxemia or an NCD that requires treatment but lacking the necessary resources to provide care or ensure timely referral.[128]

Referral mechanisms can be problematic even when diagnosis and treatment services are functioning effectively. For example, a pilot project in Malawi integrating hypertension screening

into HIV activities showed that while screening was feasible, the linkage to care for hypertension management needed improvement.[238,239]

6. Medical Products/Technologies (includes diagnostic tools)

Health technology, equipment, and an effective supply chain are some of the elements that affect the availability and quality of service delivery.[42] Integrated technologies must be fit for purpose and compatible with the facilities where they are introduced. Healthcare worker motivation is driven by firsthand experience of the benefits—both in terms of increased efficiency that makes their jobs easier and improved patient outcomes. The adoption of diagnostic technologies is more successful when the focus is on simple, reliable, and trusted devices, which offer clear and immediate clinical value such as pulse oximeters for diagnosing hypoxemia.[128]

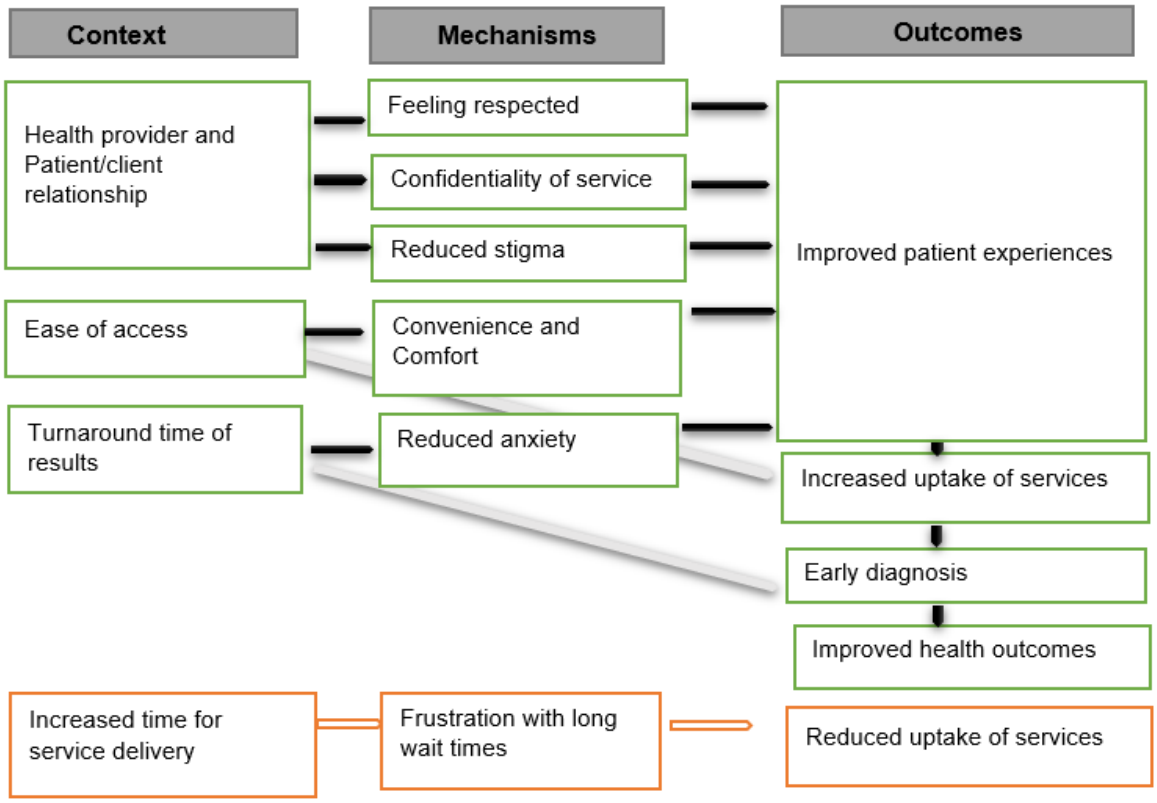
The unavailability of commodities and irregular supply of essential consumables and drugs were major barriers to the uptake of integrated HIV, syphilis, and malaria services in several countries.[231,237]

B. Clients and Patients accessing diagnostic services

Community awareness, demand, and acceptability of diagnostic services are essential for the success of integrated diagnosis interventions. Numerous frameworks for patient-centred approaches to health service delivery exist, with the "Caring About Me" framework being one notable example[103] that can help to understand the various factors that contribute to positive experiences within healthcare. However, this framework was developed in a high-income setting (Canada) and may require adaptation to reflect the realities of healthcare delivery in LMICs.

Patient perception of care as patient-centred is often rooted in the sense that healthcare providers actively collaborate with patients to address individual needs and help them self-manage their care.

Figure 8: C-M-O configurations for patients to ensure successful integrated diagnosis interventions



In LMICs, integrated diagnosis may not necessarily be about individualising care or self-management but it is about HCWs collaborating with patients to make them feel supported, heard, respected, and accepted. For example, SRH interventions emphasise creating a non-judgmental, respectful, and accepting environment, leading to positive experiences. Figure 9 illustrates the C-M-Os that can impact the success of integrated diagnosis interventions, with a focus on improving patient experiences.

Health provider and Patient/client relationship: A posiitve relationship between HCWs and clients or patients, built on respect and trust , is fundamental to how patients perceive the quality of their healthcare experience. When patients feel respected, they are more likely to report a positive experience. This underlines the importance of training HCWs to provide patient-centred care.[77]

Maintaining confidentiality can reduce the stigma associated with certain diseases, which is highly valued by clients/ patients. For instance, in some situations, a stigma is still attached to positive diagnoses for HIV or NCDs such as cancer.[94] To address this, the Epako case study in Namibia provided all services by the same nurse in the same room, ensuring that community members could not discern who was HIV positive, thereby preserving confidentiality.[212]

In Swaziland, the integra study found that inadequate privacy in healthcare facilities restricted discussions of personal matters and complete history-taking. This lack of privacy led to stress during HIV testing for some patients, who were worried about having HIV, which they perceived as a stigmatised disease. Being overheard during testing and the fear of being seen by other patients were significant concerns for many patients.[212] While provider-initiated diagnosis has been effective in increasing testing uptake[212], it does not always lead to improved patient experiences. One reason for this is the power imbalances, which can make patients reluctant to refuse suggested diagnoses. In some cases, patients fear negative consequences, such as jeopardising future medical care if they decline a suggested diagnosis. For instance, one study found that approximately 29% of patients believed it would be difficult to refuse HIV testing offered by TB nurses due to concerns about potential repercussions from HCWs.[102]

Ease of access to services: Physical space at the facility plays a vital role in the healthcare experience. This includes having private consultation rooms, comfortable waiting areas for extended waits, and straightforward access to the services.[212] Sometimes, physical separation of spaces may be necessary to prevent disease transmission and contamination. For instance, in Kenya, the perceived risk of HIV infection affected testing uptake, when HIV services were integrated with SRH services.[77]

Turnaround time of results: Faster test result delivery can significantly improve patient experiences by reducing waiting times, which can be challenging and anxiety-inducing for

patients.[240] Providing same-day results can enhance clients' confidence in the healthcare system. The integrated POC testing reduced turnaround times for HIV early infant diagnosis and viral load testing from days to hours.[99] Timely test results also help accelerate clinical decision-making, improve the quality of care and optimize health outcomes.[76,240]

Increased time for service delivery: Timely services provide convenience and can lead to better health outcomes, particularly for conditions that require timely treatment. However, integration efforts in healthcare can sometimes unintentionally increase the time spent at facilities, resulting in frustration and reduced uptake of services. Long waiting times can act as a significant barrier to integrated diagnosis interventions. For example, the integration of HIV services with primary healthcare in a Zambian clinic led to a notable increase in waiting times, from 91 to 127 minutes, due to issues related to staff and patient flow.[241] A time and motion study revealed that HCWs trained in IMCI spent almost two minutes longer per consultation on average compared to those in comparison facilities.[89] This extended time spent with HCWs, addressing multiple conditions, inadvertently made some patients feel guilty about delaying others, discouraging them from discussing other important health concerns.[212]

6.5 Discussion

6.5.1 Summary of Findings

Finding literature that focuses specifically on integrated diagnosis was difficult. The majority of the studies included focused on integrated testing of specific diseases or conditions such as TB and HIV testing, or HIV and NCD testing (diabetes or HPV) or HIV and syphliis testing, and hypoxemia testing. Integrated diagnosis was linked to technology integration and platfoms or combo RDTs. Examples of combo RDTs commercially available are HIV and syphilis dual RDTs

(*D Bioline HIV/Syphilis Duo*, *Chembio HIV-Syphilis STAT-PAK Assay),* malaria and HIV RDTs (SD Bioline Malaria Ag P.f / HIV 1/2), or malaria and dengue (SD Bioline Malaria Ag + Dengue Duo). This is a narrow definition of diagnosis, which is limited to the diagnostic technologies and not diagnosis as a process.

Integrated diagnosis interventions can improve service uptake, especially among underserved populations. Yet, the challenge lies in reconciling quality service delivery with limited healthcare staff and high patient volumes, necessitating strategic trade-offs. A persistent tension exists between enhancing the patient's experience, broadening service access, and achieving cost reductions.

The review showed that challenges in integrated diagnosis interventions are complex and variable, highlighting the need for context-specific approaches to address these issues effectively. CMOs can inform practice and guide decisions to improve the deliberate design of interventions. This realist review has identified two categories of explanatory theories relevant to HCWs and patients. Firstly, for HCWs to successfully implement integrated diagnosis interventions, they need to adopt a health systems perspective that allows for integration across different disease programmes. This includes multi-disease policies, funding, diagnostic algorithms, and integrated monitoring and reporting tools. Knowledge and training of HCWs are essential to make these systemic factors operational. Additionally, the health system's capacity needs to be developed, including having an adequate workforce and securing multi-disease funding. Diagnosis alone is insufficient to lead to improved health outcomes. Comprehensive care and treatment must be considered from the outset of the intervention's design. The availability of resources, including treatment options, builds the patient's confidence in the healthcare system. Unfortunately, these are typically available in secondary care settings in LMICs.

There is a tendency to target one aspect of the system for improvement while neglecting other critical factors. For example, introducing new diagnostic technology in a facility without considering the motivation and training of the HCW can result in well-equipped facilities with low

service uptake. Diagnosis, while just one component of the healthcare process, is part of a broader health ecosystem.

Integration is not a substitute for solving failed health systems.[3,81] It is also difficult to integrate services not operating at the same level of efficiency. Challenges in implementation can vary even within similar contexts, depending on the specific type of intervention. For instance, some HCWs may be overwhelmed by additional tasks in one facility, while this may be better managed in another facility within the same country,[223,224] which has a significant impact on the success of the intervention.[212] In addition, interventions in one part of the healthcare system may unintentionally affect other parts. For example, improved diagnostic capacity for certain diseases may deprioritise others due to an imbalance in resources and increased service utilisation.

It is also important to recognise the broader structural issues that can affect integrated diagnosis interventions. While donors and governments may express support for 'integration' at various levels, they often prioritise disease-specific partnerships and judge success based on disease-specific performance without acknowledging the potential contradiction in their approach.[242] Most research has focused on linking frontline services, many implementation challenges are related to gaps in higher-level health system functions. These challenges include the absence of appropriate regulation, unified multi-disease policies and operational frameworks, as well as the lack of coordination and alignment among donors, leading to separate financing streams for integrated services.

Patients' perspectives on integrated diagnosis are influenced by factors they value, such as convenience, confidentiality, reduced stigma, and respectful and trusting relationships with healthcare providers.

Secondly, it is important to consider clients/patients' perspectives and their desire for relationship-based care, confidentiality, ease of access, and timely services to improve their healthcare experiences. None of the things the patients value necessarily come from structural and functional integration. Patients often desire personalised and 'friendly' care to address their multiple health concerns. However, the pressure and rushed care focused on completing routine tasks can hinder their ability to articulate these needs.[212] Integration efforts can inadvertently lead to increased waiting times at healthcare facilities, which may deter patients from seeking services.

A challenge with building a robust evidence base on integrated diagnosis is that most of the interventions are small-scale, proof of concepts or feasibility studies that have not yet been scaled up. Integration models are relatively new and lack comprehensive clinical, process outcomes, and cost-effectiveness data. This immaturity hinders the ability to assess their long-term effects.[51] Moreover, most integration programmes tend to leverage the HIV programme, as a model of successful implementation, which can overshadow other healthcare programmes, making them appear less significant by comparisons.

Facility integration is more commonly and feasibly implemented in LMICs at the secondary care level, like district hospitals, whereas primary care facilities such as clinics and health posts encounter challenges related to HCW availability and physical space. Individual integration, though possible, is particularly challenging in resource-constrained primary care settings due to the intensive time and resource requirements, potentially leading to patient frustration and delayed service delivery. Decision-makers must carefully assess the trade-offs between the benefits of individual integration and the challenges in ensuring timely, high-quality patient care.

When promoting integrated diagnosis approaches, it’s crucial to address the risk of overdiagnosis.[243] Offering additional diagnostic tests can lead to identifying more conditions than necessary, potentially resulting in unnecessary treatments or interventions. There is also a concern about intentional over-diagnosis driven by financial incentives, especially in settings with

significant out-of-pocket costs. While integrated diagnosis improves accessibility and efficiency, it must be managed carefully to avoid excessive testing and maintain patient-centred care. For example, malaria is frequently over-diagnosed in clinical settings. For example, in Angola in 2017, only 90 (15.7%) of 573 patients clinically diagnosed with malaria were confirmed to have the disease—resulting in an error rate of 84.3%.[6] This over-diagnosis, coupled with the neglect of alternative diagnoses, contributes to unnecessary morbidity and mortality, underscoring the urgent need for accurate diagnostic tools and improved case management.

Strategies to mitigate these risks include establishing clear test guidelines, ensuring transparency in diagnostic processes, and implementing safeguards against unnecessary tests. These measures are vital for optimising healthcare delivery and ensuring equitable access to quality diagnostic services in LMICs.

6.5.2 Strengths, Limitations, and future research direction

While many reviews broadly examine integrated healthcare, a gap exists in the explicit coverage of integrated diagnosis or multi-disease testing. Studies on integrated diagnosis often lack detailed explanations or discussions on the intervention and the mechanisms driving outcomes. A realist approach becomes valuable in shedding light on how these interventions function and elucidating the necessary elements for enhancing patient experiences and health outcomes.

A single reviewer conducted the review, selecting and appraising articles, posing a potential risk of omitting crucial studies. To mitigate this limitation, feedback and discussions with experts were employed.Future research in this area should focus more specifically on integrated diagnosis and multi-disease testing. Additionally, longer-term studies involving larger populations are needed to assess the impact of such interventions and their effects on the overall patient healthcare experience.

6.6 Conclusion and Recommendations

The review concentrated on integrated diagnosis interventions in Africa, with potential relevance to LMICs globally. The success of integrated diagnosis is not a one-size-fits-all scenario; local contexts must guide decisions regarding the approach, conditions, and timing of integration to ensure sustainable outcomes. The review findings indicate that integrated diagnosis may be suitable at the primary care level in LMICs under specific circumstances. Successful implementation hinges on addressing both HCWs' and patients' perspectives, necessitating adequate time, resources, and a well-defined intervention model.

6.7 Chapter 6 Summary

The realist review explored the specific contexts and mechanisms necessary for the successful implementation of integrated diagnosis.

One key conclusion was that the capacity for same-day integrated diagnosis at small PHC facilities is limited. Most integrated diagnosis services are more feasible at secondary care or larger primary care hospitals in specific districts, where diagnostic technologies, doctors, and nurses are available.

Two broad sets of Context-Mechanism-Outcome (C-M-O) configurations were developed—one for healthcare workers and another for patients or clients—to reflect their distinct experiences and perceptions within the healthcare delivery process.

Healthcare workers:

Based on the literature, five key C-M-O configurations were identified:

- When multi-disease policies or guidelines (C) were translated into diagnostic algorithms and screening protocols at the facility (C) and followed by adequate training in both

guidelines and patient-centred care (M), healthcare workers experienced increased self-efficacy and provided higher-quality care (O).

- Facilities with sufficient healthcare workers and multi-disease funding covering all targeted conditions (C) gave staff confidence in their ability to deliver integrated care (M), leading to improved service coverage (O).
- The use of integrated monitoring and reporting tools that captured all diagnosed diseases (C) ensured accountability and served as reminders for healthcare workers to conduct integrated diagnosis (M), ultimately improving service coverage (O).
- Having well-defined treatment, care, and referral pathways for diagnosed diseases (C) increased healthcare workers' perception of the benefits of diagnosis (M), resulting in higher service coverage (O).
- Fit-for-purpose technology (C) improves healthcare worker motivation (M) when they experience its benefits in improving workflow efficiency and patient outcomes, ultimately leading to increased uptake and service coverage (O).

Patients/Clients:

For patients, several factors influenced their experience and engagement with integrated diagnosis:

- A positive relationship between healthcare providers and patients (C) fostered trust and respect (M), enhancing the overall patient experience of care (O).
- When services were delivered in a way that ensured confidentiality and privacy where relevant (C), it helped reduce the stigma associated with certain diagnoses (M), improving the patient experience of care (O).
- The ease of access to facilities and services (C) provided a sense of convenience and comfort (M), enhancing the patient experience (O).

- Faster test results (C) reduced patient anxiety about their diagnosis (M), leading to higher service uptake and earlier diagnosis of conditions (O).
- However, longer waiting times for same-day integrated diagnosis (C) led to frustration (M), potentially reducing the uptake of non-urgent services (O).

6.8 Personal reflections

To deepen my understanding of realist methodology, I enrolled in a short course at the University of Oxford and joined the RAMESES network, connecting with other realist researchers. These experiences have been invaluable, reinforcing the idea that while not everything works the same way in every setting, certain patterns can be reasonably applied elsewhere.

This perspective is particularly important as I explore ways to improve the delivery of integrated diagnosis. It highlights that models can be replicated if the necessary contexts and the underlying mechanisms are in place. These mechanisms can also serve as indicators for measuring the success of interventions. As a monitoring and evaluation professional, this approach brings greater precision and scrutiny in defining programme success. It ensures that we measure the right outcomes and continuously learn to refine and improve service delivery.

Chapter Seven

Core Criteria for designing integrated diagnosis interventions in low resource settings at the primary care level: A Delphi consensus study

7. Core criteria for designing integrated diagnosis interventions in LMICs at the primary care level: A Delphi Consensus Study

Publication Statement

Results of this chapter have been published in the following peer-reviewed journal:

Gwaza, G., Plüddemann, A., MacBain McCall, M. *et al.* Criteria for designing integrated diagnosis interventions in low resource settings at the primary care level: a Delphi consensus study. *BMC Health Serv Res* **25**, 1130 (2025). https://doi.org/10.1186/s12913-025-13114-9

The results were also presented in an elevator pitch and poster format at the Evidence-Based Early Diagnosis Conference, held at St Andrews University, Scotland, in May 2024.

7.1. Chapter Aim and Objectives

This chapter builds on the realist review in Chapter 6, which identified some necessary contexts and mechanisms for the success of integrated diagnosis interventions.[244] These insights formed the basis of all the criteria that were selected for prioritisation.

This chapter aims to prioritise these key factors essential for the success of integrated diagnosis interventions. This was achieved by establishing consensus among implementers, policymakers, and researchers in the field. The focus was on determining which criteria are critical for inclusion in the design of integrated diagnostic interventions that aim to improve patient experiences and health outcomes at the primary care level, particularly in low-resource settings in Africa.

7.2 Introduction

The diagnostic process includes performing a clinical history and interview, physical examination, diagnostic testing, and referring or consulting with other clinicians.[6] Integrated diagnosis was defined based on the definition established in Chapter 2, as the provision of comprehensive diagnostic services to identify multiple conditions or diseases during a single visit, ensuring ease of access, same-day results, and continuity of care, with the goal of improving patient experiences and health outcomes in primary care settings in LMICs. In this case, integrated sample referrals, where patients receive the results on a different day, are excluded. An integrated diagnosis is a clinically essential intervention for some health conditions, such as preventing and treating TB co-infection with HIV.[83] Integrated diagnosis offers patients and clients increased convenience, improved access to healthcare services, continuity of care, and a holistic approach to addressing their health needs.[244]

The health systems in LMICs are currently designed to respond to acute, predominantly infectious diseases, usually through disease-specific vertical programmes that focus on a single condition/disease.[91] In Africa, where the burden of infectious diseases such as TB and HIV remains significant [209], the inability to accurately diagnose, treat, and identify missed cases hinders effective disease management. Furthermore, only 19% of patients have access to appropriate diagnostics at the primary healthcare level in LMICs, representing the single largest gap in the healthcare pathway.[6,245]The essential diagnostics included were rapid tests for HIV, TB, malaria, pregnancy, and syphilis and other diagnostic tests for glucose, urine protein, hemoglobin, blood pressure, x-rays and ultrasound. Primary care facilities, which play a crucial role in disease detection and management, often miss opportunities for preventing onward transmission. The WHO estimates, for example, that only 64% of new TB cases are detected and notified, suggesting that over three million cases of this highly contagious disease are missed annually.[6,33] Moreover, as advancements in treatment lead to improved life expectancy and quality of life for persons with HIV, there is an emerging challenge of comorbidity with NCDs.[104] This shift

necessitates a more comprehensive and integrated approach to healthcare that goes beyond the traditional focus on infectious diseases.

There is a high level of support for integrated health care in LMICs following the WHO policy on integrated health care in 2016.[210] Diagnosis is mentioned as part of the health services, alongside health promotion, disease prevention, treatment, disease management, rehabilitation, and palliative care that should be integrated. Policy guidance is also available for integrating diagnosis and treatment of other health conditions such as TB and HIV.[4] The recommended TB and HIV tests have already been referred to in Chapter 4 and Table 14 in Chapter 6. These include the rapid tests for HIV, the Xpert HIV-1 Qual for HIV qualitative testing and for viral load monitoring, as well as the Xpert MTB/RIF assay for TB diagnosis and other chest x-rays or microscopy tests.

Numerous well-intentioned interventions aimed at integrating healthcare service delivery at the point of care in primary care settings in LMICs often fall short of improving patient experiences and health outcomes despite increasing patient uptake.[45,129] Regarding diagnosis, the tendency is to introduce diagnostic tools without fully considering other enabling aspects of the health system necessary for their success [31,244,246] or some of the necessary contexts and mechanisms identified in Chapter 6. These aspects can encompass, for example, practical factors such as the electricity requirements of the instrument vis a vis the availability at the facility where it is placed, healthcare workforce capabilities, and treatment pathways, ultimately leading to suboptimal outcomes.[31,92,247] While some considerations may seem intuitive, there is a lack of clear and comprehensive guidance available to implementers and policymakers on how interventions for integrated diagnosis should be designed to improve patient experiences and health outcomes.

7.3 Methods

This study used the Delphi method through an online survey administered to experts with knowledge and experience in integrated diagnosis. The Delphi is one method for improving the generation of critical ideas and the structured collection and processing of information gathered from experts.[248] Panels typically consist of 10 to 50 experts in the field, who are anonymous in that their identities are not disclosed to other panel members.[249-251]The Delphi method has been used extensively in developing criteria frameworks in the healthcare field.[249,252,253] The protocol for the study is provided in Appendix 10.

7.3.1 Participants

Participants were purposefully sampled based on their knowledge and experience. The international group of experts was identified as follows: (i) current working experience in the field of healthcare with a focus on integrated healthcare or diagnosis based in Africa; (ii) current experience working in global health organisations or funders of global health programmes in LMICs such as the WHO, Unitaid, Global Fund, and FIND; (iii) participants at the International Conference on Integrated Healthcare (ICIC-2023) in Belgium with proven expertise in integrated healthcare delivery; (iv) international researchers and academics in the field of primary health care and diagnosis. Efforts were made to ensure the participation of a wide variety of stakeholders in the study, focusing on geographic and occupational diversity within relevant areas of integrated health care and diagnostics and experts in various diseases and conditions.

The objective was to include a diverse sample of experts from three different categories: implementers, policymakers or funders, and researchers or academic experts. Understanding that some experts may be experts in more than one domain, email invitations were sent to 107 experts. The target was to include at least 50 experts in the study.

7.3.2 Development of the survey

The previous Chapter 6, which presented the realist review, identified key contexts and mechanisms necessary for the success of integrated diagnosis interventions at the primary healthcare (PHC) level. These contexts and mechanisms differed between healthcare workers and patients. They were mapped and categorized into thematic areas, which were then used to define the domains and criteria for this Delphi study. A total of 33 criteria were identified and grouped into six domains, each containing specific criteria, which are: Governance (8 criteria), Operational Considerations (5 criteria), Physical Integration (8 criteria), Human Resources Integration (4 criteria), Technology Integration (4 criteria) and Monitoring and Evaluation (M&E) (4 criteria). The survey was piloted with two laboratory technicians who implemented integrated diagnosis interventions and was refined based on the comments received.

7.3.3 Conduct and Analysis of the survey

Two rounds of surveys were administered online using the JISC platform. Respondents rated each criterion using a 1-5 Likert scale with 1-*Not important*, 2-*limited importance*, 3-*important but not critical*, 4- *critical to include* and 5- *Unable to rate* option should they feel that item to be beyond their expertise. 'Consensus' was considered achieved if 70% or more of the participants rated criteria four or *Critical to Include* when assessing significance. Consensus proportions for each question were determined based on the number of respondents, excluding those who selected category 5-*Unable to rate (Not my expertise)*. Consequently, the denominator for calculating consensus comprised only participants possessing relevant knowledge and expertise in the specific question under consideration.

In the Round 2 survey, criteria that previously received votes ranging from 50% to 69% for being *critical to include* (4) were all included. This approach was taken unless there were specific instances where criteria were merged or rephrased, and explanations would be provided. The intention was to include criteria in the Round 2 survey that had garnered significant support in terms of importance but had not reached the threshold for consensus in Round 1. Additional

criteria could be included in Round 2 based on recommendations by the participants. Criteria that had received less than 50% for being *critical to include* (4) were removed and not included in the final criteria after Round 1.

7.3.4 Ethical Considerations

The study received approval from the University of Oxford's Department for Continuing Education Research Ethics Committee (OUDCE C1A 23 033). Each expert provided informed consent, implied by their acceptance on the first page of the online survey and their agreement to participate in the study.

7.4 Results

In the first round, 55 experts participated, representing diverse geographical regions: 44% from Africa, 42% from Europe, 7% from Asia, and 4% from the Americas, with 4% not indicating their location. Most survey respondents were based in Switzerland (n=15), predominantly comprising international staff from prominent global health organisations such as FIND, WHO, Unitaid, and the Global Fund. Additionally, there was a notable number from Zimbabwe (n=10), the researcher's home country, as they leveraged personal networks and word of mouth to engage more implementers and policymakers. Among the participants, 54% were healthcare implementers, 24% were academics, and 22% were policymakers. In terms of sex distribution, 62% were female, 36% were male and 2% did not identify their sex. Regarding age groups, 24% fell between 51 and 64 years old, 36% were aged 41 to 50, 35% were aged 31 to 40, and 5% were aged 26 to 30.

In Round 2, 48 out of the original 55 participants responded. 65% were female and 35% were male. Geographically, 50% were based in Africa, 38% in Europe, 6% in Asia, 4% in the Americas,

and 2% did not identify their location. In terms of professional roles, 63% were implementers, 23% were policymakers and 15% were academics and researchers.

Table 15: Demographic details of participants in Rounds 1 and 2

Characteristic		**Round 1 (n=55)**	**Round 2 (n-48)**
Sex	Male	36% (n=20)	35% (n=17)
	Female	62% (n=34)	65% (n=31)
	No response	2% (n=1)	-
Age	26-30	5% (n=3)	-
	31-40	35% (n=19)	29% (n=14)
	41-50	36% (n=20)	48% (n=23)
	51-64	24% (n=13)	23% (n=11)
Region	Country where they are currently based		
Africa Round 1: 44% (n=24)	Cameroon	1	1
	Ghana	1	1
	Ethiopia	1	1
	Kenya	1	1
	Lesotho	1	3
	Nigeria	1	1

Round 2: 50% (n=24)	Rwanda	1	1
	Senegal	1	1
	South Africa	2	3
	Tanzania	1	1
	Uganda	1	1
	Zambia	2	1
	Zimbabwe	10	8
Europe Round 1: 42% (n=20) Round 2: 38% (n=18)	Belgium	2	1
	France	2	1
	Ireland	1	1
	Spain	1	1
	Switzerland	15	13
	United Kingdom	2	1
Asia Round 1: 7% (n=4) Round 2: 6% (n=3)	India	2	1
	Nepal	1	1
	Singapore	1	1
United States 4% (n=2) both rounds	The Americas	2	2
N/A 4% (n=2)	No response	2	2

Profession			
Academic Researcher/Graduate Student	Scientist/Researcher	11% (n=6)	13% (n=6)
	Professor/Lecturer	7% (n=4)	-
	Graduate student	4% (n=2)	2% (n=1)
Health Policymaker (n=13)	Senior government officials	11% (n=6)	8% (n=4)
	Management and leadership in global health organisation	13% (n=7)	15% (n=7)
Implementer	Professional working in a global health organisation, e.g., programme manager/officer	27% (n=15)	31% (n=15)
	Medical laboratory scientist	11% (n=6)	13% (n=6)
	Medical doctor/Specialist physician	9% (n=5)	10% (n=5)
	Data scientists/ Surveillance /technical officers	7% (n=4)	8% (n=4)

7.4.1 Round 1

Fourteen criteria achieved consensus, with 70% or more participants considering them as Category 4, "critical to include" (shaded in green), while ten criteria were eligible to proceed to Round 2 (shaded orange). Table 15 below displays the percentage of votes for each criterion in Round 1.

Table 16: Total Results of Round 1.

		***Critical to include* (4)**	***Important but not critical* (3)**	***Limited importance* (2)**	***Not important* (1)**
	Domain 1: Governance				
1	Clear and specific funding for diagnosis and treatment	81% (n=44/55)	13% (n=7)	4% (n=2)	2% (n=1)
2	Funding for continued training of the HCWs for diagnosis	74% (n=40)	20% (n=11)	6% (n=3)	0
3	System for coordination of donor support to avoid disease fragmentation	59% (n=32)	39% (n=21)	2% (n=1)	0
4	WHO policy or recommendation for integration	33% (n=18)	55% (n=30)	13% (n=7)	0
5	National policy or guideline for integration	85% (n=47)	13% (n=7)	2% (n=1)	0

6	Diagnostic algorithm or screening tool to guide dx	87% (n=48)	13% (n=7)		0
7	Treatment or clear referral pathway	91% (n=49)	7% (n=4)	2% (n=1)	0
8	Strong leadership, with shared vision and support for integration	81% (n=44)	17% (n=9)	2% (n=1)	0
	Domain 2: Operational Considerations				
9	Complexity of diagnosis for diseases integrated	68% (n=36)	28% (n=15)	4% (n=2)	0
10	Similar prevalence of diseases included	6% (n=3)	33% (n=18)	43% (n=23)	19% (n=10)
11	Similar target population or risk profile of intended beneficiaries	22% (n=12)	52% (n=28)	19% (n=10)	7% (n=7)
12	Combined clinical & ICT systems, including a single registration form	58% (n=30)	37% (n=19)	4% (n=2)	2% (n=1)
13	HCW training in patient-centred care	74% (n=40)	20% (n=11)	4% (n=2)	2% (n=1)
	Domain 3: Physical Integration				
14	Sufficient physical space for private examinations	72% (n=38)	26% (n=14)	2% (n=1)	0
15	Sufficient and comfortable space to sit while patients wait their turn	43% (n=23)	48% (n=26)	9% (n=5)	0
16	Clear directions on how to navigate the facility to access different services	67% (n=36)	30% (n=16)	4% (n=2)	0

17	HCW training in interpersonal collaboration	72% (n=39)	26% (n=14)	0	2% (n=1)
18	Trust and respect among HCWs of each other's expertise	54% (n=29)	41% (n=22)	4% (n=2)	2% (n=1)
19	Clear roles assigned to each HCW at the facility	87% (n=47)	7% (n=4)	6% (n=3)	0
20	Functional referral mechanism to access other services	84% (n=46)	11% (n=6)	2% (n=1)	4%
21	Follow-up mechanisms of patients who need to access referral services	76% (n=41)	19% (n=10)	4% (n=2)	2% (n=1)
	Domain 4: Human Resource Integration				
22	Training in the diagnosis and follow-up counselling	89% (n=49)	9% (n=5)	2% (n=1)	0
23	HCW should initiate diagnosis rather than the patient requesting it	52% (n=26)	42% (n=21)	4% (n=2)	2% (n=1)
24	Plan of how long it takes on average to conduct the diagnosis	47% (n=25)	49% (n=26)	2% (n=1)	2% (n=1)
25	Continuity of care: one HCW manages the health care of the same patient	28% (n=15)	39% (n=21)	30% (n=16)	4% (n=2)
	Domain 5: Technology Integration				
26	All Technical conditions for the instrument to function are met	89% (n=48)	11% (n=6)		

27	The test can be used as a screening tool; another test can confirm the results	33% (n=18)	44% (n=24)	20% (n=11)	2% (n=1)
28	The test should be both a screening and confirmatory tool for the results.	30% (n=16)	45% (n=24)	19% (n=10)	6% (n=3)
29	HCW should be able to conduct the test alone without other HCWs	33% (n=17)	42% (n=22)	15% (n=8)	23% (n=5)
	Domain 6: M&E				
30	An M&E framework with measurable indicators for intended outcomes	61% (n=33)	33% (n=18)	4% (n=2)	2% (n=1)
31	A reporting requirement for HCWs to provide reports on all diseases	57% (n=31)	31% (n=17)	6% (n=3)	6% (n=3)
32	Single reporting form or tool at the facility for all the targeted diseases	58% (n=31)	34% (n=18)	8% (n=4)	0
33	Customer feedback mechanism to report on the quality of service	54% (n=29)	41% (n=22)	4% (n=2)	2% (n=1)

Feedback was offered concerning specific criteria in each domain, with some recommendations for rephrasing and adding new criteria for consideration. There were no discernible patterns of voting based on demographic factors.

Domain 1: Governance

Consensus was reached for six out of eight criteria as being "*critical to include"*. There were additional comments to support the funding criteria, which achieved consensus from two

implementers, drawing on experiences from African countries who emphasise the preference for funding that cuts across diseases rather than being compartmentalised, especially in conjunction with historically disease-specific funding. Furthermore, another implementer commented that the available funding information should be made available at the service delivery level, as often, this information is only available at the national decision-making level.

The criterion on a system for coordinating donor support to prevent disease fragmentation (59%), had votes above 50% in category 4, "*critical to include",* and proceeded to Round 2.

However, the other criterion regarding WHO policy or recommendation for integration (33%) received less than 50% support and was subsequently removed. One comment from an implementer in a global health organisation based in Europe was that disease integration, whether at the national or global policy level, does not inherently lead to integrated diagnosis. They argued that successful integration depends on the availability of funding and the presence of implementation setups capable of facilitating it at a country level.

There were three additional criteria recommended to be added by different experts. The first from an implementer was to add disease management to treatment pathways, given that certain diseases, such as NCDs, require effective management rather than curative measures, and treatment could suggest curable treatment.

The second criteria recommended from a policymaker was to add policies enabling the full utilisation of diagnostic tools at the primary care level. In some countries, not all health workers are formally certified to conduct specific diagnostic procedures, such as blood-based tests, microscopy, or radiographic imaging. Certification in this context refers to the formal process by which a health worker is authorized, following training and assessment, to perform and interpret designated diagnostic tests. Implementation and governance typically fall under ministries of health, professional regulatory councils, or national laboratory authorities, which determine the scope of practice for each cadre. For example, in Uganda and Tanzania, community health

workers can conduct malaria RDTs but are not authorized to perform HIV testing unless they undergo additional government-approved training and certification. Similarly, in India, task-shifting policies have enabled nurses and auxiliary nurse midwives to be certified for point-of-care diagnostics such as HIV and syphilis RDTs as part of antenatal care programs. Strengthening governance of certification and accreditation processes ensures that diagnostic responsibilities are clearly defined, training is standardized, and quality of care is maintained as tasks are shifted to different cadres of health workers. These two recommendations were added in Round 2.

The third recommendation from an implementer based in an African country was to establish a government agency responsible for the supervision, regulation, and standardization of clinical and medical laboratories. The recommendation was not included in Round 2, as it was deemed to be too focused on laboratories, which were not always available at the primary care level, the main target of the study.

Domain 2: Operational considerations

One out of the five criteria achieved consensus on the training of healthcare workers in patient-centred care. Two criteria had votes above 50% in Category 4 "*critical to include"* and were moved to Round 2. These were the complexity of diagnosis and combined clinical and ICT systems, including a single registration.

Additional comments were received for the two criteria with above 50% votes. Regarding the complexity of diagnosis, two implementers offered different comments. The first was that there was a need to strike a balance between diagnostic complexity and the need for innovative approaches that streamline diagnostic procedures at the PHC level. The second comment was that the operational functionality and acceptability of the diagnostic algorithm at the facility level outweigh the simplicity of the test itself; thus, the ability and ease of integrating the diagnostic into existing procedures is more important than whether or not it is complex. This criterion was rephrased to reflect this perspective in Round 2. The criterion specifying combined clinical and

ICT systems, including a single registration form, was suggested to be rephrased as integrated information systems in Round 2. The adjustment would allow for a broader interpretation that could encompass elements discussed in Domain 6 related to monitoring and evaluation. The suggestion was adopted.

Two criteria had below 50% votes and were removed. Although there was no consensus that a similar target population or risk profile approach was critical, there was a comment that the approach could effectively address urgent needs in outbreak scenarios. However, mechanisms for integrating post-outbreak surveillance into routine services were deemed essential for sustainability and scalability.

There were recommendations to add three criteria to this domain, proposed by three different implementers, i.e., i) Community awareness, demand, and acceptability of the diagnostic services under consideration; ii) Availability of medical insurance or schemes to assist with out-of-pocket expenditures for services; iii) internet connectivity. The first two recommendations were adopted. However, the third was not included as internet connectivity could be included under other criteria in the technical integration domain.

Domain 3: Physical integration

Five out of the eight criteria reached a consensus. Although it achieved consensus, there was a comment from an implementer that a functional referral mechanism could only work if there was also an effective follow-up mechanism to track adherence and loss in the diagnostic pathway. This was added in Round 2.

Two criteria received over 50% support and advanced to the second round. These criteria were clear directions on how to navigate the facility to access different services (67%), and trust and respect among healthcare workers for each other's expertise (54%). There was a comment that clear directions on how to navigate the facility may not be sufficient without establishing clear patient pathways and points of contact to guide patients through different services. This criterion

was refined in Round 2 to reflect this. Secondly, the criterion on the importance of trust and respect among HCWs for each other's expertise was acknowledged. Still, it was noted to be challenging to understand or monitor this social and behavioural aspect at the facility.

However, one criterion, sufficient and comfortable space for patients to sit while waiting their turn (43%), did not achieve consensus and was subsequently removed. An implementer based in Africa commented on this criterion that the requirement for sufficient and comfortable waiting space needed to be revised for low-resource settings, which may face constraints in terms of space and budget.

There were suggestions to add some criteria to this domain: i) Deliberate investment to increase the number of trained health workers, including nurses, doctors, and laboratory scientists; ii) Adequate incentives for healthcare workers, such as continuous training. These were not added as they were assumed to be included under the funding in domain 1.

Domain 4: Individual or human resource integration

A consensus was achieved for one out of the four criteria, which was HCW training on diagnosis and follow-up counseling. Although the criterion on training achieved consensus, there was a comment by a policymaker based in Africa that the training needed to be qualified. They were of the view that many training programmes did not result in improved competence and ability to apply the knowledge and skills acquired effectively.

One criterion had over 50% votes: HCW should initiate diagnosis rather than the patient requesting it (52%) and was included in Round 2. There were comments on this criterion by three implementers. Firstly, it was highlighted that care and respect must be maintained throughout the diagnostic process. Secondly, it was emphasized that providers should engage in a dialogue with patients rather than dictating the diagnosis process. Thirdly, considerations were noted regarding costs that health workers may not always consider when recommending or referring diagnostic

tests. It was suggested that minimum criteria be set for providers as to when initiating integrated diagnosis might be necessary.

The remaining two criteria did not achieve consensus and were removed. The criteria for continuity of care were recommended to be broadened. In LMICs, continuity of care is not just about individualised care but can also be achieved by establishing a robust referral system that is well integrated into the healthcare framework. Functional referral systems can ensure a seamless transition of patients between different levels of care and contribute to overall healthcare integration.

Domain 5: Technical integration

Consensus was achieved for one of the four criteria, which was the technical conditions for the instrument to function are met.

A consensus was not reached on the remaining criteria, which were whether the test was a screening or confirmatory tool, or both, and whether the healthcare worker could conduct the test alone without assistance from other healthcare workers. As a result, these criteria were removed from consideration. Five implementers provided feedback on these criteria. They noted that whether the tool served as a screening or confirmatory measure or whether the health worker could independently conduct the test depended on context. Factors such as disease prevalence and the specific setting, facility, or diagnostic tool in use influenced these considerations, making them unsuitable as core criteria. Instead, emphasis was placed on healthcare workers being knowledgeable about the diagnostic algorithm for various diseases, whether they could conduct the test themselves or refer patients accordingly.

There were proposals to include additional criteria related to basic infrastructure for ensuring the security of diagnostic platforms and related consumables, as well as adherence to process safety management standards, and biosafety and bio-security elements. These were not added in

Round 2 as they could be addressed within the broader context of the technical requirements of the diagnostic tool.

Domain 6: Monitoring and evaluation (M & E)

None of the four criteria gained consensus. However, all four criteria were above the 50% threshold and were included in round 2. There were some comments from two implementers who indicated concerns about the additional burdens placed on already overworked healthcare workers due to reporting requirements from various donor agencies. There was also a perspective suggesting that customer feedback on the quality of care might be considered a separate objective from integration. The argument put forth was that integrated diagnosis should focus on a multi-disease testing approach in laboratories or clinics rather than on the patient-centred approach. A decision was made to merge some of the criteria in domain six into two criteria instead of four. For example, customer feedback was included as part of the M&E instead of a separate criterion.

Twelve criteria were moved to Round 2 at the end of Round 1; three of them were new additions, as indicated in Table 16 below.

7.4.2 Round 2

Four criteria achieved consensus as "*critical to include*," with 70% or more agreement (shaded green in the Table). One criterion falls under the governance domain, emphasising the importance of a system of donor coordination to prevent disease fragmentation. The other two criteria, both within the operational consideration domain, focus on the operational functionality and acceptability of the diagnostic algorithm as well as the community awareness, demand, and acceptability of the diagnostic services, highlighting its significance. The fourth criterion in Domain 3 on Physical integration on a clear patient pathway and point of contact to guide the patient through different services.

Four criteria received between 50% and 69% agreement, indicating they did not meet the consensus threshold for being deemed "*critical to include*" but were still considered important. The first criterion focuses on policies allowing the full use of diagnostics at the primary care level.

Three of these criteria relate to monitoring and evaluation:

1. The need for integrated information systems, including a single registration form.
2. The importance of having an M&E framework with measurable indicators and results.
3. The necessity for a single national-level health information system for reporting encompasses all relevant diseases and conditions.

There were no additional comments on the criteria.

Table 17: Results of Round 2 survey

		Critical to include	**Important but not critical**	**Limited importance**	**Not important**	**Total**
	Domain 1: Governance					
1	System for coordination of donor support to avoid disease fragmentation	77% (n=36)	23% (n=11)			100%
2	Policies to allow full use of diagnostics at the PHC level, e.g., necessary certification for healthcare workers or government allowance. **(NEW)**	68% (n=32)	28% (n=13)	4% (n=2)		100%

	Domain 2: Operational Considerations					
3	Operational functionality and acceptability of the diagnostic algorithm	79% (n=37)	21% (n=10)			100%
4	Integrated information systems, including a single registration form	50% (n=23)	46% (n=21)	4% (n=2)		100%
5	Community awareness, demand and acceptability of the diagnostic services being considered **(NEW)**	70% (n=33)	23% (n=11)	4% (n=2)	2% (n=1)	100%
6	Availability of medical insurance or medical schemes to help with out-of-pocket expenditure for services for diagnostic services **(NEW)**	45% (n=21)	36% (n=17)	17% (n=18)	2% (n=1)	100%
	Domain 3: Physical Integration					
7	Clear patient pathway and point of contact to guide the patient through different services	83% (n=38)	15% (n=7)	2% (n=1)		100%
8	Trust and respect among HCWs of each other's expertise	44% (n=21)	54% (n=26)	2% (n=1)		
9						
	Domain 4: Human Resource Integration					

10	HCW should initiate diagnosis rather than the patient requesting it	40% (n=19)	46% (n=22)	15% (n=7)		100%
	Domain 6: M&E					
11	An M&E framework with measurable indicators results	55% (n=24)	43% (n=19)	2% (n=1)		100%
12	A single national-level health information system for reporting, which includes all the relevant diseases and conditions	66% (n=31)	32% (n=15)	2% (n=1)		100%

Based on the Delphi results, eighteen criteria were identified as core criteria to be prioritised when designing integrated diagnosis interventions that result in optimum patient experiences and health outcomes. See Table 16 for the full list of core criteria that reached a consensus.

Table 18: Core criteria that reached consensus.

	Criteria	***Critical to include***
	Domain 1: Governance	
1	Treatment/disease management or clear referral pathway	91%
2	Diagnostic algorithm or screening tool to guide dx	87%
3	National policy or guideline for integration	85%
4	Strong leadership, with shared vision and support for integration	81%
5	Clear and specific funding for diagnosis and treatment	81%

6	System for coordination of donor support to avoid disease fragmentation	77%
7	Funding for continued training of the HCWs for diagnosis	74%
	Domain 2: Operational Considerations	
8	Operational functionality and acceptability of the diagnostic algorithm	79%
9	HCW training in patient-centred care	74%
10	Community awareness, demand, and acceptability of the diagnostic services being considered	70%
	Domain 3: Physical integration	
11	Clear roles assigned to each HCW at the facility	87%
12	Functional referral mechanism to access other services	84%
13	Clear patient pathway and point of contact to guide the patient through different services	83%
14	Follow-up mechanisms of patients who need to access referral services	76%
15	Sufficient physical space for private examinations	72%
16	HCW training in interpersonal collaboration	72%
	Domain 4: Human resource integration	
17	Training in the diagnosis and follow-up counseling	89%
	Domain 5: Technical integration	
18	All Technical conditions for the instrument to function are met	89%

7.5 Discussion

The Delphi study aimed to prioritise factors that were essential when designing integrated diagnosis interventions at the primary care level in low-resource settings where trade-offs must be made constantly. Eighteen core criteria across five domains were identified. The range of these criteria underscores the need for a holistic view when introducing any intervention in a health facility. Diagnosis is a crucial step in healthcare, but it is part of a larger system. Changes in one area affect others, so it is essential to consider the entire health system. Diagnosis is not just about tests and machines; it is part of patient care. Effective implementation of diagnostics requires comprehensive "deployment packages" that integrate with existing systems and patient care.[254] No single element alone can achieve the desired outcomes.

All of the 18 criteria can be aligned with the WHO health systems framework,[42] predominantly situated within the leadership/governance and service delivery pillars. This also aligns with the barriers identified in Chapter 3, which were analysed based on these health pillars. The first WHO pillar on Leadership/governance aligns with Domain 1 on Governance, including criteria such as a system for donor coordination, strong leadership with a unified vision, and the presence of national policies and guidelines on integration. Prioritising these leadership and governance aspects means paying attention to the broader issues of structural integration, which create the conditions to facilitate successful implementation.

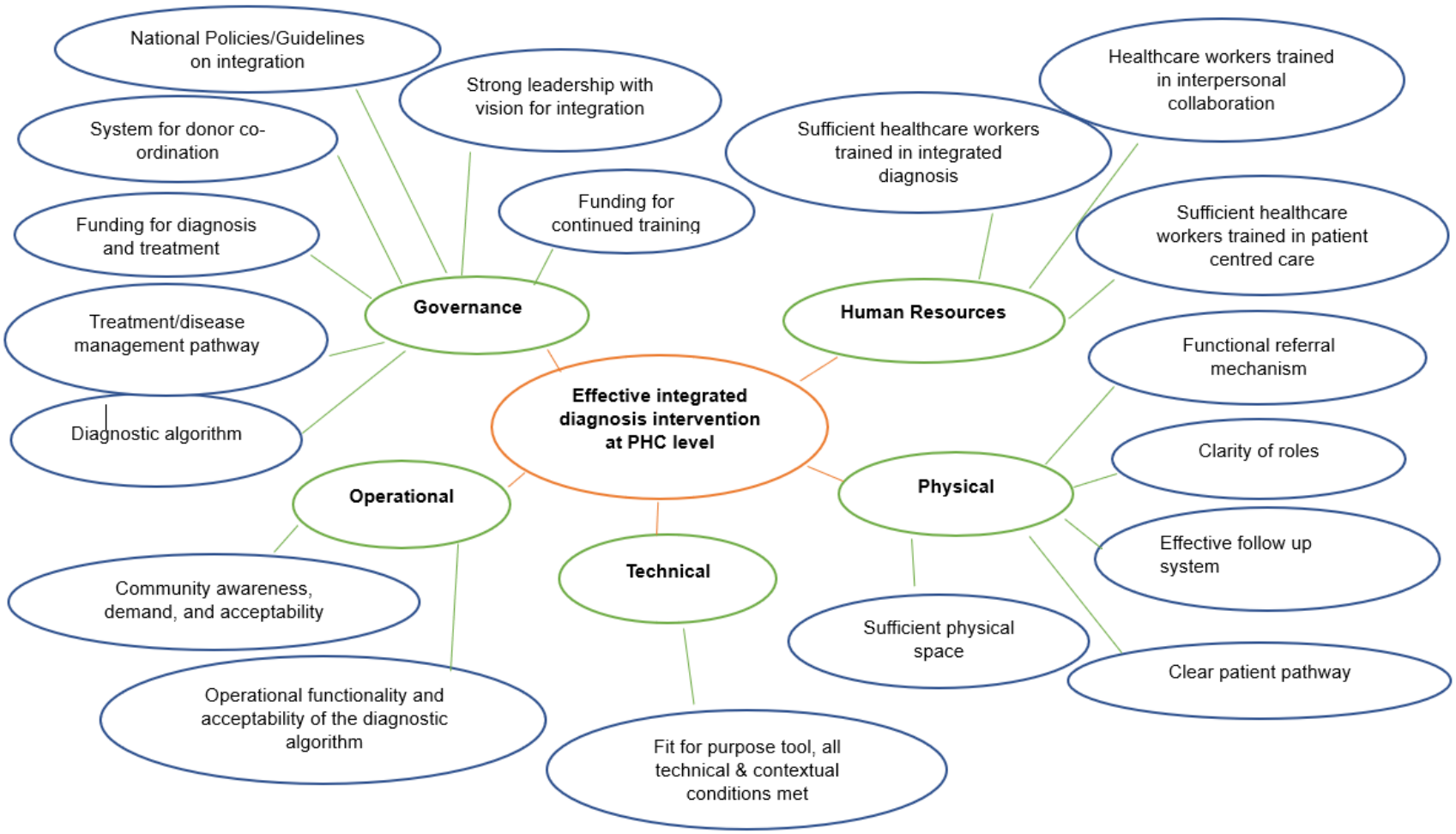


Figure 9: Criteria that reached consensus as critical to include when designing integrated diagnosis interventions

Table 19: Mapping the core criteria to the WHO Health Systems Framework

WHO Health Systems Framework	**Core criteria for integrated diagnosis interventions**	**Domain in the Delphi study**
Leadership /Governance	• A system to coordinate donors • Strong leadership, with shared vision and support for integration • National policy or guidelines for integration	Domain 1: Governance
Financing	• Clear and specific funding • Funding for training	Domain 1: Governance
Health workforce	• Training on patient-centred care • Training on diagnosis and follow-up counseling, • Training on interpersonal collaboration	Domain 2: Operational Considerations Domain 3: Physical integration Domain 4: Human Resource Integration
Service delivery	• Diagnostic algorithms or screening tools for integration • Operational functionality of the diagnostic algorithms	Domain 1: Governance Domain 2: Operational Considerations

	• Community awareness, demand, and acceptability of the diagnostics • Sufficient physical space for private examinations • Clear roles assigned to each HCW at the facility. • Functional referral mechanisms to access other diagnostic services. • Clear patient pathway to guide the patient through different services. • Follow-up mechanisms of patients who need to access referral services	Domain 3: Physical integration
Health products & technologies	• All Technical conditions for the instrument to function are met • Treatment or clear referral pathway	Domain 5: Technical Integration Domain 1: Governance
Health Information systems	No criteria matching that reached a consensus	

In the service delivery pillar, most criteria are within Domain 2 and 3 on operational considerations and physical integration. Practical factors, such as the operational requirements of diagnostic tools, must be thoroughly assessed. Instances have been reported where diagnostics, reliant on

a constant electricity supply, or optimal performance within specific temperature ranges, or require spare parts that are challenging to procure locally, end up lying idle and unused in health facilities in LMICs.[235,247,254] Considering the physical setup of facilities is also crucial, particularly when dealing with confidentiality and stigma issues related to certain diseases. Ensuring clear patient pathways, especially in facilities where services are co-located, is necessary for seamless patient flow. Unfortunately, the patient perspective is often overlooked in many interventions, and addressing these practical considerations can significantly contribute to improving overall patient experiences, preventing the underutilization of diagnostic resources, and enhancing their functionality within diverse healthcare environments. Community engagement is a critical component to creating demand for and adoption of services. There is an increasing recognition that patients and communities are integral to health decisions and processes to achieve optimal health outcomes.[66]These participatory approaches have been particularly evident in the successful introduction of self-testing technologies.[76]

The Health Products & Technologies pillar corresponds with the domain of technical integration. Diagnostic tools that meet technical standards ensure their optimal utilization. For instance, the REASSURED criteria, part of the WHO's Package of Essential Non-communicable Disease Interventions (PEN) for primary healthcare, can help assess the suitability of diagnostic tools.[255,256] The introduction of new diagnostic technologies does not always lead to their optimal use. Often, pressure from referring clinicians and patients results in the addition rather than substitution of existing tests.[257] Practical factors like limited access to stable electricity, clean water, internet, and refrigeration also impact diagnostic service uptake.[6,247] To address these challenges, global health organisations and diagnostic manufacturers prioritise developing tools suitable for LMICs. Entities like FIND and Unitaid focus on operational functionality, ensuring diagnostic algorithms align with local environments and introducing technological innovations for LMIC markets.[32,258] The focus is on providing diagnostics that fit into the local diagnostic algorithms, as tools that do not align can hinder the effectiveness of the overall diagnostic process.

Integrated diagnosis should have a primary aim of improving health outcomes. Most diagnostic integration efforts focus on increasing service uptake or process efficiency rather than patient experiences and health outcomes.[149] For diagnostics to effectively improve health outcomes, it is crucial to integrate treatment pathways and disease management into the intervention. This can either be at the facility or through established functional referral mechanisms with effective follow-up systems. Improvements in diagnostic technologies do not inevitably translate to benefits to patient care.[257] Often, assessments of diagnostic tools prioritise test performance without considering their suitability within local contexts, specific patient pathways, and health systems or their impact on patient outcomes. Consequently, decision-makers may prioritize the cost of diagnostics over their quality and potential impact on healthcare delivery.

The health workforce pillar is addressed through criteria on HCW training in diagnosis, interpersonal collaboration, and patient-centred care. Improving patient experiences of integrated diagnosis should focus on who is providing the care and how the care is delivered. As such, the training of healthcare workers is important, focusing not only on the technical aspects of diagnosis but also on social elements such as interpersonal collaboration and patient-centred care. While existing literature has often focused more on the structural aspects of integration, there is a growing recognition of the vital role played by social features, particularly interpersonal collaboration of HCWs and patient perception of care.[259] These social aspects of care consistently correlate with improved health provider experience, perceived quality of care, and clinical integration.[259,260]

No criteria achieved consensus aligning with the WHO pillar on Health Information Systems. Notably, the criteria that could align with this pillar were deemed *important but not critical*, garnering between 50% and 69% of the votes. These include the implementation of an M&E framework, the establishment of a national health information system integrating data for all diseases, and the integration of information systems utilizing a single registration form.

7.6 Limitations

While valuable, the Delphi methodology has acknowledged limitations in representativeness,[248,261,262] particularly since the selected experts may hold specific viewpoints or agendas, limiting the generalisability of the findings. For instance, the lack of consensus on the M&E domain in this study might reflect the background knowledge of experts not working in M&E field.

The Delphi approach does not rely on a large sample size for confident outputs.[248,263] This Delphi study aimed to gather input from a diverse range of experts across industry, academia, government, and health services to ensure a broad spectrum of perspectives. The 55 experts who participated were based in 23 different countries with working experiences in a combined 59 other countries within the health sector and working directly on diagnosis or integrated health care. They also represented different professions as implementers, policymakers, or researchers in the field. As such, the core criteria presented are not based on views from a single professional constituency, healthcare system, or country. Most of the experts are based and have experience in LMICs, particularly in Africa, where this study is most relevant. Still, further studies to verify and refine the results in different or extended groups of participants should be considered.

Despite these limitations, Delphi studies remain a valuable method for achieving consensus in situations where face-to-face interactions are impractical, and the collective judgment of experts is essential.

7.7 Implications of findings and Conclusion

The study introduces 18 core criteria crucial for prioritising integrated diagnosis interventions, offering invaluable guidance to policymakers, funders, implementers, and manufacturers in LMICs. The overarching objective is to enhance patient experiences and health outcomes. Emphasis is placed on ensuring that essential elements for success are thoroughly considered

during intervention design. Moreover, the study advocates against a narrow focus solely on diagnosis, urging for a holistic approach that considers the full needs of the patient and integrates with other components of the broader healthcare system.

7.8 Chapter 7 Summary

This chapter presents the findings of a Delphi study consisting of two rounds of online surveys.

- The first round included 55 experts, while the second had 48 participants, representing a diverse group of policymakers, implementers, researchers, and academics. Geographically, 60% of the participants were from LMICs, 31% from Europe, and the remainder from the USA and Asia.
- Consensus was defined as achieving at least 70% agreement among participants. A criterion was included if this level of agreement was reached on its classification as critical to include.

A total of 18 criteria across various domains were identified as critical for inclusion. These criteria include:

1. A system to coordinate donors
2. Strong leadership, with shared vision and support for integration
3. National policy or guidelines for integration
4. Diagnostic algorithms or screening tools for integration
5. Operational functionality of the diagnostic algorithms
6. Clear and specific funding
7. Funding for training
8. Community awareness, demand, and acceptability of the diagnostics

9. Sufficient physical space for private examinations
10. Training on patient-centred care
11. Training on diagnosis and follow-up counseling,
12. Training on interpersonal collaboration
13. Clear roles assigned to each HCW at the facility.
14. Functional referral mechanisms to access other diagnostic services.
15. Clear patient pathways to guide the patient through different services.
16. Follow-up mechanisms of patients who need to access referral services
17. All Technical conditions for the instrument to function are met
18. Treatment or clear referral pathway

7.9 Personal Reflections

Several criteria I initially assumed to be critical turned out to be considered merely important. For example, I had always regarded the presence of global or WHO guidelines as essential—particularly in global health, where having evidence incorporated into a WHO guideline is a significant milestone. While these guidelines were still seen as valuable, they were not deemed critical for implementation. Instead, experts emphasized that national guidelines and policies played a much more central role in practical application. In fact, algorithms and screening protocols were considered even more crucial, underscoring the need to translate global guidelines into national policies to enhance their relevance and usability.

Another criterion that was considered important, rather than critical, was the existence of policies allowing full use of diagnostics at the PHC level. This varied across countries due to restrictions

on what healthcare workers at lower-level facilities were authorised to do in terms of testing and diagnosis.

Additionally, I was surprised that integrated information systems and a robust M&E framework—with measurable indicators for intended outcomes and a single national-level reporting system—were not considered critical. As an M&E professional, I initially found this disappointing. However, experts pointed out that complex M&E processes often place a significant burden on healthcare professionals, diverting time and resources from actual service delivery. While M&E remains important, there is a need to streamline reporting processes to improve efficiency.

Chapter Eight

Experiences of the utilisation of integrated diagnostic services for maternal health care: A case study of Mabvuku Polyclinic in Harare, Zimbabwe

"I don't mind waiting, as long as I get all the care I need in one day".

8. Experiences in the utilisation of integrated diagnostic services in maternal health care: A case study of Mabvuku Polyclinic in Harare, Zimbabwe

Publication Statement

The results from this study have been accepted for publication in the following peer reviewed journal:

Gwaza GP, Zhou DT, Plüddemann A, Heneghan C. Use of integrated services in antenatal care: A case study of Mabvuku Polyclinic, Zimbabwe. African Journal of Primary Health Care & Family Medicine. 2025 May 30;17(1):e1-e13. doi: 10.4102/phcfm.v17i1.4847. PMID: 40459110; PMCID: PMC12135723.

Reuslts were also presented at the DPhil in Evidence Based health Care Summer School at Oxford University in September 2024

8.1. Chapter Aim and Objectives

One of the challenges identified in the realist review (Chapter 6) is the limited research on patient experiences. This study aims to address that gap by examining the experiences of healthcare providers and pregnant women in accessing integrated diagnosis services during antenatal care services in Zimbabwe. Moreover, the Delphi study (Chapter 7) established prioritised core criteria for successful integration. The qualitative study further confirms these criteria by assessing their relevance and application in real-world settings.

Addressing diagnostic gaps for key conditions such as diabetes, hypertension, HIV, tuberculosis, hepatitis B virus infection, and syphilis could avert approximately one million premature deaths

annually in LMICs[6]. Antenatal care provides a unique opportunity for these diseases to be diagnosed in an integrated manner, aligned with WHO recommendations for maternal and child health[6] . In Zimbabwe, maternal health services integrate diagnosis for these conditions during antenatal care visits, ideally conducted within the first 12 weeks of pregnancy.[264] Integrated diagnosis transforms health systems into patient-centric structures, moving beyond a disease-centric approach.[3]

8.2 Background

8.2.1 Zimbabwe's Healthcare System

Zimbabwe's health service delivery system is structured across four levels: primary, secondary, tertiary, and quaternary. Primary health care serves as the main framework for implementing health care programmes, encompassing maternal and child health services, health education, nutrition education, food production, immunisation programmes, infectious disease control, water and sanitation, essential drugs, and basic preventive and curative services.[265] Health services in Zimbabwe are integrated at the service delivery level, with each facility offering a full range of curative and preventive services, including maternal and child health and family planning.

The public sector, primarily through the Ministry of Health and Child Welfare (MoHCW), is the main provider of health services in both rural and urban areas of Zimbabwe. This public healthcare system is complemented by the private sector, which includes for-profit entities such as private hospitals, maternity homes, general practitioners, and not-for-profit organisations such as church-run mission clinics and hospitals. Zimbabwe is divided into ten provinces, with Harare and Bulawayo functioning as cities with provincial status. In Harare, healthcare services are delivered at two levels: primary healthcare centres managed by the Harare City Council and tertiary and quaternary care facilities overseen by the MoHCW. Consequently, Mabvuku Polyclinic operates under the jurisdiction of the Harare City Council.

8.2.2 Maternal Health Services in Zimbabwe

Maternal and neonatal health services are a key priority within Zimbabwe's healthcare system,[265] with various donors providing significant support across multiple facilities. Despite these efforts, access to maternal health services remains a significant challenge, particularly for women of lower socioeconomic status.

To address this, Zimbabwe has adopted a 'supermarket approach,' also known as the facility integration model,[265] which integrates maternal and neonatal health services within a single facility or co-located setting. This strategy offers a comprehensive range of services in one centralized location, ensuring convenience and accessibility for service users.[244]

Zimbabwe has made some progress in maternal health, with maternal mortality rates showing a positive decline from 570 per 100,000 live births in 2010 to 363 per 100,000 live births in 2015 and 357 per live births in 2020.[265,266] Despite these encouraging trends, the current maternal mortality rates remain high, underscoring the need for continued efforts to improve maternal health outcomes. Enhancing access to quality maternal health services, particularly for economically disadvantaged women, and addressing barriers to 'adequate' antenatal care are critical for sustaining progress in this area.

In terms of child health, Zimbabwe's under-5 mortality rate was 69 deaths per 1,000 live births between 2010 and 2015. The infant mortality rate decreased to 37 deaths per 1,000 live births in 2020, with 70% of these deaths occurring during infancy.[267] The neonatal mortality rate was 29 deaths per 1,000 live births, indicating that about 40% of childhood deaths occur within the first month of life,[268] emphasizing the critical need for targeted interventions during the pre and post-natal period.

The health care services mothers receive during pregnancy, childbirth, and the immediate post-natal period are crucial for the survival and well-being of both mothers and infants. In Zimbabwe, 94% of women attend at least one antenatal visit, demonstrating a high level of engagement with

maternal healthcare services. However, the percentage drops to 76% when considering the number of women who receive 'adequate' antenatal care, defined as attending at least four prenatal visits.[265] Among those who access antenatal care, 98% had a blood sample taken, 97% had their blood pressure measured, and 68% had a urine sample taken. For neonatal tetanus protection, 54% of women who gave birth had received sufficient tetanus toxoid injections.[268] These statistics underscore the importance of improving the quality and accessibility of maternal healthcare services to ensure better outcomes for both mothers and their infants.

8.2.3 Integrated diagnosis services

Diagnosis represents a critical gap in the healthcare continuum, with significant potential to enhance overall health system performance.[6] In Zimbabwe, the antenatal care protocol prescribes a comprehensive set of laboratory tests during the initial contact with a health facility, ideally within the first 12 weeks of pregnancy.[264] These tests include pregnancy testing, HIV testing (with CD4 count or viral load for those already positive), syphilis testing, and, when presumed, tests for TB and malaria.[264] The integrated diagnosis model aims to deliver these tests in a single visit with same-day results.

Strengthening diagnostic adherence during antenatal care is directly linked to addressing leading causes of maternal and infant mortality in Zimbabwe. For mothers, complications such as postpartum haemorrhage, sepsis, hypertensive disorders (including preeclampsia and eclampsia), and anemia are often preventable through early detection. Routine full blood count and urine analysis can identify anemia and hypertensive disorders; syphilis and HIV testing enable timely treatment to prevent infection-related complications; and Rh factor determination prevents hemolytic disease of the newborn. For infants, consistent maternal diagnostics reduce vertical transmission of HIV and syphilis, mitigate low birthweight and preterm birth risks, and improve neonatal survival by identifying high-risk pregnancies early.

Despite these established protocols, adherence by healthcare workers remains inconsistent. Tests such as a full blood count, Hepatitis B screening, urine analysis, blood grouping, rhesus factor determination, and ultrasound scans[269] are not consistently performed. These missed opportunities reduce the ability for early detection and management of potential health issues during antenatal visits, which can result in complications later in the maternal health journey. A more structured, integrated diagnostic approach—ensuring that all prescribed tests are administered and results acted upon during antenatal visits—could substantially reduce maternal and neonatal morbidity and mortality in Zimbabwe. This requires not only improved access to diagnostics but also strengthened training, supervision, and governance mechanisms to ensure adherence to national protocols.

8.3 Study Rationale

While several studies have explored patient experiences within integrated healthcare more broadly, fewer have focused specifically on integrated diagnosis.[45] Given that the primary objective of integrated health care is to improve patient experiences and health outcomes,[3,125] it is essential to dissect how these interventions function and how they can be optimised to achieve their goals. A human-centred problem-solving approach is advocated to strengthen health systems, emphasising the importance of considering the perspectives of end-users. This approach ensures that healthcare solutions are tailored to meet the needs and preferences of those utilizing the services, recognizing health systems as socially constructed entities.[173] Understanding the views and perceptions of healthcare workers and women regarding integrated diagnosis is critical for informing the most effective strategies for designing and implementing interventions that align with the expectations and needs of those directly involved in the healthcare process.

Maternal health serves as a robust proxy for understanding the complexities of healthcare delivery. In many LMICs, integration initiatives often build upon existing programmes, particularly

those focused on HIV or maternal health services.[36] The maternal health programme provides a valuable framework characterized by regular interactions with the health system at least four times during pregnancy. These frequent, structured touchpoints present an ideal opportunity to integrate additional health services. Making maternal health an exemplary case study. Insights gained from this context are not only relevant for improving maternal health but also have the potential to be transferable and applicable to other healthcare programmes in similar settings.

8.4 Methodology

8.4.1 Study Design

This is a qualitative study using a case study methodology rooted in postpositivist critical realist thinking, which focuses on understanding individual experiences to gain insights into external reality.[270] The study also applied human-centred design thinking to design interview questions, focusing on ideal scenarios and future models for intervention design. This meant participants were asked about their experiences as well as the ideal scenario for them, ensuring an empathetic, bottom-up strategy that includes participants perspectives to improve intervention delivery.[173] The study aimed to explore the experiences of healthcare workers and pregnant women in accessing integrated diagnosis services within the context of antenatal care at Mabvuku polyclinic. Appendix 13 provides the protocol for the study.

8.4.2 Study Setting

Mabvuku Polyclinic, located 22 km from Harare’s central business district (CBD), serves over 500,000 people, including residents of expanding high-density suburbs, such as Caledonia and Bobo Farms.[271] It offers various services, including general outpatient care, maternal and child health services, HIV counseling and testing, TB care, and laboratory services. In 2016, the clinic's

maternal health unit was upgraded to provide cesarean sections, reducing referrals to secondary and central hospitals.[271]

Before 2015, the clinic conducted about 3000 antenatal checks and 1000 deliveries annually.[271] Following the upgrade, this increased to 5,000 antenatal checks and 3,000 deliveries, with a 40% reduction in referrals to Harare Central Hospital. However, all complicated deliveries are still referred to the central hospital, and many women with anticipated complications bypass Mabvuku's maternity services, opting for direct care at Harare Central Hospital.

8.4.3 Study population

Two groups of people were targeted: healthcare providers and pregnant women accessing antenatal services.

Inclusion and Exclusion criteria

Healthcare providers: Inclusion criteria included being 18 or older, qualified as midwives, nurses, laboratory technicians, or doctors, and providing informed consent.

Pregnant women: Inclusion criteria included confirmed pregnancy, age 18 or older, actively receiving antenatal care at the clinic, and providing informed consent. No restrictions were based on literacy level, occupation, or other socio-demographic characteristics.

There are no exclusion criteria other than meeting the inclusion criteria.

8.4.4 Sampling strategy

Healthcare workers were purposively sampled based on roles and availability, with help from facility officials and the Harare City Council Department of Health, for maximum variation and to ensure targeted insights were gathered to "saturation".[272] Snowball sampling techniques were also used to seek referrals.

Pregnant women were recruited via health education announcements and randomly selected from those exiting or waiting for results. Every third pregnant woman meeting the criteria was invited, with non-qualifying women replaced by the next. Participants were briefed on the study's purpose, and informed consent was obtained via signed forms in Shona or English.

8.4.5 Data Collection

Two main data collection tools were used: an interview guide for healthcare workers and another for pregnant women. The questions were developed based on core criteria for integrated diagnostic interventions, designed using a Delphi study[273], in Chapter 7.

The interview guide for pregnant women focused on access to services, timeliness of care, relationships with healthcare workers, and challenges and recommendations for service delivery. To ensure clarity, the questions were piloted with two community members outside the facility.

The interview guide for healthcare workers was structured around the six WHO health system pillars: leadership and governance, service delivery, health workforce, information systems, health commodities, and financing. A local researcher translated these questions into Shona, the local language.

In addition, an observation checklist was used to assess key service delivery metrics, including waiting times, ease of patient access, patient pathways, healthcare worker behaviour, and general facility processes, such as the registration process.

Semi-Structured Interviews: These were conducted with healthcare workers and pregnant women using tailored guides. At least 30 interviews were planned: 10 with healthcare workers and 20 with pregnant women. Thirty-two interviews were conducted (10 healthcare workers and 22 pregnant women). The interviews lasted 20–30 minutes and were conducted face-to-face in Shona or English.

Observation: Two weeks were spent observing antenatal visits, registration processes, waiting dynamics, and reporting tools. A checklist guided the observations, and building rapport minimised the observer effects.

8.4.6 Data management and analysis

Interviews were audio-recorded and transcribed orthographically, preserving speech patterns like hesitations, pauses, and emphases. Non-essential words were removed for clarity while maintaining meaning.[274] Personal identifiers were excluded except for relevant organisational references. Transcripts were anonymized and assigned numerical codes (e.g., Participant 1–22 and Healthcare worker as HCW 1-10). Accuracy and completeness were rigorously checked.

The audio files and transcriptions were securely stored on password-protected OneDrive for Business within Oxford University's Nexus365 platform, while physical consent forms were kept in locked cabinets. Data retention follows university policy, ensuring storage for at least three years post-publication.

Qualitative data analysis was performed using NVivo (Version 14) software, employing thematic analysis to identify patterns across the data set. This method, suitable for interpreting qualitative data, used a primarily deductive approach, deriving initial codes and themes from pre-existing concepts, with a few new codes emerging from the data content.

The analysis adhered to the six-phase approach outlined by Braun and Clarke.[274] Although presented linearly, thematic analysis is inherently a recursive process.[270] The researcher constantly revisited earlier phases as new data or themes emerged, refining and adjusting the analysis accordingly.

Phase 1: Familiarising yourself with the Data - This phase involved listening to the audio recordings multiple times and reading and re-reading the transcripts at least twice to gain a comprehensive understanding of the content.

Phase 2: Generating Initial Codes—The data was coded with initial codes picked directly from the data, such as "trust the nurses" and "frustrated with waiting." These codes were designed to capture key aspects of the data.

Phase 3: Searching for Themes - Initial themes were identified based on prior research, focusing on the WHO building blocks for health systems such as "leadership and governance," "service delivery," "access to essential medicines (and diagnostics)," "financing," and "health information systems." Additional themes emerged during analysis, such as patient challenges, such as hunger and healthcare worker challenges, such as resource shortages.

Phase 4: Reviewing Themes - This phase involved refining themes to ensure they were distinct and accurately represented the data. Themes were organised within an overarching conceptual framework to ensure coherence and relevance.

Phase 5: Defining and Naming Themes - Themes were further refined and defined to ensure they were unique and specific. This phase also involved interpreting the themes and integrating them into a broader narrative framework.

Phase 6: Producing the Report—The final phase involved crafting a compelling report based on the analysed data that addressed the research objectives.

8.4.7 Ethical Considerations

The study did not provide direct individual benefits to the healthcare workers who participated. Women who chose to participate received USD 5 to cover their transport expenses, given at the end of their involvement. The study was classified as minimal risk, with no expected harm or discomfort beyond what is encountered in daily life or routine physical/psychological tests. Participants' tests were self-reported, and no medical records or sensitive health information, such as consultations or patient records, were reviewed or collected.

Ethical approval was granted by the Oxford Tropical Research Ethics Committee (Reference: 520-24) and locally by the Ethics Committee under the oversight of the Director of Health Services, City of Harare, on 27 February 2024. (Appendix 11 and 12)

8.5 Results

8.5.1 Demographic Details

Twenty-two women and ten healthcare workers were interviewed. All the participating women were pregnant and attending antenatal checkups. Among them, thirteen were visiting for the first time, six for their second or third visit, one for treatment, and one for a baby scan. The average age of the women was 27 years, with ages ranging from 18 to 36. On average, each woman had two children. Most women (16) had completed their compulsory ordinary-level education, and the majority (13) were unemployed. Only two women had higher education and worked as teachers.

The ten healthcare workers included two laboratory technicians, two primary care counselors, and six midwives' nurses. Among the midwives, three held leadership positions: sister-in-charge, district nursing officer, and acting matron. Four midwives had over fifteen years of experience at the facility, while two had nine years. Of the laboratory technicians and primary care counselors, one of each had been at the facility for one year, while the other had been there for at least five years. Only one HCW was male, a laboratory technician. Healthcare workers are referred to by their profession if needed to differentiate roles.

Table 20: Demographic details of the 22 women

Age	Frequency		Highest level of qualification	Frequency
18	1		Primary (Grade 7)	1
19	2		Form 2	1
20	3		Form 3	1
22	2		Form 4	16
23	4		Bachelors degree	2
27	1		Masters degree	1
29	2			
30	1		**Number of children**	
32	1		0	7
33	1		1	8
34	1		2	3
35	1		3	3
36	2		4	1
Profession			**Type of visit**	
Carpenter	1		1st antenatal visit	13
Cleaner	1		2nd visit for blood draw	3
Hairdresser	1		3rd visit for blood draw	3
Security guard	1		4th visit treatment	1
Teacher	2			
Unemployed	13		**How did you come to the facility?**	
Vendor	3		Kombi (public taxis)	16
			Walked	5
			Drove	1

8.5.2 Description of the Patient Journey

The interviews with the women were conducted either as they were leaving the facility after their services or while they waited for their blood test results, typically after 2 pm. The order of activities and processes varied among the women. On average, women went through nine stages, with a few additional stages for those presumed to have other conditions or who are HIV positive. Based on observations, each stage took a minimum of 10 minutes and up to thirty minutes per woman. Figure 11 illustrates the different stages in the patient journey.

Participants reported waiting outside the clinic upon arrival, spending an average of 8 to 10 hours at the facility. Based on observations and interviews, most women arrived between 5:00 - 7:30 am, with departures varying from 3:00 - 5:00 pm, depending on the services received and personal circumstances. (Table 20)

Table 21: Arrival time at the facility

Approximate time of arrival	5:00	6:00	6:30	6:45	7:00	7:30	8:00	8:30	8:40
Number of women	1	2	2	1	4	4	6	1	1

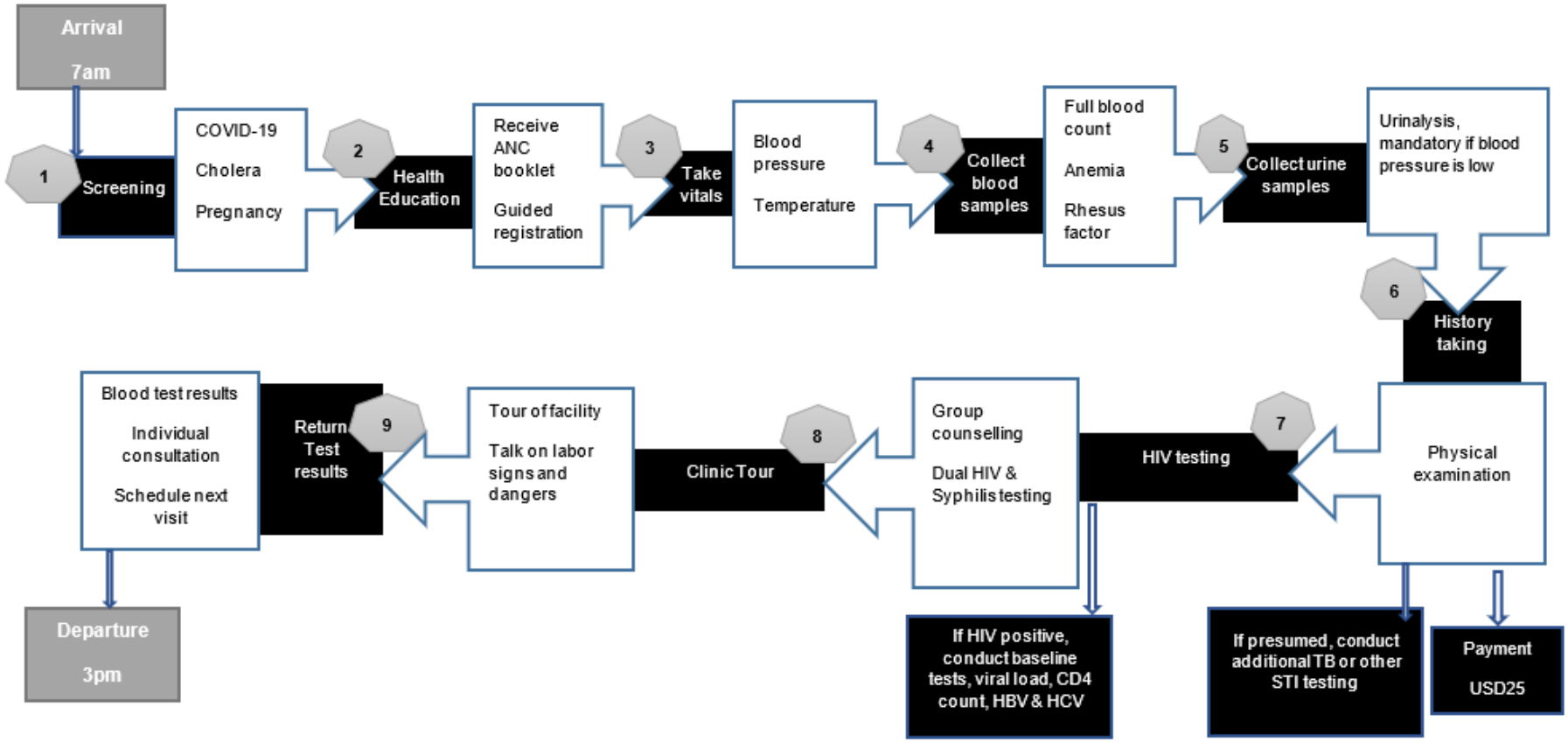


Figure 10: Patient Pathway at Mabvuku Clinic attending the first antenatal care /new booking

Women were served based on arrival time; no formal numbering system was used. COVID-19 and cholera screenings were reportedly not conducted during the study, although 14% of participants received face masks. By 8 a.m., women moved from outside benches to those within the clinic for health education sessions led by midwives. New bookings occurred from Monday to Wednesday, while repeat visits were on Thursdays and Fridays. Services were delivered in batches without individual numbering. Student nurses recorded vital signs (blood pressure and temperature), and antenatal booklets were provided for demographic information.

Midwives conducted consultations to assess medical history and symptoms. Confirmed pregnancies required a booking fee (USD25) for further services, including blood tests for full blood count, blood grouping, and urinalysis, followed by tetanus injections, group HIV counseling, and individual testing. Seropositive women were referred for treatment, with HIV viral load testing conducted if necessary. Women with a history of complicated pregnancies were referred to the central hospital. Women received a facility tour and health talks and reviewed results with midwives after a 4-hour wait. Scans were available for USD 10.

Once the results were available, each woman consulted individually with a midwife to review findings and receive prescriptions such as iron supplements for low blood counts. All participants were scheduled for their next antenatal checkup. Women accompanied by spouses, as with Participant 18, were prioritized to encourage male involvement in antenatal care and HIV and syphilis testing. Participants reported being served by at least two nurses.

8.5.3 Themes identified

Six themes were identified in the study- three from the pregnant women's perspectives and three from the healthcare workers' perspectives. A summary of the themes is provided in Table 21 below

Table 22: Summary of the main themes identified

	Themes identified
Experiences of the pregnant women receiving care	1. Preference for Integrated diagnosis despite long waiting times • Integrated diagnosis • Waiting time
	2. The participants considered respectful and dignified treatment by healthcare workers as a key measure of the quality of care. • Positive relationship between pregnant women and healthcare workers • Physical environment • Linkage to follow-up care
	3. There are hidden costs to integrated diagnosis • Cost of services • Hunger • Discomfort and Physical Strain
Experiences of the healthcare workers providing care	4. The ability to provide optimal care was hindered by a lack of resources and tools • Staff shortages • Lack of materials
	5. Effective diagnosis requires a complete continuum of care - testing, treatment, and follow-up.
	6. Fragmented donor support and inconsistent funding have disrupted effective service delivery, creating resource gaps and undermining care continuity.

8.5.3.1 Experiences of the women receiving care

Theme 1: Preference for Integrated diagnosis despite long waiting times

Integrated diagnosis

Mabvuku Polyclinic's antenatal clinic offered comprehensive, integrated diagnostic services, including full blood counts, anemia screening, and syphilis testing. Tests for the rhesus factor, crucial for preventing complications like hydrops fetalis and stillbirths, were unavailable during the study due to material shortages, though such issues are rare among African populations.[275]

Syphilis and HIV tests were conducted using dual rapid test kits managed by primary care counselors. Positive cases were referred to midwives, with HIV-positive women receiving further tests like viral load, CD4 counts, and hepatitis screenings. TB testing was provided for women with low CD4 counts. On-site laboratory machines supported diagnostics for TB, HIV, and other conditions, including simultaneous testing for TB, HIV viral loads, early infant diagnosis (EID) for HIV, and COVID-19.

Integrated diagnosis of HIV and syphillis was carried out even without the dual test. According to HCW 1, when the dual HIV and syphilis test kits ran out at Mabvuku Polyclinic, syphilis testing was continued separately in the laboratory. Primary care counselors, primarily funded by the Global Fund for HIV testing, adapted to perform syphilis tests due to the dual functionality of the kits. Once the syphilis test kits were depleted, the counselors focused solely on HIV testing. Women who tested positive for either HIV or syphilis were encouraged to invite their spouses for testing. However, some spouses were resistant, leading counselors to collect contact details for follow-up during the woman's next antenatal visit. In addition to antenatal care, the clinic offered diagnostic services for TB, diabetes, and other STIs like gonorrhea. However, a shortage of glucometer strips during the research period meant that blood glucose testing was unavailable.

These diagnostic services were part of the broader integrated healthcare approach, serving antenatal clients and the wider facility population.

Previously, delays in test processing, often lasting weeks, hindered timely care. On-site testing addressed these delays, ensuring faster results. However, at least three women reported delaying their first antenatal visits, missing opportunities for early diagnosis.

Waiting time

At least three-quarters of the time spent at the Mabvuku Polyclinic was dedicated to waiting, particularly for blood test results. Women often waited between services, with the longest wait for test results averaging four to six hours. Participant 9 noted, "*Whatever they did to me and however long it took, they need to do the same for 30 other women after me. It took me 30 minutes to finish the HIV test, and I had to wait for the others to receive the same test*."

However, despite the extended wait, many women appreciated completing all services in one day. Participant 1 remarked, *"It's better to come and wait and have everything done in one day than to come back another day for results. It's like killing many birds with one stone."* Eight of the women agreed that it saved transportation costs and minimized the time taken off from work or childcare.

However, two participants expressed frustration with the long wait time. Participant 3, a teacher, shared that she was unprepared for the long delay. According to Participant 3, "*It's my first time, maybe because I wasn't aware that it took such a long time when I came in the morning at 8 o'clock, I thought they would just check me, and I leave. But they had to take my blood and send it to the lab, and we had to wait for the results, which were delayed and only came out after 1 pm. So that was my main challenge because I was hungry and sitting on the bench for a long time*

was painful. The waiting part is a challenge, but maybe if I had known that I would have to wait, the experience might have been better." Despite this, she recognized the overall benefit of completing all services in one visit.

Theme 2: The women considered respectful and dignified treatment by healthcare workers as a key measure of the quality of care provided.

The theme of quality of care encompasses the overall patient experience through several crucial aspects. It includes the positive relationship between patients and healthcare workers, characterized by respect, kindness, and clear communication. It also includes the physical environment of the facility—such as privacy—and effective follow-up services, including timely results and clear guidance on the next steps and treatment.

Positive relationship between patients and healthcare workers

Women chose the facility for several reasons, including the positive attitude of the nurses, proximity to their homes, and comprehensive care. Positive feedback from friends and family influenced the choices of ten women. Six women selected the facility for its convenience and proximity, particularly in emergencies, though three of them planned to deliver at a private hospital. Woman 17, experiencing her first pregnancy, chose the clinic because it accepted first-time pregnancies, a service not offered by other clinics. Woman 22 preferred the facility for its expertise in handling complicated cases (even though the healthcare workers said that they referred all complicated cases), which she had encountered during her first pregnancy. Woman 13, who was visiting Mabvuku clinic for the first time, had this to say,

" *I am very happy with the services here. It's closer to my home, but I always thought the clinic would not offer many services. For my first pregnancy, I went to XX (a provincial hospital nearly 40km from her home), but the nurses' attitudes were terrible. To attend the antenatal visits, I had*

to wake up at 5 am to arrive by 7 am. I wish I had known they had such a nice facility here where I could deliver my baby."

Regarding healthcare worker attitudes, most participants (18 out of 22) reported positive experiences and feeling respected, dignified, and cared for. The midwives, affectionately called "mbuya" (grandmother), were praised for their motherly approach. Six participants appreciated their willingness to answer questions and offer guidance. Participant 13, for example, noted that a midwife encouraged her to ask questions for clarity. Participants felt well cared for, with no complaints about the staff's attitudes.

Twelve participants reported a clear understanding of the procedures, with midwives providing detailed explanations before and after each step, including blood draws and tetanus injections. They appreciated the midwives' efforts to explain the purpose of each action for their safety and that of their children. Participant 1 compared the experience favorably to her previous pregnancy at another facility, stating, "The way I was treated here is far much better."

However, two participants faced challenges with clarity. Participant 3 felt the midwives provided unclear explanations, merely directing her without context. "They were just saying come here, sit there and wait, get this injection." Given the many people, she also expressed reluctance to ask questions, fearing it would slow the process. She said, "There are too many people. They just want you to follow instructions so the line can move faster."

Figure 11: Participants describing their experiences with interaction with the health workers

Overall, participants trusted the midwives' expertise, relying on them to inform them of any issues. The trust was evident, as most participants (19) recalled only key procedures such as the HIV test, urine test, blood draw, and tetanus injection, while only four remembered the syphilis test. Two participants forgot certain tests but could refer to their booklets. Two noted that healthcare workers only explained positive results and the next steps. Four of them struggled to remember everything provided but trusted the healthcare workers to guide them on necessary steps, particularly regarding positive results. Participant 9 expressed this trust, saying, "I just trust that the nurses know what they are doing, and if there is a problem, they will tell me."

Despite overall positive feedback, four participants described feeling rushed, overwhelmed, or confused by the pace or manner of treatment. They attributed these feelings to the high patient volume.

- Participant 17 noted, *"Treatment was good, but they were rushing us a bit, which I can understand because we are too many people."*
- Participant 19 commented on the midwives' expectations, "*They just want you to be*

energetic, not dragging yourself or appearing weak. You have to make yourself strong."

- Participant 3 described the need to stay alert: "T*hey just urge you to be alert and know what's happening around you….not really rude but firm."*
- Participant 9 acknowledged the challenges healthcare workers face with a high patient volume, contrasting the care with private facilities: *"You cannot compare it with private care where there are fewer people."*

HCW reported mixed experiences in engaging with the women. HCW 9 and 10 reported that some women hesitated to open up despite their efforts to create a supportive and non-judgmental environment during HIV testing. Some women, aware of their status but not adhering to their treatment at other clinics, feared stigma or judgment, delaying disclosure until after extended discussions.

The positive and friendly demeanor was also noted during observations, as midwives were seen offering advice to pregnant women while carrying out their duties and interacting with one another. . Positive patient perceptions were attributed to several factors. Key among these was customer care training organised by the city council, involving all staff, including janitors and nurses. HCWs 4, 5, and 6 noted that reminders about patient rights, reinforced in morning briefings and through visible information sheets and posters, shaped a patient-centred approach. These materials also included feedback mechanisms deemed effective by HCWs.

HCW 4 emphasised maintaining a friendly demeanor, saying, " *I smile because it's because of patients that I get the little salary I have. If you're angry with the patient, you're in the wrong profession.*"

Figure 12: Patient charter on the wall in the waiting room of the clinic

Physical environment

The women appreciated the facility's efforts to maintain privacy and respect during their visits. Despite the high volume of patients, with usually around 30 women per visit, they valued the private consultations for sensitive matters. Critical stages of care, such as HIV testing, full-body examinations, history-taking, and test result discussions, were conducted in private rooms, ensuring confidentiality and a comfortable environment for personal health discussions. Although less sensitive procedures, like receiving injections and having blood drawn, were performed in a more communal setting with multiple women present at once (usually three at a time), the facility

effectively managed privacy during these critical aspects of care. The primary care counselors reinforced this commitment to privacy, noting that individual sessions for HIV and syphilis tests, typically lasting 25 to 30 minutes per woman, included thorough counseling and discussion. Despite the volume of patients, the counselor emphasised the importance of maintaining privacy during these individual sessions to ensure that women felt comfortable sharing their thoughts and concerns.

Linkage to follow-up care

Treatment for most conditions, including HIV and syphilis, was generally available. However, the availability of iron supplements was inconsistent. Three participants reported receiving prescriptions but were uncertain about the availability or purchasing of these supplements. HCW 5 and 6 observed that many women returned for follow-up visits with persistently low hemoglobin levels, often due to the intermittent supply of iron supplements, limiting effective anemia management.

Theme 3: There are hidden costs to integrated diagnosis

Integrated diagnostic services often come with hidden costs that can burden the women. Long waiting times resulted in discomfort, such as hunger and back pain from prolonged sitting. Participants had to bear extra expenses, such as paying for scans.

Cost of services

The antenatal care fee at the polyclinic was USD 25, covering all visits until delivery and the baby's first month of care. However, scanning services require an additional USD 10, a significant cost for many participants from the low-income community. While some opted for central hospitals

offering free maternal health services, they encountered mixed messaging. Although labeled "free," participants reported paying extra to expedite care, with one noting, "*It's free, but you have to pay something."*

Over half the participants (13) were unemployed. Financial constraints meant some delayed care, as in Participant 18's case, where she postponed her scan until she could raise funds. Three participants reported paying USD 5 extra to bypass daily limits, which healthcare workers could not confirm. The participants noted that such practices were subtle and not always apparent unless directly experienced.

Hunger

Hunger during the lengthy waiting process was a significant challenge for many participants (n=9). Participants often brought their own food or purchased meals from vendors outside the facility. Participant 14 highlighted the unpredictability of the process duration as a key concern. Participant 18 noted being delayed after leaving to find food, which disrupted her appointment schedule. Similarly, Participant 20 explained that stepping out for food risked losing her place in line, prolonging the wait. Even bringing a lunchbox was not a complete solution, as leaving to eat outside posed the same risk. She suggested hiring additional staff to reduce waiting times.

Discomfort and Physical Strain

Participant 17 attributed her back pain to the prolonged waiting time and sitting on hard benches all day. She remarked, "*They try to solve one problem but create many others. I'll probably leave more sick than I came. They need more nurses for faster service or to allow new bookings any day of the week."* The researcher observed women frequently standing, stretching, or walking to ease discomfort from back and leg pain.

8.5.3.2 Experiences of the Healthcare Workers Providing Care

Theme 4: The ability to provide optimal care was hindered by a lack of resources and tools

All the healthcare workers felt that their ability to provide integrated services was hindered by limited resources, particularly staff shortages and a lack of materials.

Staff Shortages

Mabvuku Polyclinic operates with only half the required staff, significantly straining its ability to provide integrated services. HCWs reported handling 30–50 women daily, leading to long waiting times and rushed procedures. Staff shortages forced HCWs to skip steps during peak times, increasing risks like missing breach detections during palpation. HCW 7 described working through lunch to ensure timely results, while HCW 4 lamented the "pain" of the overwhelming workload.

The scheduling system is intended to help with work planning. The clinic's schedule allocates the first three days for new bookings and the last two for repeat visits, but managing both groups' differing needs remains challenging. For instance, Participant 21 came on the wrong day and faced delays, illustrating scheduling inefficiencies.

While the HCC leadership acknowledges the staffing crisis, immediate recruitment of midwives is not feasible. The clinic also relies on contract nurses from other hospitals, but HCWs noted these arrangements are temporary fixes that are insufficient to address systemic shortages effectively. HCW 2 criticised these contract/locum nurses as wasteful and unable to understand the facility's long-term needs.

Staff shortages were also linked to low morale and retention rates hindered by little and delayed

salaries, and workers frequently sought better opportunities elsewhere. HCW 6 mentioned that she stayed because she had no other options or places to go. HCWs 4,5 and 6 also noted a lack of incentives, such as food packs, previously provided by organisations like the Red Cross.

According to HCW 6, *“Last time, the Red Cross gave us food packs and $50, which at least boosted the morale of the staff. When you are hungry and have no food at home, and you don’t have the ZIG (Zimbabwean gold currency) , and we have not received our salaries from march. What do you do? You resort to abusing materials.”*

Lack of materials

HCWs 4,5, and 6 identified severe material shortages that hindered the clinic's operational efficiency. Essential items, including infant radiant warmers, glucometers, specimen jars, syringes, and soap, were unavailable or dysfunctional. HCWs 7 and 8 also pointed out frequent breakdowns of laboratory equipment, such as the full blood count analysers, due to overuse, lack of maintenance, or missing cartridges.

The laboratory's conditions also exacerbated equipment failure; excessive heat and unreliable electricity impacted machines like the biochemistry analyser, which remained non-functional for two years. HCW 7 expressed frustration, saying, "*That machine has never worked because when it was installed, there was no electricity*."

Iron tablets were frequently unavailable, forcing HCWs to prescribe unaffordable alternatives, which led to persistent anemia among pregnant women, confirmed by three participants. HCWs also reported shortages of surgical materials, requiring patients to buy their own supplies. Critical test kits for HIV infection duration and rhesus typing were also missing, complicating newborn testing in the labor ward.

Low salaries exacerbated issues, leading to theft and misuse of resources, as some staff sold medications or used them personally. HCW 4 lamented, "*Low salaries lead to abuse... A cow must graze where she is tied*."

Donor dependency was highlighted, with HCWs suggesting charges for materials to ensure sustainability. Vandalised oxygen pipes, an unfueled generator, and a single functional BP machine symbolised the clinic's resource constraints. Despite its modern infrastructure, HCW 3 emphasized better maintenance and reliable supply chains to overcome Zimbabwe's broader economic challenges and sustain operations effectively.

Theme 5: Effective diagnosis requires a complete continuum of care - testing, treatment, and follow-up.

Limited resources, including the unavailability of anemia treatments and logistical barriers, delay care and compromise patient outcomes.

The clinic, upgraded to perform elective cesarean sections, lacks a resident doctor and refers complicated pregnancies to hospitals. While cesarean sections are scheduled weekly, only one or none are performed monthly.[271] Strict adherence to Ministry of Health protocols, requiring referrals for conditions like pre-eclampsia or diabetes, even when manageable by nurses, further delays care. HCWs 2 and 3 reported that nurses occasionally deliver babies with complications before ambulances arrive.

Referrals are hindered by ambulance accessibility. Private ambulances, costing USD 70–100, are unaffordable for most patients, while city ambulances, although more affordable and sometimes available on credit, are not consistently reliable. Participants expressed frustration, emphasising that emergencies should prioritize life over payments. Participant 19 noted, "*The nurses tell us to look for money to pay for the ambulance when the focus should be on preserving life*."

Theme 6: Fragmented donor support and inconsistent funding have disrupted effective care

Multiple partners, including the Global Fund, AIDS Healthcare Foundation (AHF), BRTI, Cordaid, Red Cross, and Zimbabwe Network for Health-Europe, fund different areas without cohesive integration. HCWs 7 and 8 reported that while the Global Fund supports HIV primary care counselors, AHF funds laboratory technicians, leaving gaps in critical areas such as internet access. For example, laboratory data transmission remains limited despite primary care counselors receiving data bundles, as these cannot be shared due to restricted allocations.

Unmet needs persist despite donor involvement. HCW 1 noted that equipment, such as UNICEF-donated blood pressure machines, sit unused due to fragmented supply chains. HCWs 2 and 3 highlighted stock shortages, often receiving "out of stock" responses for vital items with no clear inventory status at higher levels. When stock-outs occur, patients are often referred to private pharmacies or laboratories, incurring additional out-of-pocket expenses. These costs reduce uptake of diagnostic tests, particularly for vulnerable populations who may forego testing altogether.

This fragmentation has exacerbated workload disparities. Donor-funded staff often handle more tasks than city council-funded counterparts, causing resentment. As HCW 7 remarked, "*You do the work; you earn in USD*," reflecting frustration over inequitable pay structures.

Frequent staff absenteeism for donor workshops further disrupts operations. These workshops provide critical per diem for underpaid staff but leave the clinic understaffed. At the time of the study, the facility lacked substantive leadership, with only an acting matron. This leadership gap meant key issues were overlooked, diminishing care quality and efficiency.

8.6 Discussion

Mabvuku Clinic, a recently upgraded polyclinic, exemplifies the complexities of delivering effective maternal healthcare in resource-limited settings. Despite its improved infrastructure, significant barriers continue to hinder service delivery, reflecting common challenges faced in LMICs. The primary objective of this study was to explore the experiences of healthcare workers and pregnant women in accessing integrated diagnosis services within the context of antenatal care.

Six key themes were identified in the analysis—three from the pregnant women's perspectives and three from the healthcare workers' perspectives. Observations at the polyclinic confirmed the themes identified through the interviews, including challenges such as long waiting times, the positive relationships between women and the healthcare workers, complaints of hunger, discomfort and physical strain from extended waiting on hard benches and the burden on two nurses managing more than thirty women a day.

Pregnant women valued the integrated diagnostic services and respectful care provided by the nurses but faced hidden costs, including additional payments and difficulties caused by long waits. Healthcare workers highlighted systemic challenges such as inadequate resources, incomplete care continuity, and fragmented donor support. Frequent shortages of essential supplies, treatments, and diagnostic tools affected service quality, while fragmented donor contributions and inconsistent funding disrupted care delivery, creating resource gaps and breaking continuity.

The study highlights that robust healthcare systems—not just infrastructure—are essential for effective care. The results align with evidence from the Lancet Commission on Diagnostics, which found that at the advanced level of primary health care, HIV (65%) and malaria (62%) tests were the most readily available. However, key investigations recommended by WHO for antenatal care had variable but generally low availability, including syphilis testing (49%), urine dipsticks (52%),

hemoglobin testing (37%), blood glucose testing (32%), and ultrasound (12%) [6]. Using the WHO building blocks for health systems [42], which focuses on leadership and governance, financing, service delivery, workforce, medical technologies, and information systems, gaps in healthcare delivery can be identified and addressed. To facilitate the discussion, the experiences of the healthcare workers and pregnant women have been categorized according to these WHO building blocks. While integrated diagnosis aims to improve care delivery and health outcomes, achieving these outcomes requires cohesive systems and sustainable support .

Leadership and Governance:

Effective leadership and governance are vital for functional healthcare systems. Developing multi-disease policies and integrated guidelines can improve service uptake, as evidenced by antenatal guidelines at Mabvuku Clinic. However, many LMICs lack integrated testing policies, leaving separate frameworks for different diseases.[31,78] This gap hinders integration efforts. Weak policy operationalisation, common in resource-limited settings, leads to suboptimal implementation.[232] At Mabvuku Clinic, the absence of a substantive leader has created oversight and efficiency challenges.

Health Workforce:

Service delivery depends on a capable and adequately resourced workforce. The WHO emphasises that integration cannot be a substitute for addressing systemic resource gaps.[3] Expanding workloads without staff increase undermines service quality and staff well-being.[92] There are examples of interventions where healthcare workers have expressed concerns about increased workloads and pressure due to integration efforts.[16,102] In LMICs, asking HCWs to take on additional tasks without added compensation is particularly challenging unless these tasks are redefined as routine services. At Mabvuku, chronic understaffing—operating at half capacity—overburdens healthcare workers, increasing risks of errors and burnout. Locum nurses provide temporary relief but disrupt continuity and quality due to their limited familiarity with the clinic's

needs. Moreover, frequent absences due to donor-funded workshops, although beneficial for skills development, exacerbate shortages, compromising care delivery.

Addressing workforce gaps, ensuring equitable task distribution, and aligning staff capacity with service needs are vital to supporting integration. Without these measures, integrated interventions risk imposing undue strain on already stretched health systems.

Service delivery:

Service delivery is a cornerstone of effective health systems, requiring workforce capacity, timeliness, and positive interactions between healthcare providers and patients.[42,125] Timely care improves health outcomes for urgent conditions and allows patients to focus on other priorities. However, integration can inadvertently lead to inefficiencies, such as longer wait times, which frustrate patients and lower service uptake.[45,276]

Delays are a major challenge for integrated services. Studies, for example, from Zambia, show integration can lengthen wait times due to inefficient workflows.[241] While extended consultations allow for addressing multiple conditions, patients may avoid raising additional concerns to reduce delays for others.[212]

At Mabvuku Clinic, severe staff shortages result in women waiting up to eight hours, exacerbated by uncomfortable conditions. Yet, the convenience of multi-disease testing is highly appreciated. Respectful and compassionate midwives mitigate some frustrations, fostering trust and positive experiences. However, the high patient-to-nurse ratio can lead to rushed care and missed issues, increasing maternal and neonatal risks.

The quality of patient-provider relationships significantly influences patients' perceptions of care.[259] Feeling respected by HCWs is fundamental to how patients rate their overall experience [212]. Patients who perceive respect from HCWs are more likely to report positive healthcare experiences. Therefore, HCWs must receive training not only in clinical diagnosis but also in delivering integrated, patient-centreed care.

Although provider-initiated testing has been effective in increasing testing uptake [212], it does not always improve patient experiences. Power imbalances between providers and patients can make patients feel coerced into accepting tests. For instance, 29% of patients in a study reported difficulty refusing HIV testing by TB nurses, fearing negative repercussions.[102]

Health System Financing:

Funding is crucial for the success of integrated diagnostic interventions in LMICs. Many rely heavily on donor funding, but integration efforts can stall when certain conditions, such as non-communicable diseases, are not donor priorities.[94,230] While diseases like HIV benefit from significant donor support, the lack of funding for other areas undermines care.

Poor coordination of external funding often leads to fragmented services, inefficiencies, and demotivation among HCWs. In Uganda, for example, donor incentives during health campaigns caused HCWs to neglect routine services, jeopardizing sustainability when incentives ceased.[96,233]

At Mabvuku Clinic, financial constraints result in persistent resource shortages and inefficiencies. Critical equipment, such as blood pressure machines and laboratory analysers, is frequently unavailable. Patients face significant out-of-pocket costs for transport, food, and supplies, deterring care-seeking and creating confusion about the affordability of supposedly “free”

services. Despite multiple donors, fragmented funding and poor coordination exacerbate resource gaps and overburden staff, undermining morale and service delivery.

Access to Medical Products and Technologies:

Access to commodities is a significant barrier to integrated services in many LMICs. Frequent shortages of essential consumables and malfunctioning equipment significantly hinder healthcare delivery.[231,237] At Mabvuku Clinic, these issues are acute, with frequent shortages and malfunctions of essential items disrupting routine care. These shortages force healthcare workers to prioritise critical cases, compromising the efficiency and quality of care.

Health Information Systems:

High-quality evidence is crucial for effective integrated diagnostic interventions, requiring standardized reporting tools, such as templates and registers, to ensure accountability and comprehensive care.[244] Systems that prioritise all targeted diseases equally—without favoring donor-specific conditions—enable health workers to address diverse patient needs effectively.

At Mabvuku Clinic, challenges like poor connectivity and logistical barriers undermine the potential of these systems. These issues disrupt patient referrals, hinder follow-up tracking, and delay progress monitoring, reducing efficiency. Addressing these gaps is vital for optimising health outcomes and operational efficiency.

8.7 Limitations of the study

This qualitative study offers valuable insights but has limitations. Its findings are not generalisable to other settings due to the specific context of the Mabvuku Clinic. However, the study's primary goal was to provide transferable insights on integrated diagnostic services in maternal healthcare, which may inform similar contexts.

Another limitation is recall bias, as participants may not accurately remember all the details. To mitigate this, interviews were conducted shortly after health visits, and carefully designed questions minimized biases, such as acquiescence bias, ensuring a more accurate portrayal of participants' experiences.

8.8 Conclusion

The challenges at Mabvuku polyclinic emphasise the need for a comprehensive approach to strengthening the health system. Key priorities include addressing staff shortages, enhancing leadership, ensuring consistent funding, and maintaining essential medical supplies. The experiences of both healthcare workers and patients illustrate the importance of cohesive, well-supported systems for better health outcomes and patient satisfaction. Mabvuku Polyclinic serves as a reminder that robust healthcare requires more than infrastructure; it demands a strong workforce, efficient management, and reliable resources to meet community needs effectively.

8.9 Policy Implications

The Mabvuku study highlights several critical policy areas to improve integrated maternal healthcare services:

Staffing and Training: Policies must focus on recruiting and retaining skilled personnel to alleviate staff shortages and reduce waiting times. Continuous training should ensure healthcare workers stay updated on best practices and technologies.

Service Integration: Policies should prioritize fully integrated diagnostic services within maternal care. Co-locating diagnostic tests can improve efficiency and patient satisfaction. Ensuring consistent access to functional equipment and medical supplies is crucial for seamless service delivery.

Leadership and Governance: Effective management practices are essential for optimizing resources, maintaining equipment, and coordinating stakeholders. Policies should encourage

collaboration among donors, government bodies, and NGOs to reduce service fragmentation and align funding with healthcare priorities.

Patient-Centred Care: Policies must promote respectful, patient-focused practices by addressing barriers like hunger, comfort during waiting, and ambulance costs. Ensuring affordable or free maternal care services is vital while tackling corruption and improving healthcare worker compensation to prevent accessibility issues.

Data Utilisation and Monitoring: Strengthening health information systems is key to identifying gaps, monitoring patient outcomes, and guiding decisions. Policies should promote data-driven approaches to improve care delivery and policy effectiveness.

8.10 Chapter 8 Summary

This chapter presents a case study exploring the experiences of healthcare providers and women accessing integrated diagnostic services as part of antenatal care.

A total of 22 pregnant women were interviewed using a semi-structured interview guide. These women were randomly selected as they exited the healthcare facility. Additionally, 10 healthcare workers from various roles—midwives, nurses, lab specialists, primary care counselors, and leadership positions—participated in the study.

The women received integrated diagnostic services, including consultations for history-taking and medical history, full blood counts, blood typing, urinalysis, dual HIV and syphilis testing, and ultrasounds. HIV-positive women were further tested for viral load and CD4 count. Women with additional symptoms were tested for COVID-19, tuberculosis, or malaria.

Six key themes emerged from the interviews, reflecting the experiences of both the healthcare workers and the pregnant women:

For the Pregnant Women:

1. **Preference for Integrated Diagnosis Despite Long Waiting Times:** Women expressed a strong preference for integrated diagnosis, even though the process involved long waiting times.
2. **Respectful and Dignified Treatment:** The quality of care was strongly linked to respectful and dignified treatment by healthcare workers, including positive relationships with healthcare providers, the physical environment, and smooth linkage to follow-up care.
3. **Hidden Costs:** Women identified hidden costs related to integrated diagnosis, including the costs of services, ultrasound, hunger, discomfort, and physical strain.

For the Healthcare Providers:

- **Resource Limitations:** Healthcare providers reported that their ability to offer optimal care was hindered by a lack of resources, tools, staff shortages, and inadequate materials.
- **Complete Continuum of Care:** Effective diagnosis was seen as requiring a comprehensive continuum of care, including testing, treatment, and follow-up services.
- **Fragmented Donor Support:** Providers noted that fragmented donor support and inconsistent funding disrupted service delivery, creating resource gaps and undermining the continuity of care.

8.11 Reflexivity Statement

This research was conducted in my country, where I have lived and worked for many years. As a mother of four, I have direct experience with antenatal care and the public health system, having accessed follow-up care during my pregnancies. These personal experiences have shaped my

understanding of the healthcare system, allowing me to easily relate to the pregnant women in this study and empathise with the challenges they faced. Throughout the interviews, I remained aware of how my personal experiences could influence my approach to the research. While I made a conscious effort to set aside these biases, I was mindful of how my empathetic connection could deepen my understanding of the participants' experiences. I continuously reflected on my role as a researcher to ensure that the voices and perspectives of the women were central to the study and that I maintained objectivity.

In addition to interviewing the women, I also spoke with healthcare providers, many of whom expressed frustration with the broader macroeconomic challenges facing Zimbabwe—issues I had also encountered. They highlighted resource shortages, staff constraints, and the general strain on the healthcare system, all of which resonated with me on a personal level. These shared frustrations added complexity to my reflections, as I had to balance my empathy for the healthcare workers' struggles with my objective role as a researcher. Throughout the data collection process, I remained conscious of these shared experiences to ensure that they did not unduly influence my interpretations or interactions with participants. I discussed the findings with other external people, such as my supervisors at the University of Oxford and collaborators at the University of Zimbabwe, to ensure that my personal biases did not overly colour my interpretations.

Chapter Nine

Integrated diagnosis Framework and Facility Readiness Assessment Tool

9. An Integrated Diagnosis Framework and Facility Readiness Assessment Tool

Publication Statement

The integrated diagnosis framework has been published as part of the discussion of the results of the Delphi study in Chapter 7.

Gwaza, G., Plüddemann, A., MacBain McCall, M. *et al.* Criteria for designing integrated diagnosis interventions in low resource settings at the primary care level: a Delphi consensus study. *BMC Health Serv Res* **25**, 1130 (2025). https://doi.org/10.1186/s12913-025-13114-9

9.1. Chapter Aim and Objectives

This chapter synthesises the findings from the previous chapters and builds upon the Delphi (Chapter 7) and qualitative (Chapter 8) study to develop a framework for integrated diagnosis based on the prioritised criteria. Additionally, it presents a facility readiness assessment tool for the introduction of multi-disease testing technologies at PHC level. No single framework or assessment tool is appropriate for all countries or PHC facilities, but this can provide guidance to use evidence to make decisions for individual contexts.

9.2 Introduction

There is broad consensus on the feasibility and benefits of integrated diagnosis across various settings and healthcare levels. Recent initiatives, such as the triple elimination of mother-to-child transmission of HIV, syphilis, and hepatitis B, alongside persistent gaps in mortality targets from undiagnosed advanced HIV and coinfections, the rise in comorbidities and NCDs, and advances in multipurpose diagnostics, have highlighted the need for integrated approaches. Additionally, improving surveillance during outbreaks further strengthens the case for integrated diagnosis..

However, implementing integrated diagnosis effectively, especially in LMICs, remains challenging. While integrated diagnosis interventions have improved service uptake in many instances, they have not always led to significant improvements in health outcomes or patient experiences. Offering integrated diagnosis at the primary care level, with same-day results, holds the potential to transform health outcomes by enabling early diagnosis of multiple conditions, facilitating faster linkage to treatment and care, and enhancing overall service convenience. In many LMICs, primary care serves as the main entry point into the healthcare system and the foundation for programme implementation.

This thesis focuses on integrated diagnosis at the PHC level, which involves identifying multiple diseases or conditions during a single visit, with test results delivered the same day. It excludes integrated diagnosis at higher levels of care, as well as laboratory or sample integration. At the primary care level, integrated diagnosis can be achieved through co-located services, healthcare workers performing multiple diagnoses, or through technological integration using point-of-care or near-point-of-care dual or multiplex diagnostic tools. This chapter presents an evidence-based framework that provides a practical guide for policymakers, funders, and implementers to design and implement effective integrated diagnosis interventions at the primary care level.

9.3 Methods

Building on Chapter 8 of the Delphi study, the list of 18 core criteria was used to draft the initial framework. In addition, the qualitative case study in Chapter 9 was used to confirm some of the criteria. To refine the framework further, additional input was sought from experts working with Unitaid, FIND, the University of Oxford, WHO, and other individual consultants.

9.4 The Integrated Diagnosis Framework

Neglecting critical elements of integration has led to failed interventions.[212,276] This framework serves as a checklist for policymakers and implementers, ensuring essential components are considered. It also informs the necessary trade-offs in decision-making.

The framework is grounded in integration theory [234] and the WHO health systems pillars.[42] While individual criteria like expanding diagnostic algorithms or dual testing for HIV and syphilis can increase coverage and reduce costs, they do not automatically improve health outcomes or patient experiences. Meaningful improvements require incorporating all prioritised factors, such as linkage to care, patient pathways, and service acceptability.

Healthcare integration can be understood across five dimensions, system, functional, normative, interpersonal and process integration. These dimensions align with different levels of the health system. Specifically, system and functional integration are most relevant at the system or programme level, while interpersonal and process integration operate primarily at the facility level. Normative integration cuts across both levels, shaping shared values and culture. The relationship between these dimensions and their levels of relevance is summarized in Figure 14.Structural integration involves physical, financial, or legal connections such as shared infrastructure, financial resources, or centralized management.[234] Functional integration involves formal protocols and procedures for coordinated activities, improving system efficiency.[234] At the facility level, normative and interpersonal integration encompasses cultural values, teamwork, and collaboration among healthcare workers.[234,259] Process integration focuses on workflows and operational activities for seamless service delivery.

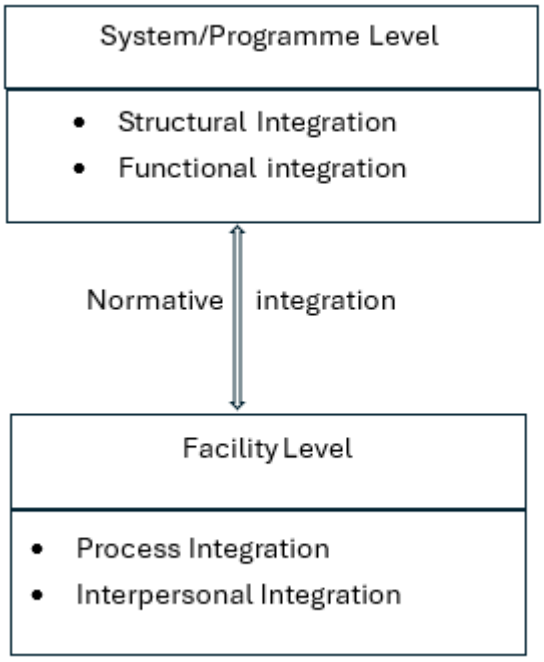


Figure 13 Dimensions of healthcare integration and their relevance across health system levels:

System/Programme Level Structural Integration

Political support and policies promoting multi-disease strategies are foundational to structural integration. For them to be effective, global guidelines from organisations like WHO must be translated into actionable national policies.

Health financing is crucial in LMICs, where external funding often supports health budgets. Effective coordination of donor funding is essential to avoid duplication, service fragmentation, and systemic confusion.

System/Programme Level Functional Integration

Once these structural elements are established at the programme level, they can facilitate functional integration. This involves developing diagnostic algorithms that align with multi-disease guidelines, such as those outlined in the IMCI, and ensuring the availability of appropriate diagnostic tools tailored for effective diagnosis.

Functional integration can include developing diagnostic algorithms aligned with multi-disease guidelines and ensuring the availability of appropriate diagnostic tools. For each diagnosis, it is crucial to establish clear treatment or disease management pathways, along with referrals that grant access to essential medications. In many LMICs, challenges often arise due to a lack of supplies and consumables for diagnostic tests, weak referral pathways, and inadequate infrastructure for integrated care. Essential elements such as a reliable power supply, air-conditioned rooms, and proper storage facilities are vital for successful implementation.[123] The term infrastructure is used here in two ways: first, the physical infrastructure needed to support diagnostic investigations, including space, power and water supplies, and equipment; and second, the operational infrastructure, including management systems, supply chain, and information technology

Facility Level Normative and Interpersonal Integration

Normative and interpersonal integration ensure facility-level practices support integrated diagnosis. Patient-centred care is essential for positive patient experiences. Local leadership must champion integration, fostering a culture valuing integrated services at primary care facilities. This often-overlooked factor is critical for success.[259]

Interpersonal integration relies on interdisciplinary collaboration among healthcare workers, requiring clear roles, practical diagnostic training, and patient-centred practices. Accepting and embracing integrated diagnostic approaches is crucial for healthcare teams. Resistance or lack of understanding among workers often leads to inconsistent implementation of protocols.[276]

When healthcare teams are fully on board, the potential for integration to improve patient outcomes increases significantly. Healthcare workers must be agreeable and accepting of integrated diagnostic approaches. Numerous interventions have failed because healthcare workers did not recognise the importance of the diagnostic processes, leading to inconsistent

application of algorithms and protocols. When healthcare teams are not fully on board, the potential for integration to improve patient outcomes diminishes significantly.

Facility-Level Process Integration

Process integration involves tailoring diagnostic workflows to specific facility needs. Operationalising new algorithms requires testing and monitoring to ensure effectiveness. Not all solutions function the same way across different settings, so each facility must assess how well the new algorithm integrates into their existing processes.[276]

On the patient side, demand creation through community education and health promotion is vital. When patients arrive at the facility—especially for co-located services—it is essential to establish a clear patient pathway. This ensures that patients understand what services they will receive and the processes they will follow. . Effective follow-up care systems, including health information systems for tracking referrals, are essential for continuity and better outcomes.

9.5 Facility Readiness Assessment Tool

To support facility-level implementation of integrated diagnostic interventions, a clear and evidence-informed decision-making model is required. The draft facility readiness assessment tool complements the broader integrated diagnosis framework (Figure 15) by translating its principles into actionable domains at the facility level. Its purpose is to help facility managers and implementers systematically assess readiness, identify strengths, and pinpoint areas needing improvement prior to introducing integrated diagnostic services.

The tool assesses six core domains—adapted from the conceptual framework but focused on facility-specific factors:

1. Governance and Leadership
    - Political will
    - Availability of integration policies and guidelines

- Existence of a donor coordination systems

2. Financing
    - Funding for diagnosis & treatment
    - Funding for continued training
3. Access to essential medicines and diagnostics
    - Availability of fit-for-purpose diagnostic tools
    - Use of diagnostics algorithm
    - Presence of disease management pathway
    - Availability of medicines
4. Health workforce
    - Presence of a strong supportive local leader
    - Clarity of roles and responsibilities
    - Proportion of staff trained in integrated diagnosis of relevant diseases
5. Service delivery
    - Community awareness of services
    - Adequacy of physical space at the facility
    - Presence of a clear patient pathway
    - Effective linkage to follow-up care
6. Health information systems
    - Functioning referral tracking and follow-up systems

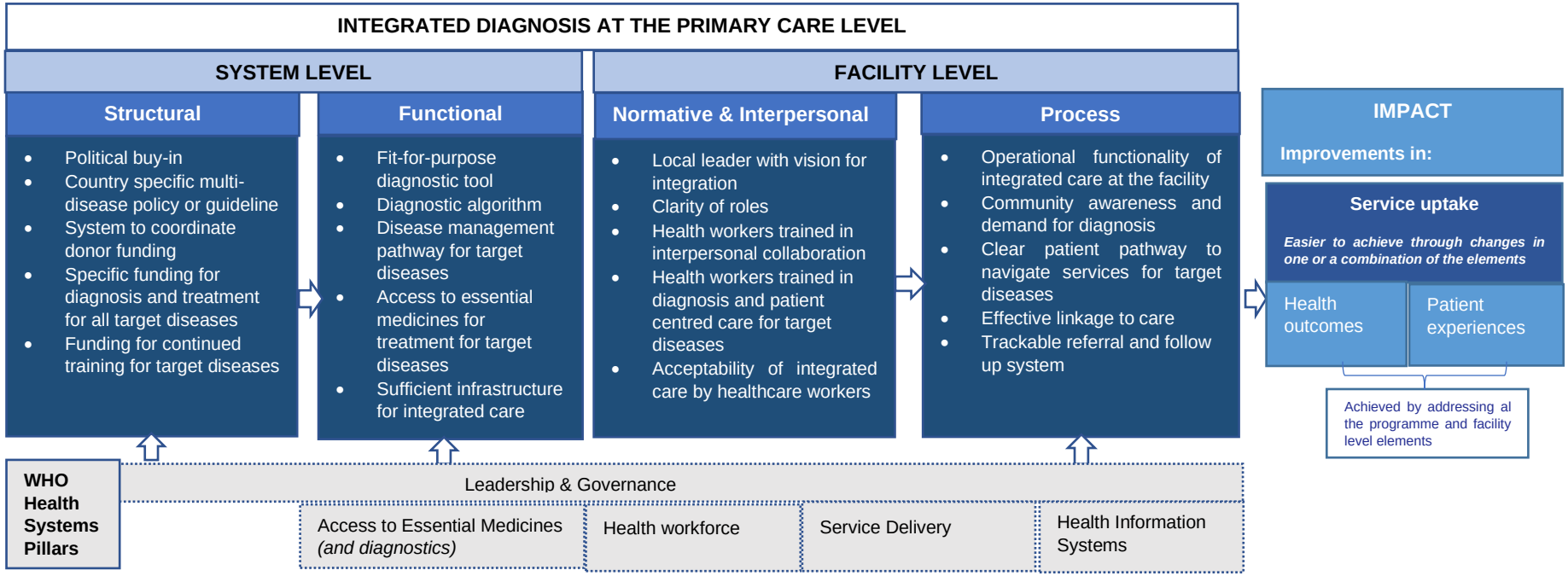
Each item is rated using a seven-point ordinal scale (Table 23). Scores across domains can help facilities identify priority areas for strengthening before or during implementation. For example, consistently low scores in the “Access to Diagnostics” domain may indicate the need for procurement planning, while low “Health Workforce” scores may point to gaps in training or role clarity.

Table 23: Rating scale for the facility readiness assessment tool

Rating	**Interpretation**
6	Fully in place
5	In place with minimal adjustments needed
4	In progress; efforts underway to remedy
3	Planned for but unclear status
2	Nothing in place
1	Not applicable
0	I don’t know / no information available

As the tool is currently in draft form, it requires further validation across different LMIC settings to ensure relevance, reliability, and adaptability to varied health-system contexts. Nevertheless, it offers a structured, context-sensitive approach to planning and monitoring integrated diagnostic readiness at the facility level.

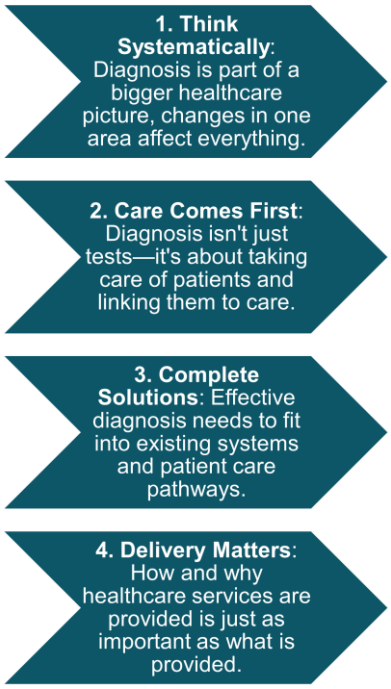
Figure 14: Conceptual Framework for effective same-day integrated diagnosis interventions at the primary health care level in low-income settings



The framework emphasises the importance of understanding the relationships between different types of integration, including potential bidirectional interactions. Aligning system-level integration with patient perceptions, while considering the health system pillars, is key to optimising patient experiences and health outcomes. This comprehensive approach is more likely to lead to meaningful improvements in delivering integrated diagnostic interventions.

Readiness Assessment Tool for Primary Care Facilities: Implementing Integrated Diagnostic Solutions

The assessment tool evaluates primary healthcare facilities using evidence-based criteria for effective interventions that improve health outcomes and patient experiences. It helps facilities identify areas where stronger leadership and governance are needed, resources should be mobilised, appropriate tools must be ensured, human resources managed effectively, training needs identified, and service delivery and processes enhanced. By highlighting strengths and areas for improvement, facility leaders can better prepare for the successful implementation of integrated diagnosis.



Rationale

As health challenges and comorbidities continue to rise, and as the importance of diagnosis becomes increasingly recognized as central to the healthcare process, integrated diagnosis is emerging as a solution to fragmented health systems. With technological innovations enabling such integration, it has the potential to facilitate early diagnosis and improve health outcomes, leading to both better health and enhanced patient experiences.

However, integrated diagnosis—whether at the facility level (e.g., co-location of services), technological (e.g., multi-disease platforms), or individual (e.g., one person skilled in multiple diagnostic tests)—does not automatically translate into improved health outcomes or better patient care. Many integrated diagnostic interventions result in increased service uptake without corresponding improvements in health outcomes or patient care quality.

Achieving these desired outcomes requires deliberate planning in the design of integrated diagnosis interventions. This planning must ensure that the entire health system is considered and that success factors are incorporated into the design, such as establishing clear treatment pathways, implementing necessary policy frameworks, and considering the specific context of each facility. Not all integrated platforms or interventions can be replicated wholesale; context-specific factors crucial to success must be taken into account.

The criteria in this tool have been developed based on primary research, evidence from other interventions, and insights from an expert consensus study involving implementers, policymakers, and researchers in LMICs. These criteria are aligned with the WHO health systems building blocks. By assessing a facility's performance against each building block, areas needing improvement can be identified, bringing the facility closer to achieving its desired impact.

Areas assessed on:

1. Governance and Leadership

✓ Political will

✓ Policies & guidelines on integration

✓ Donor coordination system

2. Financing

✓ Funding for diagnosis & treatment

✓ Funding for continued training

3. Access to essential medicine and diagnostics

✓ Fit for purpose diagnostic tools

✓ Diagnostics algorithm

✓ Disease management pathway

✓ Availability of medicines

4. Health workforce

✓ Strong local leader

✓ Clarity of roles

✓ Trained health workforce

5. Service delivery

✓ Community awareness

✓ Sufficient space at facility

✓ Clear patient pathway

✓ Effective linkage to care

6. Health information systems

✓ Trackable referral and follow-up system

The form is completed in an excel tool.

Rating Scale
6-Fully in place
5-In place with minimal adjustments needed
4-In progress, efforts underway to remedy
3-Planned for but unclear status
2-Nothing in place
1-Not applicable
0-I don't know

Facility Readiness Assessment Tool
A. Leadership and Governance
1. Is there a policy or guideline in place for integration of all targeted diseases?
2. Is there a designated substantive leader responsible for overseeing diagnosis and treatment decisions at the facility?
3. Does the leader actively support the integration of services?
4. Is the leader involved in both clinical decision making and strategic planning for the facility?
B. Financing
5. Is there dedicated funding available for the diagnosis of all the diseases targeted for integration?
6. Is there dedicated funding available for consumables?
7. Is there dedicated funding available for the treatment of all targeted diseases?
8. Is there dedicated funding available for continued training of health workers in integrated diagnosis?
9. Is there a system in place to coordinate funding from the different donors?
10. Is there a designated office or individual responsible for coordinating donor funding within the health facility or Ministry of Health?
11. Are there regular meetings or established communication channels between the facility and its various donors to discuss funding needs, priorities, and ensure alignment of goals?
C. Access to essential medicines and diagnostics

12. Is there a diagnostic algorithm in place that addresses all diseases targeted for integration?
13. Is there a treatment protocol or pathway for managing individuals who test positive?
14. Is the required medicine for treating all targeted diseases consistently available at the facility?
15. Is the integrated diagnostic tool easy to use for the healthcare staff at the facility?
16. Is training for operating the diagnostic tool readily available to healthcare staff?
17. Is there a constant and reliable power supply available at the facility to ensure uninterrupted operation of the integrated diagnostic tool, if required?
18. Is there adequate air conditioning and temperature control at the facility to maintain the required environmental conditions for the proper functioning of the diagnostic tool?
19. Are the necessary resources and qualified personnel available for regular maintenance and calibration of the integrated diagnostic tool to ensure its optimal performance?
20. Are the necessary consumables for the diagnostic tool, such as reagents and test kits, always available at the facility?
D. Health workforce
21. Are job roles clearly defined for each staff member involved in the integrated diagnosis process and patient care pathway?
22. Are the relevant healthcare workers trained in the diagnosis and treatment of all the diseases targeted for integration at the facility?
23. Is the current number of staff sufficient to manage the patient load and deliver integrated diagnosis services effectively?
24. Have all staff received training in patient-centred care or related approaches to ensure they can effectively meet patient needs?
25. Have staff received training in interpersonal collaboration or similar skills to enhance teamwork and communication within the facility?
E. Service delivery
26. Is there sufficient physical space at the facility to accommodate the targeted population, including adequate waiting areas and private rooms for diagnostic procedures?
27. Is there a system in place for staff to provide feedback on the diagnostic algorithm and processes and to suggest improvements?
28. Is there a structured process for clients/patients to provide feedback on the diagnostic services they receive?
29. Are the rights and responsibilities of both patients and staff clearly communicated and understood during the delivery of diagnostic services, and are there mechanisms in place to ensure this understanding?

30. Is there an effective method in place to inform the targeted community/population about the availability and importance of diagnostic services?
31. Is there a system in place to gather feedback from the community regarding the acceptability and quality of the diagnostic services for targeted diseases?
32. Is there a clearly defined and well-marked patient pathway that includes signs, maps, or guides to assist individuals in accessing all necessary services and navigating through the facility or stages of care?
F. Health Information systems
33. Is there a clear and efficient referral system in place to direct patients to secondary facilities for further care when needed?
34. Is there a trackable referral system in place to direct patients to secondary facilities for further care when needed?
35. Is there a trackable follow-up mechanism in place to ensure that patients referred to secondary facilities complete their care?

9.6 Conclusion

By considering these core criteria when investing in primary care-level integrated diagnosis, policymakers and funders can support effective initiatives. The framework assumes that disease prioritisation, target populations, and diagnostics have already been conducted effectively. These criteria can be further refined as new evidence on integrated diagnosis emerges, ensuring that strategies remain relevant and effective.

9.7 Chapter 9 Summary

This chapter introduced the integrated diagnosis framework, a synthesis of the core criteria that reached consensus in Chapter 7 of the Delphi study, as well as some insights from the user perspectives from the qualitative study in Chapter 8. In addition, a facility readiness assessment tool was developed, which focuses specifically on the introduction of multidiseases or multiplex diagnostic tools at facilities so that they are not just technology-focused.

Chapter Ten

Discussion and Conclusions

10. Discussion and Conclusion

10.1 Introduction

This thesis explores integrated diagnosis interventions in primary healthcare settings within LMICs, with a focus on African countries. It addresses the key questions: What is integrated diagnosis? When and how does it work?

Diagnosis has been a focal point of healthcare discourse, with integrated diagnosis emerging as a critical strategy. Maximising diagnostic opportunities during patient visits, particularly at primary care centres, can enhance early diagnosis, reduce preventable deaths, and curb the spread of infections.[3,45,51,93]

10.2 The gap addressed by the thesis

This thesis addresses four major gaps in integrated diagnosis interventions.

1. *Establishing Integrated Diagnosis as a Distinct Field:*

   In the literature, discussions on integration at the PHC level often focus on disease-specific approaches, such as HIV and TB testing or the integration of NCDs into primary care. As a result, integrated diagnosis is rarely framed as a distinct field of study. This narrow focus makes it difficult to advocate for integrated diagnosis strategies beyond specific diseases and limits cross-learning opportunities. By positioning integrated diagnosis as its own field, this thesis provides a foundation for broader advocacy, policy planning, and implementation strategies. The growing importance of integrated diagnosis in addressing disease complexity, rising comorbidities, and AMR aligns with global health priorities, especially in the wake of COVID-19, which underscored the need for stronger diagnostic systems.

2. *Defining Integrated Diagnosis More Clearly*

A key challenge in advancing integrated diagnosis is the absence of a standardised definition. While "integration" is a commonly used term in health policy, it is often vague and lacks specificity, with alternative terms like "multi-disease testing" or "integrated care" being more prevalent. This thesis contributes to the field by identifying common characteristics of integrated healthcare and integrated diagnosis from both policy and patient perspectives, helping to create a clearer conceptual framework for future research and implementation.

Shifting the Focus from Intermediate Health System Outcomes to Long-Term Impact:

Most integration efforts focus on intermediate health system outcomes such as coverage, quality, and safety, rather than broader impacts like improved patient experience and long-term health outcomes. However, achieving these broader benefits requires a deeper understanding of how diagnostic interventions contribute to overall healthcare integration. Since diagnosis is just one component of a larger health system, this thesis examines the conditions necessary for integrated diagnosis to drive meaningful, sustainable improvements in patient care and health system performance.

3. *Addressing Implementation Challenges in Integrated Diagnosis:*

In LMICs, integrated diagnosis interventions often fail due to suboptimal design and implementation, rather than the accuracy of diagnostic technologies. While multi-disease platforms and point-of-care innovations make same-day integrated diagnosis technically feasible, effective deployment remains the primary challenge. There is limited comparative analysis of integration models, and few successful implementation examples exist due to operational constraints. This thesis identifies the key contextual factors and mechanisms required for success and provides core criteria for optimizing implementation strategies at the

facility level. By shifting the focus from technological capability to practical execution, this research helps bridge the gap between innovation and real-world impact.

10.3 Positioning the thesis in existing research

Research on integrated diagnosis in LMICs is dispersed across multiple disciplines, each focusing on different aspects, such as:

- Integrated healthcare and primary healthcare as part of efforts to achieve universal health coverage (UHC)[45,204,205,277,278]
- Disease-specific screening and testing (e.g., HIV and TB integration, NCDs in primary care)[89,126,208,279-283]
- Patient-centred approaches in healthcare service delivery[86,90,91,227,284-286]
- Health policy and planning for service integration[4,31,122,226,285,287,288]
- Diagnostic innovations and technologies[2,6,26,154,161,256 109,289]
- Outbreak response and pandemic preparedness[33,34,285,290-293].

This fragmentation presents both a challenge and an opportunity. The challenge is that integrated diagnosis is often not framed as a distinct field but instead examined within broader health service integration efforts or as part of technology-focused diagnostic research. The opportunity is that by drawing insights from these diverse research areas, this thesis bridges existing gaps and presents a more comprehensive approach to integrated diagnosis.

Most research on integrated healthcare does not explicitly focus on diagnosis. For example, a systematic review of IMCI[89] focused on service delivery outcomes such as prescribing practices, vaccination coverage, and vitamin A supplements but did not examine diagnostic processes. A systematic review which assessed strategies for integrating primary health services[45] in LMICs, found that adding new services or creating linkages improved healthcare utilisation but provided

little or no evidence on whether full integration improved health outcomes. A systematic review on TB and HIV[50] integration identified five models of integration but found that most studies focused on coverage and service uptake, with limited evidence on patient experiences or health outcomes. Since these reviews, several studies have explored different aspects of integration with a diagnostic element, including effectiveness studies evaluating different integrated services,[16,23,149,171,241,294]feasibility studies on integrating diagnostic tools or testing strategies,[80,86,98,99,212,295,296] implementation research,[106,159,221,279,297-299] on integration models in healthcare facilities, and user perspectives and preferences,[91,102,286,300], though these remain underexplored.

However, evidence on how these strategies perform when scaled up and implemented in routine care is still limited. This thesis directly addresses this gap by evaluating integrated diagnosis in practice (Lesotho case study, Chapter 4), examining client perspectives on integration strategies (realist review, Chapter 6), and providing qualitative insights into patient experiences and implementation challenges (Zimbabwe qualitative study, Chapter 8).

Notably, research on patient-centred integration models has primarily been conducted in high-income settings. For instance, the "Caring About Me" framework[103] for integrated care in Canada, focusing on patients with comorbid mental and physical health conditions. While some of the key principles of patient-centred integration align across contexts, there are important differences in LMIC settings—for example, the role of effective referral systems, as patients often cannot access all services at one facility. This thesis extends the conversation by analysing how integrated diagnosis works in a low-resource setting and what mechanisms drive its success.

In global health policy, there has been increasing focus on integrating diagnostic testing to address underdiagnosis and diagnostic gaps, particularly for HIV, TB, and Hepatitic C. Key developments include the recent Lancet Commission on Diagnostics[6], which highlighted the diagnostic gap in LMICs and the need for greater policy attention; a 2023 perspective paper[31]

from global health actors, which proposed five recommendations for integrating testing programs based on lessons from COVID-19 and investments in platform technologies and the Lancet Commission on Oxygen,[128] which identified hypoxemia as a significantly underdiagnosed condition in LMICs, which needs to be integrated into primary care. This aligns with the findings in this thesis on the role of health system enablers in ensuring integrated diagnosis is effective beyond just having access to diagnostic tools. While these global efforts align with this thesis's findings, they do not provide practical implementation guidance at the facility level, incorporate patient perspectives, or identify key success factors for LMICs—all of which this thesis addresses.

Several disease-specific guidelines have also promoted integrated diagnostic strategies, such as the Integrated TB and HIV guidelines[4], Triple elimination (HIV, syphilis, and hepatitis B) implementation guidance,[283] and WHO guidelines for managing chronic respiratory diseases in primary care.[301] However, these documents focus on integrating diagnostic tests rather than examining the diagnostic process itself. They often use the term "integrated diagnostics" in a way that centers on technology rather than broader diagnostic processes. A key distinction made in this thesis is between: "Diagnostics" – referring to technologies and tests, such as laboratory assays and point-of-care tools. "Diagnosis" – refers to the broader diagnostic process, including syndromic diagnosis, which is particularly important in LMICs where access to advanced testing is limited. This thesis takes a broader systems-level perspective, recognizing that technology alone does not determine successful integration. It examines how diagnosis is embedded within healthcare systems, how different models of integration function in practice, and what conditions enable success.

10.4 Specific Research Contributions

This research addresses the existing gaps using seven interdependent studies, identifying key criteria for successful integrated diagnosis interventions from both patient and system

perspectives. It introduces an integrated diagnosis framework, providing evidence-based guidance for policymakers and implementers to optimize interventions and maximise health outcomes and patient experiences. It also presents a structured readiness assessment tool to support health managers in introducing multi-disease diagnostic technologies.

Key findings from these studies, detailed in the subsection below on the summary of research outputs, emphasize that integrated diagnosis is not a universal solution—its effectiveness depends on strategic implementation in high-impact contexts. Based on this research, integrated diagnosis is most effective in secondary care facilities, such as district hospitals, which still serve a primary healthcare function in many rural areas. Mission hospitals, with their larger infrastructure and available space, are also well-positioned to accommodate multi-disease diagnostic technologies and strategies.

Integrated diagnosis is not a fix for dysfunctional health systems but rather a tool to enhance patient care when properly designed. Several studies from the realist review found no significant difference in quality of care between integrated and non-integrated services, reinforcing that integration alone does not guarantee better outcomes. Addressing the complex, interrelated challenges within LMICs requires a multifaceted strategy spanning policy, financing, workforce capacity development, and infrastructure.

Policymakers must critically assess whether integration truly enhances patient care rather than pursuing it as an end in itself. Alternative models, such as vertical programmes and referral-based systems, have also proven effective in certain settings, despite their challenges, such as high loss to follow-up. The debate on integration has now shifted towards identifying the contexts in which vertical or integrated health service delivery models are most appropriate.

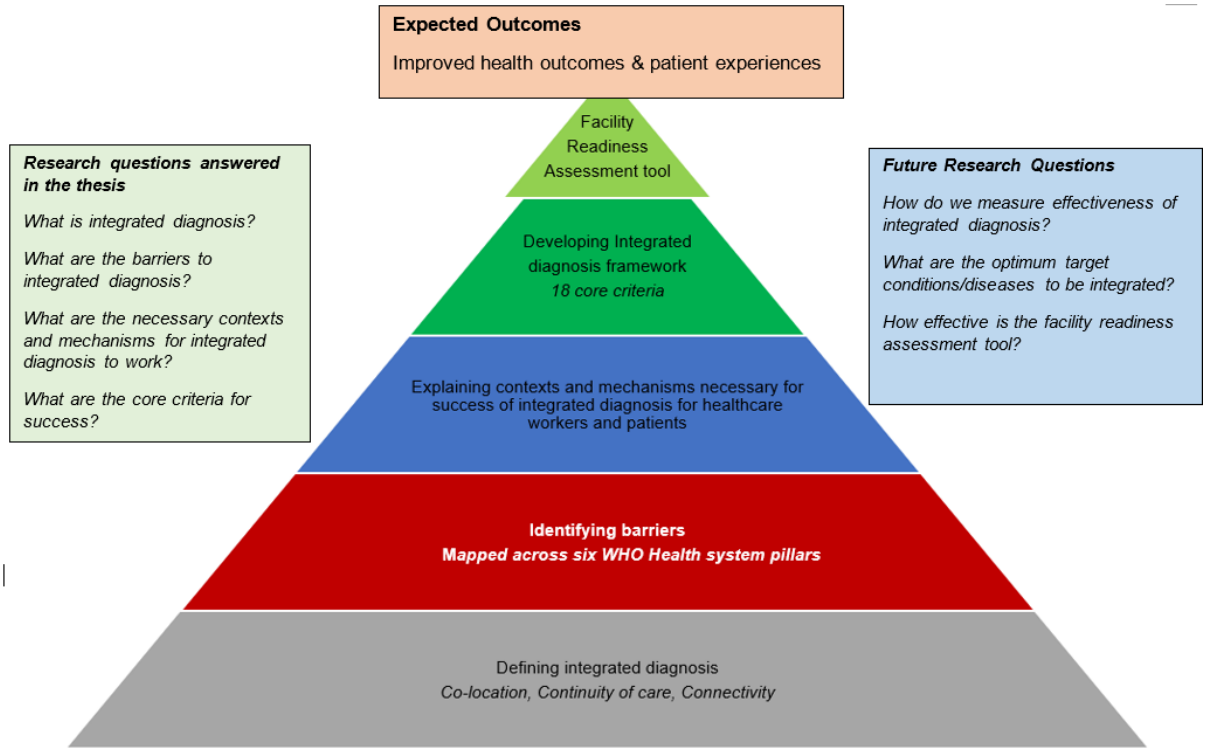


Figure 16: Summary of research questions and outputs the thesis addresses and overview of future research questions

10.4.1 Summary of Research Outputs

10.4.1.1 Defining Integrated Diagnosis:

Chapter 2 establishes a broader definition of integrated diagnosis, distinguishing it from integrated testing, which is often used interchangeably in the literature. This thesis takes a more comprehensive view, defining integrated diagnosis as:

"The provision of comprehensive diagnostic services that identify multiple conditions during a single visit, ensuring ease of access, same-day results, and continuity of care to improve patient experiences and health outcomes at the primary care level."

Three core characteristics—co-location, continuity of care, and connectivity—emerged as essential components of integrated diagnosis and healthcare, providing a foundation for standardising its implementation. Patients value comprehensive, convenient, and accessible care tailored to their needs.

10.4.1.2 Barriers to Implementation:

Strategic, operational, and systemic barriers to integrated diagnosis in LMICs were identified and analysed through the WHO's six health system pillars:

Leadership and Governance:

- There is a lack of multi-disease policies and limited local leadership capacity to guide integration. A policy analysis of eight Southern African countries (Chapter 5) found that half did not explicitly mention integrated healthcare or diagnosis, leading to low prioritisation. This review contributes a checklist for assessing PHC representation across national policies and comparative insights to standardise PHC efforts in Southern Africa.

Health Financing:

- Fragmentation due to disease-specific funding hinders integration. The Lesotho programme evaluation (Chapter 4) found that TB and HIV testing remained separate despite clear opportunities for integration, as these were funded by different donors.

Health Workforce:

- There are severe shortages of trained healthcare workers capable of handling multi-disease diagnoses and high patient loads, which impact the delivery of integrated diagnosis. The qualitative case study in Chapter 8 demonstrates these challenges and how it affect patient experiences.

Service Delivery:

- The delivery of integrated diagnosis services is hindered by a lack of essential consumables and infrastructure, further worsened by irregular supply chains. Chapter 8 of the qualitative study at Mabvuku highlights these challenges, noting shortages of critical supplies such as BP machines and cartridges needed to replenish GeneXpert machines.

Health Information Systems:

- Weak data systems and M&E structures hinder same-day delivery of services, patient tracking, disease surveillance, and service improvements. This criteria was identified as an important mechanism for success as it helped to ensure accountability of healthcare workers in Chapter 6 of the realist review. Although this criterion was not prioritised in the Delphi study, it is still an important element. In Chapter 8 of the qualitative study, the HCW explained that internet connectivity was a big problem, causing delays in results from centralised locations, making it difficult to have same-day delivery of diagnostic services.

Medical Technologies:

- POC diagnostic technologies and supplies are limited, impacting service delivery. This issue was evident at Mabvuku Clinic (Chapter 8) and in multiple primary studies identified in the realist review (Chapter 6), where essential supplies were lacking. Policy, funding, and operational constraints further hinder the adoption and integration of multi-disease diagnostic platforms. As highlighted in Chapter 5 on the policy review, many national health policies do not explicitly mention diagnostics. For example, the absence of certain diagnostic tests, such as pulse oximeters, in diagnostic and treatment guidelines means that conditions like hypoxemia often go undiagnosed.[128]

10.4.1.3 Mechanisms for Successful Implementation:

This research's realist review (Chapter 6) identifies key mechanisms and contextual factors for the success of integrated diagnosis.

For healthcare workers, five Context-Mechanism-Outcome (CMO) pathways were identified:

1. Multi-disease policies and guidelines (C), when operationalised into diagnostic algorithms and facility screening protocols (C), followed by healthcare worker training (M), improve self-efficacy and quality of care (O).
2. Adequate staffing and multi-disease funding (C) enhance confidence in service delivery (M), leading to expanded service coverage (O).
3. Integrated monitoring and reporting tools (C) enhance accountability and act as reminders (M), improving diagnostic coverage (O).
4. Having well defined treatment, care and referral pathways (C) increase perceived benefits of diagnosis (M), leading to higher service coverage (O).
5. Fit-for-purpose technology (C) improves healthcare worker motivation (M) when they experience its benefits in improving workflow efficiency and patient outcomes, ultimately leading to increased uptake and service coverage (O).

For patients, key factors influencing experience and service uptake include:

1. The perceived relationship between the healthcare provider and the client/patients (C), made the clients/patients feel respected and built trust (M), which improved the client/patient experience of care (O)
2. The service was delivered in such a way that clients/patients felt their confidentiality was respected as well as privacy where relevant (C), reduced stigma associated with some diagnoses (M), which improved the client/patient experience of care (O)

3. The ease of access of the facility and services provided (C), ensured convenience and comfort (M) to the clients/patients, which improved their experience of care (O).
6. The turnaround time of some tests (C), if it was rapid, reduced anxiety (M) of the clients/patients about the diagnosis, and increased their uptake of services (O), thereby increasing early diagnosis of conditions (O)
7. On the other hand, increased time of same-day integrated diagnosis (C), led to frustrations with long wait times (M) and could reduce uptake of services that were not considered urgent (O).

10.4.1.4 Integrated Diagnosis Framework:

The Delphi study (Chapter 7) prioritizes 18 core criteria, which form the foundation of the proposed integrated diagnosis framework. This framework highlights that integration is not merely about co-locating services or deploying multi-disease diagnostic technologies—it requires a holistic health systems approach.

Discussions on integrated diagnosis often focus on different elements, such as systems and structures or actor roles (healthcare workers, policymakers, donors, patients). This thesis's novel contribution is its ability to synthesise these elements into a single, actionable framework.

10.3.1.5 Facility Readiness Assessment Tool:

The tool ensures optimal utilisation of multi-disease diagnostic technologies, preventing underuse or the accumulation of “equipment graveyards”. To my knowledge, this is the first readiness assessment tool specifically designed for multi-disease diagnostic technologies, providing health facility managers with a structured decision-making tool.

Although completing the checklist requires time and resources, investing in a thorough assessment upfront ensures an evidence-based approach, ultimately preventing issues down the line. In LMICs, where robust data is crucial for effective decision-making, the time and cost of assessment are justified. A limitation of the tool is that facility assessments are highly contextualised, which may limit generalisability. However, this reflects the complex realities of health system resource allocation, particularly when decisions are made at national, regional, or district levels. When used effectively, the assessment tool enables facility managers to identify and address weaknesses, ensuring that multi-disease diagnostic instruments achieve their intended impact on health outcomes.

10.5 Methodological Strengths and Limitations

This thesis employed a mixed-methods research design, which due to its complementarity,[168,302] significantly enhanced the quality of evidence for integrated diagnosis at the PHC level in LMICs. The integration of qualitative and quantitative data allowed for a comprehensive understanding of how integrated diagnosis is perceived and implemented, incorporating the perspectives of policymakers, funders, health implementers, and patients.

The strengths and limitations of each methodological approach are discussed below, including considerations for future research. Table 22 summarises the research questions, methods used, advantages, and alternative approaches.

Several key strengths underpin the research methods used in this thesis:

- The research was conducted in relevant LMIC settings, ensuring that the findings capture real-world challenges and opportunities. The primary studies took place in Lesotho and Zimbabwe, both LMICs facing significant challenges in integrated diagnosis, such as

increasing comorbidities between HIV, TB, and other NCDs, as well as reliance on external health financing for multi-disease diagnostic technologies. The Delphi study also included at least 70% of respondents from LMICs, with 60% from Africa, ensuring strong representation of perspectives from these settings.

- The study employed validated methodologies, strengthening the reliability and credibility of its findings. These methodologies included the realist review method, the Delphi approach, and the use of established frameworks such as the WHO health systems building blocks and integration theory.
- A systematic approach was used to define integrated diagnosis, drawing from both a literature review and a realist review. This ensured clarity and consistency in the study's analysis and interpretation of integrated diagnosis.
- The research utilised a mixed-methods design, which allowed for triangulation by incorporating both qualitative and quantitative approaches. This methodological integration enhanced the depth and validity of insights, providing a comprehensive understanding of integrated diagnosis from multiple perspectives.
- The study actively engaged key stakeholders, ensuring that the findings were relevant and actionable. Policymakers in Lesotho and Zimbabwe were engaged throughout the research process, with study findings shared to inform decision-making in these contexts. Additionally, through six publications arising from this thesis, the research contributed to global discussions on integrated diagnosis, engaging with the global health and donor community in Switzerland and beyond.

In terms of limitations, while the integrated diagnosis framework is highly relevant to African LMICs, its applicability to other regions may require adaptation. However, evidence from the scoping review suggests that many of the challenges identified—such as fragmented healthcare services, limited resources, and weak policy alignment—are widespread across LMICs, increasing the relevance of these findings beyond Africa.

The programme evaluation in Lesotho (Chapter 4) encountered significant challenges in data access. Incomplete datasets made it difficult to compare programme sites over time. To address this, analysis focused on years with more complete data. Another challenge was that the intervention was not initially designed with an evaluation in mind and lacked a clear theory of change. This required retrospective reconstruction through stakeholder interviews to understand the original intentions and implementation rationale of the project. This reflects a common limitation in LMIC programme evaluations, where resource constraints often lead to gaps in M&E.

The national health policy review (Chapter 5) provided a comparative analysis of eight Southern African national health policies, offering valuable insights into policy gaps and inconsistencies. A key strength of this approach was its ability to highlight variations in how primary healthcare and integrated care are defined across different contexts. However, the exclusive reliance on document analysis posed limitations. Combining secondary policy analysis with primary stakeholder interviews could have provided deeper contextual understanding, particularly regarding the rationale behind policy decisions and implementation challenges. This was not feasible due to resource constraints and difficulties in accessing policymakers across all eight countries. As a result, the absence of multiple data sources may have led to a more simplified interpretation of the complexities surrounding policy formulation and implementation in these settings.

The realist review (Chapter 6) played a crucial role in unpacking mechanisms that drive successful integrated diagnosis interventions. One of its strengths was the ability to move beyond outcome reporting and explore how and why specific interventions work in different contexts. However, a limitation was the lack of detailed intervention descriptions in existing literature. Many studies on integrated healthcare and integrated diagnosis do not explicitly outline the mechanisms behind their outcomes, making it difficult to extract precise causal relationships. To address this, the review focused on contextual factors and mechanisms described in study methods and settings, rather than relying solely on results sections.

The Delphi study (Chapter 7) contributed to building consensus on key components of integrated diagnosis. A strength of this approach was the inclusion of 55 experts in various professional roles from 23 countries, with professional experience spanning 59 countries. This ensured a diverse range of perspectives across implementers, policymakers, and researchers. The study was not limited to a single professional constituency, healthcare system, or country, increasing the robustness of the findings. However, Delphi studies inherently rely on expert judgment rather than large sample sizes,[250,261] which can influence representativeness. A limitation in this study was the lack of consensus on the M &E domain, possibly due to knowledge gaps in M&E due to participants' professional backgrounds rather than the actual relevance of M&E in integrated diagnosis. Despite these limitations, the Delphi methodology remains a valuable tool[250,261] for consensus-building in situations where face-to-face interactions are impractical and expert input is essential.

The qualitative study conducted in Zimbabwe (Chapter 8) provided rich, contextual insights into the implementation of integrated diagnostic services in maternal healthcare. Although the study focused on a maternal healthcare setting, its findings are relevant to other primary care contexts. While qualitative methods do not aim for broad generalisability, this study's findings are transferable to similar settings and offer practical lessons for improving patient-centred care.

Despite these methodological challenges, this thesis successfully developed an evidence-based framework for integrated diagnosis, incorporating multiple perspectives and real-world implementation considerations. While some findings may require adaptation beyond African LMICs, the research offers a strong foundation for policymakers, implementers, and researchers aiming to improve diagnostic integration in PHC settings. The mixed-methods approach used in this thesis has strengthened the understanding of integrated diagnosis by capturing both systemic challenges and on-the-ground realities, ensuring that proposed solutions are both practical and scalable.

Table 24: Thesis derived research questions and methods used, including advantages and disadvantages of approaches and alternative approaches

Research Question	Thesis Method	Advantages of Method	Disadvantages of Method
What is integrated diagnosis?	Literature Review	Quick to conduct; improves theoretical and conceptual understanding	Limited assessment of quality, direction and weight of the higher quality evidence, no assessment of bias, may miss relevant studies
What are the barriers to integrated diagnosis in LMICs?	Scoping Review	Flexible and provides broad exploration of a topic; includes wide range of evidence; identifies gaps and areas for future research	Lack of critical appraisal of included studies
How is TB and HIV testing integrated? What are the challeges to integration in Lesotho?	Semi-structured interviews and secondary data analysis	Provides contextual data and nuances affecting programme outcomes; triangulation strengthen results	Risk of interviewer bias; secondary data may be outdated or incomplete
To what extent are integrated health care and integrated diagnosis, incorporated in national Health Policies in Southern Africa?	Document Analysis- READ Approach	Ensures consistency in data extraction and interpretation, time efficient	Documents may not capture real-time perspectives or interpretations of stakeholders
What are the necessary contexts and mechanisms for integrated diagnosis interventions to work well?	Realist Review	Provides context sensitive and transferable insights, flexible and iterative approach	Complex data collection and analysis
What are the core criteria for effective integrated dignosis interventions?	Delphi method	Structured approach, allows independent and diverse opinions; reduces bias and groupthink, can be conducted remotely	Risk of expert dropout; quality depends on expert selection
What are the experiences of users accessing integrated diagnosis services and validate some core criteria	Qualitative case study	Provides deep, contextual understanding; can explore nuanced and sensitive issues; generates practical, real-world insights; flexible and adaptable approach	Limited generalizability; risk of researcher bias

10.6 Implications for Policy

1. Elevating Diagnostics as a Health System Priority

Diagnostics remain an underfunded and under-recognized component of health systems, leading to resource shortages at all levels. To address this, strong and sustained advocacy is required to ensure diagnostics—and by extension, integrated diagnosis—are recognised as essential to achieving universal health coverage. Policymakers must integrate diagnostics explicitly into national health strategies, financing mechanisms, and essential health benefits packages to secure sustainable investment.

2. Moving Beyond a Single-Disease Approach and more informed funding process

Current integration efforts in Africa often stem from HIV-focused models, where additional diseases are layered onto existing HIV programmes. While this can be efficient, a broader health systems approach is needed to ensure that each disease added to the diagnostic algorithm is supported by appropriate infrastructure, funding, and clinical pathways. This need is particularly urgent given the recent withdrawal of major U.S. government support for HIV programs, which has disrupted a range of health services that depended on that funding[303]. Policymakers must now establish clear, system-wide guidelines for disease integration, aligning efforts with primary health care principles rather than continuing with siloed, disease-specific models.

3. Defining Integrated Diagnosis and People-Centred Care

A clear policy framework on integrated, people-centred healthcare and integrated diagnosis is necessary to avoid implementation gaps, inconsistent models, and poor evaluation outcomes. Standardized definitions and evidence-based guidelines will enable better comparisons, replication of successful models, and monitoring of effectiveness.

4. Patient-Centred Programme Design

Integration efforts must prioritise patient needs rather than solely focusing on process and disease outcomes. Policymakers should mandate patient engagement in programme design through structured feedback mechanisms to ensure services align with community expectations and real-world health-seeking behaviours. Policies must holistically address the patient pathway, ensuring that integration efforts extend beyond testing to treatment, follow-up care, and support services to achieve sustained health outcomes.

5. Strengthening Data Collection and Evidence-Based Decision-Making

Many integration efforts suffer from poor data collection and weak non-evidence-based decision-making. Policies must ensure robust M&E frameworks that align on-the-ground realities with policy assumptions. For example, the Lesotho programme evaluation revealed that integration was implemented in ways that did not match policy expectations. To prevent such gaps, policymakers should:

- Mandate real-time data collection systems to track integration efforts.
- Require disease burden assessments to guide screening programmes.
- Establish accountability measures to ensure M&E results inform policy decisions.

6. Addressing Workforce Shortages and Training Gaps

Healthcare worker shortages remain a critical barrier to successful integration. Policies should:

- Increase investment in recruitment and retention strategies to reduce waiting times and improve service quality.
- Ensure continuous training programmes to keep healthcare workers updated on best practices, new technologies, and integrated diagnostic protocols.
- Support task-shifting approaches where appropriate, allowing lower-tier health workers to perform certain diagnostic tasks under supervision.

7. Improving Diagnostic Service Delivery in Maternal Health

Maternal healthcare programmes should fully integrate diagnostic services to improve efficiency and patient satisfaction. Policymakers should:

- Co-locate diagnostic tests within maternal health clinics to reduce delays and patient travel burdens.
- Ensure consistent access to functional diagnostic equipment through improved procurement planning and maintenance programmes.
- Implement financial protection to prevent cost-related barriers to maternal healthcare access.

8. Strengthening Health System Coordination and Funding Alignment

Misaligned donors and government priorities exacerbate fragmentation in healthcare service delivery. Policies must:

- Encourage stronger coordination among donors, government agencies, and NGOs to reduce service duplication and maximise resource use.
- Align external funding streams with national healthcare priorities to ensure that investments are sustainable beyond donor funding cycles.
- Improve financial accountability mechanisms to reduce corruption and inefficiencies in fund allocation.

9. Addressing Hidden Costs in Donor-Funded "Free Healthcare" Models

While donor-funded essential health packages promote free healthcare, in practice, patients often face hidden costs such as informal payments or logistical barriers. Policymakers must:

- Ensure transparency in healthcare financing to prevent unofficial fees.
- Strengthen social protection mechanisms to subsidize costs for vulnerable populations.
- Address systemic inefficiencies that lead to long wait times, poor service delivery, and indirect financial burdens on patients.

10. Strengthening Health Information Systems

Health information systems are crucial for tracking patient outcomes, identifying service gaps, and guiding policy adjustments. To improve data-driven decision-making, policies should:

- Mandate digital health record integration to streamline diagnostic and treatment pathways.
- Enhance data-sharing protocols across healthcare facilities and levels of care.
- Incorporate real-time surveillance systems to monitor disease trends and evaluate intervention impact.

11. Balancing Early Diagnosis against Over-Diagnosis

While early diagnosis is essential for disease control, overdiagnosis[243]. can lead to unnecessary treatment, financial strain, and resource misallocation. Policymakers must:

- Establish diagnostic stewardship programmes to ensure that testing is based on clinical guidelines and epidemiological evidence.
- Regulate financial incentives to prevent unnecessary testing in settings with high out-of-pocket healthcare costs.
- Invest in quality assurance measures to improve the accuracy of diagnostics, as seen in malaria overdiagnosis in Angola (2017), where only 15.7% of clinically diagnosed cases were laboratory-confirmed[6].

10.7 Implications for Practice

1. Prioritise Context-Specific, Evidence-Based Strategies

Integrated diagnosis cannot follow a one-size-fits-all model; success depends on tailoring interventions to local contexts. Health system planners and practitioners should:

- Conduct situation analyses to determine the most appropriate approach, conditions, and timing for integration.
- Use local epidemiological data to prioritize which diseases to integrate and align efforts with national health priorities.
- Engage stakeholders, including frontline healthcare workers and patients, to ensure feasibility and acceptability of integration models.

2. Optimize Diagnostic Networks for Efficient Service Delivery

Findings from the Lesotho programme evaluation emphasise the importance of diagnostic network optimisation to enhance service efficiency. To improve service delivery, practitioners should:

- Map out existing diagnostic infrastructure to identify gaps and maximise resource allocation.
- Improve stock management by aligning supply chain planning with patient demand.
- Optimise staff distribution and training to ensure workforce capacity matches service needs.
- Coordinate donor support more effectively to prevent duplication of resources and promote flexible funding mechanisms that prioritise integration over costly equipment purchases.

3. Strengthen Monitoring, Evaluation, and Data Utilization

Monitoring and evaluation must be a routine, funded, and embedded part of integrated diagnosis implementation. To enhance M&E practices:

- Ensure dedicated budgets for M&E activities and advocate for donor and policymaker support.
- Provide technical training for healthcare facilities on data collection, analysis, and use to strengthen decision-making.
- Establish a culture of data-driven accountability, where integration outcomes are routinely reviewed and adjusted based on evidence.

4. Enhance Documentation and Knowledge Sharing

Clear and transparent documentation is essential for improving integration efforts. Practitioners should:

- Standardise documentation practices to capture integration processes, challenges, and outcomes.
- Develop practical case studies to enable cross-country learning and adoption of best practices.
- Facilitate South-South knowledge-sharing platforms to compare integration models and support implementation improvements.

5. Develop Performance Indicators for Integrated Diagnosis

To measure success and assess trade-offs with vertical programmes, specific outcome indicators should be developed and routinely tracked. These should include impact, effectiveness, efficiency, equity and surveillance indicators.

6. Implement Simple, Multi-Disease Reporting Tools

Integration efforts require user-friendly reporting tools that work within existing health information systems. To streamline data collection and reporting:

- Design multi-disease reporting templates that minimise the reporting burden on healthcare workers.
- Ensure digital health records are interoperable with national health management information systems.
- Provide on-site training and support to frontline staff to improve data accuracy and completeness.

10.8 Conclusion

By integrating insights from multiple disciplines, this thesis makes several key contributions to research. It reframes integrated diagnosis as a distinct field rather than limiting it to disease-specific testing or technology-driven integration. It provides empirical evidence on how integrated diagnosis works in practice through case studies and qualitative research, addressing gaps in previous systematic reviews. It highlights the importance of patient perspectives and system-level factors, which have been largely overlooked in existing research on diagnostic integration. It differentiates between "diagnostics" (tools) and "diagnosis" (process), broadening the scope of how integrated diagnosis is conceptualised and implemented in LMICs. It reinforces the need for policy frameworks that explicitly incorporate diagnostic algorithms and system enablers.

10.9 Future Research Directions

While the research provides a framework for designing and implementing integrated diagnosis interventions, several critical gaps remain. Many promising innovations fail to scale beyond pilot phases or short-term donor-funded initiatives, limiting their long-term impact.[49]. To build a more robust evidence base for sustainable and scalable integration efforts, future research should focus on the following priority areas:

Disease Prioritisation: What Conditions Should Be Integrated?

Research should guide which diseases to integrate by considering:

- Epidemiological burden: Which diseases contribute most to morbidity and mortality in different LMIC contexts?
- Cost-effectiveness vs. affordability: While certain diagnostic services may be cost-effective, they may still be financially unsustainable for LMICs with constrained budgets. Research should assess:
    - The realistic affordability of integrated diagnostic models in different LMIC settings.
    - Health system capacity to sustain integration beyond pilot phases.

Sustainable Financing: How Can Integrated Diagnosis Be Funded Beyond Donor Support?

Financial sustainability is a major challenge. Research should focus on:

- Domestic resource mobilisation: What strategies can LMICs adopt to finance integrated diagnosis and integrated healthcare in general?

Overdiagnosis in LMICs: What Are the Risks and How Can They Be Mitigated?

While early diagnosis is beneficial, excessive testing can lead to overdiagnosis and unnecessary treatments. Research should investigate:

- Extent of overdiagnosis: Which diseases are most prone to overdiagnosis in LMICs and what are the implications?

Facility readiness assessment tool

The facility readiness tool for introducing multi-disease diagnostic technologies at PHC facilities, developed in this thesis, requires further validation and testing. Key considerations for future research include:

- Validation and reliability**:** Does the framework effectively guide decisions on introducing multi-disease diagnostic platforms?
- Adaptability across settings: Is the tool reliable across different healthcare environments, or does it require modifications?
- Practicality and usability: How easy is it to complete and implement the tool at a primary healthcare facility?
- Assessment approach**:** Should the tool be used by facility managers, collaboratively by healthcare workers, or integrated into existing health system processes?
- Optimal implementation conditions: Under what circumstances does the tool work best, and what factors influence its successful use?

Finally, this thesis underscores the urgent need for policy frameworks that explicitly incorporate diagnostic algorithms and system enablers. Achieving meaningful change in healthcare requires improving access to diagnostic tools and transforming the way diagnosis is understood, integrated, and delivered—ensuring improvement in health outcomes and patient experiences.

10.10 Final Reflections

I began this DPhil journey with a deep awareness of my dual perspective—having been both a recipient of aid and an implementer of programmes in Africa. Now sitting across the table, contributing to decisions on how aid is distributed and programmes are shaped in LMICs. My

curiosity about the evidence underpinning integrated diagnostic interventions—particularly those I encountered while working at FIND in 2020—motivated me to seek actionable insights to improve these interventions.

As I conclude this journey, FIND itself faces severe organisational challenges and may cease to exist while I have moved to Unitaid. Through this experience, I have gained a deeper appreciation of the complexity of global health decision-making. I have learnt that while evidence is critical, it is just but one of many factors that influence policy and funding decisions. However, there is growing momentum—driven by declining global health funding and the scalability challenges of many health interventions—to seek sustainable, systems-oriented solutions.

Much of the work in this thesis has been shared through various forums, including conferences, meetings, and publications. From the outset, I made a deliberate effort to disseminate my findings to my target audience which are—first and foremost, health policymakers and implementers in Africa. One of the most significant opportunities to do so was at a high-level ministerial delegation on the sidelines of the World Health Assembly in 2023, where I presented insights from my qualitative study in Zimbabwe. In that meeting, which included the Minister of Health and senior directors from Zimbabwe's Ministry of Health, I emphasized the need for coordinated donor funding and a systems-thinking approach to health interventions—particularly in integrating care. I highlighted the critical role of diagnosis in PHC, advocating for its elevation in discussions about health service delivery. I have also shared the results of the evaluation in Lesotho with managers from the Ministry of Health, where I emphasised similar aspects.

Beyond conferences and policy discussions, I have also made a conscious effort to publish my work in African journals, such as the *African Journal of Laboratory Medicine* and the *African Journal of Primary Health Care & Medicine*, where I hope my findings will be more accessible to those who can act on them.

The recent withdrawal of U.S. government funding from global health initiatives has had a profound impact on HIV service delivery in sub-Saharan Africa. This development highlights the urgent need for African-led, sustainable health solutions and exposes the risks of over-reliance on external, disease-specific funding. One could argue that because this funding was siloed, only HIV and related programmes would be affected, potentially shielding other disease programmes supported by different donors. However, the reality is that U.S. funding also supported critical cross-cutting programmes—such as health workforce development, including community health workers—who play a crucial role in delivering PHC service across various disease areas in many LMICs. In addition, many integration efforts were built onto the HIV program. This reinforces the need for integrated, resilient health systems that are not solely dependent on fragmented external funding streams.

While my research focused specifically on integrated diagnosis, my broader goal was to highlight its critical role within the care cascade and to demonstrate how we must maximise diagnostic opportunities at health facilities. Traditionally, treatment—depending on the condition—has been provided at secondary levels or through referrals. However, in rural areas, where healthcare access is limited, people should be seen as whole individuals, not just as patients with a specific set of symptoms. This speaks to the larger challenge of integrated healthcare in Africa, a field still in its early stages but showing promise through models such as the integrated chronic disease clinics in Cambodia.[28] Achieving meaningful integration will require addressing persistent barriers such as financial constraints, geographical access, and workforce shortages.

Through this journey, I have become even more convinced of the importance of a human-centered approach in designing health programmes—one that genuinely reflects and responds to the needs of the people it serves. Health systems are complex, shaped by multiple stakeholders and layered power dynamics—not just between the Global North and South but also within these regions. In my research, I encountered divergent views within the same country or even the same

facility, depending on whether, for example, someone was a policymaker or a patient. Understanding these nuances is key to designing solutions that work in practice, not just on paper.

One of the most valuable lessons I have learned in this DPhil journey is the importance of asking the right questions. Depending on how a question is framed, you can tell a completely different story. The research skills I have developed—particularly methodologies on the realist review and systematic review approaches—have sharpened my ability to conduct focused research that answers critical questions. This, in turn, helps shape monitoring tools and frameworks that ensure we measure the right indicators and use evidence to improve patient outcomes.

Throughout this journey, I have actively engaged with colleagues in the Global North (my second target audience) and within institutions such as the WHO, Unitaid, FIND, and the Global Fund—organisations that design and fund many vertical and integrated health programmes. I have presented the integrated diagnosis framework in various forums now, and the timing is opportune: Unitaid has recently approved a new area of investment in integrated diagnosis[304], for which I am the monitoring and evaluation lead. I intend to apply the framework developed in this thesis to shape the theory of change for these investments and advocate for facility assessments, adapting tools I designed during my research. Also, I have contributed to discussions at the WHO, where efforts are underway to develop multi-disease diagnosis guidelines.

I remain hopeful that we can improve the way health services are delivered by ensuring that new innovations—such as multi-disease diagnostic tools—are introduced in ways that align with local priorities and disease burdens and strengthen health systems rather than being isolated interventions. My participation in European conferences such as the International Conference on Integrated Care in Belgium in 2022 and the Early Diagnosis Conference at St. Andrews in Scotland in 2023, has reinforced this perspective. A key takeaway from the Early Diagnosis conference was the challenge of overdiagnosis—where screening programmes, particularly for cancers, can increase coverage without necessarily reducing mortality. This serves as a

cautionary lesson: integration should not be seen as an end in itself but as one of many strategies to achieve meaningful health impact.

This framework on integrated diagnosis is a step in that direction. It calls for a fundamental shift in how we design and implement health programmes—ensuring they are aligned with broader health system goals, responsive to the needs of end-users, and sustainable in the long term. True change will require more than just technical solutions; it demands shifts in power, perception, and behaviour, as well as a willingness to listen—really listen—to both sides of the table. While the path ahead is complex, I remain optimistic that with the right approaches, we can build stronger, more resilient health systems that serve communities more effectively across Africa.

10.9 Key accomplishments

Peer Reviewed Publications

1. Integrated diagnosis at the primary care level in Africa's low- and middle-income countries: What is it, what works, and for whom? A Realist Synthesis. 2024. International Journal of Integrated Care DOI: **https://doi.org/10.5334/ ijic.7788**
2. The Primary Health Care Approach: Rhetoric or Policy? - A Review of National Health Policies in 8 Countries in Southern Africa, 2023, Global Journal of Health Sciences https://doi.org/10.5539/gjhs.v15n12p1
3. Missed opportunities for integrated testing of HIV and tuberculosis on the GeneXpert platform in Lesotho, 2023, African Journal of Laboratory Medicine https://ajlmonline.org/index.php/ajlm/article/view/2132
4. Barriers to integrating diagnostic services for febrile illness to support surveillance and patient management in Asia-Pacific, 2022, Asia and the pacific Policy Studies, https://doi.org/10.1002/app5.353

5. Gwaza GP, Zhou DT, Plüddemann A, Heneghan C. Use of integrated services in antenatal care: A case study of Mabvuku Polyclinic, Zimbabwe. African Journal of Primary Health Care & Family Medicine. 2025 May 30;17(1):e1-e13. doi: 10.4102/phcfm.v17i1.484 PMID: 40459110; PMCID: PMC12135723.
6. Gwaza, G., Plüddemann, A., MacBain McCall, M. *et al.* Criteria for designing integrated diagnosis interventions in low resource settings at the primary care level: a Delphi consensus study. *BMC Health Serv Res* **25**, 1130 (2025). https://doi.org/10.1186/s12913-025-13114-9

Presentations

1. Early Diagnosis through Integrated Diagnosis: Practical Insights for Designing Interventions in LMICs - An Expert Consensus., Elevator Pitch, 29-31 May 2024, Early Diagnosis Conference, St Andrews Scotland, I received a travel Grant from Kellogg College.
2. Presentation of the findings from the Qualitative case study findings to a ministerial delegation from Zimbabwe at the Zimbawean Embassy in Geneva on the sidelines of the World Health Assembly. June 2024
3. Poster Presentation on the Programme Evaluation of TB and HIV Testing in Lesotho., 23rd International Conference on Integrated Care, Flanders, Belgium, 22-24 May 2023. I received a travel Grant from Kellogg College.
4. Presentation of the findings of the prioritised core criteria at a virtual all staff meeting with FIND colleagues in Geneva, Feb 2024,
5. Presentation of the programme evalution results to Ministry of Health, Department of Laboratory Sciences stakeholders in Lesotho, March 2021

Short courses completed at the University of Oxford Continuing Education Department prior to or during conducting a study with the related research method

1. Introduction to Evidence-Based medicine, a primer online course
2. Complex Reviews
3. Systematic Reviews
4. Realist Reviews and Realist Evaluation
5. Introduction to Qualitative Research Methods

Appendices

Appendix 1: Chapter 2, Definitions of Integrated healthcare

Integrated care at its simplest is an approach to overcome care fragmentations.	[52]
A patient-orientated definition of Integration is 'a coherent set of methods and models on the funding, administrative, organisational, service delivery and clinical levels to create connectivity, alignment, and collaboration within and between cure and care sectors.	[22]
One important aspect of "integrative care" is that it combines two or more paradigms of care or two or more types of treatment modalities.	[11]
Integrated care is about ‘delivering seamless care for patients with complex long-term problems cutting across multiple services, providers, and settings.	[61]
Integrated care aims to link patient services by overcoming barriers between primary and secondary care, physical and mental health care, and health and social care to receive comprehensive or holistic care when they need it.	[44]
Integrated care has been broadly defined by expert consensus as a model of service delivery that combines care for physical, mental, and substance use disorders in a collaborative way to address problems identified during primary care visits.	[70]
Integration is a coherent set of methods and models on the funding, administrative, organisational, service delivery and clinical levels designed to create connectivity, alignment and collaboration within and between the cure and care sectors.	[47]
Integrated care is defined as an organising principle for care delivery that	[67]

aims to improve patient care and experience through improved coordination' with integration being 'a combined set of methods, processes, and models that bring it about.'	
An approach to strengthen people-centred health systems through the promotion of the comprehensive delivery of quality services across the life-course, designed according to the multidimensional needs of the population and the individual and delivered by a coordinated multidisciplinary team of providers working across settings and levels of care.	[68]
Integrated care is a coherent set of methods and models on the funding, administrative, organisational, service delivery and clinical levels designed to create connectivity, alignment and collaboration within and between the cure and care sectors.	[63]
Integrated care was initially defined as improved connectivity between different activities of the health system in order to provide better quality health services to users. However, there is nowadays an increasing complexity attributed to the concept.	[21]
Integration brings together the inputs, delivery, management and organisation of particular service functions in order to improve care at the point of delivery.	[56]
Integrated service provision models include co-location of services, using a single point of access, a collaboration between different service providers, or a well-organised referral system, with follow up and feedback among different service providers.	[54]
Integrated health services are health services that are managed and delivered in a way that ensures people receive a continuum of health	[29]

promotion, disease prevention, diagnosis, treatment, disease management, rehabilitation, and palliative care services at the different levels and sites of care within the health system, and according to their needs throughout their life course.	
At the most basic level, integrated care occurs when a team of co-located, multidisciplinary behavioural health and medical professionals deliver coordinated services to a common primary care outpatient population, with the intent of improving health outcomes for the patients they serve.	59
Integrated health systems have been promoted as a means to improve access, quality, and continuity of services in a more efficient way, especially for people with complex needs (e.g., multiple morbidities).	60
Strategies to integrate services aim to bring together inputs, organisation, and delivery of particular functions to increase efficiency and people's access.	45
The smooth process of assistance and care provided by multiple disciplines within Primary Care, experienced by citizens	64
Creation of packages or bundles of care	71
The search to connect the health-care system (acute, primary medical and skilled) with other human service systems (e.g., long-term care, education and vocational and housing services) to improve outcomes (clinical, satisfaction and efficiency)	Leutz (2009)
Integrated service delivery is the management and delivery of health services so that clients receive a continuum of preventive and curative services, according to their needs over time and across different levels of the health system.	3
Integrated care seeks to close the traditional division between health and	25

social care. It enables health and social care provision that is flexible, personalised, and seamless.	
Integration is a coherent set of methods and models on the funding, administrative, organisational, service delivery and clinical levels designed to create connectivity, alignment and collaboration within and between the cure and care sectors.	[62]
"[Integrated care] is a concept bringing together inputs, delivery, management and organisation of services related to diagnosis, treatment, care, rehabilitation and health promotion."	[69]
Integrated health care as a series of operations concerned in essence with the bringing together of otherwise independent administrative structures, functions and mental attitudes in such a way as to combine these into a whole	WHO (1996)
Integrated Primary Care combines medical and behavioural health services to more fully address the spectrum of problems that patients bring to primary medical care.	[7]

Appendix 1 : Chapter 4, Permission and Confirmation of study approval by FIND

SHARON SAACKS
Rue des Peupliers 22, CH-1205
sharon.saacks@gmail.com
+41 79 260 7565

---

04 July 2025

To Whom It May Concern,

This letter is to confirm that the programme evaluation conducted in Lesotho on the implementation of TB and HIV testing using the GeneXpert platform was carried out as part of the work at FIND (Foundation for Innovative New Diagnostics) looking at the feasibility of diagnostic integration.

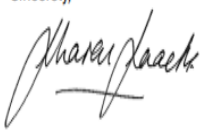
The evaluation was conducted between January and March 2020, and the results were reported as a case study in FIND's annual reporting to the PDP Funders Group. The evaluation has also been used as part of Gamuchirai Pamela Gwaza's DPhil studies in Evidence-Based Health Care.

At the time, the evaluation was led by Gamuchirai Pamela Gwaza, Monitoring and Evaluation Manager, with support from Kekeletso Kao, Access Manager. Data collection was conducted in collaboration with the Ministry of Health's Department of Research and Laboratory Services, with the involvement of Ministry officials Monkoe Leqheka and Tsietso Mots'oane.

FIND signed a Memorandum of Understanding (MoU) with the Government of Lesotho in April 2007 to support the strengthening of the national laboratory system and the introduction of innovative diagnostic technologies. https://www.who.int/news/item/06-02-2008-strengthening-laboratory-services. Since 2016, FIND has supported the Ministry of Health in Lesotho in the rollout of TB testing on the GeneXpert platform.

Please do not hesitate to contact me should you require any further information.

Sincerely,



Sharon Saacks
Operations Director (Former), FIND

Appendix 2 : Chapter 4, Laboratory Questionnaire on GeneXpert Implementation

Guidance for completing this form

Different sections of this form refer to different diagnostic tools. The list below outlines what sections of the form should be completed by diagnostic tool:

- If the clinic is testing for both HIV and TB using a GeneXpert **integrated** diagnostic tool, please complete **all** sections.
- If the clinic is testing for both HIV and TB using **non-integrated** diagnostic tools, please complete Section A, Section D and Section E.
- If the clinic is testing for HIV only using GeneXpert, please complete Section A, Section B, Section D and Section E.
- If the clinic is testing for TB only using GeneXpert, please complete Section A, Section B, Section D and Section E.
- If the clinic is testing for HIV only using non-GeneXpert, please complete Section A, Section D and Section E.
- If the clinic is testing for TB only using non-GeneXpert, please complete Section A, Section D and Section E.

Section A: Demographics

Name of respondent:	
Position:	
Name of site:	
Diagnostic tool(s) used:	
Date:	

HIV Viral Load (VL) testing		**HIV Early Infant Diagnosis (EID)**		**TB**	
GeneXpert (integrated with TB)	☐	GeneXpert (integrated with TB)	☐	GeneXpert (integrated with HIV VL)	☐
GeneXpert (not integrated with TB)	☐	GeneXpert (not integrated with TB)	☐	GeneXpert (integrated with HIV EID)	☐
Other diagnostic tools (not GeneXpert)	☐	Other diagnostic tools (not GeneXpert)	☐	GeneXpert (not integrated with HIV)	☐
We do not perform this type of testing	☐	We do not perform this type of testing	☐	Other diagnostic tools (not GeneXpert)	☐
				We do not perform this type of testing	

Section B: General site

Question	Response
Does the laboratory have onsite GeneXpert testing?	Yes: ☐ No. ☐
If yes, how many GeneXpert machines are available at the facility?	
When was/were the instrument/s installed?	
How many GeneXpert machines are currently operational?	
How many staff are trained to work on GeneXpert machine?	
Do all operators have records of competence?	Yes: ☐ No. ☐
Which staff are trained on using the GeneXpert machine? Select all that apply	☐Laboratory specialists ☐Nurses ☐Doctors ☐All medical staff Other (specify):
Is there a designated period for refresher training on using GX?	Yes: ☐ No. ☐
How many satellite sites refer to this facility?	
Does the facility conduct both TB and HIV VL /EID testing on the GeneXpert platform?	Yes: ☐ No: ☐ Yes but not on GX :☐
If yes, when did the facility start integrated TB and HIV testing?	
If no, what in your view, is the main reason why this is not done? Select all that apply	☐Lack of capacity to run both tests- machines run at full capacity on one test ☐Lack of knowledge of staff to conduct both tests ☐Lack of accreditation programme ☒Lack of space in the Lab ☐Lack of staff motivation

	☐Lack of funds ☐I don't know ☐Other (please explain)_____

Section C: Integrated TB and HIV testing

Question	Response
How many dedicated testing officers are there?	For TB screening: _____ For HIV VL testing: _____ Both (they do both): _____
Is there a data connectivity system that transmits results electronically?	**To Clinicians** Yes: ☐ No: ☐ Not sure:☐ **To an information management system** Yes: ☐ No: ☐ Not sure:☐
How often does the facility report statistics for TB to the national programme?	☐Never ☐Weekly ☐ Monthly ☐Quarterly ☐Bi-Annually (six months) ☐Annually ☐I don't know ☐Other (please specify)_____
How often does the facility report statistics for HIV to the national programme?	☐Never ☐Weekly ☐ Monthly ☐Quarterly ☐Bi-Annually (six months) ☐Annually ☐I don't know ☐Other (please specify)_____
Which tests take precedence when there is high volumes and demand from both? If done on one platform	☐TB test ☐HIV Viral Load ☐ HIV EID ☐Never faced that challenge ☐ Other (please explain)

Section D: Quality Management

Question	Response
Is the site enrolled in a QMS programme	Yes: ☐ No: ☐ Yes, EQA system:☐
Is the GX manual available?	Yes: ☐ No. ☐
Is the NTP algorithm available?	Yes: ☐ No. ☐
If not integrating, is there an SOP to refer HIV or TB patients for testing	Yes: ☐ No. ☐
Which of these has caused any service interruptions in the last 6 months? Select all that apply	☐Stock out ☐Equipment failure ☐ Power failure (electricity) ☐Staff shortages ☐Other (please specify) _____
How often is maintenance of the GX completed? Select all that apply	☐Daily ☐Weekly ☐ Monthly ☐I don't know ☐Other (please specify) _____
Is there expired stock at the site?	Yes: ☐ No: ☐
Does testing site have sufficient clean dry storage space for GX reagents?	Yes: ☐ No: ☐ Not sure:☐
Does the test site check samples for quality?	Yes: ☐ No: ☐
Is the site enrolled in a Proficiency Testing programmeme?	Yes: ☐ No: ☐
Proficiency Testing scored 100% or corrective action?	Yes: ☐ No: ☐
In which of these areas are temperatures monitored and records maintained? Select all that apply	☐Fridges storing samples placed ☐Room where GX is ☐ Storage areas ☐I don't know ☐Other (please
Are staff trained in biosafety procedures?	Yes: ☐ No: ☐

Section E: Testing Capacity

TB testing

Year	Number of tests completed	No. of errors	Number of people who tested positive	No. of GX modules	Average daily tests	Daily capacity of tests on GX	Average turnaround time between sample received at lab and when results are available for collection
2016							
2019							

HIV Viral Load Tests

Year	Number of tests completed	No. of errors	Number of people who tested positive	No. of GX modules	Average daily tests	Daily capacity of tests on GX	Average turnaround time between sample received at lab and when results are available for collection
2016							
2019							

HIV Early Infant Diagnosis (EID) Tests

Year	Number of tests completed	No. of errors	Number of people who tested positive	No. of GX modules	Average daily tests	Daily capacity of tests on GX	Average turnaround time between sample received at lab and when results are available for collection

2016							
2019							

Section F: Costs

How much does each test cost to the patient?	TB Test : HIV VL: EID:
Are any of these diagnostics tests reimbursable through health insurance? If yes, which one?	Yes: ☐ No: ☐ Not sure:☐

<u>Section G:</u> General Questions

What are the main drivers of variability in your costs?	
What are some of the factors affecting the utilisation rate of your diagnostic tools (i.e. how many tests you perform relative to your maximum capacity)?	
What are, in your experience, the benefits of integrated TB and HIV testing? Select all that apply.	☐Improved access to prevention, diagnosis and treatment services for patients ☐Improved adherence and outcome of treatment for patients

	☐ Services can be decentralized to periphery and low cadre health workers ☐Integrated and pooled staff training ☐Maximise synergy and partnership between stakeholder ☐Cost savings for the patient ☐Cost savings for the government ☐Other (please specify
What is, in your view, the key success factor for integrated testing? Select all that apply	☐Communication, collaboration and coordination among stakeholders are essential ☐Adequate numbers of qualified and motivated lab workers ☐ Enough machines to handle the load ☐Laboratory space to accommodate the workload ☐I am not sure ☐Other (Please specify) _____
What is, in your view, the major barriers for implementing integrated or multi-disease testing on the GeneXpert? Select all that apply	☒Health workers are at greater professional risk (i.e TB infection control ☐Separate programme management of HIV and TB in the country ☐ Separate funding mechanisms for HIV and TB ☐TB Infection control is difficult under current conditions ☐Heavy workload under one disease ☐Capacity of the GeneXpert machine ☐Other (please specify)_____
What is your key recommendation to other facilities/countries planning to integrate the HIV and TB tests on the GeneXpert platform?	

Appendix 3: Chapter 4, Clinical Questionnaire on GeneXpert Implementation

Guidance for completing this form

Different sections of this form refer to different diagnostic tools. The list below outlines what sections of the form should be completed by diagnostic tool:

- If the clinic is testing for both HIV and TB using a GeneXpert **integrated** diagnostic tool, please complete **all** sections.
- If the clinic is testing for both HIV and TB using **non-integrated** diagnostic tools, please complete Section A, Section B, Section C and Section D.
- If the clinic is testing for HIV only, please complete Section A, Section B and Section D.
- If the clinic is testing for TB only, please complete Section A, Section B and Section C.

Section A: Personal Information

<table>
<tr><td>Name of respondent:</td><td></td></tr>
<tr><td>Position:</td><td></td></tr>
<tr><td>Name of site:</td><td></td></tr>
<tr><td>Disease(s) diagnosed:</td><td>Tuberculosis : ☐ HIV: : ☐</td></tr>
<tr><td>Diagnostic tool(s) used in lab:</td><td>
<table>
<tr><th>HIV Viral Load (VL) testing</th><th></th><th>HIV Early Infant Diagnosis (EID)</th><th></th><th>TB</th><th></th></tr>
<tr><td>GeneXpert (integrated with TB)</td><td>☐</td><td>GeneXpert (integrated with TB)</td><td>☐</td><td>GeneXpert (integrated with HIV VL)</td><td>☐</td></tr>
<tr><td>GeneXpert (not integrated with TB)</td><td>☐</td><td>GeneXpert (not integrated with TB)</td><td>☐</td><td>GeneXpert (integrated with HIV EID)</td><td>☐</td></tr>
<tr><td>Other diagnostic tools (not GeneXpert)</td><td>☐</td><td>Other diagnostic tools (not GeneXpert)</td><td>☐</td><td>GeneXpert (not integrated with HIV)</td><td>☐</td></tr>
<tr><td>We do not perform this type of testing</td><td>☐</td><td>We do not perform this type of testing</td><td>☐</td><td>Other diagnostic tools (not GeneXpert)</td><td>☐</td></tr>
<tr><td></td><td></td><td></td><td></td><td>We do not perform this type of testing</td><td></td></tr>
</table>
</td></tr>
<tr><td>Date:</td><td></td></tr>
</table>

Section B: General Patient information

Approximately what proportion of your patients are accompanied by someone else (e.g. family or friends)?	
Approximately what proportion of your patients are informal caregivers (e.g. have children to look after or elderly)?	
What mode of transport do your patients typically use to get to the clinic?	
On average, how much time do patients spend travelling to the clinic/hospital?	
On average, how much money do patients to travel to the clinic/hospital? (Please provide answer in Lesotho Loti)	
On average, how much time do patients spend at the hospital/clinic per visit?	
On average, how many visits do patients make to the hospital/clinic in order to be tested and find out their results? Please note, this should **not** include visits for treatment.	

What is the average age of patient being tested?	For TB For HIV VL: For HIV EID:
How much do patients pay to get the tests?	TB test: HIV test:
Are any of these costs reimbursed by insurance?	Yes: ☐ No: ☐

Section C: TB

Have the staff been trained in sample collection procedures?	Yes:	☐	No:	☐
Do the staff check sputum samples for quality and quantity before submitting to the laboratory or another site?	Yes:	☐	No:	☐
Are all patients entering facility screened using the national screening tool	Yes:	☐	No:	☐
Are all TB +ves screened for HIV	Yes:	☐	No:	☐
Are all TB patients tested for HIV and initiated onto HIV treatment if positive?	Yes:	☐	No:	☐
Are patients initiated onto treatment within one week of diagnosis?	Yes:	☐	No:	☐

Are all new TB patients tested for HIV and are results documented in TB card?	Yes:	☐	No:	☐
Does the clinical site have a system for following-up newly diagnosed TB patients not yet on treatment?	Yes:	☐	No:	☐
Are patients initiated onto MDR treatment at this facility?	Yes:	☐	No:	☐

	2016	2019	Comments
Number of people tested for TB			
Number of people testing positive for TB			
Number of people testing positive for both TB and HIV (if applicable)			
Number of people initiating treatment after testing positive for TB			
Average time between testing and initiating TB treatment (in days)			
Percentage of those on TB treatment who are eventually cured			

Average time spent on TB treatment until cured of TB (if available)			
Number of those tested for TB who died			
Average age at death			

Section D: HIV

Are all PLHIV regularly screened for TB symptoms?	Yes:	☐	No:	☐
Are all new HIV patients tested for TB and initiated onto TB treatment if positive?	Yes:	☐	No:	☐

HIV Viral Load

	2016	2019	Comments
Number of people tested for HIV VL			
Number of people testing positive for HIV VL			
Number of people initiating ART treatment after testing positive for HIV VL			

Average time between testing and initiating ART treatment in days			
Percentage of those on ART who remain on ART for at least 12 months			
Number of those tested for HIV who died			
Average age at death			

HIV EID

	2016	2019	Comments
Number of people tested for HIV EID			
Number of people testing positive for HIV EID			
Number of people initiating ART treatment after testing positive for HIV			
Average time between testing and initiating ART treatment in days			

Percentage of those on ART who remain on ART for at least 12 months			
Number of those tested for HIV who died			
Average age at death			

Section E: General

What are some of the factors influencing patients' health outcomes following diagnosis? i.e completing the care cascade	
If integrated: What improvements have you seen since moving to an integrated system?	
If integrated: What challenges have you had since moving to an integrated system?	

If integrated: Have there been obstacles to fulling realising the benefits of integration?	

Appendix 4: Chapter 4, Poster presented at the 23rd International Conference on Integrated Care, Belgium

MISSED OPPORTUNITIES FOR INTEGRATED TESTING: AN EVALUATION OF THE IMPLEMENTATION OF TB AND HIV EID TESTING ON THE GENEXPERT PLATFORM IN LESOTHO

Gamuchirai P. Gwaza[1,2] Monkoe Leqheka[3], Sabine Dittrich[4,5], Tsietso Mots'oane[3], Kekeletso Kao[1]

[1]1 FIND, the global alliance for diagnostics, 2 Oxford University Nuffield Department of Primary Care, 3 Department of Laboratory Sciences, Ministry of Health Services, Lesotho
4 Deggendorf Institute of Technology, European Campus Rottal-Inn, Pfarrkirchen, Germany , [5] Nuffield Department of Medicine, Centre for Tropical Medicine and Global Health, University of Oxford
Corresponding author's email: gchituri@gmail.com

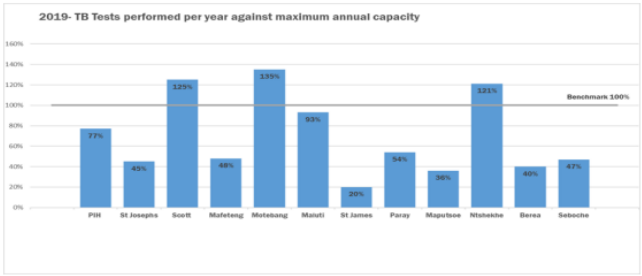
Introduction

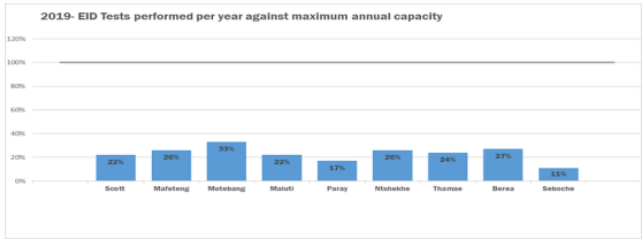
Much progress has been made in collaborative TB and HIV activities. Integrated testing of TB and HIV can improve health outcomes and save costs. The GeneXpert (GX) instrument, a multi-disease testing platform, can allow for simultaneous HIV and TB testing. However, utilization of the platform for integrated testing remains suboptimal, and there are operational barriers to implementing integrated TB and HIV testing. The evaluation aimed to determine the implementation rate or potential for integrated TB and HIV testing on the GX platform in Lesotho. The evaluation focused on HIV EID and TB testing as these were the only tests being performed on the GX at the time of the evaluation.

Methods

The evaluation used mixed methods including a survey questionnaire, semi-structured interviews, and a review of records at each health facility. Data was collected for the period 2017 and 2019. Data collected occurred between January and March of 2020 Thirteen health facilities were visited, and interviews conducted with 44 people, 24 from the TB units, 18 from the maternal health units where HIV EID testing was conducted and 2 from the central Ministry of Health offices.

Results





All thirteen health facilities had at least one GX instrument for TB or EID testing. In 2017, the average utilization rate for the GX instrument for TB and EID testing was 63% and 24%, while in 2019, the average utilization rate was 61% for TB testing and 27% for EID. However, none of the health facilities included testing for TB and HIV on the same GX instrument simultaneously. This was because of a various reasons including, human resources capacity, misalignment of donors and different reporting requirements. In general, utilization rates were sufficiently low that all the HIV and TB tests undertaken in 2017 and 2019 could have been performed using only the instruments currently dedicated to TB testing. All except for three sites (Scott, Motebang and Maluti) where the testing rates were high.

Table 2: Scenario for possible integration of TB and EID tests on the available GX instruments used for TB testing in 2019

	TB tests	EID tests	Total	Maximum capacity	Utilisation rate
Scott Hospital	3974	703	4677	3168*	148%
Mafeteng hospital	4565	1033	5598	9504***	59%
Motebang hospital	8573	835	9408	6336**	148%
Maluti hospital	2948	690	3638	3168*	115%
Paray hospital	1699	549	2248	3168*	71%
Ntsekhe hospital	3834	834	4668	6336*	74%
Berea Hospital	2553	846	3399	6336*	54%
Seboche Hospital	1476	340	1816	3168*	57%

Conclusions

It is technically feasible to integrate TB and HIV testing. However, there are practical and technical considerations if implementation of TB and HIV testing is to be successful and optimized. Technically, there is a need to understand effectiveness and capacity of the current testing platforms within each context; and practically issues related to donor coordination, human resource capacity and physical location of the instruments must be considered.

Call for Experts

To provide diverse expert input, we are seeking **experts to shape an implementation framework** for integrated diagnosis in LMICs. **If you are interested** in being part of the stakeholder group for this research, **please contact me!** gchituri@gmail.com

The work is part of PhD studies in Evidence Based Health Care at the University of Oxford.

Acknowledgements

The authors would like to thank FIND for supporting this evaluation.

Appendix 5: Chapter Six, List of primary studies included in the realist review

Study title	Authors	Country	Study Design	Diseases integrated
1. Feasibility and impact of near-point-of-care integrated tuberculosis/HIV testing in Malawi and Zimbabwe	Wang et al., 2021	Malawi, Zimbabwe	Implementation study	HIV and TB
2. Multi-disease testing for HIV and TB using the GeneXpert platform: A feasibility study in rural Zimbabwe.	Ndlovu 2018	Zimbabwe	Implementation study	HIV and TB
3. The substantial burden of non-communicable diseases amongst adults: Screening results from an integrated testing services clinic for adults in Soweto, South Africa	Hopkins et, 2021	South Africa	Cross-sectional study	HIV and NCDs
4. Integrated point-of-care testing (POCT) for HIV, syphilis, malaria, and anaemia at antenatal facilities in western Kenya: a qualitative study exploring end-users 'perspectives of appropriateness, acceptability and feasibility	Young et al., 2019	Kenya	Qualitative study	HIV, syphilis, malaria, and anaemia
5. Perspectives of healthcare workers, national and regional policy stakeholders on the management of chronic lung disease in five sub-Saharan African countries: tale of a vicious cycle of neglect.	Mulupi et al, 2022	Kenya, Malawi, Sudan, Tanzania, and Uganda	Qualitative study	Chronic lung diseases
6. The association between a detectable HIV viral load and non-communicable diseases comorbidity in HIV positive adults on antiretroviral therapy in Western Cape, South Africa.	George et al, 2019	South Africa	Unclear	HIV and NCDs
7. Implementation of 'see-and-treat' cervical cancer prevention services linked to HIV care in Zambia.	Mwanahamuntu et al, 2009	Zambia	Implementation study	HIV and Cervical cancer
8. Implementation of cervical cancer prevention services for HIV-infected women in Zambia: measuring programme effectiveness.	Parham et al, 2010	Zambia	Implementation study	HIV and Cervical cancer
9. Early experiences in integrating cervical cancer screening and treatment into HIV services in Zomba Central Hospital, Malawi	Pfaff et al, 2018	Malawi	Implementation study	HIV and Cervical cancer
10. Integrating HIV and hypertension management in low-resource settings: Lessons from Malawi.	Patel et al, 2018	Malawi	Implementation study	HIV and hypertension

11. Cervical cancer prevention in HIV-infected women using the "see and treat" approach in Botswana.	Ramogola-Masire, 2012	Botswana	Implementation study	HIV and Cervical cancer
12. The acceptability of integrated healthcare services for HIV and non-communicable diseases: experiences from patients and healthcare workers in Tanzania.	Shayo et al, 2022	Tanzania	Qualitative study	HIV and NCDs
13. Community Satisfaction with Primary Health Care Services. An evaluation undertaken in the Morogoro region of Tanzania	Gilson et al, 1994	Tanzania	Qualitative study	Primary care services
14. Patient and provider perspectives on implementation models of HIV counselling and testing for patients with TB	Corneli et al, 2008	Democratic Republic of Congo	Qualitative study	HIV and TB
15. Programmematic pathways to child survival: results of a multi-country evaluation of Integrated Management of Childhood Illness	Bryce et al, 2005	Bangladesh, Brazil, Peru, Tanzania, and Uganda.	Programme evaluation	Integrated Management of childhood illnesses
16. Integrated primary health care in low- and middle-income countries: a double challenge.	Druetz, 2018	Burkina Faso	Programme evaluation	Primary care and Malaria
17. Diagnosis and treatment of acute respiratory illness in children under five in primary care in low-, middle-, and high-income countries: A descriptive FRESH AIR study	Kjærgaardl et al, 2019	Greece, Kyrgyzstan, Vietnam, and Uganda	Observational study	Acute respiratory diseases
18. Multimorbidity and care for hypertension, diabetes and HIV among older adults in rural South Africa	Chang et al, 2019	South Africa	Longitudinal study	Hypertension, diabetes and HIV
19. A cluster-randomized controlled trial to improve the quality of integrated HIV-tuberculosis services in primary healthcare clinics in South Africa.	Gengiah et al, 2021	South Africa	Cluster-randomized controlled trial	HIV and TB
20. Exploring the Feasibility of Service Integration in a Low-Income Setting: A Mixed Methods Investigation into Different Models of Reproductive Health and HIV Care in Swaziland.	Church et al, 2015	Swaziland	Comparative case study	HIV and reproductive health
21. Impact of Integrated Services on HIV Testing: A Non-randomized Trial among Kenyan Family Planning Clients	Church et al, 2017	Kenya	Non-randomized Trial	HIV and family planning

22. Expanding access to non-communicable disease care in rural Malawi: outcomes from a retrospective cohort in an integrated NCD-HIV model.	Wroe et al, 2020	Malawi	Retrospective cohort	HIV and NCDs
23. Reaching underserved South Africans with integrated chronic disease screening and mobile HIV counselling and testing: A retrospective, longitudinal study conducted in Cape Town.	Smith et al, 2021	South Africa	Retrospective, longitudinal study	Chronic diseases including HIV
24. The impact of HIV/SRH service integration on workload: analysis from the Integra Initiative in two African settings.	Sweeny et al, 2014	Kenya and Swaziland	Programme Evaluation	HIV and SRH
25. How to Integrate HIV and Sexual and Reproductive Health Services in Namibia, the Epako Clinic Case Study	Zapata et al, 2017	Namibia	Observational study	HIV and SRH

Appendix 6: Chapter Six, List of systematic reviews included in the realist review

	Title	Author	Focus of integration
1	Strategies for integrating primary health services in low- and middle-income countries at the point of delivery	Dudley et al 2011	General Health services integration
2	Strategies for integrating primary health services in middle- and low-income countries: effects on performance, costs and patient outcomes	Briggs et al., 2001	General Health services integration
3	Integration of non-communicable disease and HIV/AIDS management: a review of healthcare policies and plans in East Africa	Adeyemi et al, 2021	NCDs and HIV/AIDS
4	Mapping Evidence of Patients' Experiences in Integrated Care: A Scoping Review	Youssef et al., 2019	General Health services integration
5	Integrating tuberculosis and HIV services in low- and middle-income countries: a systematic review.	Legido-Quigley et al, 2013	TB and HIV
6	Integrated management of childhood illness (IMCI) strategy for children under five.	Gera et al., 2016	Integrated Management of Childhood Illnesses (IMCI)
7	Integrating cardiovascular diseases, hypertension, and diabetes with HIV services: a systematic review	Haldane et al., 2017	Cardiovascular diseases, hypertension, diabetes and HIV
8	Integration of HIV/AIDS and non-communicable diseases in developing countries: rationale, policies and models.	Haregu et al., 2015	HIV/AIDS and NCDs

9	Integrating Care for Diabetes and Hypertension with HIV Care in Sub-Saharan Africa: A Scoping Review.	McCombe et al, 2022	Diabetes, Hypertension and HIV
10	Non-communicable diseases and HIV care and treatment: models of integrated service delivery.	Duffy et al., 2017	NCDs and HIV
11	A systematic review of primary care models for non-communicable disease interventions in Sub-Saharan Africa.	Kane et al., 2017	NCDs
12	Health Systems Integration of Sexual and Reproductive Health and HIV Services in Sub-Saharan Africa: A Scoping Study.	Hope et al., 2014	SRH and HIV
13	Management of Chronic Diseases in Sub-Saharan Africa: Cross-Fertilization between HIV/AIDS and Diabetes Care.	Ov et al., 2012	HIV/AIDS and Diabetes
14	Barriers and enablers to integrating maternal and child health services to antenatal care in low- and middle-income countries.	Jongh et al., 2016	Maternal and child health
15	Interventions integrating non-communicable disease prevention and reproductive, maternal, newborn, and child health: A systematic review	Kikuchu et al., 2018	NCDs, reproductive and maternal health

Appendix 7: Chapter Six, Poster presented at the ASLM conference held in December 2023 in South Africa

Integrated diagnosis in Africa's low- and middle-income countries: What is it, what works, and for whom? A Realist Synthesis

ASLM

Gamuchirai P. Gwaza, Annette Plüddemann, Marcy. McCall MacBain, Carl Heneghan

Introduction

Integrated diagnosis can improve health outcomes and patient experiences through early diagnosis and identification of cases that could otherwise be missed. It enables health systems to be structured around patients, not diseases, by identifying multiple pathogens from a single test or providing holistic care that addresses the whole person and not just the specific symptoms presented. Multiple diagnoses of various conditions can be made within one clinical visit. An integrated diagnosis is a clinically essential intervention for some health conditions, such as preventing and treating TB co-infection (Sweeny, 2011). Numerous studies have proven the feasibility of integrating diagnosis for different conditions or diseases. However, more research is needed to link integrated diagnosis to the key outcomes of improvement in patient experiences and health outcomes. The review explores how different actors in low- and middle-income countries (LMICs) conceptualize integrated diagnosis and the contexts and mechanisms necessary for integrated diagnosis to be effective.

Methodology

This study uses a realist methodology to systematically review and synthesize the available evidence to answer 2 questions i) What does an integrated diagnosis mean for different health actors ii) What contexts and mechanism are necessary for integrated diagnosis to be successful?

An initial program theory was developed based on scoping literature and discussions with experts. Primary studies and other reviews on integrated diagnosis, multi-disease testing or integrated health care (with a diagnostic component) were sought from five key data sources. The primary studies were used to contribute to helping build, refute and test the developing theoretical framework.

Results

Types of integrated diagnosis

1. **Facility Integration**, services are provided within one location or co-located, also known as the supermarket approach, one-stop shop, teamwork approach or referral-based services.
2. **Individual or human resources integration**, where services are provided by one health care provider
3. **Technology integration**, involves the use of muti-disease platforms or dual or triple point of care technologies with multiple purposes.
4. **Mobile or campaign-based integration**, where services are provided as part of a campaign or by mobile teams either within or out of health facilities. It can be a subtype of facility or individual integration. sometimes

Figure 1: Ways that integrated diagnosis have been conceptualized

Contexts and mechanisms necessary for integrated diagnosis to be successful using the realist heurist of Context, Mechanism and Outcome (C-M-O) to explain generative causation

For the health workers

1. Multi-diseases policies and diagnostic algorithms (C) with the necessary training, increase self efficacy (M) and result in improved quality of care, early diagnosis and improved health outcomes (O).
2. Adequate human resources and multi-disease funding (C) ensure health workers have the capacity (M) to do integrated diagnosis, resulting in improved coverage of services, early diagnosis and improved health outcomes (O).
3. Integrated monitoring and reporting tools (C), build accountability (M) for the health workers, ensuring they do the diagnosis, resulting in improved coverage of services, early diagnosis and improved health outcomes.
4. Having effective treatment and referral pathways (C) improves the perceived benefit (M) of the integration by the heath care workers resulting in improved coverage of services, early diagnosis and improved health outcomes.

For the patients or people utilization integrated diagnostic services

Patient perception of care is vital in determining the success of integrated diagnosis interventions.

1. The relationship between the health care worker and the patient (C) is essential to ensuring patients feel respected (M), which improves their experience of health care (O) and increase uptake of services, leading to early diagnosis and improved health outcomes (O).
2. Ensuring patients have confidentiality in receiving the services (C) will help reduce stigma (M) for some conditions, which improves their experience of health care (O) and increases uptake of services , leading to early diagnosis and improved health outcomes (O).
3. Increasing ease of access (C), ensures patients have convenience and comfort (M) while accessing services, which improves their experience of health care (O) and increase uptake of services , leading to early diagnosis and improved health outcomes (O).
4. Increasing turnaround time of results (C), reduces patient anxiety (M), which improves their experience of health care (O) and increase uptake of services , leading to early diagnosis and improved health outcomes (O).

Integration can sometimes lead to increase time spent at the health facility (C) resulting in frustration among patients (M), which reduces uptake of services.

Conclusions

Success of integrated diagnostic interventions depends on a variety of factors, that require understanding the whole health system, including the perceptions and views of health care workers and patients. Articulating what is meant by integrated diagnosis for each intervention helps in transferring lessons across contexts.

Appendix 8, Chapter Seven, Poster presented at the early diagnosis conference, St Andrews University, 2024

Early Diagnosis through Integrated Diagnosis: Practical Insights for Designing Interventions in LMICs - An Expert Consensus

Gwaza GP[1], Plüddemann A[2], McCall MacBain M[2], Dittrich S[3] and Heneghan C[2]

Affiliations: 1-Department of Continuing Education, University of Oxford, UK. 2- Centre for Evidence Based Medicine, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK. 3-Department of Global Public Health, Deggendorf Institute of Technology, Deggendorf, Germany, Nuffield Department of Medicine; Center for Tropical Medicine and Global Health, University of Oxford, UK

Introduction

Integrated diagnosis, a subset of integrated health care, is critical in addressing the health challenges in low - and middle-income countries (LMICs), including better management of comorbidities and chronic conditions. Integrated or multi-disease diagnostics are increasingly capable of rapidly and accurately testing for multiple diseases including HIV, TB, HPV, HBV, HCV, COVID19, and sexually transmitted infections (STIs) at or near the point of care. Introducing integrated diagnostics into primary care settings varies in purpose, models, diseases, target populations, scale, and results, complicating clarity on effective strategies in specific contexts.

Integrated diagnosis is the identification of multiple diseases/conditions within one visit and results are received by the client on the same day. Integrated diagnosis can ensure **early diagnosis** of critical and chronic conditions.

This study aimed to identify and reach a consensus on core criteria for designing integrated same -day diagnosis interventions at the primary care level that would improve patient experiences and health outcomes in LMICs.

Integrated diagnosis is aimed at:

IMPROVEMENT IN PATIENT EXPERIENCES

IMPROVEMENT IN HEALTH OUTCOMES

Methods

Between July and November 2023, a two -round Delphi process was used to generate consensus amongst an international panel representing a range of relevant professions. The JISC online survey tool was used. Predetermined thresholds for consensus (70% vote on critical to include) and simple majority were developed for the surveys.

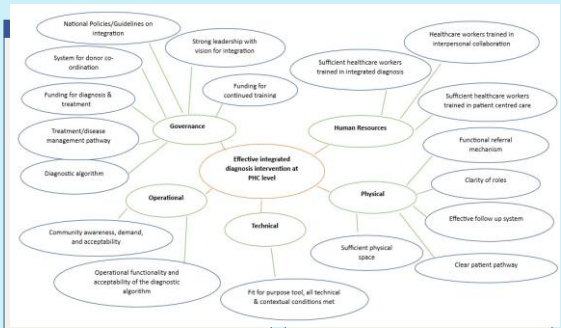
The survey had a total of 33 criteria divided into six domains, each comprising specific criteria: Governance (8 criteria), Operational Considerations (5 criteria), Physical Integration (8 criteria), Human Resources Integration (4 criteria), Technology Integration (4 criteria) and Monitoring and Evaluation (M&E) (4 criteria). The criteria were developed based on a previously conducted realist review (1).

Results

Demographic characteristics of respondents

Characteristic		Survey 1 (n=55)	Survey 2 (n=48)
Sex	Male	20	17
	Female	34	31
	No response	1	
Age	26-30	3	
	31-40	19	14
	41-50	20	23
	51-64	13	11
Current location	Africa	24	24
	Europe	23	18
	Asia	4	2
	The Americas	2	2
	No response	2	2
Profession	Academic Researcher	12	7
	Health Policymaker	11	11
	Implementer	30	30

In Round 1, 55 experts participated. 14 of 33 criteria reached consensus as *critical to include*, 9 were removed. Round 2 had 11 criteria, 3 new, 2 merged.
48 experts participated; 4 criteria reached consensus as *critical to include*. 8 criteria were not included, 4 considered *important but not critical*.
Overall, 18 criteria reached consensus on *critical to include*.



Key Messages

In many African health facilities, well-meaning integrated diagnosis tools are introduced without considering these basic principles. This leads to wasted resources and poor patient outcomes.

1. Think Systematically: Diagnosis is part of a bigger healthcare picture, changes in one area affect everything.

2. Care Comes First: Diagnosis isn't just tests—it's about taking care of patients and linking them to care.

3. Complete Solutions: Effective diagnosis needs to fit into existing systems and patient care pathways.

4. Delivery Matters: How and why healthcare services are provided is just as important as what is provided.

References

Gwaza G, Plüddemann A, McCall MC & Heneghan C. Integrated diagnosis at the primary care level in Africa's low and middle-income countries: What is it, what works, and for whom? A Realist Synthesis. 2024. https://osf.io/preprints/africarxiv/g7pm6

Contact Information

Corresponding author: Gamuchirai Pamela Gwaza

Email: gamuchirai.gwaza@kellogg.ox.ac.uk

Core criteria: What needs to be in place before (or to ensure success of) integrated diagnosis interventions introduction in primary care settings in low resource contexts such as Africa?

A. Governance and leadership:
1. Strong leadership with a shared vision for integration
2. Specific funding for diagnosis and treatment to ensure there is political will and commitment to do the work.
3. Funding for continued training of health workers for sustainability and to curb staff turnover
4. System for donor coordination to avoid fragmentation of services.
5. National policies & guidelines on integration to ensure uptake and scale up of integration within the country'
6. Diagnostic algorithms to ensure implementation at the facility level.
7. Treatment and disease management ensure diagnosis does not just identify problems without solutions.

B. Technical integration:
8. Fit for purpose tools that meet all technical and contextual requirements.

C. Human resources integration:
9. Sufficient human resources trained in diagnosis
10. Health care workers trained in patient centered care
11. Healthcare workers trained in interpersonal collaboration

D. Operational considerations
12. Operational functionality and acceptability of the diagnostics algorithm to ensure uptake at the facility level by the healthcare workers.
13. Community awareness, demand and acceptability of diagnostics to ensures uptake of services by the clients.

E. Physical integration
14. Sufficient physical space to facilitate uptake and effective implementation.
15. Functional referral mechanisms
16. Effective follow-up systems to ensure patients complete the care cascade.
17. Clear patient pathways contribute to improving patient experiences of integrated services.
18. Clarity of roles improves delivery of service and improves patient experiences..

Conclusion

These core criteria offer guidance for policymakers, funders, implementers, and manufacturers in LMICs. The primary goal of integrated diagnosis should be to improve patient experiences and health outcomes. As such it is essential to:

- consider key success factors during intervention design;
- take a health systems approach, integrating with other aspects of the broader healthcare system and patient needs.

Appendix 9: Chapter Seven, Ethical Approval from the Department for Continuing Education

SOCIAL SCIENCES & HUMANITIES
INTERDIVISIONAL RESEARCH ETHICS COMMITTEE
DEPARTMENTAL RESEARCH ETHICS COMMITTEE

DREC for the Department for Continuing Education. researchethics@conted.ox.ac.uk

UNIVERSITY OF OXFORD

8 August 2023

Dear Pamela,

Research ethics approval

Research title: A Delphi study to set minimum criteria for developing integrated same-day diagnosis interventions in LMICs

Research ethics reference: OUDCE C1A 23 033

The above application has been considered on behalf of the Department for Continuing Education Departmental Research Ethics Committee (DREC) in accordance with the University's procedures for ethical approval of all research involving human participants.

I am pleased to confirm that, on the basis of the information provided to the DREC, ethics approval has now been granted for this study.

Please note the following:

Personal data: It is the responsibility of the PI to ensure that all personal data collected during the project is managed in accordance with the University's guidance and legal requirements.

In-person activities: Any data collection involving in-person interactions with participants must have an up-to-date fieldwork risk assessment in place; further guidance is available from the Safety Office's website.

Amendments: Please notify the committee if you intend to make any amendments to the information in your ethics application as submitted at date of this approval, as all changes must receive ethical approval prior to implementation. The amendment form is available on the SSH IDREC webpage.

We welcome feedback on your experience of the ethical review process and suggestions for improvement. Please email any comments to researchethics@conted.ox.ac.uk or ethics@socsci.ox.ac.uk.

Yours sincerely

Matthew Neal

DREC Chair

cc: Annette Pluddemann, PI

Appendix 10: Chapter Seven, Protocol for the Delphi study

Minimum criteria for developing integrated same-day diagnosis interventions in LMICs: A Protocol for a Delphi study.

Student Name:	**Gamuchirai Pamela Gwaza**
Date:	**22 June 2023**
Department:	**Department of Continuing Education.**
College:	**Kellogg College**
Supervisors:	**Dr Carl Heneghan,**
	Dr Annette Plüddemann
	Dr Marcy McCall MacBain

1

Table of Contents

Abstract

Background: Integrated health care is becoming more critical in addressing the health challenges in LMICs, because of the rising comorbidities as chronic conditions such as HIV are being better managed, the increasing burden of NCDs, and health systems challenges amplified by the COVID-19 pandemic(1-3). Technological innovations also make simultaneous multi-disease testing and diagnosis possible quickly. Integrated diagnosis is defined, in the research, as the identification of multiple conditions within one visit, and results are received by the patient on the same day. Integrated diagnosis can ensure early diagnosis of critical conditions, increase uptake of health services, and improve disease surveillance, patient experiences and health outcomes(4-6). Various integrated diagnosis interventions are implemented that differ by purpose, type of models, disease combination, target populations, the scale of interventions, and results making it challenging to have clear evidence of what works effectively in specific contexts.

This Delphi study aims to identify minimum criteria for developing integrated same-day diagnosis interventions to ensure improvement in patient experiences and health outcomes. The criteria will be used as a decision aid when prioritizing components in designing integrated same-day diagnosis interventions in LMICs, particularly in Africa.

Methods: This study is a Delphi consensus-seeking exercise surveying experts, healthcare implementers and policymakers. Panellists (individual participants who will fill out the online survey) will come from diverse backgrounds and settings interested in or are involved in integrated health care and diagnosis interventions.

We aim to sample approximately 100 panellists, and the JISC online survey tool will be used. A questionnaire with six categories and 36 questions has been developed. It is envisaged that panelists will reach a consensus after two Delphi rounds. A third round will be considered if an agreement is not reached or there is agreement on everything that a prioritisation exercise is warranted. 'Consensus' will be obtained when 70% or more participants score a 4- critical to include when rating the importance.

Discussion: Establishing minimum criteria when developing integrated diagnosis interventions is helpful for implementers and manufacturers of diagnostic equipment to ensure they can achieve optimal patient experiences and health outcomes. Ultimately, this will allow systematic monitoring and evaluation of the interventions to ensure continuous learning and improvement. These criteria may change as new evidence emerges and our understanding of integrated same-day diagnosis develops.

1.0 Introduction

Integrated diagnosis is defined, in the research, as the identification of multiple conditions within one visit, and results are received by the patient on the same day. The diagnostic process includes performing a clinical history and interview, physical examination, diagnostic testing, and referring or consulting with other clinicians (7). In this case, integrated sample referrals, where patients receive the results on a different day, are excluded. The focus of integrated diagnosis should be the patient through increased convenience, ease of access, continuity of care, and holistic care. An integrated diagnosis is a clinically essential intervention for some health conditions, such as preventing and treating TB co-infection (8). Health systems in low and middle-income countries (LMICs) are currently designed to respond to acute, predominantly infectious diseases, usually through disease-specific vertical programs (9), as such focus is on a single condition instead of addressing the patient's needs, which may be broader.

The case for integrated diagnosis and integrated health care in LMICs, particularly in Africa, has been made in several forums. The failure to control and manage the burden of the disease is partly due to the inability to correctly diagnose and treat infectious cases, as opportunities to prevent onward transmission are missed, especially when people visit primary care facilities. The World Health Organization (WHO) estimates, for example, that only 64% of new tuberculosis (TB) cases are detected and notified, suggesting that over three million cases of this highly contagious disease are missed annually (7, 10). At the same time, as the life expectancy and quality of life among persons with HIV continues to improve due to treatment, there is expected comorbidity with non-communicable diseases (NCDs) (11). There is also a high level of support for integrated health care with the WHO policy on integrated health care in 2016 (12). Diagnosis is mentioned as part of the health services, alongside health promotion, disease prevention, treatment, disease management, rehabilitation and palliative care that should be integrated. Policy guidance is also available for integrating diagnosis and treatment of other health conditions such as TB and HIV(13).

The Delphi study builds on a previous realist review to identify mechanisms and contexts necessary for integrated diagnosis. Based on the review, we identified critical considerations for developing and implementing integrated diagnosis interventions in LMICs, especially in Africa. These criteria will be used as a basis for the questions discussed in the Delphi process.

2.0 Study objectives

- To identify a set of minimum criteria for developing integrated same-day diagnosis interventions

3.0 Methods

The Delphi method will be used as described below.

3.1. Study Design

This study is a prospective, cross-sectional survey that seeks to gain consensus on minimum criteria for developing an integrated same-day diagnosis intervention to ensure improvement in

patient experiences and health outcomes. A Delphi study is a protocol-based and methodologically sound way to obtain consensus on an issue by gathering opinions from diverse stakeholders through multiple structured rounds of surveys (14). The essence of the Delphi technique is to engender reflection and discussion amongst a panel of experts to get as close as possible to consensus and document both the agreements reached and the nature and extent of disagreement. Delphi surveys are anonymous and iterative, allowing participants to consider their views of a topic in the context of the opinions of their peers while minimizing the risk of conformity bias. Most recently, the WHO has used the Delphi method to develop key performance indicators for the medical oxygen ecosystem and a clinical case definition for post-COVID-19 conditions (7).

3.2. Study Participants

We aim to purposefully sample participants with knowledge and experience in designing and implementing healthcare interventions, particularly emphasizing integrated care and diagnosis. The experts chosen will include the implementers and health workers in different African countries working in ministries of health, non-governmental organizations (NGOs) and civil society, individuals working in global health organizations such as Foundation for Innovative New Diagnostics (FIND), Clinton Health Access Initiative (CHAI), PATH and Elizabeth Glassier Paediatric AIDS Foundation (EGPAF), international health funders such as the Global Fund, UNITAID and UNICEF and individual experts in public health policy and programming especially in LMICs. These will be engaged in their capacities as experts rather than as representatives of their organizations. The primary users of the agreed criteria will be designers of health interventions such as the global health organizations, policymakers, and implementers in target LMICs and manufacturers developing diagnostic tools. We will aim to have a diverse sample of healthcare workers with expertise in clinical care and multiple diagnoses, especially of crucial conditions currently used for integrated diagnoses, such as TB, HIV, NCDs, malaria and other febrile illnesses and mental health.

There are no specific inclusion or exclusion criteria for participation in the study. Multiple recruitment channels will be used, such as, personal connections and referrals at conferences and other meetings or through social media such as LinkedIn. Efforts will be made to ensure a wide variety of stakeholders can participate in the study, focusing on geographic and occupational diversity within relevant areas of integrated health care and diagnostics.

3.3. Tools

The Delphi method is a structured communication technique originally developed as a systematic, interactive forecasting method which relies on a panel of experts (15). A Delphi process is one in which a panel of experts answers a series of questionnaires over two or more rounds to achieve consensus. The Delphi has been widely used for research and has advantages over other structured forecasting approaches (16). The Delphi is based on the principle that forecasts (or decisions) from a structured group of individuals are more accurate than those from unstructured groups. The panellists answer questionnaires in two or more rounds. After each round, a facilitator or researcher

provides an anonymized summary of the panellists' responses from the previous round and the reasons they provided for their judgments. Thus, experts are encouraged to revise their earlier answers in light of the replies of other panel members. It is believed that during this process, the range of responses will decrease, and the group will converge towards the "best" answer. Finally, the process is stopped after a predefined stop criterion (in this case 70% consensus on a criteria). The mean or median scores of the final rounds determine the results (17). Special attention is paid to the formulation of the Delphi theses and the definition and selection of the panelists to avoid methodological weaknesses that could threaten the validity and reliability of the results.

The Delphi method will be delivered online through the JISC online tool. Panellists will rate each question using a 1-5 Likert scale with an "Unable to rate" option, should they feel that item is beyond their expertise (see Table 1). The survey can be managed by emailing participants regarding missing data, calculating the feedback data for individual rounds, and downloading all user and scoring data in standard CSV and Excel format.

Table 1: Likert scale to be used for a rating in the Delphi survey

Not important	Limited importance	Important but not critical	Critical to include	Unable to rate (not my expertise)
1	2	3	4	5
○	○	○	○	○

3.4. Study Procedures

The researcher will develop a list of potential participants with input from methodological experts and colleagues to identify participants. Eligible participants will be invited to participate with a recruitment email to solicit participation and engagement, along with an explanation of the study objectives, instructions, and outputs. If a positive response is received, the link to the survey will be emailed to them.

The survey will contain listed options regarding variables to consider in the criteria of minimum conditions, initially as comprehensive as possible. The agreed variables will be followed by a series of questions relating to these variables. The survey is divided into six categories with 36 variables being asked under each category. There will be some demographic questions on age, sex and profession, with responses provided as categories to ensure anonymity.

The initial survey page will have information containing details of the research, privacy and confidentiality issues as well as how to withdraw. It also contains a consent checkbox to comply with General Data Protection Regulation (GDPR) legislation. All of these fields are mandatory by default.

All questions will be evaluated on a 5-point scale, from one (1) to five (5), and participants will be asked to choose the level of importance for each variable in the definition (Table 1). The first round of the Delphi will last approximately 20 working days or a month, and participants will be sent

two reminders to complete the online survey. The survey is iterative, as the Delphi methodology requires multiple rounds of questioning until consensus is achieved.

The same survey with some revisions will be used during the second round. Respondents will be informed of question results from the first-round questions as a single panel. The questions where consensus has been reached will be removed from the second survey round. In questions where an agreement is not reached, participants will be asked to reconsider their answers to all questions against the panel's anonymized results. A third round will be considered if consensus has not been reached on some variables. In case there is agreement on all the criteria, the participants may be asked, in a third round, to prioritise the criteria by, for example, picking their top three in each category. Panel answers will be provided as numbers of respondents having chosen that answer.

3.5. Statistical Analysis Plan

Primary and Secondary Endpoints

The primary outcome will be a consensus on the importance of variable inclusion. 'Consensus' will be obtained if 70% or more of the participants score a 4- critical to include when rating the importance. For each question, consensus proportions will be based on the number of respondents (excluding the category "Not my expertise"). Therefore, the denominator for the consensus will include only participants with knowledge and expertise for that specific question. During each round, participants can add comments for each item and additional variables not mentioned (Round 1 only).

Statistical Methods/Data Analysis

All downloaded data from the JISC tool is presented in standard CSV or Excel format, allowing it to be easily imported into most statistical analysis tools. The response rate will be calculated based on the number of returned surveys. The survey results will be used descriptively. Participant responses, including baseline and demographic characteristics, will be analyzed using basic statistics such as mean, median, and range. Responses on all other domains will be analyzed in proportions and illustrated using histograms.

3.6. Sample Size and Power

The sample size for constructing a Delphi panel is not a statistically bound decision, and good results can be obtained by a comparatively small group of homogenous experts (18). The objective will be to get a diverse sample of panelists from all stakeholders, including clinical experts, research experts and policy experts. Understanding that some panelists may be experts in more than one domain, we will invite at least 30 experts from each category. This should lead to a sample size of approximately 75-100 participants and solidify the generalizability of the consensus findings. Allowing for a 10-15% non-response (or non-desire to participate) rate and a 10% drop-out rate, we will invite and engage at least 100 participants.

3.7 Data Management and Storage

In the data collection form, participants will be entered as consecutive numbers based on survey receipt and completion. The survey will be managed and stored in the University of Oxford servers, in line with their procedures for the JISC survey. Once downloaded, the database document will be stored on a secure SharePoint site in the university with password protection. Only the study team will have access to the stored survey data. The survey results will be aggregated; no response can be linked to its responder. The study database will be held for five years after the report or publication is completed and permanently deleted.

4.0 Research Integrity

4.1 Ethical Approval

Ethical approval for the study will be sought from the University of Oxford, Department for Continuing Education Research Ethics Committee.

4.2 Obtaining Informed Consent

Consent to participate in the survey will be implied by answering and returning the survey. The first part of the questionnaire explains the research's aims, how to withdraw from the study, and how the data will be used and stored. This will be followed by a tick box confirming that participants meet the inclusion criteria and agree to participate. This aligns with the Central University Research Ethics Committee's (CUREC) Best Practice guide on internet-based research (19).

5.0 Dissemination Plan

The anticipated results of the study will be to identify a set of minimum criteria for developing integrated same-day diagnosis interventions in LMICs by the consensus of a group of experts. We will develop an online repository of information, publish a manuscript, and hold a dissemination workshop to share the results. We will seek other opportunities for presentations at relevant conferences.

6.0 Funding

There is no specific funding for this study.

7.0 Indicative Workplan

Date	Task
28 June 2023	Protocol Completion
15 July 2023	Ethical approval
16 July – 16 Aug 2023	Fieldwork Round 1 Delphi
1 Nov -30 Nov	Fieldwork Round 2 Delphi
Dec 2024	Panel discussions and recommendations
Feb 2024	Completion of Delphi report

References

1. WHO. Integrated Health Services – What and Why ? ; 2008.
2. WHO. WHO global strategy on people-centred and integrated health services. 2015.
3. Vasan A, Ellner A, Lawn S, Gove S, Anatole M, Gupta N, et al. Integrated care as a means to improve primary care delivery for adults and adolescents in the developing world: a critical analysis of Integrated Management of Adolescent and Adult Illness (IMAI). BMC Medicine. 2014;12(6).
4. Legido-Quigley H, CM M, Khan P, Atun R, Fakoya A, Getahun H, et al. Integrating tuberculosis and HIV services in low- and middle-income countries: a systematic review. Tropical Medicine and International Health. 2013;18(2):199–211.
5. Kane J, Landess M, Carroll C, Nolen A, Sodhi S. A systematic review of primary care models for non-communicable disease interventions in Sub-Saharan Africa. BMC Family Practice 2017;18(46).
6. Dudley L, Garner P. Strategies for integrating primary health services in low- and middle-income countries at the point of delivery. Cochrane Database Syst Rev. 2011(7):CD003318.
7. Fleming KA, Horton S, Wilson ML, Atun R, DeStigter K, Flanigan J, et al. The Lancet Commission on diagnostics: transforming access to diagnostics. Lancet. 2021;398(10315):1997-2050.
8. Sweeney S, Obure C, Maier C, Greener R, Dehne K, Vassall A. Costs and efficiency of integrating HIV/AIDS services with other health services: a systematic review of evidence and experience. Global Health and Development, . 2011.
9. Mulupi S, Ayakaka I, Tolhurst R, Kozak N, Shayo E, Abdalla E, et al. Perspectives of healthcare workers, national and regional policy stakeholders on the management of chronic lung disease in five sub-saharan African countries: tale of a vicious cycle of neglect. Preprint. 2022.
10. Umubyeyi Nyaruhirira A, Scholten JN, Gidado M, Suarez PG. Coronavirus Disease 2019 Diagnosis in Low- and Middle-Income Countries: The Big New Bully Disrupting TB and HIV Diagnostic Services. J Mol Diagn. 2022;24(4):289-93.
11. George S, McGrath N, Oni T. The association between a detectable HIV viral load and non-communicable diseases comorbidity in HIV positive adults on antiretroviral therapy in Western Cape, South Africa. BMC Infect Dis. 2019;19(1):348.
12. Organisation WH. Framework on integrated, people-centred health services. 2016.
13. WHO. WHO policy on collaborative TB/HIV activities: Guidelines for national programmes and other stakeholders. 2012.
14. Barrett D, Heale R. What are Delphi studies? Evidence Based Nursing. 2020.

9

15. Dalkey N, Helmer O. An Experimental Application of the Delphi method to the use of Experts. United States Air Force Project Rand; 1962.
16. Green K, Armstrong S, Graefe A. Methods to Elicit Forecasts from Groups: Delphi and Prediction Markets Compared. Foresight: The International Journal of Applied Forecasting. 200?.
17. Rowe G, Wright G. The Delphi technique as a forecasting tool: issues and analysis. International Journal of Forecasting. 1999;15:353–75.
18. Akins RB, Tolson H, Cole BR. Stability of response characteristics of a Delphi panel: application of bootstrap data expansion. BMC Med Res Methodol. 2005;5:37.
19. Oxford Uo. Central University Research Ethics Committee (CUREC) Best Practice Guidance 06 Version 7.: Internet-mediated research.

10

Appendix 11: Chapter Eight, OxTREC Minimal Risk Ethical Approval

Oxford Tropical Research Ethics Committee

University of Oxford
Research Services, Research Governance, Ethics & Assurance
Boundary Brook House, Churchill Drive, Oxford OX3 7GB
Tel. +44 (0)1865 (2)82106
E-mail: oxtrec@admin.ox.ac.uk

Gamuchirai Pamela Gwaza
via email

1 May 2024

Dear Gamuchirai,

Full Title of Study: Experiences of health care providers and women in utilising integrated same-day diagnosis services for antenatal care: A Case Study of Mabvuku Clinic in Harare, Zimbabwe

OxTREC Reference: 520-24

Thank you for your email of 25 April 2024 and updated minimal risk study application and documents

I am pleased to confirm that approval has now been granted for this study. This is valid for the planned duration of the study as detailed in the application and is subject to receiving the local ethical approval (if this approval has not yet been received).

The documents approved for this study are as follows:

Documents:	Version:	Date:
Minimal risk application form		
PIS/ICF	V2.0	25/04/24
Data Collection Instruments	V2.0	

Any subsequent changes to the application must be submitted to the Committee as an Amendment. This should include a letter to give the reasons for the proposed modifications and all revised documents with changes tracked.

Please ensure that you submit a completed Annual Report form on every anniversary of this approval and a final End of Study Report. The relevant forms can be found on the OxTREC website.

Finally, please note the following **important information**:

Data safety—all studies
It is the responsibility of the PI to ensure that all data collected during the course of the study is stored and transferred safely and securely. Further guidance and advice are available from the Research Data Team.

Only studies that will involve storing human tissue samples in Oxford
If you are planning to import the samples into England, you will need to make arrangements before the samples are transferred to store them under the governance of a Human Tissue Authority (HTA) licence. It is a legal requirement that any tissue or fluid made up of or containing human cells to be used for the purpose of research is stored on premises licensed by the HTA unless covered by an exemption. OxTREC approval is not a recognised exemption. Further information may be found on the University's human tissue governance web pages.

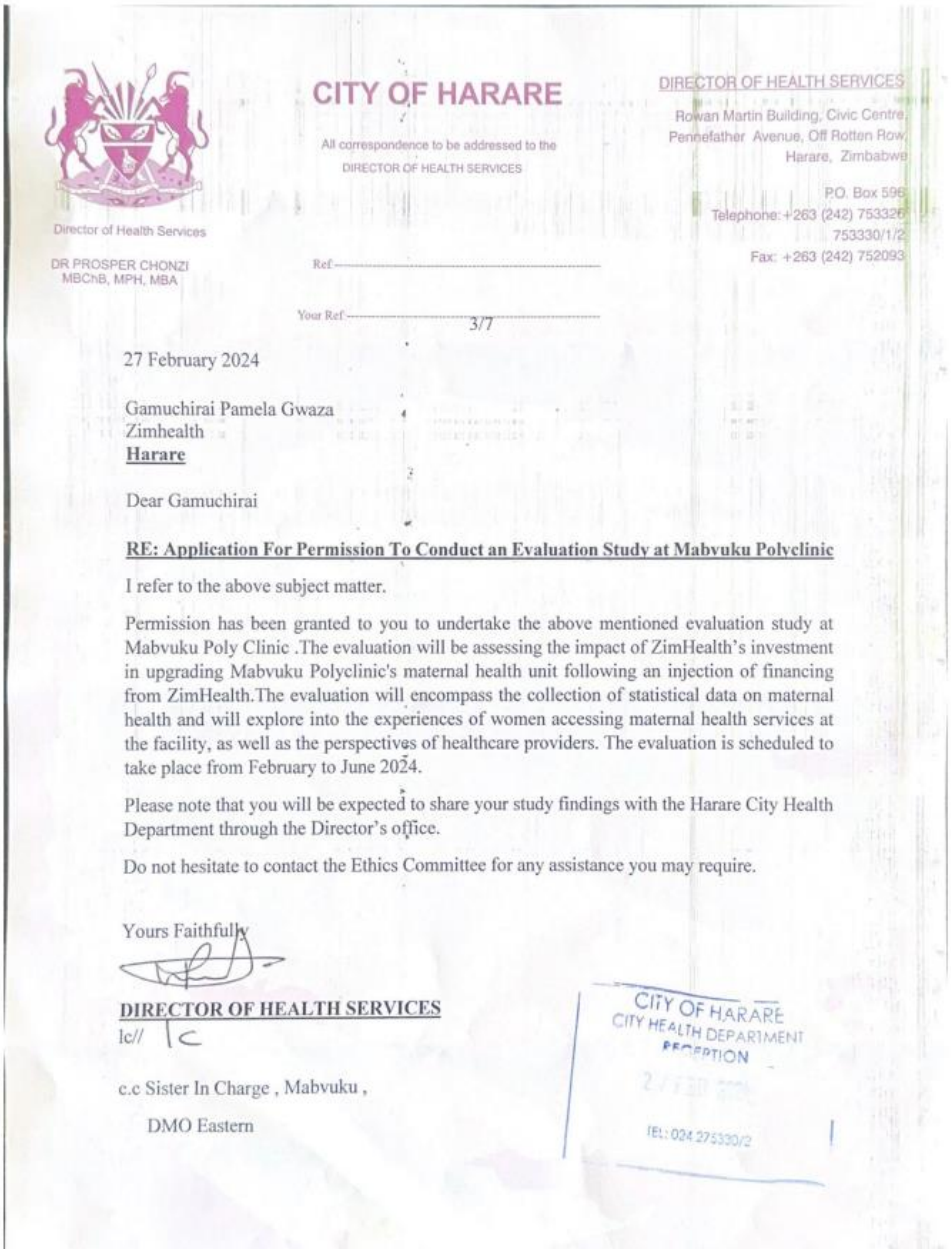
Yours sincerely,

DocuSigned by:
Sami Kelsh
B4D7A3E9687644...

Sami Kelsh
Research Ethics Administrator, OxTREC

for
Dr Rosemary Musesengwa
Research Ethics Manager, OxTREC

Appendix 12: Chapter Eight, City of Harare Health Ethics Committee Permission



CITY OF HARARE

All correspondence to be addressed to the
DIRECTOR OF HEALTH SERVICES

DIRECTOR OF HEALTH SERVICES
Rowan Martin Building, Civic Centre,
Pennefather Avenue, Off Rotten Row,
Harare, Zimbabwe

P.O. Box 596
Telephone: +263 (242) 753326
753330/1/2
Fax: +263 (242) 752093

Director of Health Services

DR PROSPER CHONZI
MBChB, MPH, MBA

Ref:

Your Ref: 3/7

27 February 2024

Gamuchirai Pamela Gwaza
Zimhealth
Harare

Dear Gamuchirai

RE: Application For Permission To Conduct an Evaluation Study at Mabvuku Polyclinic

I refer to the above subject matter.

Permission has been granted to you to undertake the above mentioned evaluation study at Mabvuku Poly Clinic .The evaluation will be assessing the impact of ZimHealth's investment in upgrading Mabvuku Polyclinic's maternal health unit following an injection of financing from ZimHealth.The evaluation will encompass the collection of statistical data on maternal health and will explore into the experiences of women accessing maternal health services at the facility, as well as the perspectives of healthcare providers. The evaluation is scheduled to take place from February to June 2024.

Please note that you will be expected to share your study findings with the Harare City Health Department through the Director's office.

Do not hesitate to contact the Ethics Committee for any assistance you may require.

Yours Faithfully

DIRECTOR OF HEALTH SERVICES
lc//

c.c Sister In Charge , Mabvuku ,
DMO Eastern

CITY OF HARARE
CITY HEALTH DEPARTMENT
RECEPTION
TEL: 024 275330/2

Appendix 13: Chapter Eight, Protocol for the Qualitative case study on experiences of users of integrated diagnostic services

Protocol

Title:

Experiences of health care providers and women in utilising integrated same-day diagnosis services for antenatal care: A Case Study of Mabvuku Clinic in Harare, Zimbabwe

Date:	25 January 2024
Student Name:	Gamuchirai Pamela Gwaza
Department:	Department of Continuing Education, Kellogg College
Supervisors:	Dr Carl Heneghan, Dr Annette Plüddemann, Dr Marcy McCall MacBain, Nuffield Department of Primary Care Health Sciences
Collaborator:	Dr Danai Zhou, University of Zimbabwe, Department of Laboratory Diagnostic and Investigative Sciences

Abstract

Introduction

Integrated diagnosis allows for multiple diseases to be identified within one visit, which can improve health outcomes and patient experiences. Antenatal care provides a unique opportunity to reduce mortality from multiple diseases as women have the opportunity to be diagnosed with several conditions during their periodic visits. The study's objective is to explore the experiences of healthcare providers and women utilising integrated diagnosis in antenatal care.

Methods

This study uses a qualitative, exploratory case study approach. It focuses specifically on a high-traffic maternal health unit at Mabvuku clinic in Harare, Zimbabwe. Semi-structured interviews of ten healthcare workers and thirty women accessing antenatal services and on-site observations will be conducted at the facility to gather insights into the current integrated diagnostic practices and challenges.

Thematic analysis using NVivo qualitative data analysis software will be used to analyse the data. The study will adhere to ethical standards, with approval sought from the Department of Continuing Education at the University of Oxford, the Harare City Health Department, and the Medical Research Council of Zimbabwe.

Results and Conclusion

The study will provide insights that will contribute to improvement in integrated healthcare practices as well as develop a framework for designing integrated diagnostic interventions tailored specifically for low-resource settings.

This research will contribute to advancing integrated healthcare strategies in LMICs by providing evidence-informed insights into critical considerations for effective context-specific integrated diagnosis interventions.

1. Introduction

Diagnosis is a pivotal step in the health care pathway, crucial for the early identification of conditions and optimising treatment and care (1). Integrated diagnosis transforms health systems into patient-centric structures, moving beyond a disease-centric approach. This is achieved by either identifying multiple pathogens through a single test or delivering care that considers the individual's holistic well-being, surpassing the confines of specific symptoms. The essence of integrated diagnosis lies in the capacity to make multiple diagnoses for various conditions within a single clinical visit. Integrated diagnosis functions as a specialised component within the broader framework of integrated healthcare, concentrating on a specific stage in the care cascade.

This study aims to explore the experiences of healthcare providers and women accessing integrated diagnosis services during their antenatal care at a health facility in Zimbabwe. The results will generate insights to develop more refined and contextually informed integrated diagnostic interventions.

1.1 Background

Diagnosis represents a critical gap in the care cascade, which holds significant potential for substantial improvements in general health system performance (1). At least one million premature deaths in low-income and middle-income countries (LMICs) could be avoided annually by reducing the diagnostic gap for six priority conditions: diabetes, hypertension, HIV, and tuberculosis in the overall population, and hepatitis B virus infection and syphilis for pregnant women (1). Within the realm of maternal health care, a unique opportunity arises where these six tracer conditions can be diagnosed in an integrated manner.

In Zimbabwe, the antenatal care protocol prescribes a comprehensive set of laboratory tests during the initial contact with the health facility, preferably within the first 12 weeks of pregnancy. These tests encompass pregnancy testing, HIV testing, syphilis testing, TB testing (if presumed), and malaria testing (if presumed) (2). However, despite the established protocols, adherence by healthcare workers to the recommended battery of standard clinical tests for each pregnant woman's visit, including additional tests like a full blood count, Hepatitis B, urine analysis, blood grouping, rhesus factor, and ultrasound scans, is not consistently observed (3). This lack of adherence results in missed opportunities to address specific conditions during antenatal visits, potentially leading to complications later in the maternal health journey.

Maternal and neonatal health services are prominent among the prioritised healthcare services in Zimbabwe (4). Various donors actively support these services across different facilities; however, despite these efforts, access to maternal health services remains a formidable challenge in the country, particularly for women with lower socioeconomic status. Zimbabwe has witnessed some progress in maternal health indicators, with maternal mortality showing a positive trajectory, decreasing from 570 per 100,000 live births in 2010 to 363 per 100,000 live births in 2015 (4, 5). Notably, 94% of women attend at least one antenatal visit, signifying a substantial level of engagement with maternal healthcare services. However, this figure drops to 76% when considering the proportion of women accessing 'adequate' antenatal care services, defined as attending at least four prenatal visits (4).

Maternal and neonatal health services are intricately woven into the broader fabric of the health delivery system in Zimbabwe, adopting a 'supermarket approach' or facility integration model(4). This integration strategy involves the delivery of services within a singular facility or a co-located setting, streamlining access to comprehensive care. In the 'supermarket approach,' a diverse array of maternal and neonatal health services is offered within a centralised location, promoting convenience and accessibility for service users. This model reflects a commitment to providing holistic care within a unified healthcare setting, facilitating seamless coordination and delivery of essential maternal and neonatal well-being services.

Mabvuku Polyclinic is a public primary care health centre approximately 22 km from the Harare city centre. This facility plays a pivotal role in serving a population exceeding 500,000 people. It is one of the busiest and most active polyclinics. Its catchment area has increased due to the development of new highly populated areas in the periphery of Mabvuku's high-density suburbs, namely Caledonia and Bobo Farms. Mabvuku Polyclinic offers a comprehensive range of healthcare services, encompassing general outpatient care and maternal and child health services, including antenatal care (ANC), deliveries, post-natal care (PNC), prevention of mother-to-child transmission of HIV (PMTCT), immunisations, HIV counselling and testing, HIV and TB integrated care, as well as laboratory services.[1] In alignment with the City Health Department's vision to expand comprehensive healthcare services at the community level, the Mabvuku maternal health unit was upgraded in 2016 to provide cesarean services. Prior to 2015, Mabvuku clinic had 35 maternity beds, conducted about 3000 antenatal checks per year and 1000 deliveries. Currently, all complicated deliveries are referred to Harare Central Hospital, and because of this, many women bypass the maternity services and go straight to Harare Hospital if they anticipate or have had previous complications.

An informal discussion with a midwife at Mabvuku Polyclinic revealed that all women, particularly during their first visit, are expected to undergo at least two mandatory tests — typically HIV and syphilis tests. Additional tests such as hypertension (HBP), blood sugar, malaria, and TB may also be administered depending on individual risk factors. This comprehensive testing approach ensures that all women visiting the clinic for antenatal care receive an integrated diagnosis, aligning with the facility's commitment to holistic and thorough healthcare provision.

1.2 Study Rationale

This study is an extension of prior research conducted within the framework of the DPhil in Evidence-Based Health Care. Earlier investigations included a realist review aimed at understanding the conceptualisation of integrated diagnosis and identifying the diverse contexts and mechanisms necessary for enhancing patient experiences and health outcomes. The outcomes of this review served as the foundation for a subsequent Delphi study, which sought consensus on the core criteria essential for designing integrated diagnosis interventions in LMICs. By corroborating and extending the insights from prior research, this study plays a crucial role in advancing our understanding of integrated diagnosis within diverse primary healthcare settings, particularly in resource-constrained environments.

[1] https://zimhealth.org/our-work/our-projects/mabvuku-polyclinic-harare/

Several studies have delved into understanding patient experiences more broadly within integrated health care (6) and not integrated diagnosis more specifically. Given that the overarching goal of integrated health care is to enhance patient experiences and health outcomes directly (7, 8), it becomes imperative to unravel the intricacies of how these interventions operate and how they can be optimised to achieve their intended results. A human-centred problem-solving approach is advocated, emphasising the importance of considering the perspectives of end-users. This approach ensures that solutions are tailor-made to meet the needs and preferences of those utilising the healthcare services, recognising health systems as inherently socially constructed entities (9). Understanding the views and perceptions of healthcare workers (HCWs) and women regarding integrated diagnosis is key to informing the most effective strategies for designing and implementing interventions that resonate with the experiences and expectations of those directly involved in the healthcare process.

Maternal health is a robust proxy for comprehending the complexities of healthcare delivery. In many LMICs, integration initiatives often leverage existing programs, notably the HIV program or maternal health services(10). The maternal health program offers a valuable framework characterised by regular touchpoints involving women engaging with the health system at least four times during pregnancy. This frequent and structured interaction presents a prime opportunity for the integration of additional health services. Consequently, the maternal health program becomes an exemplary case study. It provides insights into integrated care that can be insightful for its immediate context and transferable and applicable to other analogous healthcare programs.

2. Research Objective

The main objective of the research is to examine the experiences of healthcare providers and women in accessing antenatal care, including diagnostic services.

3. Methodology

The study uses a case study methodology, integrating human-centred design thinking in formulating interview questions to explore ideal scenarios and desirable future state models for designing and delivering interventions (9). Incorporating human-centred design thinking ensures an empathetic and bottom-up approach encompassing multiple stakeholders' perspectives.

The interview questions are anchored in themes generated in previous research and structured according to the criteria developed from previous research. This case study serves as a validation platform for testing and refining these criteria in a real-world context. The study will use semi-structured interviews and observation to collect data. There is a degree of flexibility required in research design to allow for modification of interview focus which may expand from the stated themes to allow for the in-depth analysis of experiences.

Semi-Structured Interviews: Two separate interview guides will be developed for healthcare workers and women attending the clinics to facilitate guided discussions (see Annex 1 and 2). The indicative questions in the interview guide for healthcare workers will be tailored to each healthcare worker depending on whether they are the administrator, midwife, nurse, laboratory technician or doctor. All the interviews will be conducted face-to-face.

Field Observation: The researcher will spend a minimum of one week at each facility, observing the organisation and functioning of various aspects, including the registration process for women, average time spent by women at the facility, waiting room dynamics, healthcare workers' attitudes, and the reporting tools employed by healthcare staff. An observation checklist will be developed to guide the analysis (Annex 3). The goal of the observation is to understand the integrated diagnosis process and the steps women undergo during their interactions at the facility. The tests that each woman undergo will be self-reported and not through reviewing medical records. No sensitive health information, such as health consultations or patient records, will be observed or collected during this process.

3.1 Target Population Groups

Two population groups will be targeted at the health facilities:

Healthcare Providers

The Inclusion Criteria for this group will be:

- Individuals aged 18 years or older.
- Qualified healthcare workers who provide antenatal care at the health facility (e.g., midwives, nurses, laboratory technicians, and doctors).
- Willingness to participate in the study after providing informed consent.

Women Accessing antenatal care services:

The Inclusion Criteria for this group will be:

- Individuals aged 18 years or older.
- Actively accessing antenatal care and have received more than one test or diagnosis.
- Willingness to participate in the study after providing informed consent.
- All eligible women will be included, without restrictions, based on literacy level, occupation, profession, or other socio-demographic characteristics.

The exclusion Criteria for Both Population Groups include:

- Individuals younger than 18 years old.
- Individuals unable or unwilling to read the informed consent documents (or have them read to them).
- Individuals unable or unwilling to provide informed consent for participation.
- Women who are not receiving antenatal care (e.g., accompanying other women).

- Women who have not received any tests or diagnosis

3.2 Sample Size

This research aims to conduct a minimum of 30 individual interviews at each facility, comprising 10 interviews with healthcare workers and 20 interviews with individual women accessing antenatal care at the facility. The choice of 30 interviews aligns with the pursuit of saturation, in qualitative research, ensuring that the data collected is comprehensive and insightful, meeting the depth-oriented objectives of qualitative research.

In qualitative research, sample size is determined by the richness of the interviewees' narratives. Emphasis is placed on depth rather than breadth, focusing on narratives contributing to achieving the research objectives. The goal is not to generate generalisable data but rather transferable insights. The sample size is considered achieved when, during a contemporaneous and iterative data collection and analysis process, researchers find that the properties of the categories of analysis are 'saturated' or fully understood (11).

3.3 Sampling and Recruitment

Healthcare workers: The research will employ a purposive sampling technique to identify healthcare workers involved in antenatal care at the facility. Identification will be facilitated through collaboration with officials in charge of the facility. Snowballing techniques will also be employed, seeking referrals of potential interviewees from the initially identified healthcare workers. Interviews with healthcare workers will be scheduled individually, ensuring a personalised approach.

The timing of the interviews will be agreed upon, accommodating the convenience of the healthcare workers. The interview venue will be chosen based on the comfort and preferences of the participants. This approach aims to ensure a thoughtful and comprehensive selection of healthcare workers involved in antenatal care, fostering a detailed exploration of their perspectives and experiences with integrated diagnosis.

Women accessing antenatal care: Purposive sampling will be utilised to identify women for interviews at the end of their visits to the health facility on specific days. Healthcare workers who have a comprehensive understanding of the facility's activities can assist in identifying women who have received multiple diagnoses.

Identified women will be approached during their visit to the health facility. Women will be asked to participate in the study either on the day of receiving services, such as waiting for test results, or at a scheduled location and time of their choosing. The snowballing technique will be employed, encouraging participating women to identify others meeting the inclusion criteria.

3.3.1 Interview process

Informed consent will be sought, with the interviewees going through the informed consent form, which will be read to them if needed. The informed consent form will also be translated to the local language, Shona with the support of the local collaborator. Two copies of the consent form

(Annex 4) will be provided, with interviewees keeping one copy and the researcher retaining the other. The audio recorder will only be activated after explicit consent is obtained and the interview commences.

The interviews are expected to last between 20 to 60 minutes. A semi-structured guide will be employed designed to avoid overly sensitive items. Interviews will be conducted in either Shona or English, based on the respondent's language preference. This approach ensures a respectful and participant-centred engagement, with a focus on creating a conducive environment for open and insightful discussions.

3.4 Data management

Audio recordings of interviews will be transcribed verbatim in an MS Word document. The recordings will be deleted once the audio has been transcribed. Personal identifiers will not be transcribed, such as names, addresses, employers, and organisations mentioned during interviews. Pseudonyms will be employed for any identifying characteristics.

Transcripts from interviews conducted in Shona will be translated into English. Transcripts will be thoroughly checked to ensure their accuracy, integrity, and completeness. The interview transcripts will be labelled with codes that allow for linkages to be made with the audio recordings.

The research data will be stored in OneDrive for Business, provided as part of the University's Nexus365 offering, which the University's Information Security team has approved for the storage of research data.

The recordings and transcriptions will not be shared with third parties or individuals outside the research team. Data will be stored for a minimum of 3 years after publication according to university policy.

3.5 Data Analysis

Data will be uploaded onto NVivo software for qualitative data analysis. A deductive thematic analysis approach will be used, where data will be analysed based on a set of expected themes developed from prior research. All interview transcripts will be coded based on predefined and emerging themes. Any new themes arising will also be factored in.

Attention will be given to understanding how narratives may differ based on socio-demographic characteristics such as respondent's age, education, and number of children for women. Special attention will be paid to identifying and understanding isolated or divergent opinions on aspects relevant to the design or implementation of interventions.

3.6 Minimisation of bias

The primary aim of this case study is to generate specific insights that may not be representative but can be transferable to similar settings.

Recall bias will be minimised by asking about the last healthcare encounter they would have had on that same day. All interviews should be done on the day of the health visit or within a few days

afterwards to enhance the accuracy of recollection. Questions will be carefully phrased neutrally to avoid implying a 'correct' answer, thereby minimising acquiescence bias.

3.7 Benefit/Risk Assessment

This study is classified as involving minimal risk, with anticipated harm and discomfort not exceeding those encountered in daily life or routine physical/psychological tests. The researcher will adhere to local health authorities' hygiene and prevention recommendations to ensure participant safety. In addition, no minors or individuals with cognitive disabilities will be interviewed, interviews will be conducted in a confidential space.

Participants will be reimbursed for transport expenses, up to 5 USD/person. This is in line with local research standards by University students. The money will serve as an incentive to stay for the interview, which may be at the end of the day and avoid transport inconveniences. The participant do not need to return the money even if the participant withdraws.

Participants will be reminded during the consent process that they are free not to answer any questions or to stop participation at any time without consequences, including still receiving transport reimbursement. If any question is reported as sensitive, it will be reworded or removed.

The information participants provide anticipated to yield several community benefits, such as contributing to advancements in maternal health and focusing on enhancing patient experiences and health outcomes.

.

4. Regulatory and Ethical Considerations

The research protocol will undergo submission to the ethics boards of the University of Oxford Department for Continuing Education and the Medical Research Council of Zimbabwe (MRCZ). Permission will be sought from the Harare City Health Department.

The study will adhere to the protocol and consensus ethical principles derived from international guidelines, including The Declaration of Helsinki and Applicable Good Clinical Practice Guidelines: ICH GCP E6 (R2)

4.1 Data Protection

Participants will be assigned a unique identifier, which will ensure the participant's identity cannot be transferred or disclosed. The participant will be informed how their study-related data will be used following local data protection law. The level of disclosure will also be explained to the participant. Whilst data will be made available to other researchers in the team, confidentiality will be protected.

The use of study-related data, in accordance with local data protection laws, will be transparently explained to participants. Participants will be informed about the level of disclosure associated with their data and how it will be handled throughout the study.

4.2 Ethics in Dissemination

The researcher will produce dissemination outputs for internal meetings, regional and international conferences, and peer-reviewed journals. In addition, a meeting will be organised with the relevant healthcare professionals and from the Ministry of Health to share the results. Efforts will also be made to share results with global health actors supporting the design and implementation of integrated healthcare.

Global health actors will be invited to contribute their expertise to suggest how study findings can be translated into policy and practice recommendations. This comprehensive dissemination plan ensures that the study's insights reach diverse audiences, fostering positive change at both local and global levels.

Annex 1: Interview Guide for healthcare workers

Interview questions will be tailored based on the interviewee's role and awareness of the topics. Not everyone will receive the comprehensive list of questions provided. For instance, queries concerning policy and funding will be directed to the administrator rather than the midwives. Furthermore, follow-up questions will only be introduced if the interviewee demonstrates awareness or knowledge of the subject matter under discussion.

Thematic areas	Indicative questions
Service delivery	• Can you describe the patient journey, from the moment a woman arrives at the facility until her departure, including key steps and interactions? • Are you aware of any specific diagnoses or tests recommended for pregnant women, elaborating on their significance? Which of these tests do you have experience and confidence in providing? • What do you understand by the term 'integrated diagnoses? Are there any examples of this at this facility • Are you aware of any specific diagnostic tests that the facility refers to other facilities or departments at the clinic? Who is responsible for initiating and managing these referrals?
Coordination, leadership, and funding	• Can you tell me about any policies or guidelines on diagnosis or testing relevant to pregnant women that the facility is currently implementing? In what ways does leadership demonstrate a commitment to integrated healthcare? If yes, give examples. Can you tell us what you know about the funding allocations for various diseases or procedures being addressed for maternal health, i.e., diagnoses/tests at the clinic? Does it cover training?
Community engagement	• Can you recall activities or programs conducted to raise awareness within the community regarding the services offered at the facility? If so, could you specifically elaborate on these initiatives?
Critical factors	• How would you describe a successful integrated diagnosis intervention? What factors would you say are critical for success? • Can you identify some key challenges or gaps faced at the clinic in relation to these success factors for integrated diagnosis? • Is there anything you want to add that is important for you that we should have covered during our conversation?
Demographic information	• Sex: • Age: • Highest level of education level • Current profession or role (and how long in that position)

Annex 2: Interview guide for women who received multiple diagnosis/tests

Thematic area	Indicative questions
Access	Can you tell me about your experience accessing this facility? *Probing questions* • How did you end up at this facility (e.g., closest to home, referral, or recommendation)? • Can you estimate how long it takes you to get to the clinic from your home? Approximately how far is it? • Can you recall the general costs to access services at this facility?
Timeliness of services	• How would you describe the timeliness of the services you have received since your arrival? Approximately how long have you been here? *Probing questions* • Can you recall how long you had to wait before you were attended to? • What were the different services you received? Can you recall any tests that you received? Do you understand why you received the tests that you got? Were you informed about the results?
Relationship between the healthcare worker and the clients	Can you tell me about your experiences with the healthcare workers with whom you interacted? *Probing questions* • How did the staff behave towards you? • What was important to you about the staff behaviour? What do you wish they had done differently?
Confidentiality	Can you tell me about your experience with issues of confidentiality and privacy? *Probing questions* • Do you feel you had the right level of confidentiality in the services you received? If not, why not? • Are you aware of any stigmas associated with specific health services, diagnoses, or conditions in the community, particularly concerning the tests individuals may have taken at the facility? • Did you feel a sense of safety and trust in the staff or system? If not, please elaborate on the factors that contributed to any concerns or lack of confidence.
• Challenges & Recommendations	How would you describe your overall satisfaction with the services provided? Why? *Probing questions*

	• Are there any challenges you faced accessing services at the facility? • Are you aware of any system for giving feedback about your experience with the services? • How would you improve the services offered at this facility?
Other factors	• Is there anything else you want to share or anything else on your mind about your healthcare experience today? • Why did you agree to participate?
Demographic Information	• Identity Code • Age: • Highest level of education level • Current profession or role • How many children do you have?

Annex 3: Observation Checklist Guide

The researcher will visit the facility daily for at least two weeks to observe the activities at the clinic. The checklist provides a list of the areas that will be observed. The checklist is meant as a reminder of things to look out for. These will be recorded as detailed notes separately by the researcher.

1. Patient Flow:
   - ☐ Observe the flow of clients within the facility, noting any bottlenecks or congestion.
2. Reception and Information Desk:
   - ☐ A dedicated reception or information desk available to assist clients.
3. Signage and Wayfinding:
   - ☐ Check for clear signs and wayfinding aids guiding clients to different departments or services.
4. Time Recording:
   - ☐ Record the time taken by at least five clients to access different services at the facility.
5. Patient Intake and Registration:
   - ☐ Observe the processes related to patient intake and registration
6. Site map or pictures to assess distances between services and location of ancillary services such as labs and

Annex 4: Consent form to take part in the integrated diagnosis study

Information Sheet

Purpose of Study: My name is Gamuchirai, and I would like to ask you to participate in this research project, which is part of my DPhil studies at the University of Oxford in the UK. The research aims to explore your experiences accessing or providing health services at the Mabvuku clinic. We are particularly interested in your access to integrated diagnostic services. In this case, integrated diagnosis means a person can access or receive a diagnosis or multiple tests for different diseases and conditions within one visit. They will also be informed of the results of the diagnosis on that same visit. The findings from the research will help us add to our understanding of how integrated diagnosis can be delivered in a way that ensures patients have a good experience of care and improves health outcomes. You need to know that your participation or refusal to participate will not affect the health care services that you received or will receive in the future.

Why are we asking you to participate? Your collaboration is requested because you work at the facility, or you have accessed services at the facility.

What do you have to do to participate? You can participate in the research by agreeing to the consent statements at the end of this Information Sheet. There will be an interview, which contains questions on your experiences of accessing services focusing on different themes. The interviews are estimated to last between 20-60 minutes.

What are the risks of participating? There are no risks associated with participation. There are no questions about your religious or political beliefs or any sensitive private issue. However, if you feel uncomfortable, you can abstain from answering any of the questions, without any penalty or prejudice. You are free to stop your participation at any time.

What are the benefits? There are no personal benefits to taking part in this survey. You will be reimbursed for transport costs for participating in the study.

How will your data be treated? The interview will be recorded in audio and later transcribed onto a Word document. The recording will be deleted after the transcription has been confirmed. The documents will be saved on Onedrive for Business on the University of Oxford servers. No names or personal identifiers will be transcribed. Only a Unique Identifier, written at the end of the consent form below, will link this document to your interview's recording and transcript. Your anonymity will be safeguarded, as only your interview data will be available for qualitative analysis. No data from this interview will be transferred to third parties except under legal obligation. For legal purposes, the consent form is the only document where we will ask for your name. This document will be scanned and stored on OneDrive and hard copies locked in a secure cabinet.

Based on the results of this study, scientific communications may be prepared to be presented in conferences, meetings and scientific journals. Still, they will not include anything that can identify you.

Who is funding this study? This is academic research being conducted to fulfil a DPhil in Evidence-Based Health Care at the University of Oxford, UK. A research grant application has been made to the Africa Oxford Initiative.

Will you be informed about the results of the study? You have the right to know the results of this study if you wish. If you want to know the results, you can provide your contact details below so I can send them to you in your preferred format.

Can you change your mind? Your participation is completely voluntary; you can decide not to participate or withdraw from the study at any time without giving explanations. State your intention to me, and your participation in the interview will stop immediately. Before aggregation and analysis, you can request that your data be destroyed and no further use is made of them by emailing the researcher. After the data has been aggregated and analyzed, it will no longer be possible to withdraw your participation.

What happens if you have any doubts about your participation? You can reach me on email gamuchirai.gwaza@kellogg.ox.ac.uk or telephone (+41 795030095) if you have any questions. If you are unsatisfied or have a complaint that you think you cannot tell me, you can get my supervisor at the University of Oxford, Dr Plüddemann or local collaborator at the University of Zimbabwe, Dr Zhou, or you can contact the Medical Research Council of Zimbabwe, which approved the research (ethical approval reference: XXX). You can also file a complaint by calling the following numbers: (XXX). If you want to participate, please read aloud the statements in the consent form below.

Consent Form

Please initial each box if you agree with the statement

I confirm that I have read and understand the information sheet, dated __XX_____, for the above research. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	☐
I understand that my participation is voluntary and that I am free to withdraw at any point [until **dd/mmm/yy**] without giving any reason.	☐
I understand who will have access to personal data, how the data will be stored, and what will happen to the data at the end of the project.	☐

I understand that I will not be identifiable from any publications or reports and my name will not be used in any communication or research outputs.	☐
I consent to be audio recorded.	☐
I understand how the audio recordings will be used in research outputs.	☐

Use of quotations: Please indicate your preference (select *one* option):

• I do not wish to be quoted. **or** • I agree to the use of quotations in research outputs if I am not identifiable. **or**	☐
• [If appropriate] I agree to the use of direct quotations attributed to my name in research outputs.	☐
I give permission for you to contact me again to clarify information.	☐
I understand how to raise a concern or make a complaint.	☐
I agree to take part.	☐

_____	dd / mm / yyyy	_____
Name of participant	Date	Signature

_____	dd / mm / yyyy	_____
Name of person taking consent	Date	Signature

References

1. Fleming KA, Horton S, Wilson ML, Atun R, DeStigter K, Flanigan J, et al. The Lancet Commission on diagnostics: transforming access to diagnostics. Lancet. 2021;398(10315):1997-2050.
2. Zimbabwe MoH. Zimbabwe Antenatal Care Protocol Version 4. In: Welfare MoHaC, editor. 2018.
3. David R, Evans R, Fraser HS. Modelling Prenatal Care Pathways at a Central Hospital in Zimbabwe. Health Serv Insights. 2021;14:11786329211062742.
4. Welfare MoHaC. The Zimbabwe National Maternal and
Neonatal Health Road Map 2007-2015. Ministry of Health and Child Welfare, Government of Zimbabwe; 2007.
5. ZimStat. Population and housing census preliminary report on population figures. Zimbabwe National Statistics Agency; 2022.
6. Dudley L, Garner P. Strategies for integrating primary health services in low- and middle-income countries at the point of delivery. Cochrane Database Syst Rev. 2011(7):CD003318.
7. WHO. Integrated Health Services – What and Why ? ; 2008.
8. WHO. WHO global strategy on people-centred and integrated health services. 2015.
9. Teo KW, Hu Y, Chew KT, Pek WY, Chua HC, Matchar DB, et al. Health System Transformation Playbook and Unified Care Model: an integrated design, systems & complexity thinking approach to health system transformation. Front Health Serv. 2023;3:1157038.
10. WHO. Integrated care models overview. 2016.
11. Hennink M, Kaiser BN. Sample sizes for saturation in qualitative research: A systematic review of empirical tests. Soc Sci Med. 2022;292:114523.

References

References

1. WHO. Declaration of Astana. Global Conference on Primary Health Care; 25-26 October 2018, 2018; Astana, Kazakhstan.
2. Unitaid. Multi-Disease diagnostic landscape for integrated management of HIV, HCV, TB and other coinfections. 2018.
3. WHO. *Integrated Health Services – What and Why ?* 2008.
4. WHO. *WHO policy on collaborative TB/HIV activities: Guidelines for national programmes and other stakeholders.* 2012.
5. WHO. *Considerations for adoption and use of multidisease testing devices in integrated laboratory networks.* 2017.
6. Fleming KA, Horton S, Wilson ML, et al. The Lancet Commission on diagnostics: transforming access to diagnostics. *Lancet.* 2021;398(10315):1997-2050.
7. Blount A, Bayona J. Toward a System of Integrated Primary Care. *Family Systems Medicine.* 1994;12(2):171-182.
8. Cueto M. The origins of Primary Health Care and Selective Primary Health Care. *American Journal of Public Health.* 2004;94.
9. Cloninger C, L Salvador-Carulla, L J. Kirmayer, et al. A Time for Action on Health Inequities: Foundations of the 2014 Geneva Declaration on Person- and People-centered Integrated Health Care for All. *Int J Pers Cent Med.* 2014;4:69–89.
10. WHO. *International Conference on Primary Healthcare and Health Systems in Africa Final Report.* 28–30 April 2008, Ouagadougou, Burkina Faso2008.
11. Frisch NC. What's in a Definition? Holistic Nursing, Integrative Health Care, and Integrative Nursing. *Journal of Holistic Nursing.* 2019;37.
12. Chatora RR, Tumusime P. Primary health care: a review of its implementation in sub-Saharan Africa. *Primary Health Care Research and Development.* 2004;5(4):296-306.
13. Chabot H. Primary Health Care will fail if we do not change our approach. *Lancet.* 1984.
14. Shakarishvili G, Atun R, Berman P, Hsiao W, Burgess C, Lansang M. Converging Health Systems Frameworks: Towards A Concepts-to-Actions Roadmap for Health Systems Strengthening in Low and Middle Income Countries. *Global Health Governance.* 2010;3(2).
15. Atun R, de Jongh T, Secci F, Ohiri K, Adeyi O. A systematic review of the evidence on integration of targeted health interventions into health systems. *Health Policy Plan.* 2010;25(1):1-14.
16. Jongh, Gurol-Urganci, Allen, Zhu, Atun. Integration of antenatal care services with health programmes in low- and middle-income countries: systematic review. *J Glob Health.* 2016;6(1):010403.
17. WHO, UNICEF. *A vision for primary health care in the 21st century: towards universal health coverage and the Sustainable Development Goals. .* World Health Organization and the United Nations Children's Fund (UNICEF);;2018.
18. Briggs CJ, Capdegelle P, Garner P. Strategies for integrating primary health services in middle- and low-income countries: effects on performance, costs and patient outcomes. *Cochrane Database Syst Rev.* 2001(4):CD003318.
19. Sibiya MN, Gwele NS. A model for the integration of primary health-care services in the province of KwaZulu-Natal, South Africa. *J Nurs Manag.* 2013;21(2):387-395.
20. Willcox ML, Peersman W, Daou P, et al. Human resources for primary health care in sub-Saharan Africa: progress or stagnation? *Hum Resour Health.* 2015;13:76.
21. Borgermans L, Devroey D. A Policy Guide on Integrated Care (PGIC): Lessons Learned from EU Project INTEGRATE and Beyond. *Int J Integr Care.* 2017;17(4):8.

22. Dawda P. Integrated healthcare: the past, present and future. *Integrated Healthcare Journal.* 2019;1(1).
23. Tham TY, Tran TL, Prueksaritanond S, Isidro JS, Setia S, Welluppillai V. Integrated health care systems in Asia: an urgent necessity. *Clin Interv Aging.* 2018;13:2527-2538.
24. WHO. *The world health report 2006: working together for health.* 2006.
25. Lloyd, Wait. Integrated Care: A guide for policymakers. 2006.
26. McNerney R. Diagnostics for Developing Countries. *Diagnostics (Basel).* 2015;5(2):200-209.
27. Otoo JA, Schlappi TS. REASSURED Multiplex Diagnostics: A Critical Review and Forecast. *Biosensors (Basel).* 2022;12(2).
28. UNAIDS. *Chronic care of HIV and noncommunicable diseases: How to leverage the HIV experience.* 2011.
29. WHO. WHO global strategy on people-centred and integrated health services. 2015.
30. WHO. Strengthening diagnostics capacity, Seventy-sixth World Health Assembly. In: WHA76.5, ed2023.
31. Alemnji G, Mosha F, Maggiore P, et al. Building Integrated Testing Programs for Infectious Diseases. *J Infect Dis.* 2023.
32. FIND GAfD. *Industry partnerships to pioneer new advances in diagnostic testing.* FIND, Global Alliance for Diagnosis;2024.
33. Umubyeyi Nyaruhirira A, Scholten JN, Gidado M, Suarez PG. Coronavirus Disease 2019 Diagnosis in Low- and Middle-Income Countries: The Big New Bully Disrupting TB and HIV Diagnostic Services. *J Mol Diagn.* 2022;24(4):289-293.
34. Global Fund *Mitigating the impact of COVID-19 on countries affected by HIV, Tuberculosis and malaria.* 2020.
35. Haregu TN, Setswe G, Elliott J, Oldenburg B. Integration of HIV/AIDS and noncommunicable diseases in developing countries: rationale, policies and models. *International Journal of Healthcare.* 2015;1(1).
36. WHO Regional Office for Europe. *Integrated care models overview.* 2016. https://wyoleg.gov/InterimCommittee/2019/10-201906132.WHOIntegrated-care-models-overview.pdf
37. Huntington D, Aplogan A. The Integration of Family Planning and Childhood Immunization Services in Togo. *Studies in Family Planning.* 1994;25(3).
38. Mark KE, Meinzen-Derr J, Stephenson R, et al. Contraception among HIV concordant and discordant couples in Zambia: a randomized controlled trial. *J Womens Health (Larchmt).* 2007;16(8):1200-1210.
39. Pope, DeLuca, Kali, et al. A Cluster-Randomized Trial of Provider-Initiated Opt-Out) HIV Counseling and Testing of Tuberculosis Patients in South Africa. *J Acquir Immune Defic Syndr.* 2008;48(2).
40. Leon, Naidoo, Mathews, Lewin, Lombard. The impact of provider-initiated (opt-out) HIV testing and counseling of patients with sexually transmitted infection in Cape Town, South Africa: a controlled trial. *Implementation Science.* 2010;5(8).
41. Gregson S, Adamson S, Papaya S, et al. Impact and process evaluation of integrated community and clinic-based HIV-1 control: a cluster-randomised trial in eastern Zimbabwe. *PLoS Med.* 2007;4(3):e102.
42. WHO. *Monitoring the building blocks of health systems: A handbook of indicators and their measurement strategies.* World Health Organisation;2010.
43. Haldane V, Legido-Quigley H, Chuah FLH, et al. Integrating cardiovascular diseases, hypertension, and diabetes with HIV services: a systematic review. *AIDS Care.* 2017;30(1):103-115.

44. Trankle SA, Usherwood T, Abbott P, et al. Integrating health care in Australia: a qualitative evaluation. *BMC Health Serv Res.* 2019;19(1):954.
45. Dudley L, Garner P. Strategies for integrating primary health services in low- and middle-income countries at the point of delivery. *Cochrane Database Syst Rev.* 2011(7):CD003318.
46. Jolanki O, Tynkkynen L-K, Sinervo T. Professionals' views on integrated care. *Journal of Integrated Care.* 2017;25(4):247-255.
47. Lewis S, Damarell RA, Tieman JJ, Trenerry C. Finding the Integrated Care Evidence Base in PubMed and Beyond: A Bibliometric Study of the Challenges. *Int J Integr Care.* 2018;18(3):11.
48. Goodwin N. Understanding Integrated Care. *Int J Integr Care.* 2016;16(4):6.
49. Goodwin N. Integrated care as a scientific discipline: the need for more theory and new analytical methods. *International Journal of Integrated Care.* 2010;10.
50. Legido-Quigley H, Montgomery CM, Khan P, et al. Integrating tuberculosis and HIV services in low- and middle-income countries: a systematic review. *Trop Med Int Health.* 2013;18(2):199-211.
51. McCombe G, Lim J, Hout MCV, et al. Integrating Care for Diabetes and Hypertension with HIV Care in Sub-Saharan Africa: A Scoping Review. *Int J Integr Care.* 2022;22(1):6.
52. Gray CS, Zonneveld N, Breton M, Anderson GM, Wodchis† WP. Comparing International Models of Integrated Care: How Can We Learn Across Borders? *International Journal of Integrated Care.* 2020;20.
53. Robinson P, Lowe J. Literature reviews vs systematic reviews. *Aust N Z J Public Health.* 2015;39(2):103.
54. de Jongh TE, Gurol-Urganci I, Allen E, Jiayue Zhu N, Atun R. Barriers and enablers to integrating maternal and child health services to antenatal care in low and middle income countries. *BJOG.* 2016;123(4):549-557.
55. Kodner DL, Spreeuwenberg C. Integrated care: meaning, logic, applications, and implications – a discussion paper. *Integrated Healthcare Journal.* 2002;2.
56. Ciapponi A, Lewin S, Herrera CA, et al. Delivery arrangements for health systems in low-income countries: an overview of systematic reviews. *Cochrane Database Syst Rev.* 2017;9:CD011083.
57. Grone O, Garcia-Barbero M. A position paper of the WHO European office for integrated health care services. *International Journal of Integrated Care.* 2001;1.
58. WHO. *Integration of Health care delivery- Report of a WHO Study Group.* 1996.
59. Huang H, Meller W, Kishi Y, Kathol RG. What is integrated care? *Int Rev Psychiatry.* 2014;26(6):620-628.
60. Valentijn PP, SM S, Wm O, M B. Understanding integrated care: a comprehensive conceptual framework based on the integrative functions of primary care. *International Journal of Integrated Care.* 2013;13.
61. Nieuwboer MS, van der Sande R, van der Marck MA, Olde Rikkert MGM, Perry M. Clinical leadership and integrated primary care: A systematic literature review. *Eur J Gen Pract.* 2019;25(1):7-18.
62. Kodner DL, Spreeuwenberg C. Integrated care: meaning, logic, applications, and implications – a discussion paper. *International Journal of Integrated Care.* 2002;2.
63. Gonzalez-Ortiz LG, Calciolari S, Goodwin N, Stein V. The Core Dimensions of Integrated Care: A Literature Review to Support the Development of a Comprehensive Framework for Implementing Integrated Care. *Int J Integr Care.* 2018;18(3):10.
64. Bruijnweels M. Research of organization of integrated primary care: a conceptual model. *International Journal of Integrated Care.* 2011;11.
65. Goodwin N. Taking integrated care forward: the need for shared values. *International Journal of Integrated Care.* 2013;13.

66. Steele Gray C, Wodchis WP, Baker GR, et al. Mapping for Conceptual Clarity: Exploring Implementation of Integrated Community-Based Primary Health Care from a Whole Systems Perspective. *Int J Integr Care.* 2018;18(1):14.
67. Kozlowska O, GD T, R R. Barriers and facilitators to integrating primary and specialist healthcare in the United Kingdom: a narrative literature review. *Future Healthcare.* 2018;5(1).
68. Zonneveld N, Driessen N, Stussgen RAJ, Minkman MMN. Values of Integrated Care: A Systematic Review. *Int J Integr Care.* 2018;18(4):9.
69. Grone O, Garcia-Barbero M. Integrated care- A position paper of the WHO European office for integrated health care services. *International Journal of Integrated Care.* 2001;1.
70. Ramanuj P, Ferenchik E, Docherty M, Spaeth-Rublee B, Pincus HA. Evolving Models of Integrated Behavioral Health and Primary Care. *Curr Psychiatry Rep.* 2019;21(1):4.
71. Kabatereine NB, Malecela M, Lado M, Zaramba S, Amiel O, Kolaczinski JH. How to (or not to) integrate vertical programmes for the control of major neglected tropical diseases in sub-Saharan Africa. *PLoS Negl Trop Dis.* 2010;4(6):e755.
72. Druetz T. Integrated primary health care in low- and middle-income countries: a double challenge. *BMC Med Ethics.* 2018;19(Suppl 1):48.
73. Banfield M, Jowsey T, Parkinson A, Douglas KA, Dawda P. Experiencing integration: a qualitative pilot study of consumer and provider experiences of integrated primary health care in Australia. *BMC Fam Pract.* 2017;18(1):2.
74. Mwanahamuntu MH, Sahasrabuddhe VV, Pfaendler KS, et al. Implementation of 'see-and-treat' cervical cancer prevention services linked to HIV care in Zambia. *AIDS.* 2009;23(6):N1-5.
75. Parham GP, Mwanahamuntu MH, Sahasrabuddhe VV, et al. Implementation of cervical cancer prevention services for HIV-infected women in Zambia: measuring program effectiveness. *HIV Ther.* 2010;4(6):703-722.
76. Hopkins KL, Hlongwane KE, Otwombe K, et al. The substantial burden of non-communicable diseases and HIV-comorbidity amongst adults: Screening results from an integrated HIV testing services clinic for adults in Soweto, South Africa. *EClinicalMedicine.* 2021;38:101015.
77. Church K, Warren CE, Birdthistle I, et al. Impact of Integrated Services on HIV Testing: A Nonrandomized Trial among Kenyan Family Planning Clients. *Stud Fam Plann.* 2017;48(2):201-218.
78. Gengiah S, Barker PM, Yende-Zuma N, et al. A cluster-randomized controlled trial to improve the quality of integrated HIV-tuberculosis services in primary healthcareclinics in South Africa. *J Int AIDS Soc.* 2021;24(9):e25803.
79. Bygrave H, Golob L, Wilkinson L, Roberts T, Grimsrud A. Let's talk chronic disease: can differentiated service delivery address the syndemics of HIV, hypertension and diabetes? *Curr Opin HIV AIDS.* 2020;15(4):256-260.
80. Ramogola-Masire D, de Klerk R, Monare B, Ratshaa B, Friedman HM, Zetola NM. Cervical cancer prevention in HIV-infected women using the "see and treat" approach in Botswana. *J Acquir Immune Defic Syndr.* 2012;59(3):308-313.
81. Maina W. Integrating noncommunicable disease prevention into maternal and child health programs: Can it be done and what will it take? *International Journal of Gynecology and Obstetrics.* 2011;115.
82. Wroe EB, Kalanga N, Dunbar EL, et al. Expanding access to non-communicable disease care in rural Malawi: outcomes from a retrospective cohort in an integrated NCD-HIV model. *BMJ Open.* 2020;10(10):e036836.

83. Sweeney S, Obure C, Maier C, Greener R, Dehne K, Vassall A. Costs and efficiency of integrating HIV/AIDS services with other health services: a systematic review of evidence and experience. *Global Health and Development, .* 2011.
84. Kikuchu K, Ayer R, Okawa S, et al. Interventions integrating non-communicable disease prevention and reproductive, maternal, newborn, and child health: A systematic review. *BioScience Trends.* 2018;12(2):116-125.
85. Raben D, Hoekstra M, Combs L, et al. A call to action toward integrated testing and earlier care for viral hepatitis, HIV, STIs and TB. *HIV Medicine.* 2020;21:403-408.
86. Young N, Achieng F, Desai M, et al. Integrated point-of-care testing (POCT) for HIV, syphilis, malaria and anaemia at antenatal facilities in western Kenya: a qualitative study exploring end-users' perspectives of appropriateness, acceptability and feasibility. *BMC Health Serv Res.* 2019;19(1):74.
87. Bryce J, Victora CG, Habicht JP, Black RE, R S. *Programmatic pathways to child survival: results of a multi-country evaluation of Integrated Management of Childhood Illness.* Oxford University Press in association with The London School of Hygiene and Tropical Medicine.;2005.
88. KjærgaardI, Anastasaki, Østergaard, et al. Diagnosis and treatment of acute respiratory illness in children under five in primary care in low-, middle-, and high-income countries: A descriptive FRESH AIR study. *PLoS ONE.* 2019;14(11).
89. Gera, Shah, Garner, Richardson, Sachdev. Integrated management of childhood illness (IMCI) strategy for children under five. *Cochrane Database Syst Rev.* 2016(6):CD010123.
90. Shayo EH, Kivuyo S, Seeley J, et al. The acceptability of integrated healthcare services for HIV and non-communicable diseases: experiences from patients and healthcare workers in Tanzania. *BMC Health Serv Res.* 2022;22(1):655.
91. Mulupi S, Ayakaka I, Tolhurst R, et al. Perspectives of healthcare workers, national and regional policy stakeholders on the management of chronic lung disease in five sub-saharan African countries: tale of a vicious cycle of neglect. *Preprint.* 2022.
92. Sweeny S, Obure C, Terris-Prestholt F, et al. The impact of HIV/SRH service integration on workload: analysis from the Integra Initiative in two African settings. *Human Resources for Health.* 2014;12.
93. Bryce J, Victora CG, Habicht JP, Vaughan JP, Black RE. The multi-country evaluation of the integrated management of childhood illness strategy: lessons for the evaluation of public health interventions. *Am J Public Health.* 2004;94(3):406-415.
94. Duffy M, Ojikutu B, Andrian S, Sohng E, Minior T, Hirschhorn L. Non-communicable diseases and HIV care and treatment: models of integrated service delivery. *Tropical Medicine and International Health.* 2017;22:926–937.
95. Smith PJ, Davey DJ, Green H, Cornell M, Bekker LG. Reaching underserved South Africans with integrated chronic disease screening and mobile HIV counselling and testing: A retrospective, longitudinal study conducted in Cape Town. *PLoS One.* 2021;16(5):e0249600.
96. Doherty T, Chopra M, Tomlinson M, Oliphant N, Nsibande D, E M. Moving from vertical to integrated child health programmes: experiences from a multi-country assessment of the Child Health Days approach in Africa. *Tropical Medicine and International Health.* 2010;15:296–305.
97. Abstracts of the XIX International AIDS Conference. Track E Implementation Science, Health Systems and Economics. *Journal of the International AIDS Society.* 2012;15(Suppl 3).
98. Wang M, Boeke CE, Rioja MR, et al. Feasibility and impact of near-point-of-care integrated tuberculosis/HIV testing in Malawi and Zimbabwe. *AIDS.* 2021;35(15):2531-2537.

99. Ndlovu Z, Fajardo E, Mbofana E, et al. Multidisease testing for HIV and TB using the GeneXpert platform: A feasibility study in rural Zimbabwe. *PLoS One.* 2018;13(3):e0193577.
100. WHO. *Considerations for Adoption and Use of Multidisease testing devices in Integrated Laboratory networks.* 2017.
101. Manosuthi W, Wiboonchutikul S, Sungkanuparph S. Integrated therapy for HIV and tuberculosis. *AIDS Res Ther.* 2016;13:22.
102. Corneli A, Jarrett N, Sabue M, et al. Patient and provider perspectives on implementation models of HIV counseling and testing for patients with TB. *International Journal of Tuberculosis and Lung diseases.* 2008;12(3):579–584.
103. Youssef A, Wiljer D, Mylopoulos M, Maunder R, Sockalingam S. “Caring About Me": a pilot framework to understand patient- centered care experience in integrated care - a qualitative study. *BMJ Open.* 2020;10.
104. George S, McGrath N, Oni T. The association between a detectable HIV viral load and non-communicable diseases comorbidity in HIV positive adults on antiretroviral therapy in Western Cape, South Africa. *BMC Infect Dis.* 2019;19(1):348.
105. Phetlhu D, Bimerew M, Marie-Modeste R, Naidoo M, Igumbor J. Nurses’ Knowledge ofTuberculosis, HIV, and Integrated HIV/TB Care Policies in Rural Western Cape, South Africa. *JOURNAL OF THE ASSOCIATION OF NURSES IN AIDS CARE.* 2018;29.
106. Tambo E, Chen JH, Zhou XN, Khater EI. Outwitting dengue threat and epidemics resurgence in Asia-Pacific countries: strengthening integrated dengue surveillance, monitoring and response systems. *Infect Dis Poverty.* 2016;5(1):56.
107. Bautista MA, Nurjono M, Lim YW, Dessers E, Vrijhoef H. Instruments Measuring Integrated Care: A Systematic Review of Measurement Properties. *The Milbank Quarterly Multidisciplinary Journal of Population and Health.* 2016:861-917.
108. Armittage G, Suter E, Oelke N, Adair C. Health systems integration: state of the evidence. *International Journal of Integrated Care.* 2009;9.
109. Kitson A, Marshall A, Bassett K, Zeitz K. What are the core elements of patient-centred care? A narrative review and synthesis of the literature from health policy, medicine and nursing. *J Adv Nurs.* 2013;69(1):4-15.
110. Langlois EV, McKenzie A, Schneider H, Mecaskey JW. Measures to strengthen primary health-care systems in low- and middle-income countries. *Bull World Health Organ.* 2020;98(11):781-791.
111. McLean, Wai HP, Thu AM, et al. Malaria elimination in remote communities requires integration of malaria control activities into general health care: an observational study and interrupted time series analysis in Myanmar. *BMC Med.* 2018;16(1):183.
112. Lao. *National Strategic Plan for Malaria Control and Elimination 2016-2020.* 2016.
113. Cambodia. *The National Strategic Plan For Elimination of Malaria in the Kingdom of Cambodia 2011-2025.* 2011.
114. WHO. *Strategy for Malaria Elimination in the Greator Mekong Subregion (2015 to 2030)* 2015.
115. Kounnavong S, Gopinath D, Hongvanthong B, Khamkong C, Sichanthongthip O. Malaria elimination in Lao PDR: the challenges associated with population mobility. *Infect Dis Poverty.* 2017;6(1):81.
116. Chhim S, Piola P, Housen T, Herbreteau V, Tol B. Malaria in Cambodia: A Retrospective Analysis of a Changing Epidemiology 2006-2019. *Int J Environ Res Public Health.* 2021;18(4).
117. Smith JL, Ghimire P, Rijal KR, et al. Designing malaria surveillance strategies for mobile and migrant populations in Nepal: a mixed-methods study. *Malar J.* 2019;18(1):158.

118. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Med Res Methodol.* 2018;18(1):143.
119. WHO. *The World health report 2000 : health systems : improving performance.* 2000.
120. Sheikh K, Ghaffar A. PRIMASYS: a health policy and systems research approach for the assessment of country primary health care systems. *Health Res Policy Syst.* 2021;19(1):31.
121. Haregu T, Setswe G, Elliot J, Oldenburg B. Developing an Action Model for Integration of Health System Response to HIV/AIDS and Noncommunicable Diseases (NCDs) in Developing Countries. *Global Journal of Health Science.* 2014;6(1).
122. UCN/NCD/ISD W. *Implementation Guidance to INTEGRATE Noncommunicable Disease Services into Other Programmatic Areas and Health Systems: Draft.* 2021.
123. Fowkes FJ, Draper BL, Hellard M, Stoove M. Achieving development goals for HIV, tuberculosis and malaria in sub-Saharan Africa through integrated antenatal care: barriers and challenges. *BMC Med.* 2016;14(1):202.
124. Chairman`s Statement of 9th East Asia Summit [press release]. 2014. https://asean.org/speechandstatement/chairmans-statement-of-the-9th-east-asia-summit-foreign-ministers-meeting/
125. WHO. *WHO global strategy on people-centred and integrated health services.* 2015.
126. Anders KL, Hay SI. Lessons from malaria control to help meet the rising challenge of dengue. *The Lancet Infectious Diseases.* 2012;12(12):977-984.
127. Shiff C. Integrated approach to malaria control. *Clin Microbiol Rev.* 2002;15(2):278-293.
128. Graham HR, King C, Rahman AE, et al. Reducing global inequities in medical oxygen access: the Lancet Global Health Commission on medical oxygen security. *Lancet Glob Health.* 2025;13(3):e528-e584.
129. de Jongh TE, Gurol-Urganci I, Allen E, Jiayue Zhu N, Atun R. Barriers and enablers to integrating maternal and child health services to antenatal care in low and middle income countries. *BJOG.* 2016;123(4):549-557.
130. Shretta R, Silal SP, Celhay OJ, et al. Malaria elimination transmission and costing in the Asia-Pacific: Developing an investment case. *Wellcome Open Res.* 2019;4:60.
131. Palagyi A, Dodd R, Jan S, et al. Organisation of primary health care in the Asia-Pacific region: developing a prioritised research agenda. *BMJ Glob Health.* 2019;4(Suppl 8):e001467.
132. Shah S, Abbas G, Riaz N, Anees ur R, Hanif M, Rasool MF. Burden of communicable diseases and cost of illness: Asia pacific region. *Expert Review of Pharmacoeconomics & Outcomes Research.* 2020;20(4):343-354.
133. Brieger. Integrating public health programmes with malaria control. *Africa Health.* 2010:15–18.
134. Hewitt SE. Let's 'cut to the chase' on malaria elimination in the Greater Mekong Subregion. *Trans R Soc Trop Med Hyg.* 2019;113(4):161-162.
135. Wen S, Harvard KE, Gueye CS, et al. Targeting populations at higher risk for malaria: a survey of national malaria elimination programmes in the Asia Pacific. *Malar J.* 2016;15(1):271.
136. Nagpal. Strengthening of vector control in South-East Asia: Outcomes from a WHO regional workshop. *J Vector Borne Dis.* 2018;55:247–257.
137. Rahi M, Chaturvedi R, Das P, Sharma A. India can consider integration of three eliminable disease control programmes on malaria, lymphatic filariasis, and visceral leishmaniasis. *PLoS Pathog.* 2021;17(5):e1009492.
138. Suwonkerd, Vrzheid. Progress of partial integration of malaria control with other vector borne diseases control in Northern Thailand. *The Southeast Asian journal of tropical medicine and public health* 2010.

139. Burkot TR, Farlow R, Min M, Espino E, Mnzava A, Russell TL. A global analysis of National Malaria Control Programme vector surveillance by elimination and control status in 2018. *Malaria Journal.* 2019;18(1):399.
140. Baird JK. Asia-Pacific malaria is singular, pervasive, diverse and invisible. *Int J Parasitol.* 2017;47(7):371-377.
141. Sundararajan R, Kalkonde Y, Gokhale C, Greenough PG, Bang A. Barriers to malaria control among marginalized tribal communities: a qualitative study. *PLoS One.* 2013;8(12):e81966.
142. Derda R, Gitaka J, Klapperich CM, et al. Enabling the Development and Deployment of Next Generation Point-of-Care Diagnostics. *PLoS Negl Trop Dis.* 2015;9(5):e0003676.
143. Mannava P, Abdullah A, James C, Dodd R, Annear PL. Health systems and noncommunicable diseases in the Asia-Pacific region: a review of the published literature. *Asia Pac J Public Health.* 2015;27(2):NP1-19.
144. Dodd R, Palagyi A, Jan S, et al. Organisation of primary health care systems in low- and middle-income countries: review of evidence on what works and why in the Asia-Pacific region. *BMJ Glob Health.* 2019;4(Suppl 8):e001487.
145. Gera R, Kapoor N, Haldar P, et al. Implementation of "health systems approach" to improve vaccination at birth in institutional deliveries at public health facilities; experience from six states of India. *J Family Med Prim Care.* 2019;8(5):1630-1636.
146. Kyaw SS, Drake T, Thi A, et al. Malaria community health workers in Myanmar: a cost analysis. *Malar J.* 2016;15:41.
147. WHO. *Interim Policy on Collaborative TB/HIV Activities.* 2004.
148. Wallrauch C, Heller T, Lessels R, Kekana M, Barnighusen T, M N. High uptake of HIV testing for tuberculosis patients in an integrated primary health care HIV/TB programme in rural KwaZulu-Natal. *Issues in Medicine.* 2010;100(3).
149. Baxter S, Johnson M, Chambers D, Sutton A, Goyder E, Booth A. The effects of integrated care: a systematic review of UK and international evidence. *BMC Health Serv Res.* 2018;18(1):350.
150. UNAIDS. TB_FactSheet. 2022. https://www.unaids.org/sites/default/files/media_asset/20220324_TB_FactSheet_en.pdf
151. WHO. *Global Tuberculosis Report.* 2021.
152. Okoto-Chono R, Mugisha F, Adatu F, Madraa E, Dlodlo R, Fujiwara P. Health system barriers affecting the implementation of collaborative TB-HIV services in Uganda. *The International Journal of Tuberculosis and Lung Disease.* 2009;13(8):955–961.
153. Small P, Madhukar P. Tuberculosis Diagnosis — Time for a Game Change. *The new england journal of medicine.* 2010.
154. Scott LE, McCarthy K, Gous N, et al. Comparison of Xpert MTB/RIF with other nucleic acid technologies for diagnosing pulmonary tuberculosis in a high HIV prevalence setting: a prospective study. *PLoS Med.* 2011;8(7):e1001061.
155. Simoes D, Ehsani S, Stanojevic M, et al. Integrated use of laboratory services for multiple infectious diseases in the WHO European Region during the COVID-19 pandemic and beyond. *Euro Surveill.* 2022;27(29).
156. WHO. WHO List of prequalified in vitro diagnostics products. 2022; https://extranet.who.int/pqweb/sites/default/files/documents/220804_prequalified_IVD_product_list.pdf. Accessed 27 August 2022.
157. WHO. *HIV Diagnostics: Novel Point-of-Care Tools for Early Infant Diagnosis of HIV.* 2017.
158. Bianchi F, Cohn J, Sacks E, et al. Evaluation of a routine point-of-care intervention for early infant diagnosis of HIV: an observational study in eight African countries. *The Lancet HIV.* 2019;6(6):e373-e381.

159. Peter T, Zeh C, Katz Z, et al. Scaling up HIV viral load - lessons from the large-scale implementation of HIV early infant diagnosis and CD4 testing. *J Int AIDS Soc.* 2017;20 Suppl 7.
160. WHO. *Global Tuberculosis Report 2020.* 2020. https://www.who.int/publications/i/item/9789240013131
161. Ford N. Viral load platforms for point-of care testing and opportunities for TB/HIV integration. WHO Prequalification Team – Diagnostics Assessment; 2016.
162. PEPFAR. Lesotho_Country Operational Plan 2019-Strategic-Directional-Summary_public.pdf. In:2019.
163. Freitas M, Mareka M, Lebina M. *GeneXpert Implementation Programme Evaluation Report Lesotho.* Foundation for Innovative New Diagnostics;2016.
164. WHO. WHO recommendations on the diagnosis of HIV infection in infants and children>. 2010.
165. WHO. *Automated Real-time Nucleic Acid Amplification Technology for Rapid and Simultaneous Detection of Tuberculosis and Rifampicin Resistance: Xpert MTB/RIF System: Policy Statement.* 2011.
166. FIND. <*Diagnostic network analysis to inform TB diagnostic technology placement and optimization of laboratory services in Lesotho>.* 2017.
167. Albert H, Purcell R, Wang YY, et al. Designing an optimized diagnostic network to improve access to TB diagnosis and treatment in Lesotho. *PLoS One.* 2020;15(6):e0233620.
168. Plano Clark VL. Mixed methods research. *The Journal of Positive Psychology.* 2016;12(3):305-306.
169. Tiam A, Gill MM, Hoffman HJ, et al. Conventional early infant diagnosis in Lesotho from specimen collection to results usage to manage patients: Where are the bottlenecks? *PLoS One.* 2017;12(10):e0184769.
170. STOP TB Partnership. *GLI Practical guide to TB Laboratory Strengthening.* 2017.
171. Frank SC, Cohn J, Dunning L, et al. Clinical effect and cost-effectiveness of incorporation of point-of-care assays into early infant HIV diagnosis programmes in Zimbabwe: a modelling study. *The Lancet HIV.* 2019;6(3):e182-e190.
172. Lesotho Government. <*Final Report for a Joint Review of HIV/Tuberculosis and Hepatitis Programmes>.* 2017.
173. Teo KW, Hu Y, Chew KT, et al. Health System Transformation Playbook and Unified Care Model: an integrated design, systems & complexity thinking approach to health system transformation. *Front Health Serv.* 2023;3:1157038.
174. Langlois EV, Daniels K, E AA, eds. *Evidence Synthesis for Health Policy and Systems: A Methods Guide.* WHO2018.
175. Collins T. Health policy analysis: a simple tool for policy makers. *Public Health.* 2005;119(3):192-196.
176. Terwindt F, D R. *Strategic planning: transforming priorities into plans Chapter 5.* 2016.
177. Weiner. *Health Policy analysis checklist for the Development, Selection, and Assessment of Program Policies Within Health Care Organizations.* Unit on Medical Care Policy: Johns Hopkins Bloomberg School of Public Health HPM- 300.600 - Introduction to Health Policy;2005.
178. Gilson L, Orgill M, CZ S, eds. *A Health Policy Analysis Reader: The Politics of Policy Change in Low and middle income countries.* WHO Alliance for Health Policy and Systems Research; 2018.
179. Funk M, Drew N, Faydi E, Freeman M, Ndyanabangi. *Checklist for Evaluating a Mental Health Policy.* World Health Organisation;2011.
180. B R. Integrating Primary care and Publich Health. *Eurohealth International.* 2020;26(1).

181. WHO. *Report on the Review of Primary Health Care in the African Region.* WHO Regional Office for Africa;2008.
182. WHO. *The World Health Report Primary Health Care – Now More Than Ever.* World Health Organization;2008.
183. WHO 2010. Monitoring the building blocks of health systems:A handbook of indicators and their measurement strategies.
184. CNA. *Fact Sheet_The Primary Health Care Approach.* Canadian Nurses Association;2000.
185. Lusaka Agenda . *The Lusaka Agenda: Conclusions of the future of global Initiatives Process.* 12 December 2023.
186. Makaula P, Bloch P, Banda H, et al. Primary health care in rural Malawi - a qualitative assessment exploring the relevance of the community-directed interventions approach. *BMC Health Services Research.* 2012;12.
187. Dalglish SL, Khalid H, McMahon SA. Document analysis in health policy research: the READ approach. *Health Policy Plan.* 2021;35(10):1424-1431.
188. Bowen GA. Document Analysis as a Qualitative Research Method. *Qualitative Research Journal.* 2009;9(2):27-40.
189. SADC. Member States _ SADC. 2025; https://www.sadc.int/member-states. Accessed 14 February 2025.
190. WHO. The Country Planning Cycle Database. 2025; https://extranet.who.int/countryplanningcycles/. Accessed 14 February 2025.
191. World Bank. World Bank Group country classifications by income level for FY24 (July 1, 2023- June 30, 2024). *https://blogs.worldbank.org/opendata/new-world-bank-group-country-classifications-income-level-fy24#:~:text=The%20World%20Bank%20Group%20assigns,of%20the%20previous%20calendar%20year.* 2023. Accessed 9 Sept 2023.
192. Kasonde JM, J M. *Experiences with primary health care in Zambia.* World Health Organization;1994.
193. Makwero MT. Delivery of primary health care in Malawi. *Afr J Prim Health Care Fam Med.* 2018;10(1):e1-e3.
194. Maluka S, Chitama D, Dungumaro E, Masawe C, Rao K, Shroff Z. Contracting-out primary health care services in Tanzania towards UHC: how policy processes and context influence policy design and implementation. *Int J Equity Health.* 2018;17(1):118.
195. Molutsi P. *District Control and Accountability in Botswana's Health Care System.* Washington DC: The International Bank for Reconstruction and Development / THE WORLD BANK;1998.
196. NDP. Tanzania National Five Year Development Plan 2016/17 – 2020/21. In: Planning MoFa, ed: THE UNITED REPUBLIC OF TANZANIA; 2016.
197. MoH Tanzania. *The National Health sector Policy Final 2016 - 2026.*
198. MoH Tanzania. *National Health Policy document 2007.*
199. Maluka S, Chitama D. *Primary Health Care Systems (PRIMASYS): Comprehensive case study from United Republic of Tanzania.* World Health Organisation2017.
200. WHO. *WHO Community Engagement Framework for Quality, People-Centred and Resilient Health Services.* World Health Organization;2017.
201. WHO. *Health in All Policies as part of the primary health care agenda on multisectoral action.* World Health Organization;2018.
202. PESS. Mozambique Health Sector Strategic Plan -2014-2019. In: Health Mo, ed: Republic of Mozambique; 2014.
203. NHSSP. The Second National Health Sector Strategic Plan 2014 - 2018 for Swaziland. In: Health Mo, ed: Kingdom of Swaziland; 2014.
204. Seidman G. *Achieving Universal Primary Health Care Through Health Systems*

Strengthening: Lesotho's National Primary Health Care Reform: Harvard T.H. Chan School of Public Health, Havard University; 2017.
205. WHO. *Primary health care on the road to universal health coverage: 2019 monitoring report: executive summary.* Geneva: World Health Organization;2019.
206. WHO. *WHO package of essential noncommunicable (PEN) disease interventions for primary health care.* Geneva: World Health Organization;2020.
207. Sherr K, Cuembelo F, Michel C, et al. Strengthening integrated primary health care in Sofala, Mozambique. *BMC Health Services Research.* 2013;13.
208. Chaitkin M, Blanchet N, Su Y, et al. *Integrating Vertical Programs into Primary Health Care: A Decision-Making Approach for Policymakers.* Washington, DC: Results for Development2019.
209. Sentes K, Kipp W. *Global Burden of Disease: Huge Inequities in the Health Status in Developing and Developed Countries: Brief report.* 2003.
210. WHO. *Framework on integrated, people-centred health services.* 2016.
211. WHO, ASLM. *Molecular Diagnostics Integration Global Meeting Report, 10–12 July, Geneva, Switzerland.* https://www.who.int/publications/i/item/97892400021352019.
212. Church K, Wringe A, Lewin S, et al. Exploring the Feasibility of Service Integration in a Low-Income Setting: A Mixed Methods Investigation into Different Models of Reproductive Health and HIV Care in Swaziland. *PloS One.* 2015;10(5).
213. Legido-Quigley H, CM M, Khan P, et al. Integrating tuberculosis and HIV services in low- and middle-income countries: a systematic review. *Tropical Medicine and International Health.* 2013;18(2):199–211.
214. Jagosh J. Realist Synthesis for Public Health: Building an Ontologically Deep Understanding of How Programs Work, For Whom, and In Which Contexts. *Annu Rev Public Health.* 2019;40:361-372.
215. Wong G, Greenhalgh T, Westhorp G, Buckingham J, R P. RAMESES publication standards: realist syntheses. *BMC Medicine.* 2013.
216. Rycroft-Malone J, McCormack B, Hutchinson A, et al. Realist synthesis: illustrating the method for implementation research. *Implementation Science.* 2012;7.
217. Pawson R, Greenhalg, Harvey G, K W. Realist review – a new method of systematic review designed for complex policy interventions. *Journal of Health Services Research & Policy* 2005;10:21–34.
218. Rycroft-Malone J, McCormack B, Hutchinson A, et al. Realist synthesis: illustrating the method for implementation research. *Implementation Science.* 2012;7(33).
219. Jagosh J. Retroductive theorizing in Pawson and Tilley's applied scientific realism. *Journal of Critical Realism.* 2020;19(2):121-130.
220. Pfaff C, Singano V, Akello H, et al. Early experiences in integrating cervical cancer screening and treatment into HIV services in Zomba Central Hospital, Malawi. *Malawi Med J.* 2018;30(3):211-214.
221. Patel P, Speight C, Maida A, et al. Integrating HIV and hypertension management in low-resource settings: Lessons from Malawi. *PLoS Med.* 2018;15(3):e1002523.
222. Gilson L, Alilio M, Heggenhougen K. Community Satisfaction with Primary Health Care Services. An evaluation undertaken in the Morogoro region of Tanwania. *Soc Sci Med.* 1994;39(6).
223. Sweeny S, Obure C, F T-P, et al. The impact of HIV/SRH service integration on workload: analysis from the Integra Initiative in two African settings. *Human Resources for Health.* 2014;12(42).
224. Zapata T, Forster N, Campuzano P, et al. How to Integrate HIV and Sexual and Reproductive Health Services in Namibia, the Epako Clinic Case Study. *International Journal of Integrated Care.* 2017;17(4).

225. Chang AY, Gómez-Olivé FX, Manne-Goehler J, et al. Multimorbidity and care for hypertension, diabetes and HIV among older adults in rural South Africa. *Bulletin of the World Health Organization.* 2019;97(1):10-23.
226. Adeyemi O, Lyons M, Njim T, et al. Integration of non-communicable disease and HIV/AIDS management: a review of healthcare policies and plans in East Africa. *BMJ Glob Health.* 2021;6(5).
227. Youssef A, Chaudhary Z, Wiljer D, Mylopoulos M. Mapping Evidence of Patients' Experiences in Integrated Care: A Scoping Review. *General Hospital Psychiatry.* 2019;61.
228. Kane J, Landess M, Carroll C, Nolen A, Sodhi S. A systematic review of primary care models for non-communicable disease interventions in Sub-Saharan Africa. *BMC Family Practice* 2017;18(46).
229. J Ov, Schellevis F, WV D, Kegels G, Rasschaert F. Management of Chronic Diseases in Sub-Saharan Africa: Cross-Fertilisation between HIV/AIDS and Diabetes Care. *Journal ofTropical Medicine.* 2012.
230. Hope R, Kendall T, Langer T, Barningausen T. Health Systems Integration of Sexual and Reproductive Health and HIV Services in Sub-Saharan Africa: A Scoping Study. *J Acquir Immune Defic Syndr.* 2014;67.
231. Jongh T, I G-U, Allen EZ, NJ, Atun R. Barriers and enablers to integrating maternal and child health services to antenatal care in low and middle income countries. *BJOG An International Journal of Obstetrics and Gynaecology* 2016.
232. Tapela N, Tshisimogo, Shatera, et al. Integrating noncommunicable disease services into primary health care, Botswana. *Bull World Health Organ.* 2019;97:142–153.
233. Torpey K, Iwelunmor J, Ezechi O, et al. Capabilities, opportunities and motivations for integrating evidence-based strategy for hypertension control into HIV clinics in Southwest Nigeria. *Plos One.* 2019;14(6).
234. Singer SJ, Kerrissey M, Friedberg M, Phillips R. A Comprehensive Theory of Integration. *Medical Care Research and Review.* 2018;77(2):196-207.
235. Gwaza G, Leqheka M, Dittrich S, Mots'oane T, Kao K. Missed opportunities for integrated testing: An Evaluation of the implementation of TB and HIV EID Testing on the GeneXpert platform in Lesotho. *African Journal for Laboratory Science.* 2023.
236. Farooq S. Collaborative care for depression: a literature review and a model for implementation in developing countries. *Int Health.* 2013;5:24–28.
237. Gwaza GP, Lamy M, Datta R, Dittrich S. Barriers to integrating diagnostic services for febrile illness to support surveillance and patient management in Asia-Pacific. *Asia & the Pacific Policy Studies.* 2022;9(2):196-212.
238. Chopra M, Binkin N, Mason E, Wolfheim C. Integrated management of childhood illness: what have we learned and how can it be improved? *Global Child Health.* 2012.
239. Mitambo C, Khan S, Matanje-Mwagomba BL, et al. Improving the screening and treatment of hypertension in people living with HIV: An evidence-based policy brief by Malawi's Knowledge Translation Platform. *Malawi Med J.* 2017;29(2):224-228.
240. CHAI. *Integrated Testing for TB and HIV using GeneXpert Devices expands access to near-point-of-care testing: lessons learned from Zimbabwe.* August 2019.
241. Hyle P, Naidoo K, Su A, El-Sadr M, Freedberg A. HIV, Tuberculosis, and Non-Communicable Diseases: What is known about the costs, effects, and cost-effectiveness of integrated care? *J Acquir Immune Defic Syndr.* 2014;67(1):S87–S95.
242. Storeng K, Behague D. "Lives in the balance": The politics of integration in the Partnership for Maternal, Newborn and Child Health. *Health Policy and Planning.* 2016;31:992–1000.
243. Brodersen J, Schwartz L, Heneghan C, O'Sullivan J, Aronson J, Woloshin S. Overdiagnosis: what it is and what it isn't. *BMJ Evidence-Based Medicine.* 2018;23(1).

244. Gwaza G, A P, M M, Heneghan C. Integrated diagnosis at the primary care level in Africa's low- and middleincome countries: What is it, what works, and for whom? A Realist Synthesis. In. AfricArXiv Preprints2024.
245. PATH. *Market Failures and Opportunities for Increasing Access to Diagnostics in Low- and Middle-Income Countries.* Seattle: PATH;2022.
246. Gwaza G, Leqheka M, Mots'oane T, Dittrich S, Kao K. Missed opportunities for integrated testing of HIV and tuberculosis on the GeneXpert platform in Lesotho. *African Journal of Laboratory Medicine.* 2023;12(1).
247. Welland A. *Electrification of health clinics in rural areas: Challenges and opportunities.* Trinity College, Cambridge: CMEDT - Smart Villages Initiative;2017.
248. Adler M, E Z. *Gazing into the oracle: Delphi method and its application to social policy and public health.* Bristol, PA: Jessica Kingsley Publishers, 1996.
249. Plüddemann A, Heneghan C, Thompson M, et al. Prioritisation criteria for the selection of new diagnostic technologies for evaluation. *BMC Health Services Research.* 2010;10(109).
250. Niederberger M, Spranger J. Delphi Technique in Health Sciences: A Map. *Front Public Health.* 2020;8:457.
251. Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ.* 2006;333(7565):417.
252. WHO. *Developing key performance indicators for the medical oxygen ecosystem through Delphi consensus.* 2023.
253. Verhagen A, de Vet H, De Bie R, et al. The Delphi List: A Criteria List for Quality Assessment of Randomized Clinical Trials for Conducting Systematic Reviews Developed by Delphi Consensus. *J Clin Epidemiol.* 1998;51(12).
254. Sciences TAoM. *Improving the development and deployment of rapid diagnostic tests in LMICs: Workshop Report.* London, UK: The Academy of Medical Sciences;2016.
255. Organization WH. *WHO package of essential noncommunicable (PEN) disease interventions for primary health care.* Geneva: World Health Organization;2020.
256. Bernabe-Ortiz A, Zafra-Tanaka JH, Moscoso-Porras M, et al. Diagnostics and monitoring tools for noncommunicable diseases: a missing component in the global response. *Global Health.* 2021;17(1):26.
257. Jeffrey G, Jarvik M. Study Design for the New Millennium: Changing How We Perform Research and Practice Medicine. *Radiology.* 2002.
258. Unitaid. *Unitaid Strategy 2023-2027.* 2023.
259. Kerrissey M, Tietschert M, Novikov Z, et al. Social Features of Integration in Health Systems and Their Relationship to Provider Experience, Care Quality and Clinical Integration. *Med Care Res Rev.* 2022;79(3):359-370.
260. Kerrissey MJ, Clark JR, Friedberg MW, et al. Medical Group Structural Integration May Not Ensure That Care Is Integrated, From The Patient's Perspective. *Health Affairs.* 2017;36(5):885-892.
261. Rowe G, Wright G. The Delphi technique as a forecasting tool: issues and analysis. *International Journal of Forecasting.* 1999;15:353–375.
262. Barrett D, Heale R. What are Delphi studies? *Evidence Based Nursing.* 2020.
263. Brown B. *Delphi Process A methodology Used for the Elicitation of Opinions of Experts.* 1968.
264. Zimbabwe MoH. Zimbabwe Antenatal Care Protocol Version 4. In: Welfare MoHaC, ed2018.
265. MoH Zimbabwe. *The Zimbabwe National Maternal and Neonatal Health Road Map 2007-2015.* Ministry of Health and Child Welfare, Government of Zimbabwe;2007.

266. ZimStat. *Population and housing census preliminary report on population figures.* Zimbabwe National Statistics Agency;2022.
267. Mbunge E, Chemhaka G, Dzinamarira T, et al. Determinants of under-five mortality in Zimbabwe: Evidence from the 2015–2016 Zimbabwe demographic Health Survey data. *Women and Children Nursing.* 2024;2(1):1-8.
268. International ZNSAaI. *Zimbabwe Demographic Health Survey 2015: Final report.* Rockville, Marzland, USA: Zimbabwe National Statistics Agency;2016.
269. David R, Evans R, Fraser HS. Modelling Prenatal Care Pathways at a Central Hospital in Zimbabwe. *Health Serv Insights.* 2021;14:11786329211062742.
270. Kiger ME, Varpio L. Thematic analysis of qualitative data: AMEE Guide No. 131. *Med Teach.* 2020;42(8):846-854.
271. Gwaza G. *Evaluation of ZimHealth's investment in upgrading Mabvuku Polyclinic Zimbabwe.* 2024.
272. Hennink M, Kaiser BN. Sample sizes for saturation in qualitative research: A systematic review of empirical tests. *Soc Sci Med.* 2022;292:114523.
273. Gwaza GP, Plüddemann A, McCall M, Dittrich S, Heneghan C. Criteria for designing integrated diagnosis interventions in low resource settings at the primary care level: A Delphi consensus study. 2024.
274. Braun V, Clarke V. Thematic analysis. In: *APA handbook of research methods in psychology, Vol 2: Research designs: Quantitative, qualitative, neuropsychological, and biological.*2012:57-71.
275. Eric Omo I, Chikodili Adolphus M, Godwin Bernard O, Onyekwuo Chinonye F, Angela Adaugo J-I. Effect of Rhesus factor incompatibility on maternal outcome (fertility): A comprehensive review. *International Journal of Frontiers in Life Science Research.* 2023;5(2):001-007.
276. Gwaza G, Pluddemann A, McCall M, Heneghan C. Integrated Diagnosis in Africa's Low- and Middle-Income Countries: What Is It, What Works, and for Whom? A Realist Synthesis. *Int J Integr Care.* 2024;24(3):20.
277. Sibiya M. A model for the integration of primary healthcare services in the province of KwaZulu-Natal, South Africa. *International Journal of Integrated Care.* 2010;10.
278. P V, S S, W O, M B. Understanding integrated care: a comprehensive conceptual framework based on the integrative functions of primary care. *Int J Integr Care.* 2013.
279. Yadav H, Shah D, Sayed S, Horton S, Schroeder LF. Availability of essential diagnostics in ten low-income and middle-income countries: results from national health facility surveys. *Lancet Glob Health.* 2021;9(11):e1553-e1560.
280. Wallruch C, Heller T, Lessels R, Kekana M, Bärnighausen T, Newell M. High uptake of HIV testing for tuberculosis patients in an integrated primary health care HIV/TB programme in rural KwaZulu-Natal. *Issues in Medicine.* 2010.
281. Odeny TA, Penner J, Lewis-Kulzer J, et al. Integration of HIV Care with Primary Health Care Services: Effect on Patient Satisfaction and Stigma in Rural Kenya. *AIDS Res Treat.* 2013;2013:485715.
282. Rabkin M, Melaku Z, Bruce K, et al. Strengthening Health Systems for Chronic Care: Leveraging HIV Programs to Support Diabetes Services in Ethiopia and Swaziland. *J Trop Med.* 2012;2012:137460.
283. WHO. *Introducing a framework for implementing triple elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus: policy brief.* Geneva 2023.
284. Pfaff C, Scott V, Hoffman R, Mwagomba B. You can treat my HIV - But can you treat my blood pressure? Availability of integrated HIV and non-communicable disease care in northern Malawi. *Afr J Prim Health Care Fam Med.* 2017;9(1):e1-e8.

285. Zhou S, Feng X, Hu Y, et al. Factors associated with the utilization of diagnostic tools among countries with different income levels during the COVID-19 pandemic. *Glob Health Res Policy.* 2023;8(1):45.
286. Ameh S, Klipstein-Grobusch K, D'Ambruoso L, Kahn K, Tollman SM, Gomez-Olive FX. Quality of integrated chronic disease care in rural South Africa: user and provider perspectives. *Health Policy Plan.* 2017;32(2):257-266.
287. Schierhout G, Palagyi A, Gadsen T, Dubois G, Renshaw N, R D. *Leveraging Global Health Wins for Sustainable, Person-Centered Healthcare Systems.*: CD Alliance / The Helmsley Charitable Trust Policy Research Repor;2021.
288. Lloyd, Wait. *Integrated Care: A guide for policymakers.* 2006.
289. Maher D, Smeeth L, Sekajugo J. Health transition in Africa: practical policy proposals for primary care. *Bull World Health Organ.* 2010;88(12):943-948.
290. Dittrich S, Lamy M, Acharya S, et al. Diagnosing malaria and other febrile illnesses during the COVID-19 pandemic. *The Lancet Global Health.* 2020;8(7):e879-e880.
291. WHO. *Tailoring malaria interventions in the COVID-19 response.* 2020.
292. Ranaweera P, Wickremasinghe R, Mendis K. Preventing the re-establishment of malaria in Sri Lanka amidst the COVID-19 pandemic. *Malar J.* 2020;19(1):386.
293. Cuen AJ, Kante A, Tsemo S, Djoudalbaye B. Fighting COVID-19 and HIV through community mobilisation: lessons from an integrated approach to the Africa CDC Partnership to Accelerate COVID-19 Testing (PACT) initiative in seven countries. *Afr J AIDS Res.* 2022;21(2):132-142.
294. Abegunde D, Orobaton N, Bassi A, et al. The Impact of Integrated Community Case Management of Childhood Diseases Interventions to Prevent Malaria Fever in Children Less than Five Years Old in Bauchi State of Nigeria. *PLoS One.* 2016;11(2):0148586.
295. Janssens, Van Damme, Raleigh, et al. Offering integrated care for HIV/AIDS, diabetes and hypertension within chronic disease clinics in Cambodia. *Bull World Health Organ.* 2007;85(11):880-885.
296. Fischer V, Morris J, Martines J. Developmental Screening Tools: Feasibility of Use at Primary Healthcare Level in Low- and Middle-income Settings. *J HEALTH POPUL NUTR.* 2014;2:314-326.
297. Awoonor-Williams JK, Appiah-Denkyira E. Bridging the intervention-implementation gap in primary health care delivery: the critical role of integrated implementation research. *BMC Health Serv Res.* 2017;17(Suppl 3):772.
298. Tapia-Conyer R, Saucedo-Martínez R, Mújica-Rosales R, et al. A Policy Analysis on the Proactive Prevention of Chronic Disease: Learnings from the Initial Implementation of Integrated Measurement for Early Detection (MIDO). *Int J Health Policy Management.* 2017;6(6):339–344.
299. C K. The implementation of a diarrheal disease control program in Honduras: Is it 'Selective primary health care' or 'Integrated primary health care? *Soc Sci Med.* 1988;27(1):17-23.
300. Musoke D, Miiro G, Karani G, et al. Promising perceptions, divergent practices and barriers to integrated malaria prevention in Wakiso district, Uganda: a mixed methods study. *PLoS One.* 2015;10(4):e0122699.
301. Halbert RJ, Isonaka S. International Primary Care Respiratory Group (IPCRG) Guidelines: integrating diagnostic guidelines for managing chronic respiratory diseases in primary care. *Prim Care Respir J.* 2006;15(1):13-19.
302. RB J, AJ O. Mixed Methods Research: A Research Paradigm Whose Time Has Come. *Educational Researcher.* 2004;33(7):14–26.
303. Demeshko A, DrakeT,Yakhelef N . A New Era for Global Health: Can African Countries Agree a New Compact with External Donors? In*.* Vol 2025: Center for Global Development; 2025:CGD Brief.

304. Unitaid, Area for Intervention: Improving people-centered care through integrated diagnostic tools and delivery approaches [press release]. 2024.