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Developing a Novel Approach for Improving Supply Chain Management for SARS-CoV-2 Point-of-Care Diagnostic Services in Resource-Limited Settings: A Case Study of Mopani District Municipality in Limpopo Province, South Africa.

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Dedication

To my late brother, Hlomani Maluleke,

I would like to dedicate this work to you, as you have been a source of unwavering support throughout my career. Your sacrifices have played a significant role in shaping my path, and for that, I am truly grateful.

You stood by me during both the highs and lows of my early career, offering your guidance and encouragement. Although you may not have been here to witness this milestone, I believe that you are rejoicing in heaven as I cross the finish line. This achievement is a testament to your belief in me.

I want you to know that this accomplishment is not only mine but ours. Your memory and influence will forever be intertwined with my journey, and I carry you in my heart as I move forward.

This one is for you, dear brother. Thank you for everything.

With love and gratitude,

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Declaration: Authorship

“I declare that the thesis, which I hereby submit for the degree Doctor in Philosophy in Public Health at the University of Pretoria, is my own work and has not previously been submitted by me for a degree at another university”.

Signature _____ Date: __20 June 2023_____

Declaration: Publications

Journal articles published

1. **Maluleke, K**.; Musekiwa, A.; Kgarosi, K.; Gregor, E.M.; Dlangalala, T.; Nkambule, S.; Mashamba-Thompson, T. A Scoping Review of Supply Chain Management Systems for Point of Care Diagnostic Services: Optimising COVID-19 Testing Capacity in Resource-Limited Settings. *Diagnostics 2021*, 11(12), 2299.

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Executive summary

Introduction: In settings with limited access to laboratory diagnostic services, point-of-care (POC) testing offers a suitable alternative for diagnosing COVID-19. We conducted a scoping review to guide the objectives of this study. The scoping review highlighted the importance of equitable access to diagnostic tests at POC through well-coordinated supply chain management (SCM) systems, particularly for settings with limited access to diagnostic laboratory services. It also revealed a research gap on SCM of POC diagnostic services in low- and middle-income countries (LMICs). Guided by the scoping review results, the overarching aim of this thesis is to contribute knowledge to inform development of a novel approach for improving SCM for COVID-19 POC diagnostic services in resource-limited settings with poor access to laboratory diagnostic services, using Mopani District in Limpopo Province, South Africa, as a study setting.

Methods: This multiphase mixed methods study consisted of four phases, starting with the scoping review that guided the thesis objectives. Phase 2 involved a geospatial analysis to assess the spatial distribution of COVID-19 POC testing services in the Mopani District. Phase 3 involved an audit of primary healthcare (PHC) clinics providing COVID-19 POC diagnostic services to evaluate the impact of SCM on accessibility and identify barriers and enablers. Based on the findings from the initial phases, Phase 4 employed a nominal group technique (NGT) to collaborate with key stakeholders in co-creating a novel approach for improving SCM systems for COVID-19 POC diagnostic services. Finally, we synthesised results from the above phases to inform development of an evidence-informed context specific framework for improving POC diagnostics services SCM.

Results: The geospatial analysis indicated that the majority of the population (78.2%) had adequate accessibility to COVID-19 diagnostic services, assuming they utilized the nearest healthcare facility. However, an uneven distribution of services within the region was identified. The audit revealed non-compliance with SCM practices in PHC clinics in the Mopani District, particularly in inventory management, distribution, and human resource capacity. However, compliance was observed in procurement, redistribution, and quality assurance. Through collaboration with key stakeholders we were able to identify key priority areas that needed to be addressed

to improve SCM systems for POC diagnostic services in the Mopani District. The following areas were identified to be a priority: availability of testing kits, monitoring of stock levels, unknown demand, information on SCM during a pandemic, demand planning and standardisation of procurement policies. Informed by the above results, we proposed an intersectoral POC diagnostics SCM framework for resource-limited settings.

Conclusion: This thesis has successfully guided the development of a novel approach to improving SCM of SARS-CoV-2 POC diagnostic services in resource-limited settings, using Mopani District in Limpopo Province, South Africa, as a study setting. This thesis offers guidance on achieving increased accessibility, responsiveness, optimal inventory management, quality assurance, standardization, and data-driven decision-making. These advantages can contribute to more effective healthcare delivery, improved patient outcomes, and enhanced management of public health. Additionally, this thesis proposes implementing an intersectoral framework for improvement of SCM for POC diagnostics in resource-limited settings. The findings of this thesis have significant implications for policymakers and implementers involved in POC diagnostics in resource-constrained settings. Further research is necessary to determine the feasibility of implementing the intersectoral framework for improving SCM for POC diagnostics in resource-limited settings.

Keywords: COVID-19; point-of-care diagnostics; resource-limited settings; supply chain management, primary healthcare

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Definition of terms

Supply chain management- In general, supply chain management refers to the regulation of the flow of medical goods and services from the manufacturer to the patient. It involves obtaining resources, managing supplies, and delivering goods and services to providers and patients in a timely and cost-effective manner (1). In this study, we define supply chain management in a context of accessibility of point-of-care diagnostics. It is the coordination and optimization of processes, logistics, and resources to ensure timely availability, efficient distribution, and proper utilization of these tests at the point-of-care.

Coronavirus Disease -2019 (COVID-19)- A highly infectious acute respiratory disease caused by SARS-CoV-2 virus (2).

SARS-CoV-2- Severe Acute Respiratory Syndrome Corona-Virus-2 is a highly transmissible and pathogenic virus that emerged in late 2019 and has caused a pandemic of acute respiratory disease, COVID-19 (3).

RT-PCR- Reverse transcription polymerase chain reaction is a nuclear-derived method for detecting the presence of specific genetic material in any pathogen, including a virus. It is one of the most widely used laboratory methods for detecting the COVID-19 virus (4).

Point-of-care diagnostic services- In this study, we define point-of-care diagnostics as healthcare services that provide diagnostic testing and analysis at or near the location where the patient is receiving care, allowing for rapid and convenient diagnosis, monitoring, and treatment decision-making (5). This study focused on COVID-19 POC diagnostic services.

Rapid diagnostic test- Innovative medical technologies used to detect the presence of viral protein (antigens) in a blood sample. This technology provides rapid results to enable fast clinical diagnosis (6).

Primary Healthcare Clinic (PHC)- In this study, we refer to healthcare facilities located in the Mopani District of Limpopo Province, South Africa, which serve as the initial point of contact for individuals seeking basic medical care, preventive services,

and initial diagnosis and treatment of common illnesses. These clinics provide essential healthcare services, including primary care consultations, vaccinations, health promotion, family planning, and management of chronic diseases at the community level. They are typically staffed by general practitioners, nurses, and other healthcare professionals, and they play a crucial role in delivering primary healthcare services to the local population.

Resource-limited setting- In this study we refer to a resource-limited setting as an environment where there are constraints in terms of infrastructure, financial resources, trained personnel, and access to diagnostic technologies. These settings often face challenges such as limited laboratory capacity, inadequate healthcare facilities, constrained budgets, and a lack of trained personnel, making it difficult to implement and sustain comprehensive diagnostic services.

Key stakeholders- In this study we define key stakeholders as individuals, organizations, or groups that have a significant interest or influence in the development, deployment, and utilization of point-of-care diagnostic technologies and services. These stakeholders play crucial roles in shaping policies, standards, and practices related to point-of-care diagnostics and contribute to improving healthcare outcomes for patients.

Acronyms and abbreviations

SARS-CoV-2	Severe acute respiratory syndrome coronavirus type II
RT-PCR	Reverse transcription polymerase chain reaction
COVID-19	Coronavirus disease 2019
WHO	World Health Organisation
POC	Point-of-care
SCM	Supply chain management
RDT	Rapid Diagnostic Test
SDG	Sustainable Development Goal
NDP	National Development Plan
MDM	Mopani District Municipality
PHC	Primary Health Care
NHLS	National Health Laboratory Service
LMIS	Logistic Management Information System
DHIS	District Health Information System
SVS	Stock Visibility System
GIS	Geographic Information System
NICD	National Institute for Communicable Diseases
LMIC	Low- and Middle-Income Countries
NDoH	National Department of Health
NGT	Nominal Group Technique
SAHPRA	South African Health Products Regulatory Authority

Chapter 1: Introduction

Chapter 1 presents the introduction to the thesis, providing a concise background and explaining the rationale behind the research study. It includes a clear problem statement, research aim, and objectives.

1. Thesis introduction

Coronavirus disease 2019 (COVID-19) is a highly infectious respiratory disease caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) (7, 8). The virus was first identified and reported in December 2019, in Wuhan, Hubei Province, China (9, 10). It spread globally in a short period of time and was declared a global pandemic by the World Health Organization (WHO) in March 2020 (11, 12). Thus far, the world has lost many lives due to the pandemic hence the WHO worked closely with global experts to come up with strategies to limit the spread of the virus (13, 14). One of the strategies was scaling up of COVID-19 POC diagnostics particularly in resource-limited settings where there is poor access to laboratory diagnostic services (15).

POC tests offer valuable advantages in resource-limited settings despite having certain limitations in sensitivity (75-90%) and specificity (95-100%) compared to PCR testing with both sensitivity and specificity exceeding 95% (16). While PCR is considered the gold standard for diagnosing various infectious diseases due to its high sensitivity and specificity, it often requires sophisticated laboratory infrastructure, skilled personnel, and longer turnaround times for results (17). In contrast, POC tests are designed for rapid on-site diagnosis, providing real-time results without the need for complex laboratory equipment or extensive processing (16, 17). Although POC tests may exhibit slightly lower sensitivity and specificity, they still offer crucial benefits in resource-limited settings, where access to timely and accurate diagnoses is essential. These tests enable early detection and timely intervention, improving patient management and containment of disease outbreaks in areas with limited healthcare resources and infrastructure. Thus, despite their limitations, POC tests remain a valuable tool for enhancing healthcare outcomes in resource-limited settings (18). Effective SCM of POC diagnostics is essential for ensuring that healthcare providers have access to reliable, high-quality diagnostic

tools when and where they need them (19). This, in turn, can improve patient outcomes by enabling early and accurate diagnosis of diseases and conditions (20).

The availability of COVID-19 rapid tests in resource-limited settings has been challenging due to supply chain disruptions, high costs, and limited availability (21, 22). Efforts have been made to improve access, including collaborations between the WHO and manufacturers to increase production and distribution of affordable tests in low- and middle-income countries (23, 24). International organizations, governments, and NGOs have provided support by donating tests, subsidizing costs, improving distribution networks, and offering training to healthcare workers (25, 26). Despite these efforts, challenges remain in reaching resource-limited settings, including SCM issues and regulatory barriers (27, 28, 29, 30). However, ongoing efforts are crucial to control the spread of COVID-19 and improve health outcomes in vulnerable populations (31). This calls for evidence-informed interventions for improving SCM for COVID-19 POC diagnostic services in resource-limited settings with poor access to laboratory diagnostic services.

2. Thesis background

Although the South African healthcare system is well-developed compared to other African countries, the pandemic had a significant impact on the country (2). As of February 2023, South Africa reported 4 055 656 confirmed cases of COVID-19 and 102 595 deaths due to COVID-19 (32). The National Institute for Communicable Diseases (NICD), which serves as the reference laboratory for the diagnosis and surveillance of communicable diseases in South Africa, was the driver for all COVID-19 polymerase chain reaction (PCR) testing (33). In resource-limited settings with poor access to laboratory diagnostic services, testing of all suspected cases of COVID-19 was delayed because laboratory diagnostic services are located at district hospitals causing a delay in the timely diagnosis of COVID-19 (34, 35).

South Africa introduced COVID-19 rapid testing as an alternative to PCR testing in May 2020 after the South African Health Products Regulatory Authority (SAHPRA) approved the use of rapid antigen tests for COVID-19, including the Abbott PanBio COVID-19 antigen rapid test device (44). COVID-19 rapid testing provides instant results and enables early treatment and implementation of control measures (36, 37). Since then, several types of rapid antigen tests have become available in South

Africa, and they are used in various settings such as clinics, hospitals, and testing centres to support the rapid identification and isolation of COVID-19 cases.

The supply chain of COVID-19 rapid tests in South Africa has been affected by various factors since the onset of the pandemic. Initially, the country experienced a shortage of rapid diagnostic tests due to global demand and supply chain disruptions caused by COVID-19 restrictions (38). In addition, there were issues with the quality of some of the rapid tests that were imported into the country, which led to concerns about their accuracy and reliability (39). This resulted in SAHPRA tightening regulations for the importation and use of rapid diagnostic tests (40, 41).

Furthermore, logistical challenges have also affected the supply chain of rapid tests in South Africa, particularly settings with limited laboratory infrastructure such as Mopani District. The country has a large and complex healthcare system with multiple distribution points, including hospitals, clinics, and laboratories (42, 43). These distribution points are often located in remote or hard-to-reach areas, which can make it difficult to transport and distribute rapid tests to most rural and resource-limited settings with limited laboratory infrastructure (44). The aim of this thesis was to present evidence for the development of an improved SCM for SARS-CoV-2 POC diagnostic services in resource-limited settings, using Mopani District in Limpopo Province, South Africa, as a study setting. It is anticipated that the results of this thesis will guide development of a tailored POC diagnostic services SCM for resource-limited settings and contribute to improving the accessibility of diagnostics to all who need them.

3. Problem statement

Reverse transcription polymerase chain reaction (RT-PCR) testing is considered the most accurate method for detecting the presence of the SARS-CoV-2 virus (3). However, its widespread implementation is hindered in resource-limited settings due to the lack of sophisticated laboratory equipment required for PCR testing (4, 45). This limitation poses challenges for fast and accurate detection of SARS-CoV-2 in these settings. The COVID-19 pandemic has exposed weaknesses in healthcare services, particularly in terms of limited accessibility to diagnostic services, especially in resource-limited settings where laboratory infrastructure is lacking such as Mopani District in Limpopo province. In such contexts, alternative diagnostic methods like

POC testing offer a viable solution to alleviate the burden on healthcare facilities and laboratory services (3, 46).

Since the onset of the pandemic, the availability and accessibility of COVID-19 rapid tests in resource-limited settings have been a significant challenge. Factors related to poor SCM are likely to have caused the limited availability of an uneven distribution of testing services such as POC diagnostics (47) (Figure 1). This situation has made it difficult for individuals, particularly those residing in high-prevalence areas, to access testing services. Efforts towards optimising SCM is crucial to ensure sustainable accessibility and availability of diagnostics at POC, to reach all who need the services.

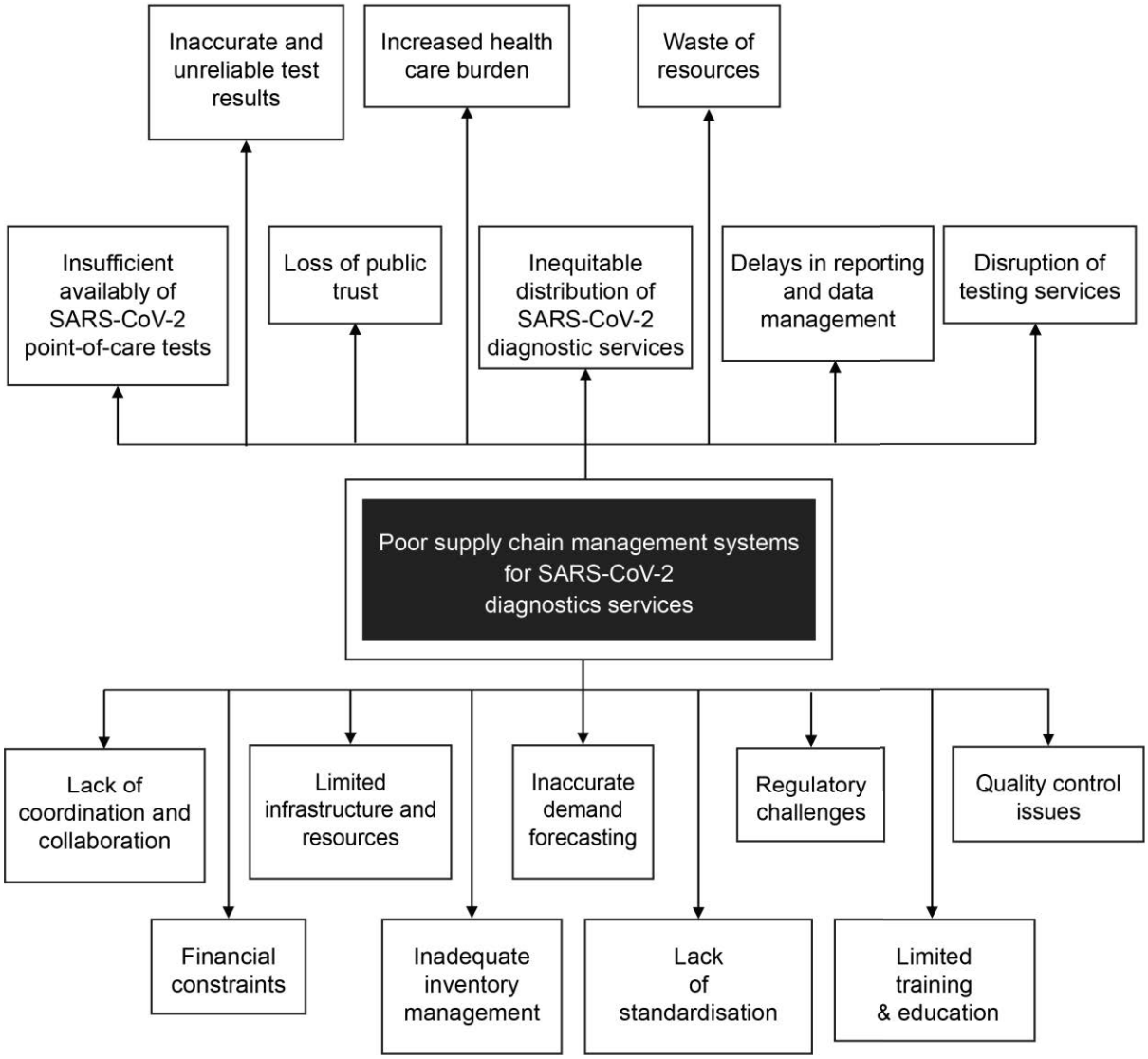

Figure 1: Problem analysis diagram

4. Purpose of the study

POC diagnostic services play a crucial role in the control and management of COVID-19. It is essential to enhance COVID-19 testing services by ensuring that all suspected cases are tested, while also considering the importance of achieving Sustainable Development Goal (SDG) 3, which aims to promote good health and well-being for all by 2030 (48). In the context of South Africa, the extensive roll-out of COVID-19 POC testing aligns with the goals outlined in the National Development Plan (NDP), which seeks to prevent and reduce the disease burden while promoting good health (49). As COVID-19 testing is scaled up, it is vital to ensure that POC tests are accessible and available to those who require them. This requires optimizing SCM to guarantee the continual delivery of high-quality POC testing services, especially during a pandemic.

To date, there is limited research on the SCM of POC diagnostics for resource-limited settings (50). Conducting primary studies addressing SCM for POC diagnostics in this context is urgently needed to identify research barriers and enablers. The findings of such research can help inform future research on SCM POC diagnostics. The results also have potential to provide valuable insights to guide implementers of POC diagnostics to improve management of epidemics and pandemics in resource-limited settings.

5. Aims and objectives

5.1. Aim

The overarching aim of the study was to guide the development of a novel approach to improving SCM of SARS-CoV-2 POC diagnostic services in resource-limited settings, using Mopani District in Limpopo Province, South Africa, as a study setting.

5.2. Objectives

The objectives of the study were to:

1. To investigate the spatial distribution of COVID-19 testing services in Mopani District.
2. To evaluate the effect of SCM on accessibility of SARS-CoV-2 POC diagnostics services in Mopani District.

3. To reveal SCM barriers and enablers of accessibility of SARS-CoV-2 POC diagnostic services in Mopani District.
4. To collaborate with key stakeholders in co-creation of a novel approach for improving SCM for SARS-CoV-2 POC diagnostic services.

Chapter 2: Literature review

Chapter 2 presents the literature review that was conducted as a scoping review that aimed to map the evidence on SCM systems for POC diagnostic services in low- and middle-income countries (LMICs). It provides an overview of the literature by synthesizing existing evidence obtained from searches of online databases. The focus of the review was on SCM systems for POC diagnostic services in LMICs globally.

The findings of this scoping review have been published in the *MDPI Diagnostics* Journal under the title: *"A Scoping Review of Supply Chain Management Systems for Point of Care Diagnostic Services: Optimizing COVID-19 Testing Capacity in Resource-Limited Settings."*

diagnostics

MDPI

Review

A Scoping Review of Supply Chain Management Systems for Point of Care Diagnostic Services: Optimising COVID-19 Testing Capacity in Resource-Limited Settings

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Abstract: Background: Point of care (POC) testing has enabled rapid coronavirus disease 2019 (COVID-19) diagnosis in resource-limited settings with limited laboratory infrastructure and high disease burden. However, the accessibility of the tests is not optimal in these settings. This scoping review mapped evidence on supply chain management (SCM) systems for POC diagnostic services to reveal evidence that can help guide future research and inform the improved implementation of SARS-CoV-2 POC diagnostics in resource-limited settings. Methodology: This scoping review was guided by an adapted version of the Arksey and O'Malley methodological framework. We searched the following electronic databases: Medline Ovid, Medline EBSCO, Scopus, PubMed, PsychInfo, Web of Science and EBSCOHost. We also searched grey literature in the form of dissertations/theses, conference proceedings, websites of international organisations such as the World Health Organisation and government reports. A search summary table was used to test the efficacy of the search strategy. The quality of the included studies was appraised using the mixed method appraisal tool (MMAT) version 2018. Results: We retrieved 1206 articles (databases $n = 1192$, grey literature $n = 14$). Of these, 31 articles were included following abstract and full-text screening. Fifteen were primary studies conducted in LMICs, and 16 were reviews. The following themes emerged from the included articles: availability and accessibility of POC diagnostic services; reasons for stockouts of POC diagnostic tests (procurement, storage, distribution, inventory management and quality assurance) and human resources capacity in POC diagnostic services. Of the 31 eligible articles, 15 underwent methodological quality appraisal with scores between 90% and 100%. Conclusions: Our findings revealed limited published research on SCM systems for POC diagnostic services globally. We recommend primary studies aimed at investigating the barriers and enablers of SCM systems for POC diagnostic services for highly infectious pathogens such SARS-CoV-2 in high disease-burdened settings with limited laboratory infrastructures.

Keywords: point of care diagnostic services; supply chain management; COVID-19; resource-limited settings

1. Background

The primary goal of severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) testing is to reduce the spread of coronavirus disease 2019 (COVID-19) [1,2]. Due to

the highly infectious nature of SARS-CoV-2, there is an urgent need for a fast turnaround of results to institute preventative measures such as the isolation of confirmed cases and contact tracing [1,3]. Currently, reverse transcription polymerase chain reaction (RT-PCR) tests are the gold standard for diagnosing COVID-19 [4–6]. The laboratory equipment required to perform RT-PCR is often lacking in resource-limited settings, hindering the fast and accurate detection of SARS-CoV-2 [7,8].

To ease the burden on health facilities and laboratory services, alternative diagnostic methods such as point of care (POC) testing may improve the disease diagnosis [7,8]. POC testing refers to diagnostic testing that enables near-patient disease diagnosis to inform clinical decisions [9]. The benefits of POC tests are numerous, including affordability, ease of use and able to be deployed both at the site of triage and outside healthcare facilities to guide disease management [4,10]. POC tests deliver prompt results; therefore, they are of utmost importance in containing highly infectious diseases such as COVID-19 [10].

The WHO recommended scaling up testing programmes for SARS-CoV-2 by testing all suspected cases [1,10]. This recommendation was prompted by a resurgence of COVID-19 and the limited testing capacity in settings that have poor access to laboratory infrastructures [11]. The use of POC testing would significantly increase the testing capacity and allow for more accurate reporting and management of SARS-CoV-2. Rapid antigen tests also allow for the decentralisation of SARS-CoV-2 testing, thus increasing testing coverage, which may allow policymakers to institute effective adaptive policy responses [1]. To ensure the equitable availability and accessibility of POC tests, efficient supply chain management (SCM) is necessary. Supply chain refers to resources and processes needed to deliver goods and services to consumers with complete satisfaction in a cost-optimized manner [12,13]. SCM is a multifaceted system that involves production, selection, quantification, procurement, storage, distribution, redistribution, quality assurance and inventory management [10,14].

Evidence in supply chain systems for POC diagnostics is not clear nor readily available. This scoping review is aimed at mapping the evidence of SCM systems of all existing POC diagnostic services in order to reveal gaps to guide future research. It is also anticipated that the results of this review will help guide POC diagnostics implementers in implementing sustainable SCM for POC diagnostics to help manage highly infectious pathogens such as SARS CoV-2 in resource-limited settings. For the purposes of this study, resource-limited settings are defined as settings characterised with having limited access to laboratory infrastructures and limited capability to provide care for life-threatening illness and limited basic critical care resources.

2. Methodology

This scoping review was conducted as part of a multi-phase PhD study aimed at developing a novel approach for improving the SCM of SARS-CoV-2 POC diagnostic services in resource-limited settings. This scoping review protocol was registered with the Open Science Framework (OSF) under the title: "A Scoping Review Protocol for supply chain management systems for point of care diagnostics services: Optimising COVID-19 testing capacity in resource-limited settings" (File S1). The published methodology was made available on 19 September 2021 for public comments via the link below: https://doi.org/10.17605/OSF.IO/RHGEF.

This review was guided by the methodological framework proposed by Arksey and O'Malley 2005 [15] and further advanced by Levac et al., 2010 [16]. According to this framework, we conducted the review in the following five stages: (i) identify the research question; (ii) identify relevant studies; (iii) select eligible studies; (iv) charting the data and (v) collating, summarising and reporting the results. Arksey and O'Malley 2005 proposed a sixth optional stage comprising consultations with key stakeholders to provide insights beyond those found in the literature [15]. This scoping review did not include consultations with stakeholders.

The results of the scoping review were presented according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Extension for Scoping Reviews (PRISMA-ScR) [17].

2.1. Identification of the Research Question

The research question for this study was: What is the evidence in SCM systems for POC diagnostics services globally? To determine the eligibility of the proposed research question for a scoping review, we used the Population, Concept and Context (PCC) framework, as depicted in Table 1.

Table 1. PCC framework for determining the eligibility of the research question.

Population	Point of Care (POC) diagnostic services: Diagnostic services that use innovative medical technologies that enable near-patient disease diagnosis [10].
Concept	Supply Chain Management (SCM) systems: Resources and processes needed to deliver goods and services to consumers with complete satisfaction in a cost-optimized manner [13,18].
Context	Globally

2.2. Identification of Relevant Studies

We conducted a comprehensive and reproducible literature search using the following electronic databases: Medline Ovid, Medline Elton B. Stephens Company (EBSCO), Scopus, PubMed, PsychInfo, Web of Science and EBSCOHost. We also searched for grey literature, including dissertations/theses, conference proceedings, websites of international organisations such as WHO and government reports. We identified additional relevant studies by manually searching all references cited in the included studies to identify studies not indexed in electronic databases. Language restrictions were not applied to minimise the risk of excluding relevant studies.

This comprehensive search strategy was codeveloped by the principal investigator (PI), subject specialist and university librarian to ensure the correct use of indexing terminology and Medical Subject Headings (MeSH) terms. The following keywords or MeSH terms were used: (1) "supply chain management" or "supply chain" or "supply chain flow" or "supply chain systems", (2) "point of care" or "point of care testing" or "point of care diagnosis" or "point of care diagnostic services" and (3) "SARS-CoV-2" or "COVID-19" or "Coronavirus". The keywords were refined to suit each database. Each search was documented in detail, showing the keywords/MeSH terms, date of search, electronic database and number of retrieved studies, and the results of the search were tabulated in File S2.

The search strategy was optimised by adopting the search summary table (SST) outlined by Bethel et al. [19] as a guide. The SST was used to improve and report on the effectiveness of the search strategy.

2.3. Selection of Eligible Articles

This scoping review was guided by inclusion and exclusion criteria to ensure the correct identification and selection of relevant articles.

2.3.1. Inclusion Criteria

The included articles met the following criteria:

- Articles reporting evidence on SCM systems of all diseases
- Articles reporting evidence of SCM systems for all POC diagnostics services at all levels of the healthcare continuum
- Articles reporting evidence of primary studies conducted in LMICs
- All reviews providing evidence of SCM systems for all POC diagnostic services
- Articles published since inception

2.3.2. Exclusion Criteria

Articles were excluded from the scoping review if they had the following characteristics:

- Articles that lacked evidence on SCM systems for all POC diagnostics services
- Articles reporting SCM systems of laboratory-based POC diagnoses
- Articles reporting evidence of primary studies conducted in high-income countries

2.4. Selection of Sources of Evidence

The articles were screened in three stages, namely title, abstract and full-article screening. Reviewers used a screening tool (File S3) developed by the PI and pilot tested by the reviewers. The eligible articles were exported to an Endnote 20 library, and the duplicates were removed. The PI screened abstracts in parallel with the co-reviewer (EM). After screening the abstracts, the reviewers discussed any discrepancies in the selected articles until a consensus was reached. Two reviewers (KM and EM) then screened the full texts of articles selected during the first stage. A third screener (TD) resolved any discrepancies in the selected articles after full-text screening. Both abstract and full-article screening were guided by the screening tool that factored all aspects of the inclusion/exclusion criteria and the PCC elements.

The level of agreement between screeners' results after screening the abstracts and full articles was determined by calculating Cohen's kappa statistics. The kappa statistics were interpreted as follows: values <0.1 indicate no agreement and 0.10–0.20 indicate none to slight, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as substantial and 0.81–1.00 as almost perfect agreement.

2.5. Charting the Data

Data were captured from each included article using a data charting form. Two independent reviewers (KM and TD) piloted the data charting form and recommended modifications that were implemented. The following data were extracted from the included articles: author and year of publication, title of study, aim of study, country, study design, study setting, study population, type of point-of-care test investigated, stage of SCM investigated, main findings and other significant findings.

2.6. Collating, Summarizing and Reporting the Results

We thematically analysed the data extracted from the included articles. The themes were narratively summarised. The following themes emerged from the data: availability and accessibility of POC diagnostic services; reasons for stockouts of POC diagnostic tests (procurement, storage, distribution, inventory management and quality assurance) and human resources capacity in POC diagnostic services.

2.7. Quality Appraisal

We used the mixed method appraisal tool (MMAT) version 2018 to evaluate the quality of the included articles [20]. Using MMAT, we appraised the methodological quality of five categories of research: qualitative research, randomised controlled trials, nonrandomised studies, quantitative descriptive studies and mixed methods studies [20]. Two independent reviewers (KM and TD) carried out the quality appraisal process. The following percentage scores were used to grade the quality of evidence: (i) ≤50% represented low-quality evidence, (ii) 51–75% represented average-quality evidence and (iii) 76–100% represented high-quality evidence.

2.8. Ethical Considerations

This scoping review relied on a synthesis of the existing literature, and therefore, ethical approval was not required.

3. Results

3.1. Screening Results

Our screening search involved title screening and returned a total of 882 results, which consisted of 868 articles and 14 articles from grey literature (Figure 1). Following the removal of 735 duplicate articles, 147 remained. The 147 articles were included in abstract screening. During abstract screening, 47 articles met the inclusion criteria for full-article screening, and 100 were excluded. Of these 47 articles that were included in full-article screening, 22 did not meet the inclusion criteria, and they were excluded. The data were extracted from the remaining 25 articles. The reasons for excluding the 22 articles included were as follows: 12 articles focused on laboratory-based POC diagnostic services, 3 articles did not discuss any aspect of the SCM system, 4 articles focused on the SCM of health systems and 3 articles focused on pharmaceutical and hospital pharmacy SCM. An additional search was performed on 28 October 2021, and it returned 324 articles. Based on the title screening, 29 articles were found eligible and screened for abstracts. After abstract screening, we excluded 14 articles, and 15 articles met the inclusion criteria for full-article screening. Of these, we excluded 9 articles. Additional data were extracted from the remaining six articles. The reasons for excluding the nine articles included: three articles focused on laboratory-based POC tests, and six articles focused on evaluating the performances of the POC tests. After full-text screening, there was a high agreement of 96.77% vs. 50% expected by chance (Kappa statistics = 0.93, $p < 0.05$). In addition, McNamar's chi-square statistics suggested no significant differences in the proportions of yes/no answers by the reviewers ($p > 0.05$) (File S4). The search strategy was continuously improved. An updated search (rerun) was essential, because SARS-CoV-2 is a novel virus, and new research is published frequently (File S5).

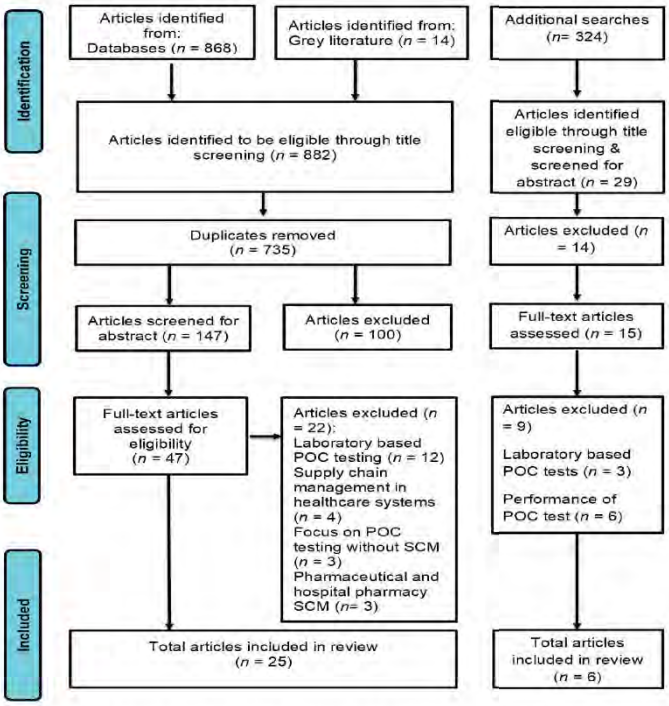

Figure 1. PRISMA-ScR flow chart showing the literature search and selection of articles.

3.2. *Characteristics of the Included Articles*

The characteristics of the included articles are summarised in Table 2. The eligible studies were published between 2011 and 2021. The 31 articles included 15 reviews [10,12,21–32], 1 website of an international organisation [33], 2 randomised controlled trials [34,35], 1 cross-sectional study [36], 1 case study [37], 1 cohort study [38] and 10 studies that used mixed method approaches ranging from focus group discussions to interviews to direct observations [39–48]. The included articles presented evidence of research conducted in the following countries: Mozambique [34,36,44], Zimbabwe [49], Ghana [12,21,22,40,45,48], Malawi [42], Namibia [41], India [43], Sierra Leone [37], Burkina Faso [38], The Philippines [38], Senegal [38,47], Ethiopia [38], Uganda [39,46], Brazil [39], Peru [39], China [39], Tanzania [39] and Zambia [35,39]. Figure 2 shows the distribution of eligible articles by country. Peru, Brazil, China, Namibia, The Philippines and India are middle-income countries, and Mozambique, Ghana, Malawi, Sierra Leone, Burkina Faso, Senegal, Ethiopia, Uganda, Tanzania, Zimbabwe and Zambia are low-income countries. Two articles were conducted in more than one study setting. A cohort study by Albertini et al. was conducted in Senegal, Burkina Faso, Ethiopia and The Philippines [38]. A mixed methods qualitative study by Mabey et al. was conducted in Peru, Brazil, China, Uganda, Zambia and Tanzania [39].

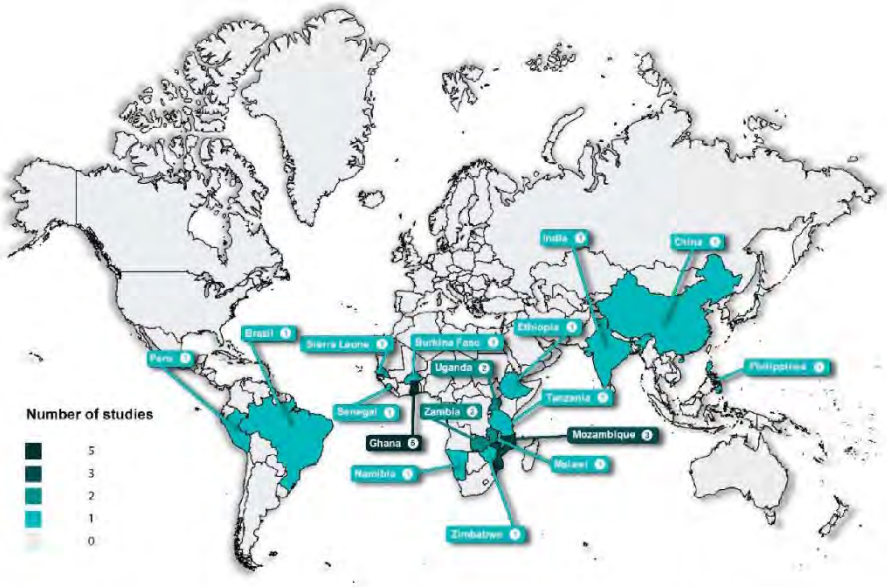

Figure 2. World map showing the distribution of the articles included in the scoping review on supply chain management systems for point-of-care diagnostic services.

Table 2. Characteristics and findings of the studies included in the scoping review.

Author and Year of Publication	Title of Study	Aim of Study	Country	Study Design	Study Setting	Study Population	Type of POC Test Investigated	Stage of SCM Investigated	Main Findings
Kuupiel et al., 2017 [10]	Improving the Accessibility and Efficiency of Point-of-Care Diagnostics Services in Low and Middle-Income Countries: Lean and Agile Supply Chain Management	The review provides an overview of the impact of POC diagnostics on healthcare outcomes and factors that contribute to the accessibility of POC diagnostics in LMICs	Global	Review	Low and middle income	General population	HIV, Syphilis and Malaria rapid diagnostic test	Accessibility and availability of POC tests, Test production, selection, quantification, procurement, storage, distribution, quality assurance, inventory management	Barriers to supply chain: Irregular supply, poor forecasting, selection of appropriate diagnostics, unclear procurement systems, delay distribution systems, poor maintenance of quality assurance, and inadequate stock affect existing diagnostics
Kuupiel et al., 2019 [12]	Supply chain management and accessibility to point-of-care testing in resource-limited settings: a systematic scoping review	The study aimed to map evidence on SCM of and accessibility to POC testing focusing on availability and use of POC tests in LMICs.	Global	Review	Low and middle income	General population	Malaria, Syphilis, HIV, Diabetes, Dyslipidaemia, RST and Hepatitis B virus rapid diagnostic tests	Availability of tests, Stockouts, Quantification, Forecasting, Inventory management, Distribution and Storage	Challenges reported: weak procurement, inventory and stock management, and human resource capacity for SCM resulted in test stockouts as well as, declined use of POC tests. Availability of adequate quality POC diagnostic tests increases access to POC testing and improved healthcare. Need to strengthen quantification and forecasting, procurement, inventory management, distribution systems, quality management systems, and human resource capacity to prevent test stockouts, sustain POC testing services, and maximize the benefits of implementing POC testing programmes in LMICs.
Kuupiel et al., 2019 [21]	Empirical Framework for Point-of-Care Diagnostics Supply Chain Management for Accessibility and Sustainability of Diagnostic Services in Ghana's Primary Health Care Clinics	The aim of the review is to describe the significance of supply chain management in relation to POC diagnostic tests in rural PHC clinics.	Ghana	Review	Low income	General population	Not specified	Stockouts, Distribution, Storage, Inventory management	SCM challenges reported: poor inventory management, clinic managers mostly do not have the autonomy to purchase medical consumables or supplies such as POC tests on their own, clinic managers mostly request POC tests either from centralised regional/provincial medical stores or from their respective district health directorates, and the timely supply of tests is mostly dependent on availability of the test. Even when the POC tests are made available at various medical stores, supply chain management challenges arise: storage, transportation, quality management, inventory management challenges, and human resource capacity for POC testing may be weak and could threaten the sustainability of the service at the PHC level.

Table 2. *Cont.*

Author and Year of Publication	Title of Study	Aim of Study	Country	Study Design	Study Setting	Study Population	Type of POC Test Investigated	Stage of SCM Investigated	Main Findings
Kuupiel et al., 2019 [22]	Poor supply chain management and stockouts of point-of-care diagnostic tests in Upper East Region's primary healthcare clinics, Ghana	The aim of the study is to audit the supply chain management for POC diagnostic tests in rural Upper East Region's (UER) PHC clinics, Ghana to determine the reasons for POC tests deficiencies	Ghana	Review	Low income	General population	Haemoglobin, HIV, Syphilis, Hepatitis B, Blood glucose, Malaria, Urine pregnancy and Urine protein	Inventory management, Selection, Distribution, Stock levels	Inventory management: responsibility of the clinic supervisor/manager within the clinic. Test selection: responsibility of higher authorities at the District, Regional, and National levels (ASSURED guidelines). Distribution: responsibility of the health authorities at the Regional medical store and District Health Directorate upon request by the PHC clinics. Stockouts: due to inadequate inventory management and test stockout at the Regional Medical Store/District Health Directorates
Peeling 2015 [23]	Diagnostics in a digital age: an opportunity to strengthen health systems and improve health outcomes	Re-examine the Achilles heel and explore the promises and challenges of diagnostics in a digital age.	Global	Review	Global coverage	General population	Malaria, HIV and Syphilis rapid diagnostic tests	Access to testing, Quality Assurance, Stockouts	Enablers of SCM: Real-time data monitoring via electronic readers to improve coordination. Data on stocks, device usage and condition can be uploaded via Wi-Fi or cellular networks and transmitted to central databases. By linking the data to SCM software, stockouts can be avoided, health system efficiency improved.
Stevens et al., 2014 [24]	Feasibility of HIV point-of-care tests for resource-limited settings: challenges and solutions	The aim of the study is to outline challenges and solution in the implementation of HIV point of care tests in resource-limited settings	Global	Review	Low and middle income	General population	HIV rapid diagnostic test	Procurement, Production and Quality Assurance	Raises challenges with reimbursement, quality monitoring, lack guideline and regulations
Alemnji et al., 2011 [25]	HIV testing in developing countries: What is required?	This article highlights some of the challenges being faced during decentralization of testing facilities in developing countries and some thoughtful considerations for improving infrastructure and quality systems	Global	Review	Low and middle income	General population	HIV rapid diagnostic test	Procurement, Inventory management	Enablers of SCM: efficient procurement, reagent inventory and stock maintenance, cold chain and establishment of equipment service contracts to ensure uninterrupted, timely and quality testing.

Table 2. *Cont.*

Author and Year of Publication	Title of Study	Aim of Study	Country	Study Design	Study Setting	Study Population	Type of POC Test Investigated	Stage of SCM Investigated	Main Findings
Alemnji et al., 2020 [26]	Building and Sustaining Optimized Diagnostic Networks to Scale-up HIV Viral Load and Early Infant Diagnosis	Reviewing the set of frameworks identified for the effective use of both POC-based and laboratory-based technologies in large-scale VL and EID testing programs among countries, implementing partners, and donors.	Global	Review	Global coverage	General population	HIV rapid diagnostic test	Procurement	The daily challenges that commonly limit the functioning of testing centres: reagent stockouts, inadequate quality assurance and waste management. Moving from laboratory to POC testing does not reduce these challenges, many of which are associated with procurement and supply chain systems. Instead, they may be exacerbated because of the need to manage a larger number of testing sites.
Valera et al., 2021 [27]	COVID-19 Point-of-Care Diagnostics: Present and Future	To analyse the current state of POC technologies for the diagnosis and monitoring of COVID-19 infection and discuss future challenges in COVID-19 diagnostics	Global	Review	Global coverage	General population	COVID-19 rapid test	Availability of POC Accessibility of POC Procurement Quality assurance	Stakeholders injecting funds to speed up the development of rapid and widely accessible COVID-19 testing. Stakeholders to increase the testing capacity at the POC or at home with new molecular and antigen devices authorized for OTC, at-home testing, the challenges will be to ensure adequate sample collection (to ensure the quality of the test), correct collection technique (to avoid patient harm), and a price that allows continuous access to available tests.
Benda et al., 2021 [28]	COVID-19 Testing and Diagnostics: A Review of Commercialized Technologies for Cost, Convenience and Quality of Tests	Our objective here is to review the commercialized in vitro diagnostic tests for the detection of SARS-CoV-2, primarily focusing on tests granted Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA).	Global	Review	Global coverage	General population	COVID-19 rapid test	Accessibility and availability of POC Selection	Despite commendable efforts, the pandemic continues to rattle several parts of the world, especially the low- and middle-income households where testing sites are inaccessible and test kits are cost-prohibitive or in limited supply. Conventional test-trace-isolate strategies for SARS-CoV-2 may eventually be replaced by at-home, low-cost, self-testing based on personal preferences. This requires making COVID-19 testing resources easily accessible, affordable, scalable, quicker, and convenient for the general population. At present, it is paramount to ramp up population-scale testing in low and middle-income countries by building a sustainable supply chain logistics.

Table 2. *Cont.*

Author and Year of Publication	Title of Study	Aim of Study	Country	Study Design	Study Setting	Study Population	Type of POC Test Investigated	Stage of SCM Investigated	Main Findings
Poole et al., 2021 [29]	How are rapid diagnostic tests for infectious diseases used in clinical practice: a global survey by the International Society of Antimicrobial Chemotherapy (ISAC)	The study aims to assess the current patterns of use around the world, identify issues for successful implementation and suggest best practice advice on how to introduce new tests.	Global	Review	Global coverage	General population	Influenza, HIV, Hepatitis B, Hepatitis C and Meningitis rapid tests	Availability Quality control	Lower-income countries reported a lower proportion in the availability of rapid tests, but HIV and hepatitis testing were available in greater proportions. HIV and Hepatitis are prevalent in LMICs and are given high priority. The cost of each test is likely to also be a factor in the difference of availability, with multiplexed assays generally being considerably more expensive and requiring more complex logistical support. Methods for reducing the costs of many RDTs are lacking, which limit their availability in low-income settings. There are several existing international regulatory processes for drugs and medications, providing safeguards for their safety and efficacy, they are often lacking for RDTs. As a result, diagnostic tests are often sold and used without any evidence of effectiveness.
Kumar et al., 2021 [30]	Aspects of Point-of-Care Diagnostics for Personalized Health Wellness	The review focuses on practical scenarios associated with miniaturized analytical diagnostic devices at POC application for targeted disease diagnostics smartly and efficiently.	Global	Review	Global coverage	General population	Dengue, TB, HIV, Hepatitis B and COVID-19 rapid tests	Human resource capacity	The major concern for POC testing is to achieve the improvement in accuracy and precision of diagnosis at various stages. To prevent wastages of POC tests appropriate sample handling approaches are required to re-duce errors during sampling and measurement.

Table 2. *Cont.*

Author and Year of Publication	Title of Study	Aim of Study	Country	Study Design	Study Setting	Study Population	Type of POC Test Investigated	Stage of SCM Investigated	Main Findings
Fleming et al., 2021 [31]	The Lancet Commission on diagnostics: transforming access to diagnostics	In this Commission, we analyse the current status of diagnostics with the use of the six WHO building blocks of health systems, namely health service delivery, health workforce, health information systems, access to diagnostics (analogous to essential medicines), financing, and leadership and governance, as the basis.	Global	Review	Global coverage	General population	Diabetes, Hypertension, HIV, TB, Hepatitis B, Syphilis, COVID-19 rapid tests	Accessibility Quality assurance	Forty-seven percent of the global population has little to no access to diagnostics. Diagnostics are central and fundamental to quality health care. This notion is under recognised, leading to underfunding and inadequate resources at all levels. The level of primary health care is the diagnostic so-called last mile and particularly affects poor, rural, and marginalised communities globally; appropriate access is essential for equity and social justice. The COVID-19 pandemic has emphasised the crucial role of diagnostics in health care and that without access to diagnostics, delivery of universal health coverage, antimicrobial resistance mitigation, and pandemic preparedness cannot be achieved. Innovations within the past 15 years in many areas (e.g., in financing, technology, and workforce) can reduce the diagnostic gap, improve access, and democratise diagnostics to empower patients. As an example of the potential impact, 1.1 million premature deaths in low-income and middle-income countries 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.
Bristow et al., 2015 [32]	A review of recent advances in rapid point-of-care tests for syphilis	The objective of this paper is to assess recent performance data, summarize the latest developments in rapid, point-of care syphilis testing technology and discuss strategies and future directions in the implementation and use of this technology for the prevention and control of syphilis.	Global	Review	Global coverage	Antenatal care clinics	Syphilis rapid diagnostic test	Accessibility, quality assurance	Decentralisation of testing using POC tests can result in increased case finding and treatment for those who need it. The introduction of syphilis rapid tests increased the proportion of antenatal care attendees screened for syphilis to over 90% in all regions that had previously had some testing. WHO helps to make rapid tests available in the places that they are needed through their prequalification program and bulk procurement system. For point-of-care rapid tests to be effective, training on the use and interpretation of tests must be properly provided, and supply chains must be able to sustain access to tests and effective treatment.

Table 2. *Cont.*

Author and Year of Publication	Title of Study	Aim of Study	Country	Study Design	Study Setting	Study Population	Type of POC Test Investigated	Stage of SCM Investigated	Main Findings
WHO 2021 [33]	COVID-19 Supply Chain System Procurement Considerations for COVID-19 Diagnostics	This document aims to bring clarity on the process of requesting and receiving globally sourced COVID-19 critical diagnostics supplies	Global	Website	Low and middle income	General population	COVID-19 rapid test	Procurement Selection Availability of POC	Low- and middle-income countries, as well as some high-income small island developing states, have continued to experience restrictions in test access due to competition for limited volumes with high-income countries. Manufacturers have also faced challenges scaling up manufacturing to meet all testing needs. Prices for diagnostic products remain high and some national governments continue to face restricted access to tests. To access POC tests, purchasers may place orders directly with the companies or utilize one of the available multilateral procurement channels. The funded demand and requests are being followed closely to determine whether these tests may be constrained in volume availability. If they become constrained, an allocation model using the same principles as above will be implemented to ensure equitable distribution.
Betran et al., 2018 [34]	Provision of medical supply kits to improve quality of antenatal care in Mozambique: a stepped-wedge cluster randomised trial	The formative research component of the study assessed factors affecting the implementation of evidence-based antenatal care service	Mozambique	Randomised controlled trial	Low income	Antenatal care clinics	Proteinuria, Anaemia, malaria, HIV, syphilis rapid diagnostic test	Procurement, Distribution, accessibility	Limitations of the health system: packaging of all required supplies and timely delivery of these kits at the clinics addressed weaknesses in the procurement and supply systems. Poor procurement process at higher levels. Scaling up *and sustainability were important* considerations. Scaling up means assessing the cost effectiveness and ensuring accessibility/availability of the POC test.
Hamer et al., 2012 [35]	Quality and safety of integrated community case management of malaria using rapid diagnostic tests and pneumonia by community health workers	To assess the quality and safety of having community health workers (CHWs) in rural Zambia use rapid diagnostic tests (RDTs) and provide integrated management of malaria and pneumonia.	Zambia	Randomised controlled trial	Low income	Child clinic	Malaria rapid diagnostic test	Inventory management Human resource	Enablers of SCM: transparency provided by well-organized record keeping by CHWs and the engagement of study supervisors to ensure adequate supplies. To strengthen stock management, daily registers and periodic reconciliation of stocks was performed to assess commodity use and ensure that none have passed their expiration dates.

Table 2. *Cont.*

Author and Year of Publication	Title of Study	Aim of Study	Country	Study Design	Study Setting	Study Population	Type of POC Test Investigated	Stage of SCM Investigated	Main Findings
Wahlfeld et al., 2019 [36]	HIV Rapid Diagnostic Test Inventories in Zambézia Province, Mozambique: A Tale of 2 Test Kits	The aim of was to evaluate the inventory levels of HIV RDT kits at healthcare facilities in Zambézia province, Mozambique by identifying patterns of threatened inventory levels and/or stockouts of the RDTs.	Mozambique	Cross-sectional	Low income	General healthcare facilities	HIV rapid diagnostic test	Procurement, Storage, Distribution, Inventory management	Disparities in inventory levels were reported at 3 districts. Barriers to supply chain: insufficient access to, and communication with, the provincial warehouse to be able to avoid the high levels of stockouts that were reported.
Ekambaram et al., 2019 [37]	Analysis of Failure Modes: Case study of Ruggedizing a low-cost Screening Technology in Sub-Saharan Africa	The article outlines the steps taken by the Ukweli Test Strips venture to ensure the quality of the UTI and preeclampsia urinalysis screening strips in Sierra Leone.	Sierra Leone	Case study	Low income	General health facilities	UTI and Preeclampsia urinalysis screening strips	Quality assurance	Potential quality control problems throughout the supply chain (1) original equipment manufacturer: manufacturing standards (2) Boat transport: humidity and temperature (3) Warehouse storage: human error and storage issues (4) Truck transport: humidity, temperature and travel issues (5) District storage: human error and storage issues (6) Motorcycle transport: humidity, temperature and storage issues (7) Clinics and community health care workers: humidity, light, temperature, human error and storage issues
Albertini et al., 2012 [38]	Malaria rapid diagnostic test transport and storage conditions in Burkina Faso, Senegal, Ethiopia and the Philippines	This study aimed to gather data on actual temperatures and humidity levels, in different climatic zones, to which RDTs are subjected as they move through the supply chains that typically serve malaria-endemic countries.	Burkina Faso, Senegal, Philippines and Ethiopia	Cohort study	Low and middle income	General population	Malaria rapid diagnostic test	Storage, Distribution	Storage conditions: high temperatures were recorded at central storage facilities in some countries, conditions were inappropriate for many of the RDTs on the market and frequently exceeded common pharmaceutical storage standards.

Table 2. *Cont.*

Author and Year of Publication	Title of Study	Aim of Study	Country	Study Design	Study Setting	Study Population	Type of POC Test Investigated	Stage of SCM Investigated	Main Findings
Mabey et al., 2012 [39]	Point-of-Care Tests to Strengthen Health Systems and Save Newborn Lives: The Case of Syphilis	Our goal was to determine the feasibility of introducing POCTs into different settings in countries with different health systems and cultural and socio-economic contexts.	Brazil, Peru, Tanzania, Uganda, China and Zambia	Mixed methods	Low and middle income	Antenatal care clinics	Syphilis rapid diagnostic test	Quality assurance, availability of POC	For quality assurance, supervisors were provided with proficiency panels prepared by a reference health care facility. Syphilis POCTs were provided to health facilities through the normal supply chain (training in stock management, record keeping, and quality control) to allow the PIs to monitor supply chain problems and provide sustainable solutions in case of stockouts.
Palmer et al., 2020 [40]	Improving the effectiveness of point of care tests for malaria and anaemia: a qualitative study across three Ghanaian antenatal clinics	This study utilises qualitative interviews to identify the current practice of POCT use, to explore the enablers and barriers to effective implementation of POCT, and to determine how relationships between each of the stakeholder groups may impact on POCT use.	Ghana	Interviews and Focus Group Discussions	Low income	Pregnant women	Malaria and Anaemia rapid diagnostic test	Stockouts, Human resource capacity	Barriers of SCM: lack of consistency in the supply of both mRDTs and HCS to the healthcare facilities, regular stockouts of mRDTs, HCS was unavailable in all three facilities (they were available and consistently supplied only during the trial period), concerns about procurement and regular supply of HCS kits (after the trial period). Health workers reported often having to resort to purchasing mRDTs privately.
Magesa et al., 2020 [41]	Factors associated with stock out of malaria test kit in Oshana region, Namibia	This study focuses its attention on factors associates with stockout of mRDT	Namibia	Mixed methods	Middle income	General health facilities	Malaria rapid diagnostic test	Stockouts, Distribution, Storage	Four themes arose from the study. Theme 1: Stock out of mRDT. Theme 2: Medicine policy and decision makers Theme 3: Shortage of knowledge/training in supply chain logistics. Theme 4: Delays in transportation.
Maddox et al., 2017 [42]	Assessing stakeholder perceptions of the acceptability and feasibility of national scale-up for a dual HIV/syphilis rapid diagnostic test in Malawi	This evaluation explores stakeholder perceptions of a novel, dual HIV/syphilis rapid diagnostic test and potential barriers to national scale-up of the dual test in Malawi.	Malawi	Interviews	Low income	Stakeholders involved in provision of antenatal care	HIV and Syphilis rapid diagnostic test	Stockouts, Procurement	Perceived reasons for HIV and syphilis test kit stockouts: low baseline supply of tests given limited funding, expired test kits or staff unwillingness to conduct the tests because they have not received training. Syphilis test kits were stocked out because they were expired, and people wanted to be trained to use the test kits

Table 2. *Cont.*

Author and Year of Publication	Title of Study	Aim of Study	Country	Study Design	Study Setting	Study Population	Type of POC Test Investigated	Stage of SCM Investigated	Main Findings
Hussain et al., 2013 [43]	Public health system readiness to treat malaria in Odisha State of India	The study attempted to evaluate the system readiness to deploy RDTs and ACT for malaria control across the State through health facility surveys and interviews with community workers.	India	Mixed methods	Middle income	General healthcare facilities and stake-holders in malaria control	Malaria rapid diagnostic test	Stockouts	Readiness was assessed in terms of the availability of trained human resources, drugs and diagnostics. Despite a high level of knowledge about how best to diagnose and treat malaria, the ability of the peripheral health workers to optimize fever management and malaria diagnosis was compromised by a failure of the supply chain (poor availability of POC tests due to poor communication/procurement system)
Hasselback et al., 2014 [44]	Rapid diagnostic test supply chain and consumption study in Cabo Delgado, Mozambique: estimating stock shortages and identifying drivers of stockouts	The aim of the study is to estimate malaria RDT stock shortages and the percentage of overall need met by the existing stock in the Cabo Delgado province of Mozambique	Mozambique	Mixed methods	Low income	General health facilities	Malaria rapid diagnostic test	Procurement, stockouts	SCM challenges: procurement for tests was donor supported and requisition-based supply chain has been associated with supply dysfunction (stockouts followed by periods of excessive stock). Supply chains need to respond to timely consumption data to ensure that inventory is appropriately stocked with respect to demand. Stockouts: poor data control and consumption tracking, system responded to an underestimate of the true demand thereby positioning lower inventory than needed in the supply chain.
Dassah et al., 2018 [45]	Rollout of rapid point of care tests for antenatal syphilis screening in Ghana: healthcare provider perspectives and experiences	The aim of the study is to present the perspective of healthcare providers in public health facilities in selected regions of Ghana in relation to their experiences and challenges following a national rollout of rapid syphilis POCTs in Ghana.	Ghana	Mixed methods	Low income	Antenatal care clinics	Syphilis rapid diagnostic test	Stockouts	Interruptions in the supply of syphilis POCTs and penicillin: lack of clear communication channels and poor monitoring and supervision adversely affected implementation of the programme, expired tests kits and failure to replenish stocks, healthcare providers and programme coordinators blamed each other for stockouts.

Table 2. *Cont.*

Author and Year of Publication	Title of Study	Aim of Study	Country	Study Design	Study Setting	Study Population	Type of POC Test Investigated	Stage of SCM Investigated	Main Findings
Blanas et al., 2013 [47]	Barriers to community case management of malaria in Saraya, Senegal: training, and supply-chains	The study evaluates communities' perceptions of a new community case management of malaria programme in Senegal	Senegal	Mixed methods	Low income	General population	Malaria rapid diagnostic test	Availability, Stockouts, human resource capacity	Stockouts were reported: attributed to inaccurate record-keeping and ignored supply requests, procurement system failures and inadequate central stores.
Boadu et al., 2016 [48]	Challenges with implementing malaria rapid diagnostic tests at primary care facilities in a Ghanaian district: a qualitative study	The aim of the study was to determine which factors influenced RDT implementation for routine malaria management at primary care facilities in the study district.	Ghana	Interviews, focus group discussions, direct observation	Low income	Primary health care facilities	Malaria rapid diagnostic test	Storage, Quality Assurance, Distribution Accessibility	RDT supplies from the district health directorate to their facilities were often insufficient and sporadic. This challenge was more pronounced at remote facilities solely dependent on government supplies and a major hindrance to routine malaria testing at all facilities. At the time of the study four facilities had limited RDTs while two had none. Stockouts were common, sometimes lasting several months, making providers hesitant to use limited quantities when available. Malaria testing at public facilities dependent on government RDT supplies was interrupted due to frequent and prolonged RDT stock outs. Some private providers mentioned purchasing RDTs from independent sources when available. Others abandoned RDT use altogether, citing the economic and technical advantages of microscopy over RDTs.
Asiimwe et al., 2012 [46]	Early experiences on the feasibility, acceptability, and use of malaria rapid diagnostic tests at peripheral health centres in Uganda-insights into some barriers and facilitators	This study and other operational research were conceived and carried out to facilitate evidence-based policy formulation and high-quality implementation of mRDT-led, parasite-based diagnosis.	Uganda	Qualitative Cross-sectional	Low income	General health facilities	Malaria rapid diagnostic test	Selection, Quality Assurance and Safe Disposal	Test selection: Given the predominance of P. falciparum as the cause of malaria in this setting, it was decided to use a histidine rich protein-2 (HRP2) type of mRDT. In deciding the mRDT brand to use, a basic assessment of ease of- use was carried out on four brands amongst nine health workers at a health centre not involved in this study. The brand was chosen on the basis of packaging and labelling, ease of performance, readability of the results, cost, heat stability data, and reported sensitivity and specificity.

Table 2. *Cont.*

Author and Year of Publication	Title of Study	Aim of Study	Country	Study Design	Study Setting	Study Population	Type of POC Test Investigated	Stage of SCM Investigated	Main Findings
Cheng et al., 2016 [49]	Data connectivity: A critical tool for external quality assessment	The aim of the study is to address challenges in training and quality assurance when embedding connectivity in their new POC diagnostic instruments or providing some form of channel for electronic result exchange.	Zimbabwe	Review	Low income	General health facilities	HIV rapid diagnostic test	Quality assurance, Stockouts	Connectivity has shown that it is possible for Ministries of Health to have up-to-the-hour information on testing and test results across the country. These systems can also be twinned to supply chain management software to monitor supplies at each site, providing an automated system for alerts to avoid stockouts.

Evidence on the following POC diagnostic tests were provided: COVID-19 [27,28,33]; HIV [10,12,22–26,34,36,42,49]; malaria [10,12,22,23,34,35,38,40,41,43,44,46–48]; syphilis [10,12,23,32,34,39,42,45]; tuberculosis [30,31] and others comprising of anaemia [34,40], UTI [37], diabetes [12,31], blood glucose [22], preeclampsia urinalysis [37], urine pregnancy [22], urine protein [22,34], haemoglobin [22], dyslipidaemia [12], dengue [30], meningitis [29], hepatitis C [29] and hepatitis B [12,22,29–31]. Figure 3 shows the types of POC diagnostic tests in the included articles. Malaria POC diagnostic tests were investigated in 14 articles, HIV POC diagnostic tests in 11 articles, syphilis POC diagnostic tests in 8 articles, COVID-19 POC tests in 3 articles, TB POC tests in 2 articles and the other POC diagnostic tests were investigated in 12 articles.

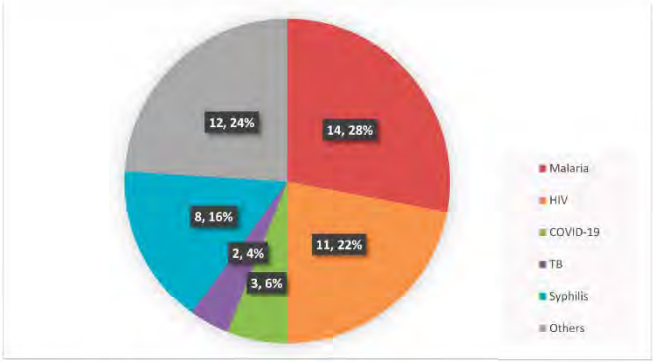

Figure 3. Distribution of the types of POC diagnostic tests in the articles included in the scoping review of supply chain management systems for point-of-care diagnostic services.

The eligible studies provided evidence on at least one aspect of the SCM system. The aspects of the SCM systems covered were procurement and stockouts [10,12,21,24–26,33,34,36,41–45,47,49], quality assurance [10,23,24,27,29,31,32,37,46,48,49], safe disposal [46], inventory management [10,12,21,25,35,36], selection [10,22,28,33,46], distribution [12,21,22,34,38,41,48], quantification [12], storage [12,21,38,41,48], human resource capacity [30,35,40,47] and the availability and accessibility of POC diagnostic services [10,12,23,32,39,47,48]. Figure 4 shows the aspects of the SCM systems described in the included articles.

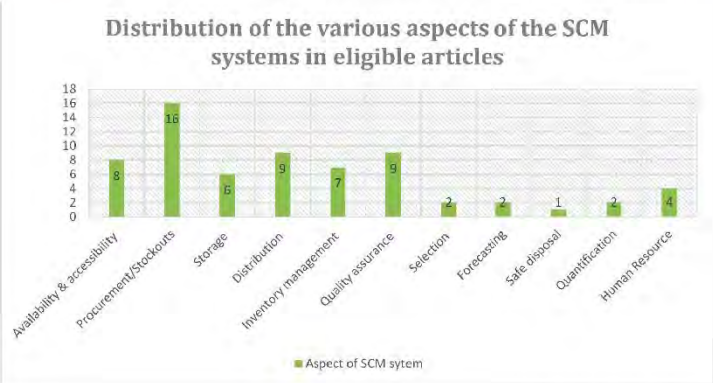

Figure 4. Aspects of supply chain management systems in the articles included in the scoping review on supply chain management systems for point-of-care diagnostic services.

3.3. Quality of Evidence

From the 31 included articles, 15 primary studies were appraised for methodological quality using MMAT version 2018 [20]. The remaining 10 articles were excluded because they were not primary studies [10,12,21–26,32,49]. After categorising each study, we rated the criteria of the chosen categories to establish whether the criteria for each study design had been met. The 15 studies that were appraised for methodological quality scored between 90% and 100%, which showed high methodological quality. Twelve studies scored the highest quality score of 100% [34–36,39–45,47,48]. One study scored 95% [38]. The remaining two studies scored 90% and 92% [37,46] (File S6).

3.4. Main Findings

All the included articles presented evidence of at least one aspect of SCM of POC diagnostic services globally. The following themes emerged from the included articles: availability and accessibility of POC diagnostic services, reasons for stockouts of POC diagnostic tests (procurement, storage, distribution, inventory management and quality assurance) and human resources capacity in POC diagnostic services.

3.4.1. Accessibility and Availability of POC Diagnostics Services

Eight articles reported evidence on the availability and accessibility of POC diagnostic services [10,12,23,27,34,39,47,48]. These articles showed that the accessibility and availability of POC diagnostic services in resource-limited PHC clinics contributed to improved health outcomes [12]. A review conducted by Peeling [23] showed that, in Peru, it would take five to six visits spread over 27 days to screen and treat pregnant women for syphilis. With the introduction of rapid diagnostic tests (RDTs), the testing and treatment of infected mothers was done on the same day [23]. A randomised controlled trial conducted in Mozambique found that introducing POC diagnostic testing for pregnant women improved antenatal care [34]. A significant improvement in the accessibility of antenatal POC diagnostic tests was reported in all implementation sites. In the first visits, 5519 (14.6%) out of 37,826 women were screened for anaemia compared to 30,057 (97.7%) out of 30,772 in the intervention, 3739 (9.9%) out of 37,826 women were screened for proteinuria during the control period compared with 29,874 (97.1%) out of 30,772 in the intervention period and 17,926 (51.4%) out of 34,842 received mebendazole during the control period compared with 24,960 (88.2%) out of 28,294 during the intervention period [34].

In a survey conducted by Poole et al., 2021 highlighting the current state of RDTs globally, most of the respondents reported 24/7 availability of tests [29]. High-income countries reported a higher availability of the rapid influenza test compared to low-income countries [29]. Low-income countries reported a high availability of HIV and hepatitis rapid tests. The reason given for this pattern is that hepatitis and HIV are more prevalent in developing countries, where public health interventions are less likely to identify and treat patients early during illness [29]. Another reason is that the priorities for treatment are different: influenza management in secondary care is a less-pressing need in resource-limited settings where patient isolation facilities are less readily available [29]. Additionally, the cost of identifying an influenza case is less than HIV or hepatitis, where early identification and treatment make a greater difference. The cost of each test is likely to also be a factor in the difference of availability, with multiplexed assays generally being considerably more expensive and requiring more complex logistical support. Methods for reducing the costs of many RDTs are lacking, which limits their availability in low-income settings [29].

Decentralisation was an important factor promoting the accessibility and availability of POC diagnostic services. The decentralisation of POC diagnostic services increased detection, patient management and prompt treatment initiation when necessary [23,32,39]. Mabey et al., 2012 reported on the introduction of POC testing for syphilis in various urban (China and Peru) and rural settings (villages in East Africa). The proportion of antenatal care attendees increased by more 90% in areas that previously had some testing [39]. In areas where syphilis POC diagnostic testing had previously not been available, the

screening rate increased by more than 50% [39]. In all settings, more than 90% of those who tested positive received syphilis treatment [39].

In most of the studies, POC diagnostic services relied solely on government supplies [35,37,39,41–43,45]. Two articles reported that the supply of POC diagnostic tests was insufficient and sporadic [12,48]. This affected malaria testing in a study conducted in Ghana, which determined the factors that influenced the implementation of POC diagnostic tests in routine malaria management at PHC facilities [48]. At the time of the study, four study sites had limited malaria RDTs, while two sites had none [48]. As RDTs became less available, the rate of blind treatment increased. Other patients opted to buy test kits privately, causing financial strain [48]. The RDT supplies were interrupted due to frequent and prolonged RDT stockouts [48].

3.4.2. Reasons for Stockouts of POC Diagnostic Tests

The reviewed articles revealed that stockouts of POC diagnostic tests were caused by problems in procurement, inventory management, storage, distribution and quality assurance.

- Procurement of POC diagnostic tests

Sixteen articles reported stockouts due to procurement issues [10,12,21,24–26,34,36,40–45,47,49]. Of the 16 articles, one article reported an adequate inventory of test kits more than 89% of the time across the 75 facilities from a study conducted in Mozambique [36]. In this study, the HIV RDT stock levels were well-maintained due to technical support received from a nongovernment organisation affiliated with the Global Fund [36]. The stock levels were also monitored during monthly visits and followed up with planning and coordinating supply chain logistics with health facilities [36].

The other 15 articles reported poor procurement processes. Two qualitative studies conducted by Magesa et al., 2019 and Maddox, et al., 2017 reported that more than 60% of the key informants from all levels of the supply chain reported stockouts due to a lack of proper knowledge and training in procurement processes [41,42]. A randomised control trial conducted by Betrán et al. [34] reported that, during the intervention period, two clinics had a single 3-day period with no kits due to clinics making late requisitions to the health directorate [34]. According to Hussain, Dandona, David and Schellenberg [43], malaria diagnoses were compromised by a failure of the supply chain due to poor communication or procurement systems compromising the availability of POC tests at PHC facilities. Almost half (48%) of the facilities did not have test kits. Similar findings were reported by Hasselback et al. [44], where 59% of health facilities reported stockouts due to poor communication between health facilities and suppliers [44]. This resulted in a high rate of referral to private healthcare facilities, which hindered the early diagnosis and complete treatment of malaria [43].

The WHO, in a document that aims to bring clarity on the process of requesting and receiving globally sourced COVID-19 critical diagnostics supplies, stated that low- and middle-income countries have continued to experience restrictions in test access due to competition for limited volumes with high-income countries [33]. Manufacturers have also faced challenges in scaling up manufacturing to meet all testing needs. Prices for diagnostic products remain high, and some national governments continue to face restricted access to tests. To access POC tests, purchasers may place orders directly with the companies or utilize one of the available multilateral procurement channels. The funded demand and requests are being followed closely to determine whether these tests may be constrained in volume availability. If they become constrained, an allocation model using the same principles as above will be implemented to ensure equitable distribution [33].

- Inventory management of POC diagnostic tests

Consumption data was important to guide the quantity of inventories procured at all implementation sites [47]. Adequate inventory was promoted by a well-managed and monitored system to enable clear communication between PHC facilities and regional

or provincial offices [24,41,45]. Lack of consumption data contributed to stockouts of malaria RDTs as a results of a poorly functioning Facility Electronic Stock Card (FESC) in Namibian PHC facilities [41]. A lack of consumption data resulted in a high rate of expired medicine and wastage of malaria RDTs due to overstock, while other study sites experienced stockouts due to underestimated consumption [41]. In their review, Peeling et al., 2015 concluded that real-time data monitoring via electronic readers improved inventory management [23]. Operational data on stocks, device usage and conditions were uploaded via Wi-Fi or cellular networks and transmitted to central databases [23]. Linking the data to SCM software helped avoid stockouts and improved the efficiency of the health system [23].

In Mozambique, 15 health facilities were surveyed over 120 time points [44]. Stockout patterns varied by data source, with an average of 59% of health centres reporting stockouts on stock cards every month, preventing the proper documentation of consumption data [44]. Each ten-unit increase in monthly-observed consumption was associated with a nine-unit increase in lost consumption, indicating higher rates of stockouts at higher levels of observed consumption [44]. Stockouts were caused by the inaccurate tracking of lost consumption, insufficient sophistication in inventory management and replenishment and poor process compliance by facility workers, all stemming from inadequate attention to design and implementation of the inventory management system [44].

- Storage of POC diagnostic tests

Six articles mentioned that RDTs should be stored under recommended temperatures, because exposure to adverse environmental conditions had the potential to degrade POC diagnostic tests [12,21,37,38,41,48]. A study investigating storage and temperature conditions in Burkina Faso, Senegal and Ethiopia revealed that malaria RDTs were being stored at temperatures exceeding the recommended RDT manufacturer temperature limit [38]. In three of the eight facilities in Burkina Faso, temperatures rose above the recommended RDT manufacturer temperature limit of 40 °C [38]. In 11 of the 13 facilities in Ethiopia, temperatures exceeded the recommended RDT manufacturer temperature limit of 30 °C. In five out of ten facilities in Senegal, temperatures exceeded the recommended RDT manufactured limit of 40 °C [38]. In this study, RDTs were exposed to unfavourable conditions for only brief periods, making it difficult to detect if product shelf lives were shortened [38]. When RDTs are exposed to extreme conditions for some time, it is costly to retest a withdrawn batch, and the continuity of diagnostic services is disrupted [38,46]. Ways to lower temperatures were explored in Uganda [46]. This was done by implementing techniques such as underground storage and the use of evaporative cooler boxes. These studies concluded that RDTs should be selected according to the expected field conditions [38,46].

An association between the limited storage capacity contributed and stockouts was reported in Namibia [41]. Most clinical settings (n = 16, 94%) reported problems with storage resulting in the expiration of diagnostic tests. Stock was stored in the wrong place, and staff were not always aware that there was stock. Some study sites would pile up boxes on the floor, compromising the qualities of the diagnostic tests [41].

Evidence has reported the robustness of syphilis rapid tests, because they do not require special storage or transport conditions [32]. Syphilis tests can be stored at temperatures ranging from 8 to 30 °C [32]. If clinics are warmer than 30 °C, the shelf life of rapid tests is reduced, and sensitivity is lost [32]. In settings that rely on POC diagnostic tests, it is important to conduct periodic quality control checks to ensure ongoing validity. Health authorities should visit study sites to ensure that POC diagnostic tests are functioning as expected [32].

In Ghana, malaria RDTs are not always distributed timeously, and there is limited storage space at the district office, resulting in RDTs being left outdoors, exposed to sunlight and other weather conditions [48]. Providers were concerned with compromised test qualities due to poor storage, and they had little confidence in the accuracy of the test results [48].

- Distribution of POC diagnostic tests

Nine articles discussed the distribution of POC diagnostic tests and highlighted that regional or national health directorates were responsible for distributing POC diagnostic tests to PHC clinics [12,21,22,34,38,41,48]. The timely distribution of POC diagnostic tests to PHC clinics often depends on the availability of tests at the regional or national health directorate. In Ghana, Kuupiel, Tlou, Bawontuo, Drain and Mashamba-Thompson [22] found that 90% of the PHC clinics received POC diagnostic supplies within 24 h after requisition. While the distribution of POC tests was adequately managed, PHC staff revealed documentation challenges that would limit their ability to forecast demands. They further recommended that PHC staff require training on the documentation of test stock levels to aid forecasting demands to ensure the continued supply of diagnostic tests to match consumption [22].

In Ghana, healthcare providers reported their perspectives and experiences in the rollout of rapid POC tests for antenatal syphilis screening [45]. Almost half (6/13) of the facilities that had started antenatal syphilis screening did not have any syphilis test kits, while HIV test kits were available in all the 14 facilities that were screening pregnant women for HIV [45]. In some facilities, stockouts of syphilis test kits were quite frequent, but pregnant women were not referred to other facilities for testing and were only screened when the test kits became available [45]. In one region, healthcare providers blamed stockouts of test kits on inadequate regional supplies, while the regional staff blamed stockouts on the lack of returns from districts and healthcare facilities and, less commonly, insufficient supplies from national headquarters [45].

Mozambique experiences rainy seasons, which are associated with a high prevalence of malaria and distribution difficulties. Rural areas are not easily accessed due to poor road infrastructure [44]. Large trucks cannot drive on wet dirt roads sometimes, causing motorcycles to be the primary mode of distribution, which does not allow for the same protection as trucks [37]. The use of malaria RDTs increases by more than 300% in the rainy season; therefore, it is important to plan the distribution aspects to prevent stockouts during such a critical season [44].

- Quality assurance of POC diagnostic tests

Eight articles discussed the importance of following quality assurance processes when handling POC diagnostic tests [10,23,24,32,37,46,48,49]. These articles showed that poor regulatory mechanisms further limited RDT implementation. Quality assurance processes were seldom in place, preventing the ongoing monitoring of POC diagnostic tests. Infrequent quality assurance and control visits to facilities by authorities further undermined providers' willingness to use RDTs [10,23,24,32,37,46,48,49].

Evidence revealed that the current setup of RDTs appears to be more laboratory-centred. Governance and quality control were reported to be the responsibility of laboratories in the vast majority of those surveyed [29]. A total of 90% of those who responded to the survey reported that tests were carried out in their institution by laboratory staff [29]. Simpler tests, RDTs, were conducted more during point-of-care. While there are several existing international regulatory processes for drugs and medications, providing safeguards for their safety and efficacy, they are often lacking for RDTs [29]. As a result, diagnostic tests are often sold and used in the developing world without any evidence of effectiveness. For example, a study conducted to evaluate the performance of RDTs by Mak et al. [26] reported the sensitivity of an RDT for SARS-CoV-2 of 11.1–45.7% when the manufacturer had claimed it was 98%. This is indicative of poor-quality assurance mechanisms in the sites surveyed.

3.4.3. Human Resource Capacity in POC Diagnostic Services

Four articles discussed the importance of human capacity in POC diagnostic services [35,37,40,47]. Two studies reviewed how the services of community healthcare workers (CHWs) are used to assisting in providing POC diagnostic services in resource-limited

settings. In Sierra Leone, Ekambaram, Gomanie and Mehta [37] reported that CHWs had no formal training and that human error contributed to losing POC tests [37]. In Senegal, Blanas et al. [47] reported that most lay health workers acquired important skills, but few did not understand the RDT algorithm soon after the training. Although the scores improved by 10–20% after two months of field training, half of the CHWs still could not interpret the RDT algorithm correctly, and almost half could not prescribe artemisinin-based combination therapy (ACT) correctly [47].

Hamer et al. [35] evaluated the ability of CHWs to provide high-quality, safe, integrated care for malaria and pneumonia in two rural districts in Zambia. Community health workers were able to manage malaria using RDTs at the community level. The CHWs performed RDTs with 90% accuracy and with 93% correctness after a 3-h training session assisted by visual job aids and RDT package inserts. With enough training, CHWs were able to handle RDTs without significant risks to themselves and their patients, reducing wastage linked to the improper use of RDTs [35]. In Zambia, CHWs also contributed to successful SCM by keeping accurate records and engaging with supervisors to ensure adequate supplies [35].

A review conducted by Kumar et al. [30] further emphasised the importance of human resource capacity in the improvement of diagnostic accuracy and precision. They reported that appropriate sample handling approaches are important in reducing errors during sampling, testing and interpretation of the POC test. For an infectious disease diagnosis, the sample could take different forms, such as urine, serum, blood, plasma, stool or saliva. The different physical properties and chemical compositions of these samples demand proper and appropriate approaches that can accommodate the target analyte in an acceptable form [30]. The Lancet commission also found that the reliability of the diagnostic test depends not just on the performance characteristics of the actual test but on all the elements involved in the testing—for example, sample collection and preparation (PALM), result interpretation and result communication [31]. All these elements rely on users being adequately trained and having ongoing access to quality control materials and technical support and maintenance for instruments. It is therefore pivotal to incorporate adequate quality assurance and quality control into the point-of-care testing protocols. Additionally, these point-of-care diagnostics should only be used in situations in which there are referral pathways and there is healthcare provider buy-in and patient trust [31].

4. Discussion

We conducted a scoping review to map the evidence on SCM systems for POC diagnostic services with the goal of optimising the COVID-19 testing capacity in resource-limited settings. Our scoping review results show that there is limited published research on SCM systems of POC diagnostic services. Studies have been conducted in sixteen low- and middle-income countries. This is a major public health concern and requires immediate action from all relevant stakeholders, especially since 47% of the global population has little to no access to diagnostic services [31]. The COVID-19 pandemic has emphasised the crucial role of diagnostics in healthcare and that, without access to diagnostics, the delivery of universal health coverage, antimicrobial resistance mitigation and pandemic preparedness cannot be achieved, thereby hampering the progress towards achieving sustainable development goal (SDG) 3 that aims to promote good health and well-being for all by 2030 [50]. Our scoping review findings also demonstrate that, for the continuum of POC diagnostic services, POC diagnostic tests must be available and accessible to all who need them through sustainable SCM systems [34,43,47,48]. Sustainable SCM systems are influenced by several factors, some of which are procurement, inventory management, storage, distribution, quality assurance and the human resource capacity, as revealed in most of the study settings explored [34–36,38,39,41,46,47]. Weak SCM systems may lead to significant stockouts of POC diagnostic tests [21,36,43]. Stockouts result in the reduced use of POC diagnostic tests in resource-limited settings, which negatively impacts health outcomes [35,39,45].

The WHO has been the main driver in ensuring that POC diagnostic tests are available in resource-limited settings through their prequalification program and bulk procurement systems [14,32]. The prequalification program facilitates access to medicines and medical equipment that meets unified standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis, with the aim of reducing widespread disease in countries with limited access [14,32]. Currently, the Foundation for Innovative New Diagnostics (FIND), in collaboration with WHO and other organisations, is playing a pivotal role in scaling up the development and delivery of COVID-19 tests through its Access to COVID-19 Tools (ACT) Accelerator and provide sustainable solutions beyond the COVID-19 pandemic [51]. To provide sustainable solutions in providing POC diagnostic tests and to avoid past uncoordinated procurement issues, various stakeholders have joined forces to speed up the end of the pandemic by supporting the development and equitable distribution of the tests, treatments and vaccines the world needs to reduce mortality and severe disease, restoring full societal and economic activity globally in the near term, and facilitating a high-level control of COVID-19 in the medium term [51]. The collaboration supports the coordinated, uninterrupted provision of timely, high-quality diagnostic tests in resource-limited settings [26]. The collaboration serves as a platform for information exchange, as well as alignment, on procurement principles, planning and addressing key SCM issues [26]. They also ensure that there are adequate funds to purchase projected POC diagnostic tests to make them available for use at the POC in a timeous manner.

Effective SCM is dependent on the skilled human resource capacity for POC diagnostic services [21]. Staff in PHCs should be trained in various aspects of POC diagnostic test SCM [21]. Staff should also be trained in how to perform POC diagnostic testing accurately to prevent wastage [21]. Training is also important to aid in stock management and the safe disposal of used test kits to ensure personnel and environmental safety [21]. Training programs complemented with strengthened monitoring and supervision support at the clinics may ensure compliance with SCM guidelines, and acceptable standards will further enable the suitability of diagnostic services.

Storage, distribution and inventory management are equally important in the SCM system. Regional or provincial warehouses should have enough stock to ensure adequate distribution to all PHC facilities. Regional warehouses and PHC storage facilities need to meet storage requirements. While distributing POC diagnostic tests, harsh environmental conditions should be avoided by using refrigerators and cold chain facilities [21]. Improved inventory management will ensure that enough tests are available to meet demand. Health facilities should have set minimum and maximum levels and follow the First Expired, First Out principle, thus preventing tests from expiring. Inventory management linking national, regional, district and PHC facilities could potentially benefit from the adoption of digital technology, such as blockchain. Blockchain is an emerging digital technology that has unique characteristics, such as immutability, decentralisation and transparency, that can be used for the coordination of large-scale operations such as population-level mass screening, rapid contact tracing and supply chain management [52]. This modern technology is widely used in high-income countries [53]. In resource-limited settings, the adoption of blockchain digital technology may be costly; therefore, low-cost blockchain may be more sustainable [54].

The adoption of real-time technology such as the Stock Visibility System (SVS) can bring visibility to the supply chain process, make it seamless, and can facilitate effective and efficient inventory management at all levels [55]. The SVS facilitates the detection of high- and low-consumption PHC clinics to enable the redistribution of tests to prevent the overstocking and expiration of POC tests [55]. The distribution of SARS-CoV-2 POC diagnostic tests can be optimised by using unmanned aerial vehicles (UAVs) or drones that can be operated either autonomously or remotely by humans [56]. The use of drones has been extensively adopted for the faster and safe transfer of essential products, assisting authorities to deal with and possibly overcome the constraints and health emergencies imposed on society by the COVID-19 pandemic [57,58]. Drones have been shown to prevent

the spread of coronavirus infection by limiting person-to-person contact and stopping the unwanted movement of people during the lockdown [58]. Their independence on road infrastructure and remote operations enables them to be a viable option for various supply chains in hard-to-reach settings [56]. The use of drone technology has been proven to be effective in the delivery of much-needed medical supplies to Rwanda, Lesotho and Ghana's rural hospitals [59–61]. Drone technology has also been shown to be effective in inventory management more efficiently than humans through the movement of items, locating specific inventory, surveying large areas and inspecting labels while saving time and eliminating human error [56]. In addition to diagnostic supplies to remote and hard-to-reach settings, the concept of using inventory drones can be adapted and implemented to help improve the efficiency in monitoring stock levels of POC diagnostic tests at storage facilities. As with other health technologies, the effective and sustainable implementation of this technology will need to be context-specific and include the involvement of all key stakeholders.

4.1. Implications for Practice

All the primary studies included in this scoping review were conducted in resource-limited settings in LMICs, as these settings have been reported to have weak health systems and limited coverage or access to diagnostic services. Resource-limited settings have serious SCM barriers. Stockouts of POC tests are a major challenge, and most PHC facilities do not procure POC tests on their own but rely on making requisitions at the district or national level. Distribution to PHC facilities is normally delayed, negatively affecting health outcomes, because patients cannot be tested in a timely manner. A sustainable, well-managed SCM system is important in resource-limited settings, and digital technology may be a viable option. The following SCM measures can be implemented to ensure sustainability: strengthen procurement systems, appropriate forecasting, the efficient training of SCM and health personnel, equitable and timely distribution, efficient inventory management and adequate quality assurance.

4.2. Implications for Research

We found limited published research on the SCM of POC diagnostic services in resource-limited settings. Our scoping review revealed that there are currently no primary studies on the SCM systems of COVID-19 POC diagnostic services. We therefore recommend further research to investigate the COVID-19 SCM of POC diagnostic services, explore SCM systems utilised in high-income countries with the aim of adopting sustainable solutions for LMICs and systematic analyses of the impacts of the COVID-19 pandemic on SCM systems. We also recommend primary studies investigating the barriers and enablers of SCM systems in resource-limited settings to provide sustainable solutions to SCM challenges.

4.3. Strengths and Limitations

This scoping review is one of the few to comprehensively map the evidence of SCM systems for POC diagnostics services globally with the aim of optimising COVID-19 POC diagnostic services. This scoping review revealed significant gaps in the literature on SCM systems of COVID-19 POC diagnostic services. The use of a scoping review to map evidence allowed the incorporation of different study designs, and we used a transparent and reproducible method to identify, chart, analyse and appraise the articles [15]. The strength of this scoping review is that a comprehensive literature search in relevant electronic databases was conducted. The search included all articles published from inception to date, and no language restrictions were applied. In order to be as comprehensive as possible, the scoping review utilised many keywords and used Medical Subject Heading terms. Despite attempts to be as comprehensive as possible, other published and grey literature may have been missed during the literature search, because COVID-19 is a novel virus, and more research is being published frequently.

This scoping review mapped evidence on the SCM of POC diagnostic services while optimising the COVID-19 testing capacity in resource-limited settings; however, there were no primary studies retrieved that assessed the SCM of COVID-19 POC diagnostic services. It is recommended that primary studies to investigate the SCM of COVID-19 diagnostic services in resource-limited settings are conducted.

5. Conclusions

This scoping review revealed that there is limited research on the SCM of POC diagnostic testing in resource-limited settings. POC diagnostic services are fundamental in the timely control and management of COVID-19. The supply chain of POC diagnostic testing should be optimised to ensure access to all patients. The adoption of digital technology can play a crucial role in mitigating the SCM challenges arising from the COVID-19 pandemic. There is currently no research focusing on the SCM of POC tests in the control and management of COVID-19. Therefore, there is an urgent need to conduct primary studies that will investigate the SCM for SARS-CoV-2 POC testing services in order to reveal the research gaps and provide evidence-based solutions for policymakers and implementers of this service.

Supplementary Materials: The following are available online at https://www.mdpi.com/article/10.3390/diagnostics11122299/s1: File S1: Scoping Review Protocol. File S2: Electronic database search results. File S3: The screening tool. File S4: Full article screening results and agreement. File S5: Search summary table. File S6: MMAT quality appraisal.

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Abbreviations

SARS-CoV-2	Severe acute respiratory syndrome coronavirus type 2
RT-PCR	Reverse transcription polymerase chain reaction
COVID-19	Coronavirus 19
WHO	World Health Organisation
POC	Point of care
SCM	Supply chain management
PRISMA-ScR	Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping review
MMAT	Mixed method appraisal tool

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Chapter 3: Methodology & Conceptual Framework

Chapter 3 presents a published protocol for the study, outlining the methodology employed to address each of the study objectives. Additionally, it presents the conceptual framework that guided the overall study design and analysis.

The manuscript is published in *BMJ Open* and is titled *"Study protocol for developing a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in resource-limited settings: a case study of Mopani District in Limpopo province, South Africa."*

BMJ Open

Study protocol for developing a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in resource-limited settings: a case study of Mopani District in Limpopo province, South Africa

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ABSTRACT

Introduction Recent evidence shows that point-of-care (POC) testing is a more feasible alternative for diagnosis of COVID-19 in settings that have poor access to laboratory diagnostic services. Equitable access to POC testing can be optimised through well-established supply chain management (SCM) systems. The proposed study aims to develop a novel approach for improving SCM for COVID-19 POC diagnostic services in resource-limited settings with poor access to laboratory diagnostic services, using Mopani District in Limpopo Province, South Africa as a study setting.

Methods and analysis This study was guided by results of the scoping review. Following the scoping review, we propose a mixed-methods study, which will be implemented in three phases. First, we will perform a geospatial analysis to investigate the spatial distribution of COVID-19 testing services. Second, we will perform an audit of POC diagnostic services including its supply chain to evaluate the effect of SCM on accessibility of COVID-19 POC diagnostic services and reveal SCM barriers and enablers of accessibility of COVID-19 POC diagnostic services. Third, we will perform a nominal group technique to collaborate with key stakeholders in co-creation of a novel approach for improving SCM systems for COVID-19 POC diagnostic services. For the geospatial analysis, we will employ the ArcGIS Software. For the analysis of quantitative and qualitative data that will be generated from the audit and nominal group discussion, we will employ Stata software and NVivo software, respectively.

Ethics and dissemination This study has been ethically reviewed and approved by two institutional review boards: University of Pretoria Faculty of Health Sciences Research Ethics Committee (approval number 655/2021) and Limpopo Department of Health Research Ethics Committee (approval number LP-2021-12-007). The results of this study will be disseminated through national and international presentations and peer-reviewed publications.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study was informed by results of a scoping review, which found limited published research on supply chain management (SCM) of COVID-19 point-of-care (POC) diagnostic services in resource-limited settings.
⇒ It is a multiphase mixed-methods study to improve SCM for COVID-19 POC diagnostic services in resource-limited settings.
⇒ Geographical information system will be used to visualise the spatial distribution of COVID-19 diagnostic services.
⇒ A nominal group technique will be used to collaborate with key stakeholders in co-creation of a novel SCM approach for improving COVID-19 POC diagnostic services.
⇒ Data will be collected from key stakeholders involved in SCM of COVID-19 POC diagnostic services.

INTRODUCTION

Although sub-Saharan Africa (SSA) was the last continent to be hit by COVID-19 pandemic, it has experienced the most devastating effects. According to the global coronavirus surveillance data, among SSA countries, South Africa was the most affected country with over 3.6 million COVID-19 confirmed cases as at 28 February 2022.[1] Poor health infrastructure has been reported as one of the major hurdles in the control of COVID-19 pandemic.[2] In Limpopo Province, South Africa, the control of COVID-19 has been negatively impacted by limited laboratory infrastructure. The available laboratory services were overwhelmed due to the exponential rise in COVID-19 cases and resulted in a backlog that caused a delay in receiving

the results.[3] Resource-limited settings, such as Limpopo Province, which are characterised by limited access to hospitals and diagnostic laboratories, rapid point-of-care (POC) tests, are beneficial to help improve access to diseases diagnosis, monitoring as well as help prevent the spread of infectious diseases.[4] In this study, POC tests are defined as rapid diagnostic tests that are performed near or close to the patient with instant availability of results to guide immediate informed clinical decisions about disease management and patient care.[5]

COVID-19 is a highly transmissible disease; therefore, rapid and timely diagnosis is important in the control and management of the virus.[6] The healthcare system must remain uninterrupted to ensure availability and accessibility of POC tests that are needed on a large scale for efficient control and management of COVID-19.[7] The availability and accessibility of POC tests are dependent on numerous factors including an efficient supply chain management (SCM) system.[8] SCM is a vehicle that ensures that POC tests reach the end-user on time.[5 8] The SCM of POC diagnostic services is a complex and fragmented process that is controlled by four main links, namely, producers, purchasers, providers and patients, who contribute to creating cost-effective opportunities across the healthcare sector.[9] SCM involves obtaining resources, managing supplies, and delivering goods and services to providers and patients. For an effective and complete SCM system, it is essential to accurately forecast and prevent stockouts of POC test in order to improve the health outcomes.[10]

Diagnosis is key to surveillance and management of pandemics such as COVID-19. POC testing has been shown to help improve access to disease diagnosis in settings that have poor access to laboratory infrastructure.[11] Based on the critical role that SCM has on the availability and accessibility of POC tests, there is an urgent need to develop a tailored novel approach to improve the SCM systems for COVID-19 POC diagnostic services, particularly in settings that have poor access to laboratory services such as Limpopo Province, South Africa. The main aim of this study is to develop a novel approach to improve the SCM systems for COVID-19 POC diagnostic services for resource-limited settings, using Mopani District in Limpopo Province as a study setting. We anticipate that the findings of the study will guide future research on SCM for POC diagnostic testing and provide useful information to guide implementers of POC diagnostics in resource-limited settings. The study findings are likely to provide sustainable solutions to improve SCM systems for POC diagnostic services not only in Mopani District in Limpopo province, South Africa but also in similar resource-limited settings with poor access to laboratory diagnostic services.

METHODS

Study design

This study was guided by results of a scoping review.[12] Following the scoping review, we propose a multiphase mixed-method study, which will be implemented in three phases. The results of the scoping review revealed that for the continuum of POC diagnostic services, POC diagnostic tests must be available and accessible to all who need them through a sustainable SCM system which is a multi-faceted system influenced by several factors.[12] The scoping review also revealed that there is limited published research on SCM of POC diagnostic services in resource-limited settings and that there are currently no primary studies on the SCM systems of COVID-19 POC diagnostic services.[12] In phase 1, we will perform a geospatial analysis to investigate the spatial distribution of COVID-19 testing services. In phase 2, we will perform an audit of POC diagnostic services including its supply chain to evaluate the effect of SCM on accessibility of COVID-19 POC diagnostics services and reveal SCM barriers and enablers of accessibility of COVID-19 POC diagnostic services. In phase 3, we will perform a nominal group technique to collaborate with key stakeholders in co-creation of a novel approach for improving SCM systems for COVID-19 POC diagnostic services.

Conceptual framework

This proposed study will be guided by the lean and agile SCM framework, a hybrid framework that has the potential to provide efficient SCM solutions when implemented simultaneously.[13] The lean and agile framework will be enhanced by the World Health Organisation (WHO) manual for procurement of diagnostics and related laboratory items and equipment (figure 1).[14–16] This manual aims to provide information on the procurement processes of diagnostics and related items or equipment that are considered essential to ensure high-quality testing services.[14] The building blocks for this manual include production and prequalification, selection, quantification, procurement and storage, quality assurance, distribution and redistribution, and inventory management.[5 14] These building blocks work concurrently to ensure accessibility and availability POC diagnostic services.[17]

The agile component of the framework emphasises on how rapid the health system must respond to the increase in demand for POC diagnostic testing by ensuring adequate supplies of POC tests.[13] The demand in POC testing can fluctuate based on seasonal variations since the pandemic is still evolving.[14] New COVID-19 strains may be discovered causing further COVID-19 waves.

SCM is controlled by various factors such as procurement, quality assurance, storage, distribution and human resource capacity. The procurement process needs to be thorough to ensure value for money while not compromising on the quality of POC tests procured.[17] Once the POC tests are procured, they need to undergo rigorous quality assurance tests to validate if they meet the quality assurance guidelines. The temperature at the storage facilities must be appropriate to contain the POC tests without compromising the quality of the POC test. Timely distribution of POC tests and inventory management must constantly be monitored to prevent stockouts.

For the purpose of this study, we will include an additional building block, human resource capacity. The

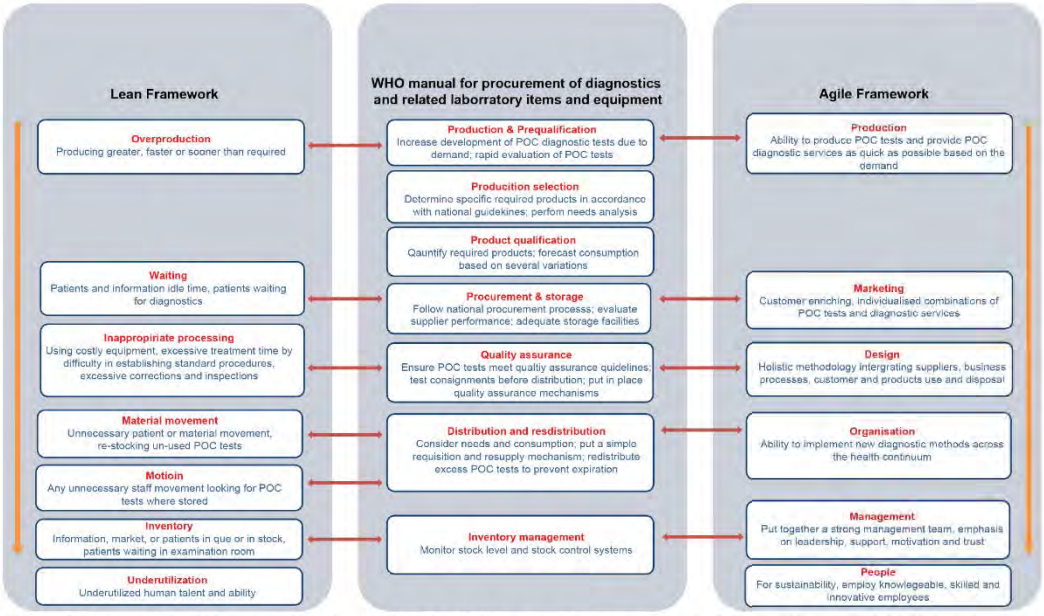

Figure 1 Lean and agile frameworks enhanced by the WHO manual for procurement of diagnostics and related laboratory items and equipment.

lean SCM framework is an approach that does more with less and at the same time offer customers exactly what they want.[15] This means using less human effort, equipment, time and space to increase the value and minimise waste simultaneously.[10 15] The agile SCM framework is an approach designed to create the ability to respond rapidly and cost-effectively to unpredictable changes in the health system such as in a case of a pandemic like COVID-19.[16] The lean and agile frameworks both strive to reduce costs but in different ways.[13] The lean framework addresses the economies of scale (economy in relation to each product), while the agile framework addresses the economies of scope, that is the economy in relation to the organisation as a whole.[13] While the lean strategy focuses on eliminating non-value adding activities to achieve high levels of efficiency, profitability and flexibility within the value stream in the supply chain, the agile strategy focuses on market sensitiveness, using market knowledge to respond to real demand.[18]

Study setting

The study will use Mopani District as a study setting, one of the five districts in Limpopo Province, South Africa. The district is confronted by service delivery challenges recording lower averages than the national averages with regards to the provision of basic services.[19] Mopani comprises five subdistricts/local municipalities as depicted in figure 2[20]; namely, Greater Giyani, Ba-Phalaborwa, Greater Letaba, Greater Tzaneen and Maruleng. The seat of Mopani is Giyani. Mopani District covers an area of 20 011 km^2 and is made up of 16 urban areas (towns and townships) and 354 villages (rural settlements).[19] It has a population of 1 167 598 as of the 2016 community survey.[21]

The study population includes primary healthcare clinics (PHC) involved in the management of COVID-19. The district has a total of 97 clinics as shown in table 1; 26 in Greater Giyani, 9 in Ba-Phalaborwa, 11 in Maruleng, 31 in Greater Tzaneen and 20 in Greater Letaba.[21] According to an area-specific live geographical information system (GIS) vulnerability mapping conducted by the Council for Science and Industrial Research (CSIR) in 2020, it showed that the areas that show higher vulnerability to COVID-19 are those that are more densely populated and with higher poverty.[19] These are the areas surrounding Greater Giyani, Greater Letaba, Greater Tzaneen and the mining areas in Ba-Phalaborwa.[19]

Phase 1: geospatial analysis

Objective

To investigate the spatial distribution of COVID-19 testing services.

Design

A cross-sectional study will be used and a GIS will be used for mapping the spatial distribution of COVID-19 diagnostic services. Geospatial analysis is pivotal in public health because it allows us to use geographical techniques

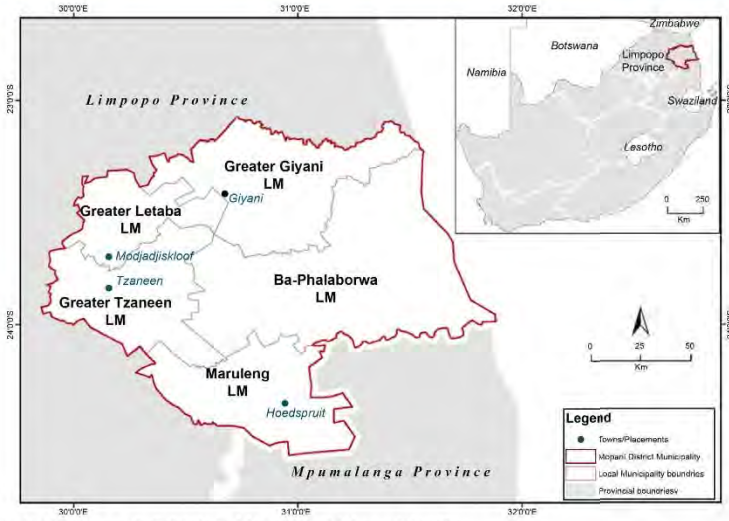

Figure 2 Map showing the five subdistricts in Mopani district municipality.

such as mapping to establish the impact of a person's surroundings on their health outcome.[22] Geospatial analysis will help us establish the proximity of COVID-19 diagnostic services to the population. We will employ GIS mapping to estimate the geographical distribution of COVID-19 diagnostic services to the population density. We will show and demonstrate access to COVID-19 diagnostic services. We will also identify areas with large populations but poor availability of diagnostic services.

Data source

A list of all PHC clinics in Mopani District Municipality.

Analysis

To determine the spatial distribution or the distance from the place of residence to nearest PHC clinic, a Moran's Index (MI) will be run on the ArcMap software. The MI, z-scores and p values for the distance between the place of residence and the PHC clinic will be reported. The MI values will be interpreted as follows: An MI>0 will be interpreted as spatially clustered, an MI<0 will be interpreted as spatially dispersed and an MI=0 will be interpreted as spatial random distribution. The estimated distances will be computed in Microsoft Excel and imported to Stata Software for analysis. Means, SD and 95% CI will be generated for the distances.

Outcome measures

The primary outcome of geospatial analysis is the accessibility of COVID-19 diagnostic services from the place of residence. In this study, accessibility to COVID-19 diagnostic services will be measured as the distance travelled from the place of residence to the nearest PHC clinic. A <5 km will be interpreted as high accessibility, 5–10 km will be interpreted as moderate accessibility and >10 km will be interpreted as poor accessibility based on the CSIR guidelines for the provision of social facilities in South Africa.[23] Another outcome for geospatial analysis is to map PHC clinics that serve a large population but have poor accessibility of COVID-19 diagnostic services.

Table 1 Vulnerability to COVID-19 per subdistrict

Subdistrict	Population	No of PHC clinics	Least vulnerable	Slightly vulnerable	Vulnerable	Highly vulnerable	Extremely vulnerable
Overall	1 167 598	97	12.51%	20.18%	37.99%	29.21%	0.12%
Ba-Phalaborwa	149 463	9	40.61%	36.78%	18.85%	3.73%	0.04%
Greater Giyani	281 667	26	8.24%	13.01%	44.46%	33.93%	0.36%
Greater Letaba	226 558	20	5.54%	20.48%	39.06%	34.79%	0.13%
Greater Tzaneen	404 375	31	9.43%	17.81%	39.05%	33.7%	–
Maruleng	105 535	11	10.85%	24.2%	41.48%	23.47%	–

PHC, primary healthcare clinic.

Phase 2: an audit of PHC providing POC diagnostic services

Objectives

- To evaluate the effect of SCM on accessibility of COVID-19 POC diagnostics services in Mopani District.
- To reveal SCM barriers and enablers of accessibility of COVID-19 POC diagnostic services in Mopani District.

Design

A cross-sectional mixed-methods study will be utilised, and data will be collected using an audit. Purposive sampling will be used to sample the largest PHC clinics with COVID-19 diagnostic services and sample large PHC clinics without COVID-19 diagnostic services. The number of PHC clinics sampled will be guided by the results of the geospatial analysis conducted to address objective 1, investigate the spatial distribution of COVID-19 testing services. We will conduct an audit on the sampled clinics. We have put together an adopted audit tool (online supplemental material 1) guided by the WHO guidelines for improving the quality of POC testing and the Management Science for Health (MSH) laboratory diagnostic supply chain guideline.[24] To perform the audits, we will visit the PHC clinics sampled and ask the set of questions prepared. The audit tool will be piloted in five non-participating PHC clinics prior to data collection and the audit tool will be adjusted based on the assessor's feedback. The participants of the audit will be briefed about the purpose of the audit and given information on how to complete the questionnaire.

Recruitment strategy

We will write to the PHC clinic managers and request for their participation in the study. On approval from the PHC clinic manager, we will request participation from all the PHC clinic staff who are involved in the SCM system to complete the audit tool.

Data source

An audit tool consisting of questions aimed at assessing aspects of the supply chain namely: selection, quantification, storage, procurement, quality assurance, distribution and redistribution, inventory management and human resource capacity.

Analysis

The data collected will be captured into an excel file, cleaned, validated and exported to Stata statistical software for analysis. Descriptive statistics, such as frequencies and percentages for categorical data and means (SD) or medians for numerical data, will be used to summarise audit scores. The Pearson correlation coefficient will be used to show the relationship between numerical variables. Linear regression will be used to model the relationship between the correlates. The results will be statistically significant at $p \leq 0.05$. The main themes that will arise from probing further the causes of non-compliance from the individual interviews will be analysed as themes.

Outcome measures

To evaluate the effect of SCM on accessibility of COVID-19 POC diagnostic services, we will summarise the audit scores. The audit scores will be summarised through rating the audit scores. We will sum of the scores for each component to obtain the overall percentage rating. To measure SCM a point will be allocated for each question. The overall percentage score will be calculated from each audit questionnaire. Compliance to SCM will be interpreted as follows: ratings between 90% and 100% will indicate compliant SCM and ratings <90% will indicate non-compliant SCM. These ratings are based on the stipulated WHO guidelines for improving the quality of POC testing and MSH diagnostic laboratory diagnostic supply chain guideline.[24]

To reveal SCM barriers and enablers of accessibility of COVID-19 POC diagnostic services, the sections deemed compliant after the audit will be the enablers of accessibility of COVID-19 POC diagnostic services and sections deemed non-compliant will be the barriers of accessibility of COVID-19 POC diagnostic services. We will discuss the causes of the non-compliance with the participants in order to ascertain the causes for this non-compliance.

Phase 3: nominal group discussion

Objective

To collaborate with key stakeholders in cocreation of a novel approach for improving SCM systems of COVID-19 POC diagnostic services.

Design

A mixed-methods approach will be used, and a nominal group technique will be used to collect the data. Purposive sampling will be used to obtain a representative sample of relevant key stakeholders who will help to develop a novel approach for improving SCM systems for COVID-19 POC diagnostic services. We intend to conduct one online nominal group discussion using Zoom platform. We will ensure that the nominal group discussion consists of at least one participant from the identified key stakeholders from each of the five sub-districts in Mopani District municipality.

The following key stakeholders have been identified:

- PHC district manager; oversees all the five subdistricts.
- PHC subdistrict managers; oversee the subdistrict.
- Pharmaceutical depot manager; distribution of POC tests to the districts from the provincial office.
- SCM, procurement of POC tests at provincial and district levels.
- Pharmacy assistants; inventory management at PHC clinics.
- Clinic managers, oversee the PHC clinic.
- Professional nurses; use the POC tests to test patients.
- Drivers; transport POC tests from district hospitals to PHC clinics.

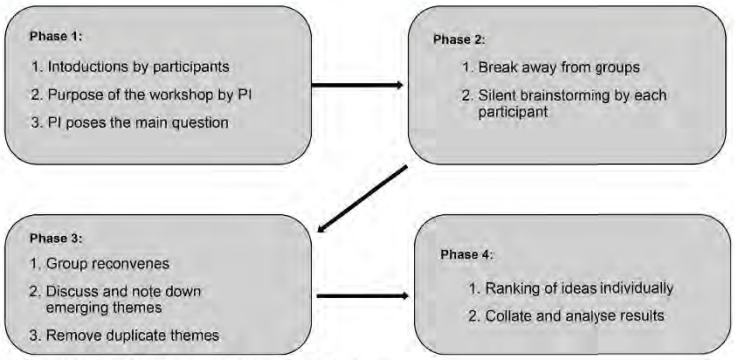

Figure 3 Process to be followed for the nominal group technique.

Recruitment strategy

We will write to the identified key stakeholders and request for their participation in the nominal group technique.

Data source

We will use a nominal group technique to collaborate with key stakeholders in co-creation of a novel SCM approach for improving COVID-POC diagnostic services. This data collection method was selected to promote group participation in the decision-making processes. It will involve a collaboration of a small group of relevant people to reach a consensus on the identification of key issues in the supply chain process.[25]

The principal investigator (PI), with the help of a research assistant, will facilitate the online nominal group discussion. The identified participants will be invited to participate in the stakeholder engagement. The invitation will include a summary of the purpose of creating a platform for key stakeholders to discuss innovative approaches to improving SCM of COVID-19 POC diagnostic services.

Data collection

The nominal group technique will be conducted in four phases, as illustrated in figure 3.

Phase 1 activities:

- Introduction of participants and purpose of the workshop (15–30 min): The discussion will start with brief introductions by the participants. The PI will give a background of the workshop and share the programme of the day. The participants will be asked to complete and sign the consent form.
- Creating of groups (10 min): The participants will be divided into two or three groups. Each group will consist of at least one participant from each of the stakeholders represented.
- Silent brainstorming by each participant and noting down relevant ideas (15–20 min): A question will be posed to initiate the discussion: What are the challenges faced in the supply chain of COVID-19 POC diagnostic services in Mopani District? A follow-up question will be asked: What are the possible strategies that can be implemented to address these barriers? There will be a break-away session where each participant will be given some time for silent brainstorming and to write down all the ideas that come to mind. This process will allow key stakeholders to reflect on the barriers that prevent a seamless supply chain system. Discussions will not be allowed at this stage however participants will be able to seek clarity from the facilitators.

Phase 2 activities:

- Groups reconvene and share ideas (30–45 min): The groups will reconvene, and the participants will be given an opportunity to share their main ideas with the other group members before grouping them according to themes on a flip chart. There will be no debate about items at this stage and participants are encouraged to write down any new ideas that may arise from what others share. This process will ensure that all participants get an opportunity to make an equal contribution and provide a written record of all ideas generated by the group.
- Group discussion (20–30 min): Participants will be given an opportunity to probe further and seek clarity about any of the ideas that their fellow group members have discussed. The PI will ensure that each person can contribute, and that discussion of all ideas is thorough without spending too much time on one idea. We will ensure that the process is as neutral as possible, avoiding judgement and criticism. The group may suggest new items for discussion and combine items into categories, but no ideas will be discarded.

Phase 3 activities:

- Presentations to the whole team and removal of duplicates (45–60 min): Each team will be asked to present their group ideas to the workshop participants. Following the discussion, questions and discussions will be encouraged. As the participants are presenting, the facilitators will write down the emerging themes on a chart sheet. After the discussion, the facilitators

will group similar themes and duplicate themes will be removed. The results of the discussion will be presented by the facilitators to the group as priority areas to be ranked during the next phase.

Phase 4 activities:

- Ranking of ideas (45–60 min): This phase involves ranking of ideas, assigning a value to an idea according to its priority. A Google form will be used. The top five priority themes will be ranked using a Likert scale of 1–5, with 1 representing a very low priority and 5 representing the highest priority. The participants will complete the Google form independently.
- Collate and analyse results (45–60 min): The results will be collated and analysed by the facilitators. All recorded data and written information recorded in flip charts will be collected and saved securely for further analysis.

Analysis

Two types of data, quantitative and qualitative, will be collected from the nominal group discussions. The qualitative data will be recorded using a voice recorder and a chart sheet during the nominal group discussion for analysis at a later stage. Quantitative data will be obtained from the ranking tool created on Google form. The use of a ranking tool allows facilitators to provide feedback of the results during the workshop and probe further on the ranking data presented.

Data analysis will start with consolidating all the ideas raised by the participants of the nominal group discussion during the silent brainstorming stage. A similar group of ideas will be grouped together according to the emerging themes.

Quantitative data analysis

The quantitative data will be analysed by summing the votes allocated to each idea to determine the overall priority score. The participants will rank the ideas on a scale of 1–5 on Google form and the overall priority score will be calculated. The results of the summation of scores will be shared with the group.

Stata statistical software will be used for analysis. We will calculate the descriptive statistics, means and distributions. We will further preform a Friedman test, which is used to analyse ranked data. We will conclude the analysis by performing a post hoc test, Bonferroni Correction.

Qualitative data analysis

We will conduct a qualitative thematic analysis of the top five overall priority scores. Qualitative research analysis software NVivo will be used to conduct a conceptual analysis and code the interviews by grouping common topics and issues and categorising them under labels which represent themes that will emerge. A relational analysis will then be conducted using NVivo to examine relationships between the themes that will be derived from the data.

Outcome measures: To establish the challenges faced in the supply chain of COVID-19 POC diagnostic services in Mopani District Municipality and come up with sustainable solutions to overcome these challenges.

Patient and public involvement

No patients or members of the public were involved in the design or conduct of this study.

Data security

The study will be conducted in accordance with the protection of personal information act.[26] The study will abide by the national COVID-19 regulations, guidelines and protocols in order to protect the health of the investigators and participants throughout the duration of the study. The participants will be briefed about the purpose of the study, issues around confidentiality of their information and written informed consent will be sought prior to participation. The participants will be provided with a copy of the signed informed consent for future reference. All the data that will be collected from the participants, both written and voice recorded, will be handled with strict confidentiality. All the data will be stored in a password protected server with access limited only to the members of the internal research team. Backup data will be saved on a password protected Google cloud storage. Transfer of data between members of the research team will be through a secure file transfer. Data collected during the study will be kept confidential in a storage for a maximum 2 years poststudy. The PI will deidentify the records in a way that will prevent reconstruction after the 2-year period. No personal identifiers will be shared with the public during the dissemination of results. It will be the responsibility of the PI and the research team to ensure that the source is unidentifiable, and the source cannot be linked to any statements made or discussed during data collection.

DISCUSSION

The aim of this study is to develop a novel approach for improving SCM for COVID-19 POC diagnostic services in resource-limited settings. To the best of our knowledge, this study is the first to assess and reveal barriers and enablers of SCM for COVID-19 diagnostic services in resource-limited settings. This study is in line with the WHO recommendation for scaling up testing programmes for COVID-19 by testing all suspected cases.[27] This recommendation led to an increased demand for POC diagnostic services, especially in high-burden areas where there is poor access to healthcare facilities and laboratory services.

To ensure equitable accessibility and availability of POC tests, it is important that COVID-19 testing is optimised through well-established SCM systems. Currently, the Foundation for Innovative New Diagnostics in collaboration with WHO and other organisations, are playing a pivotal role in scaling up the development and delivery

of COVID-19 tests through its Access to COVID-19 Tools Accelerator and provide sustainable solutions beyond the COVID-19 pandemic.[28] To provide sustainable solutions in providing POC diagnostic tests and to avoid past uncoordinated procurement issues, various stakeholders have joined forces to speed up the end of the pandemic by supporting the development and equitable distribution of tests, treatments and vaccines the world needs to reduce mortality and severe disease, restoring full societal and economic activity globally in the near term, and facilitating high-level control of COVID-19 in the medium term.[28] The collaboration supports coordinated, uninterrupted provision of timely, high-quality diagnostic tests in resource limited settings.[29] The collaboration serves as a platform for information exchange as well as alignment on procurement principles, planning and addressing key SCM issues.[29] They also ensure that there are adequate funds to purchase projected POC diagnostic tests to make them available for use at the POC in a timeous manner.

An insufficient SCM prevents a rapid and specific diagnostic approach that is essential in identifying COVID-19 cases not only at an individual patient management level but at a population level as a public health measure to control the pandemic.[30] Therefore, this study aims to investigate COVID-19 POC tests SCM in order to reveal barriers and enablers of SCM systems for COVID-19 POC diagnostic services in settings that have poor access to laboratory diagnostic services. The study also aims to provide sustainable and evidence-based solutions for policymakers and implementers of POC diagnostic services.

There are several anticipated limitations for this study. Geospatial analysis uses secondary data and it may be difficult to obtain information specific to the objective. We have applied for ethical approval from the Limpopo Department of Health which will allow us access to the District Health Information System where essential data for health services is stored. The audit and the nominal group technique will be carried out at the PHC facilities, which is the place of work for the participants. There is a high possibility that this can affect the daily operations and duties at the health facility. To mitigate this limitation, the research team will prepare the participants well in advance. We will inform them of the estimated time to complete the questionnaire and to engage in the focus group discussions. The research team will ensure that the time limits are adhered to and if exceeded for any reason, the participants will be allowed to terminate completion of the questionnaire and participation in the focus group discussion so that they can go back and resume their daily duties.

Ethical considerations

This study has been ethically reviewed and approved by two institutional review boards: University of Pretoria Faculty of Health Sciences Research Ethics Committee (approval number 655/2021) and Limpopo Department of Health Research Ethics Committee (approval number LP-2021-12-007). All participants will sign an informed consent form (online supplemental material 2) prior to participation in the study.

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Contributors KM conceptualised and wrote the draft manuscript under the supervision of TPM-T and AM. TPM-T and AM critically reviewed and provided input to revise the manuscript. All authors have read and agreed to the published version of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

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Chapter 4: Manuscript addressing Objective 1

The scoping review findings presented in chapter 2, presents a gap in evidence on POC diagnostics SCM for resource-limited settings, highlighting the necessity for conducting primary studies to investigate the challenges and enablers for POC diagnostics SCM in this context. Chapter 4 addresses the first objective of the thesis, to investigate the spatial distribution of COVID-19 diagnostic services in Mopani District.

Chapter 4 is presented in a manuscript format in line with target journal guidelines. The thesis is currently undergoing peer-review in *BMJ Public Health*. The manuscript is titled: *"Spatial distribution of COVID-19 diagnostic services in Mopani District, Limpopo province, South Africa."*

Article

Spatial distribution of COVID-19 diagnostic services in Mopani District, Limpopo province, South Africa

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ABSTRACT

Introduction

Access to health care facilities in rural areas remains a problem, especially during the COVID-19 pandemic. We used a geographic information system-based approach to investigate the spatial distribution of COVID-19 POC diagnostic services in Mopani District, Limpopo province, South Africa.

Methods

In this descriptive cross-sectional study, secondary data were analyzed using a dasymetric mapping technique to disaggregate and re-aggregate population data into analytical units to investigate the spatial distribution and accessibility of COVID-19 diagnostic services. The accessibility to COVID-19 diagnostic services was measured as the distance travelled from residences to the nearest primary healthcare clinics (< 5km) and from primary healthcare clinics to the nearest district hospitals (< 30km).

Results

The Mopani District has an estimated population of 1 202 916 people, out of which 942 801 (78.4%) have access to clinics within 5 km. There are 105 primary healthcare clinics in the district, with each serving around 11 456 people. Among these clinics, 72 (68.6%) are located within 30 km of a district hospital. Ba-phalaborwa, Maruleng, Greater Tzaneen, and Greater Letaba have good access to healthcare services, with a high percentage of the population residing within 5 km of a clinic and a high percentage of clinics located within 30 km of population centers. Greater Giyani has limited access to healthcare services.

Conclusion

Most (78.4%) of the people living in the Mopani District of South Africa lived within 5 km of COVID-19 diagnostic services. Access to healthcare facilities beyond the standard travelling distances can be a limiting factor for diseases such as COVID-19 where timely diagnosis is critical. We recommend strengthening POC diagnostics services among populations with poor accessibility.

Key questions

What is already known?

People living in resource-limited settings generally have poor access to diagnostic services. COVID-19 has severely impacted the South African health system, but data on access to COVID-19 diagnostic services are not readily available. Currently, there are no systems to quantify which populations have poor access to COVID-19 diagnostic services and to identify where these populations reside. Geospatial analysis has been used to analyze access to public healthcare services in many countries, however, this technique has not been applied in resource-limited settings with poor access to laboratory infrastructure.

What are the new findings?

- The PHC clinics were well distributed but unevenly located.
- A large majority of the population (78.5%) lived within 5 km of a PHC clinic.
- Of the 105 PHC clinics, 72 (68.4%) were located within 30 km of a district hospital.
- On average, each PHC clinic in the district served 11 546 people.
- The study mapped the areas with inadequate access to COVID-19 diagnostic services.

What do the new findings imply?

By providing insight into the spatial distribution of COVID-19 diagnostic services and identifying areas with inadequate access, this study's results could assist policymakers in resource-limited settings in developing strategies to optimize accessibility and reduce disparities. The study's findings could also aid decision-making when planning new facilities and allocating resources.

BACKGROUND

Access to primary healthcare (PHC) is a fundamental human right (1). All governments aim to ensure that all members of society have equal and adequate access to PHC, regardless of socio-economic and geographic factors. Adequate access to PHC will also facilitate achieving Sustainable Development Goal (SDG) 3, ensuring good health and well-being for all (2). The coronavirus disease 2019 (COVID-19) pandemic threatened the public health systems of many low-and middle-income countries (LMICs) where insufficient resources, inadequate infrastructure, and poor access to health services negatively impacted disease outcomes. In response to the pandemic, the World Health Organization (WHO) recommended scaling up COVID-19 point-of-care (POC) diagnostic testing in resource-limited settings with poor access to laboratory infrastructure (3, 4). The Access to COVID-19 Tools (ACT) Accelerator, a global collaboration to accelerate development, production, and equitable access to COVID-19 tests has been supporting high disease burdened countries and areas with the greatest need, including resource-limited settings in South Africa (5).

South Africa's health sector faces a significant challenge in developing a unified national health system capable of delivering quality health care to all citizens, but there are large disparities in the spatial distribution of health services (6). Health facilities are in fixed locations while health needs vary across space and time, especially in resource-limited settings (7, 8, 9). The most immediate factor affecting geographical accessibility is the distance and time it takes to travel to a well-equipped and adequately staffed healthcare facility (10). Several studies in LMICs have provided evidence that physical proximity to healthcare services plays an important role in the use of healthcare facilities (11). Healthcare facilities are usually in densely populated areas, and people living in remote settings often have to travel further when seeking primary healthcare (10). When distance to healthcare hinders accessibility, the detection of infectious diseases may be delayed (12). Mild infections might develop into severe disease, potentially leading to suboptimal care or even mortality (13, 14). In this study, we define geographical accessibility as the physical distance travelled to the nearest healthcare facility.

In this study, we investigate the spatial distribution of COVID-19 diagnostic services in relation to population density and identify areas deprived of these health services in the Mopani District in Limpopo Province, South Africa. Currently, providing health facilities to all settlements in the district is a problem because there are many settlements that vary in size, with most settlements being relatively small and scattered throughout the district. To completely understand the spatial distribution of COVID-19 diagnostic services in relation to population density, we identified the physical location of PHC clinics and district hospitals

(areas of supply), showed the population distribution (areas of demand), calculated the travel distances from areas of demand to areas of supply, and examined variations of spatial accessibility in different areas. Finally, we identified areas with a paucity of COVID-19 diagnostic services. To achieve this, we conducted a geographic information systems (GIS) based accessibility analysis.

METHODS

Study design

In this descriptive cross-sectional study, we used a GIS approach to investigate the spatial distribution of COVID-19 diagnostic services. This study design was useful for collecting benchmark data that demonstrates the size of a problem (distance travelled to access COVID-19 diagnostic services) at a specified point in time (15).

Study setting

The study was set in Mopani District located in the Limpopo Province in South Africa (Fig 1). In 2021, a total of 1 207 020 people lived in the province (20 011 km^2) (16). In the Mopani District, 81% of people live in rural areas, 14% live in urban areas, while 5% live on farms (17). Mopani District consists of five sub-districts, namely Greater Giyani, Greater Letaba, Greater Tzaneen, Ba-Phalaborwa and Maruleng (Fig 1). Most of the population rely on the public health system for essential diagnostic services.

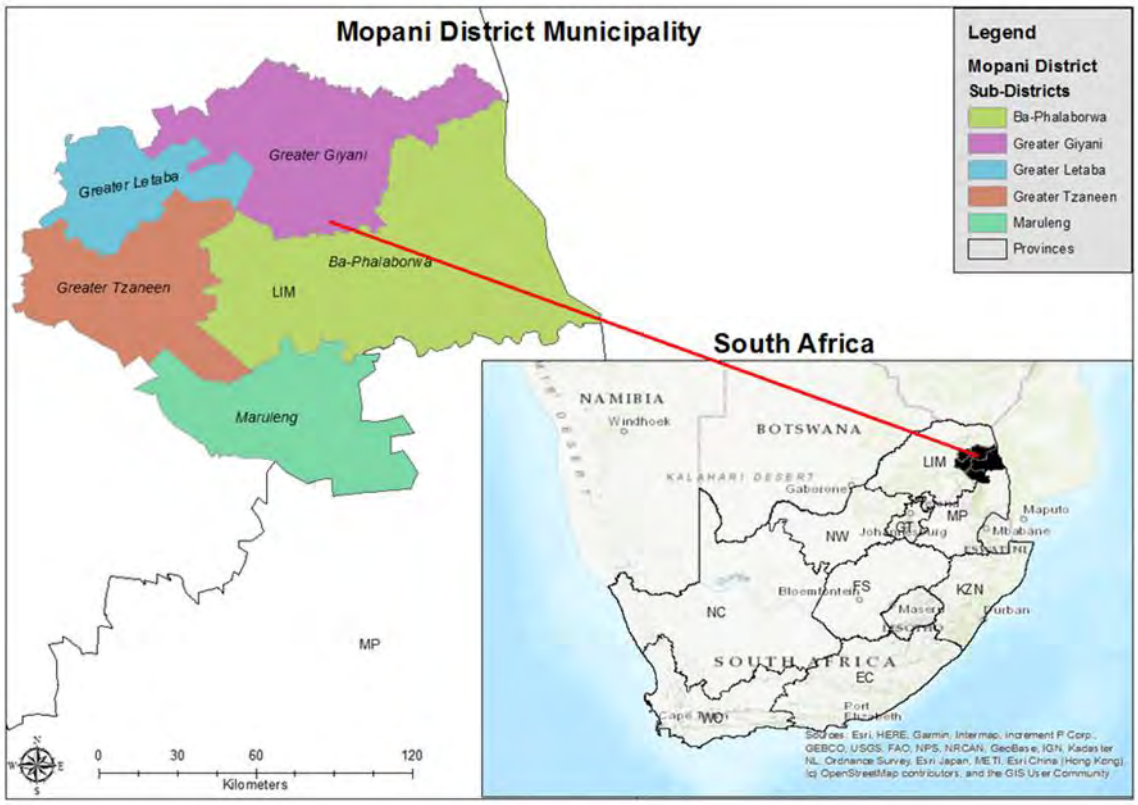


Figure 1: Location of the Mopani District, Limpopo Province, South Africa

GIS accessibility analysis

ArcGIS 10.8.2 software was employed to determine i) travel distances from places of residence to the nearest PHC clinics and ii) travel distances from PHC clinics to the nearest district hospital where National Health Laboratory Services (NHLS) were located. The GIS accessibility analysis followed a stepwise approach similar to that described in Baloyi et al. (18).

Data manipulation

To investigate spatial distribution of COVID-19 diagnostic services in Mopani District, three main data types were used; i) the population distribution, ii) the physical location of the PHC clinic, and iii) the spatial layout of the road network.

Physical location of PHC clinics and district hospitals (areas of supply)

The district has 105 PHC clinics and seven district hospitals.(19) There are 28 PHC clinics in Greater Giyani, 10 in Ba-Phalaborwa, 11 in Maruleng, 35 in Greater Tzaneen, and 21 in Greater Letaba (Fig 2). All the districts have one hospital, except for Greater Tzaneen and Greater Letaba that have two district hospitals each. All the included PHC clinics offer

COVID-19 POC diagnostic services, are administered by the public sector, and have a fixed geographical location. The geographic coordinates of the PHC clinics were obtained from the South African National Department of Health (NDoH) website (https://www.health.gov.za/) and the Mopani District Municipality GIS unit (19). The two datasets were merged, and duplicate coordinates for each PHC clinic were removed. Due to the absence of fixed residential addresses, we used the PHC clinic's catchment areas to ascertain the residences of the patients.

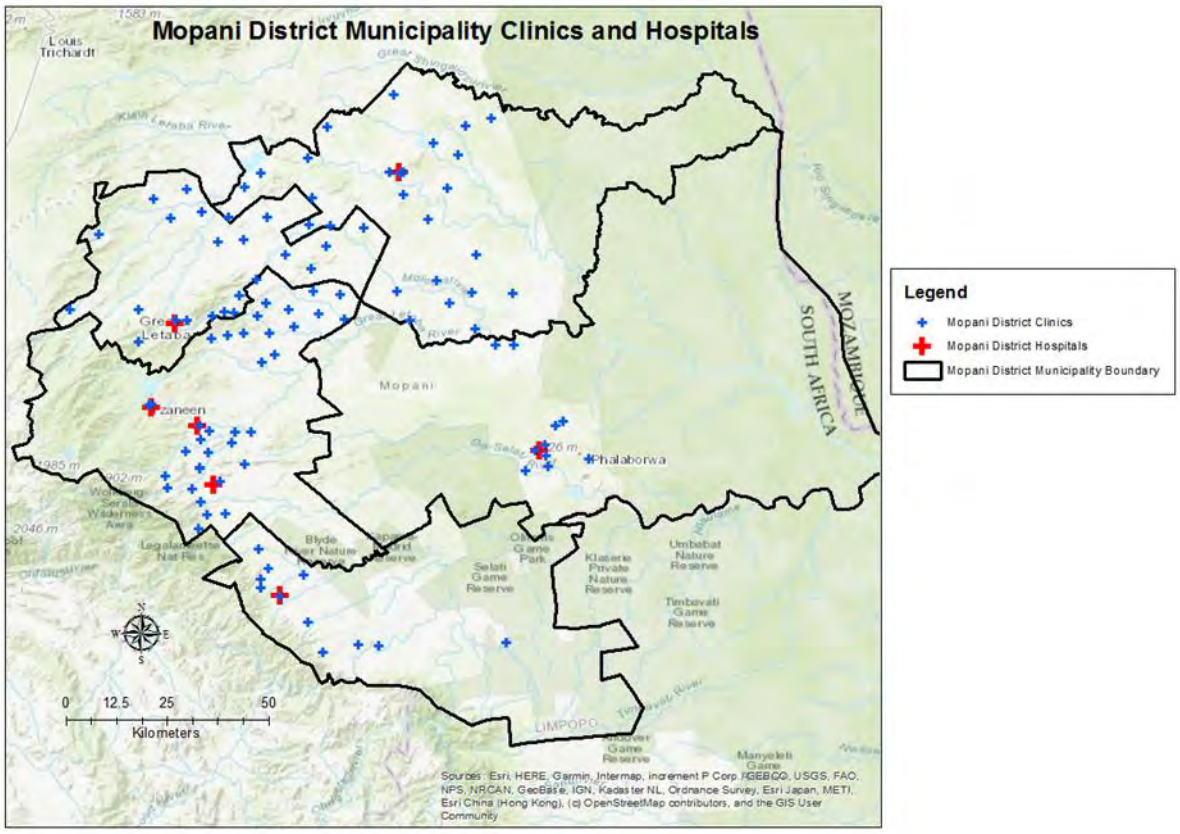


Figure 2. Location of PHC clinics and district hospitals in Mopani District, Limpopo province, South Africa.

Population disaggregation (areas of demand)

To identify areas of demand, the Mopani District was disaggregated into 20-hectare hexagons using a dasymetric mapping technique. The hexagons were then populated with the 2021 population data. For each hexagon, a population weighted centroid was calculated based on the population distribution (20). The 2021 community survey conducted by Statistics South Africa (https://www.statssa.gov.za/) formed the base data for the analysis (16). Figure 3 shows the 2021 population of the Mopani District on a dasymetric map.

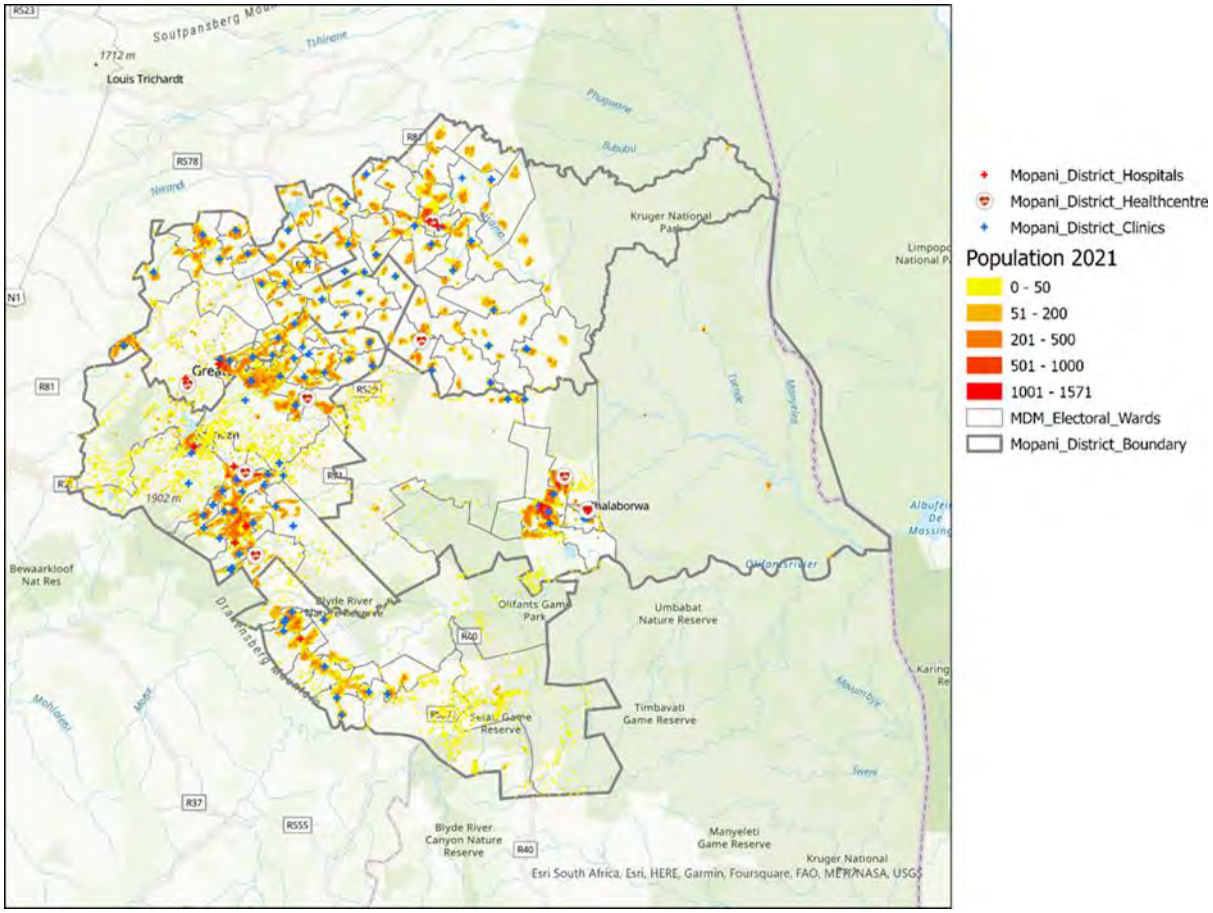


Figure 3. Population distribution of the Mopani District in 2021

Road network data

We measured geographic accessibility using road network distance, which is more realistic than straight line distance. The road network distance was measured on a flow map from each hexagon centroid to the PHC clinic using an origin-destination matrix. A road network for the Mopani District was obtained from the GIS unit at Mopani District Municipality (Fig 4). The implicit mode of travel was used to calculate distance between locations. The implicit mode of travel states that the physical distance is a function of mode of travel and is not related to the patient (i.e. speed/rate may differ even though the physical distance covered is the same) (21).

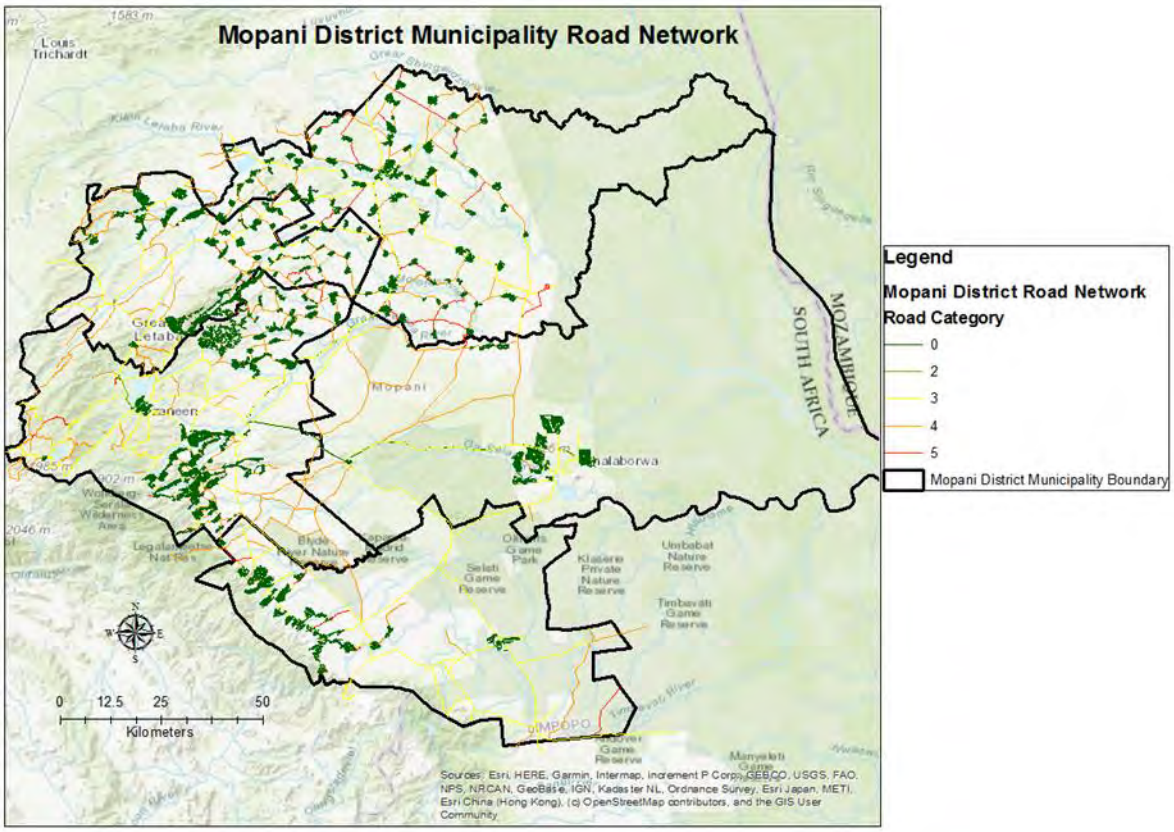


Figure 4. Mopani District road network used for the travel distance analysis

Input standards

We assumed that patients would travel to the nearest PHC clinic for COVID-19 diagnostic services. We categorized people who lived within < 5 km as having high accessibility; 5–10 km, moderate accessibility; and > 10 km, poor accessibility based on the CSIR guidelines for the provision of social facilities in South Africa (22). The ideal distance from a PHC clinic to the nearest district hospital was 30 km, therefore any distance above this threshold was deemed inaccessible (22).

Role of funding source

The funders had no role in study design, data collection and analysis, writing, or preparation of the manuscript. The authors had full access to all the data in the study and had final responsibility for the decision to submit the manuscript for publication.

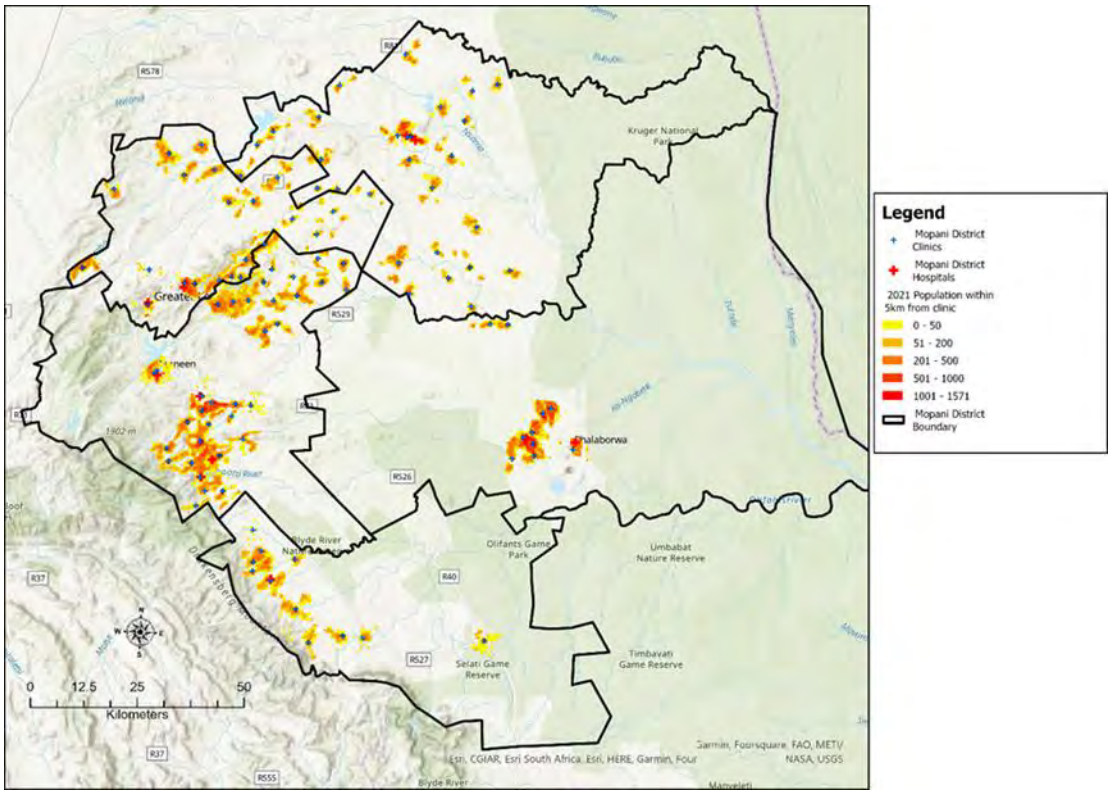
RESULTS

Within the Mopani district, 78.4% of the population (942 801 people) had access to a PHC clinic within a 5 km travel distance, while 21.6% of the population (260 115 people) had to travel further than 5 km to access a PHC clinic (Table 1).

Table 1. Population data per sub-district

Subdistrict	***Population***	***Number of clinics***	***Population Density***	***Population within 5km (%)***	***Clinics within 30km (%)***
Ba-Phalaborwa	*186 741*	*10*	*18674*	*159401 (85.4)*	*8 (80)*
Greater Giyani	*265 721*	*28*	*9490*	*159339 (60)*	*15 (53.6)*
Greater Letaba	*215 478*	*21*	*10261*	*168292 (78.1)*	*10 (47.6)*
Greater Tzaneen	*431 957*	*35*	*12342*	*382071 (88.5)*	*29 (82.9)*
Maruleng	*103 019*	*11*	*9365*	*73698 (71.5)*	*10 (90.9)*
Total	***1 202 916***	***105***	***11 456***	***942 801 (78.4)***	***72 (68.6)***

Figure 5a displays the spatial distribution of the population in the Mopani district who were able to access primary healthcare (PHC) clinics providing COVID-19 diagnostic services within a 5 km travel distance, with a mean travelling distance of 2.95 km (95% CI: 2.46 km - 3.45 km). The district's built-up areas, which include major towns and their surroundings such as Phalaborwa, Giyani, Tzaneen, and Modjadjiskloof, have a higher population density. In contrast, the Hoedspruit sub-district has a scattered population due to a significant number of farms and game farms occupying large portions of land (Fig 5b). Greater Giyani sub-district had the highest percentage (40%) of population living beyond 5 km from a PHC clinic, followed by Maruleng (28.5%), Greater Letaba (21.9%), Ba-Phalaborwa (14.6%), and Greater Tzaneen (21.9%).



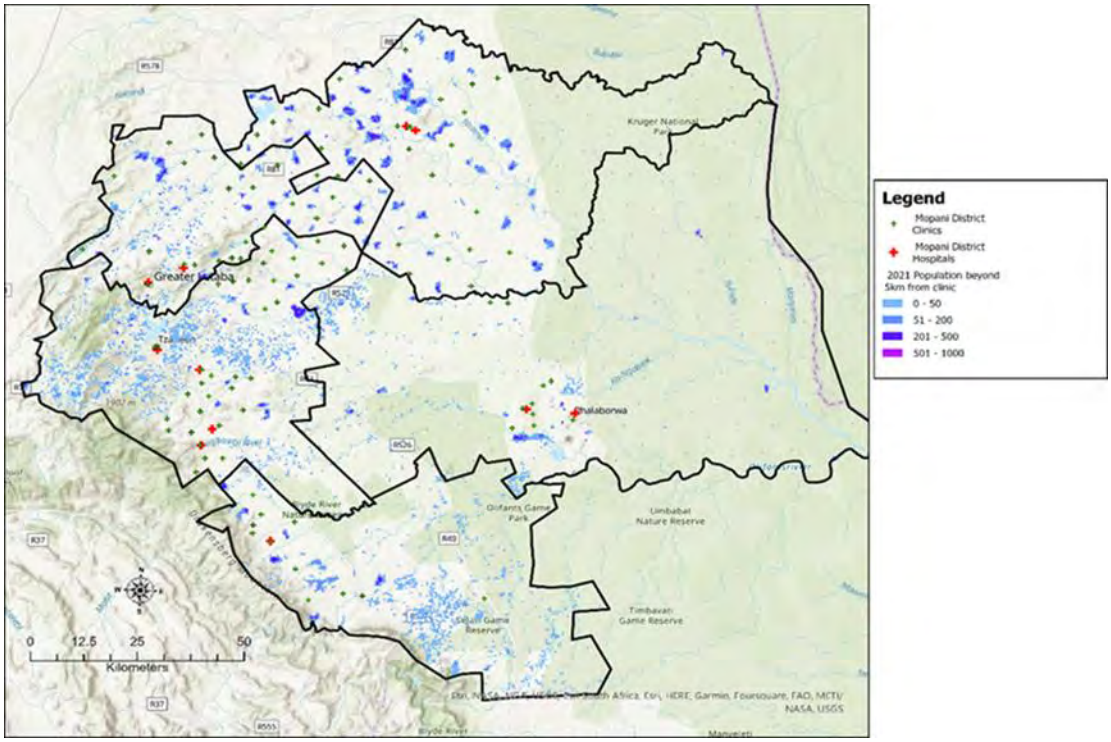


Figure 5. The travel distance analysis showing population density in relation to the location of public health clinics. The figures show population density within 5 km of a PHC clinic (a) and (b) more than 5 km from a PHC clinic.

Figure 6 displays the distances between PHC clinics and the nearest district hospital. According to the data in supplementary material 1, the average distance between PHC clinics and district hospitals in the Mopani District was 20.9 km (95%CI: 17.9 km–23.9 km). Out of the 105 PHC clinics, 34 (32.4%) were located within 0-10 km from the nearest district hospital, 19 (18.1%) were within 10-20 km, 19 (18.1%) were within 20-30 km, and 33 (31.4%) were more than 30 km away.

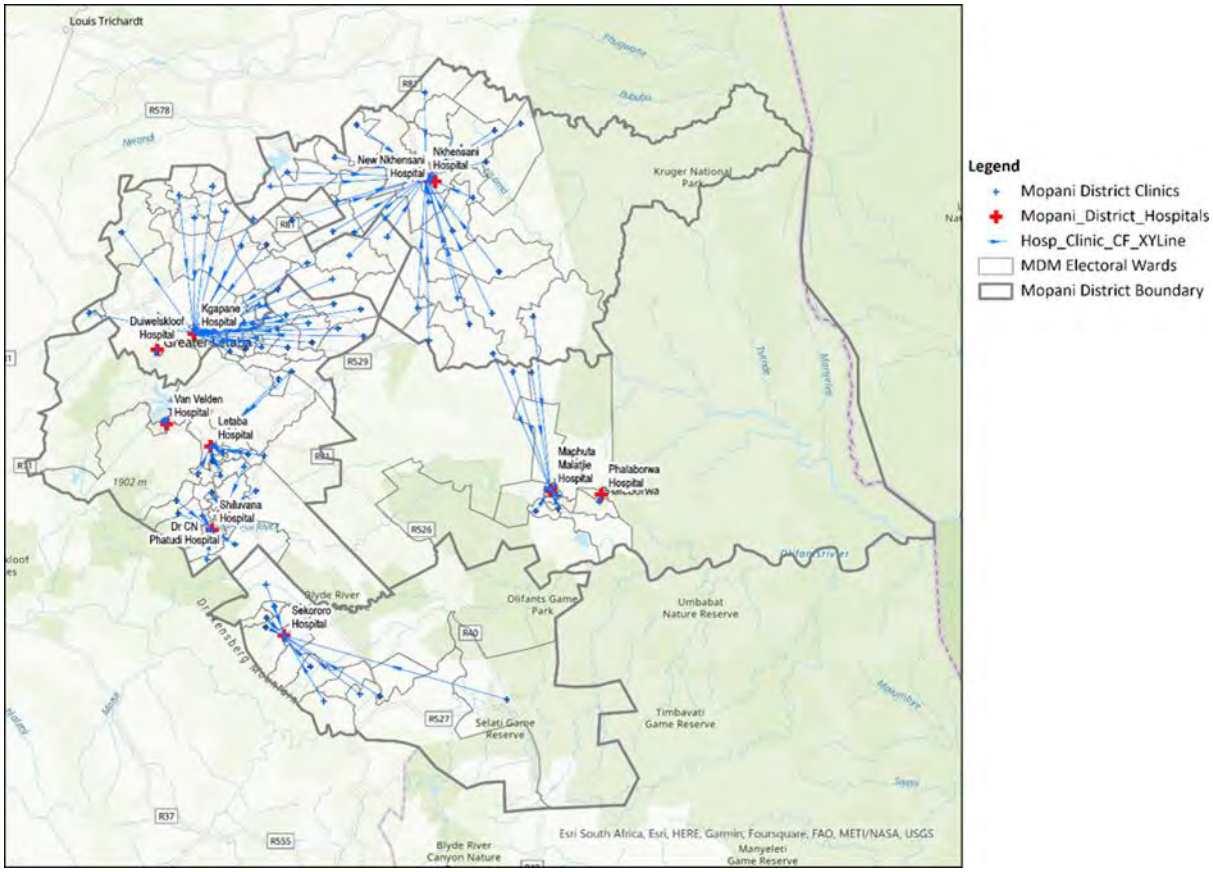


Figure 6. Distances from PHC clinics to the nearest district hospitals

On average, each clinic in the district serves 11 546 people. The sub-district of Ba-Phalaborwa has the highest number of people per clinic, with 18 674 people per clinic. Greater Giyani has an average of 9 490 people per clinic, Greater Letaba has 10 261, Greater Tzaneen has 12 342, and Maruleng has an average of 9 365 people per clinic (Table 1).

DISCUSSION

We used GIS accessibility analysis to map the spatial distribution of COVID-19 diagnostic services in relation to population density in the Mopani district, Limpopo Province, South Africa. The study identified areas of supply and demand, with a total population of 1 202 916 in the Mopani district, 105 PHC clinics, and seven district hospitals. We found that on average, each clinic in the district served approximately 11 456 people. We found that PHC clinics were well equitable but unevenly distributed in the Mopani district, with most of the population (78.5%) residing within 5 km of a PHC clinic. Of the 105 PHC clinics, 72 (68.4%) were located within a 30 km radius of a district hospital. In the district, most of the population is concentrated in areas that have a PHC clinic and district hospital within acceptable travelling distance. Ba-phalaborwa and Maruleng have good access to healthcare services

with high percentages of population living within 5km of a clinic and a high percentage of clinics located within 30km of the population centers. Greater Letaba and Greater Tzaneen also have relatively good access to healthcare services with a high percentage of the population living within 5km of a clinic and a relatively high percentage of clinics within 30km of the population centers. In contrast, Greater Giyani has the lowest percentage of the population living within 5km of a clinic, which suggests that access to healthcare services in this district may be more challenging. Moreover, only 53.6% of clinics are located within 30km of the population centers, which could further limit accessibility for some individuals.

Our research adds to a growing body of evidence indicating that travel distance is a crucial factor affecting patient access to healthcare services (23, 24, 25). In our study, the mean travelling distance to the closest PHC clinic is 2.95km, which is encouraging compared to an urban study that reported an average travel distance of 3.5km to access a healthcare facility (25). However, other studies reported poor access to healthcare services among patients living in areas deprived of healthcare services, reporting a travel distance of more than 5 km to access healthcare services (26, 27, 28, 29). Most of these studies reported that poor infrastructure, including transportation and utility systems, were some of the challenges to access healthcare services (27, 28, 29).

The Mopani district, like other areas in Limpopo, experienced four COVID-19 waves. The first wave occurred in July and August 2020, followed by the second wave in December 2020 to January 2021, the third wave in June to August 2021, and the fourth wave in December 2021 to January 2022 (30). During these waves, the government responded by providing free diagnostic testing to symptomatic patients (31). While district hospitals provided COVID-19 polymerase chain reaction (PCR) testing, which took 48-72 hours to release results, PHC clinics provided COVID-19 point-of-care (POC) tests with immediate results, enabling rapid control measures. Although the average travel distance from a clinic to the nearest hospital in the Mopani district was 20.9 km, which is deemed acceptable by South African standards, the time it took district hospitals to send results was detrimental to COVID-19 control and management. Hence, COVID-19 rapid testing provided at PHC was a suitable alternative. This may explain why COVID-19 was difficult to track in rural areas of South Africa, where the travel distance to accurate diagnostic testing and the distance between health clinics and district hospitals are challenging to extrapolate to the population.

This study's findings could help policymakers better understand the spatial distribution of COVID-19 diagnostic services, identify areas with insufficient access to these services, and develop integrated strategies to optimize accessibility and reduce disparities in resource-limited settings. The study's results can also aid decision-making when planning new

facilities and allocating resources. However, to improve the accuracy of accessibility assessments, future research should consider transportation modes and geographical barriers such as mountains and rivers, which can significantly impact travel distance and accessibility.

This is the first study, to our knowledge, that uses geospatial analysis to determine the spatial distribution of COVID-19 diagnostic services in this setting. The use of geospatial analyses provided a platform for providing insights into the accessibility of healthcare services, as larger datasets can be processed quickly, efficiently, and consistently (32). Moreover, these analyses are adaptable and can be routinely updated if the population grows.

While our study made significant contributions to understanding healthcare accessibility in rural areas, there were several limitations that should be considered. First, due to the lack of fixed residential addresses in the rural community, we had to rely on catchment areas and PHC clinics as a proxy for linking residential areas to the nearest district hospital. Second, our analysis only used travel distance as a measure of accessibility, overlooking other important factors such as cost, quality, and cultural and linguistic barriers. It is essential to consider these factors to ensure that healthcare services are accessible to all individuals and communities. Another limitation of the study is that it assumed patients would always use the nearest healthcare facility to their residence, while in reality, patients in South Africa have the freedom to choose their healthcare provider. Moreover, the sub-districts in rural areas in South Africa have well-connected roads and public transport, allowing patients to access healthcare facilities near their workplace or along transportation routes.

Conclusion

Improving equitable access to healthcare is essential for achieving SDG 3. Regular evaluation of access, efficiency, and planning for future demand is critical to achieve this goal. In our study, we found that most of the rural population had good access to COVID-19 diagnostic services based on the assumption that patients use the closest healthcare facility. However, we also identified an uneven distribution of these services in the area. The population in the Mopani district was mainly concentrated in regions with primary healthcare (PHC) clinics and district hospitals, as indicated by our GIS-based accessibility analysis that considered population density. On average, each clinic in the district served 11 456 people, with 76% of them living within 5 km of a PHC clinic, and 72 (68.6%) clinics were located within 30 km of a district hospital. To ensure equitable access to healthcare services, we recommend strengthening areas with limited COVID-19 diagnostic services by exploring new

and innovative approaches to testing to reach as many people as possible and help control the spread of COVID-19. It is crucial to regularly evaluate access and efficiency, as well as plan for future demand to achieve SDG 3.

Declarations

Ethics approval and consent to participate: This study is part of a multi-phase study that was approved by the University of Pretoria Faculty of Health Research Ethics Committee (Reference No: 655/2021, Dated: 24 November 2021) and the Limpopo Department of Health ethics committee (Reference No: LP_2021-12-007, Dated: 27 February 2022). Data used in this study did not contain any personal identifiers. No human participants were involved in the study therefore consent to participate was not applicable.

Consent for publication: Not applicable

Patient involvement: Not applicable

Availability of data and material: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request. The Limpopo-DoH is the custodian for the DHIS data (available on request from Limpopo-DoH: http://www.doh.limpopo.gov.za). The Mopani District Municipality is the custodian for the shapefile and all GIS-based related data. The Mopani District population data is publicly available on the Statistics South Africa website (https://www.statssa.gov.za/). The geographic coordinates for the PHC clinic are publicly available on the NDoH website (https://www.health.gov.za/).

Competing interests: The authors declare that they have no competing interests.

Authors contribution: K.M. conceptualised and wrote the draft manuscript under the supervision of T.M.-T. and A.M. K.M. and E.B. collected and cleaned the data and wrote the results. D.M. analysed the data. T.M.-T. and A.M. critically reviewed and provided input to revise the manuscript. All authors have read and agreed to the published version of the manuscript.

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Chapter 5: Manuscript addressing Objective 2 and 3

Chapter 4 presented results of the GIS-based travel-distance analysis conducted in Mopani District. The results of the GIS analysis showed uneven distribution of COVID-19 diagnostic services in this region. Following this study, it was deemed necessary to determine the effect of SCM on accessibility of SARS-CoV-2 POC diagnostic services in order to identify barriers and enablers of SCM in Mopani District.

Chapter 5 presents the findings from an audit of PHC clinics which addressed two thesis objectives: **objective 2**- to evaluate the effect of SCM on the accessibility of SARS-CoV-2 POC diagnostic services in Mopani District and **objective 3** - to reveal SCM barriers and enablers of accessibility to SARS-CoV-2 POC diagnostic services in Mopani District. This chapter is presented in a manuscript format in line with the guidelines of the target journal. The manuscript is in production with the *PLOS One Journal*. The title of the manuscript is *"Evaluating the supply chain management of SARS-CoV-2 point-of-care (POC) diagnostic services in primary healthcare clinics in Mopani District, Limpopo Province, South Africa."*

PLOS ONE

RESEARCH ARTICLE

Evaluating supply chain management of SARS-CoV-2 point-of-care (POC) diagnostic services in primary healthcare clinics in Mopani District, Limpopo Province, South Africa

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Abstract

Access to point-of-care (POC) diagnostics in resource-limited settings, where laboratory-based diagnostics are limited, depends on efficient supply chain management (SCM). This study evaluated the SCM for SARS-CoV-2 POC diagnostic services in resource-limited settings to determine the effect of SCM on accessibility to SARS-CoV-2 POC tests and to identify barriers and enablers of accessibility to SARS-CoV-2 diagnostic services in Mopani District, Limpopo Province, South Africa. We purposively assessed 47 clinics providing POC diagnostic services between June and September 2022. One participant per clinic completed an audit tool developed by the authors with guidance from the World Health Organization and the Management Sciences for Health guidelines. The audit tool evaluated the following SCM parameters: selection, quantification, storage, procurement, quality assurance, distribution, redistribution, inventory management, and human resource capacity. Percentage rating scores between 90–100% indicated that the facility was compliant with SCM guidelines, while rating scores < 90% indicated non-compliance. The clinic audit scores were summarized and compared across clinics and sub-districts. Clinics had compliance scores ranging from 60.5% to 89.2%. Compliance scores were the highest for procurement, redistribution, and quality assurance (all 100%), followed by storage (mean = 95.2%, 95% CI: 90.7–99.7), quantification (mean = 89.4%, 95% CI: 80.2–98.5), and selection (mean = 87.5%, 95% CI: 87.5%–87.5%). Compliance scores were the lowest for inventory management (mean = 53.2%, 95% CI: 47.9%–58.5%), distribution (mean = 48.6%, 95% CI: 44.6%–52.7%), and human resource capacity (mean = 50.6%, 95% CI: 43.3%–58.0%). A significant correlation was found between compliance score and clinic headcount (r = 0.4, p = 0.008), and compliance score and ideal clinic score (r = 0.4, p = 0.0003). Overall, the 47 clinics audited did not comply with international SCM guidelines. Of the nine SCM parameters evaluated, only procurement, redistribution, and quality assurance did not need improvement. All parameters are key in ensuring full

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Abbreviations: CI, Confidence Interval; COVID-19, Coronavirus 19; CSA, Covid Screening Application; DoH, Department of Health; EDL, Essential Drug List; LMIC, Low- and middle-income countries; MSH, Management Sciences for Health; NDoH, National Department of Health; NHLS, National Health Laboratory Service; OPM, Operational Manager; OPM, Operational Manager; PHC, Primary Healthcare; PI, Principal Investigator; POC, Point-of-care; SARS-CoV-2, Severe acute respiratory syndrome coronavirus type 2; SCM, Supply chain management; SVS, Stock Visibility System; WHO, World Health Organisation.

functionality of SCM systems and equitable access to SARS-CoV-2 POC diagnostics in resource limited settings.

Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19), cannot be properly identified or managed without correct diagnosis [1]. Timely access to health services enables rapid testing and prevents disease progression, resulting in improved individual and public health outcomes [2, 3]. Access to health services is defined as the ability to use services when and where they are needed [4]. In resource-limited settings where access to laboratories is limited, primary healthcare (PHC) is the center point of access to health services, including access to point-of-care (POC) diagnostic services. The introduction of POC tests in resource-limited settings have been proven to be effective for strengthening health systems by providing rapid results to improve timely initiation of suitable therapy, facilitate linkages to care, and improve health outcomes [5].

Supply chain management (SCM) includes the resources and processes needed to deliver the goods and services for POC diagnostic services [6]. Poor SCM systems may lead to stock outs of POC diagnostic tests [7]. This causes a ripple effect because stock outs result in the reduced use of POC diagnostic tests, which negatively impacts health outcomes [8–10].

The procurement of essential drugs and health-related commodities by the South African government follows a closed tender system, with drug distribution limited to the Essential Drug List and registered products [11]. The National Department of Health manages the tender system with input from the National Treasury, while the provinces procure their drugs from preferred suppliers on the national database [12–14]. The medications are then repacked at provincial depots before being sent to district hospitals and eventually to PHC facilities [13]. However, irregularities during the COVID-19 pandemic emergency procurement strategy were identified due to the lack of an adequate regulatory framework [12].

Evidence shows that SCM systems can be influenced by both barriers and enabling factors, including selection, quantification, storage, procurement, quality assurance, distribution, redistribution, inventory management, and human resource capacity [15]. As the demand for POC tests and other COVID-19 medical supplies increased in 2020 due to an increase in the number of daily cases, various SCM systems, including procurement, transportation, and manufacturing, were disrupted [16, 17]. During 2020 and through 2021, there were border closures, lockdowns in the supply market, interruptions in vehicle movements and international trade, labor shortages, and irregularities in health and safety protocols in manufacturing facilities [18].

As the COVID-19 pandemic draws to a close, POC testing has made great strides in diagnosing and managing the disease burden in Africa [19]. The results of this study will be useful to both supply chain managers and policymakers. Supply chain managers can use these findings to monitor and improve quality over time at individual, sub-district and district levels. Policy makers who are responsible for implementing POC diagnostic services in PHC clinics in resource-limited settings can identify strategies that could be embedded to the current policies to encourage successful implementation of POC diagnostic services.

The main objective of this study was to evaluate the SCM for SARS-CoV-2 POC diagnostic services in resource-limited settings. This evaluation was aimed at determining the effect of SCM on accessibility to SARS-CoV-2 POC tests and to identify barriers and enablers of accessibility to SARS-CoV-2 diagnostic services.

Methods

Study design

This study is the third phase of a multi-phase study, which aimed to develop a novel approach for improving SCM for SARS-CoV-2 POC diagnostic services in resource-limited settings. We used the Mopani District in Limpopo Province, South Africa as a case study [20]. In this phase, we conducted an audit of PHC clinics in the Mopani District using a cross-sectional survey designed to collect and collate data relating to the prevalence of particular events [21]. We compared the collected benchmark data to a set of well-defined standards that were previously used to identify the changes needed to improve the quality of POC diagnostic services [21, 22].

Study population

This study was conducted in the Mopani District, one of the five districts in Limpopo Province, South Africa. The district has five sub-districts: Ba-phalaborwa, Greater Giyani, Maruleng, Greater Tzaneen, and Greater Letaba (Fig 1). This resource-limited setting was selected

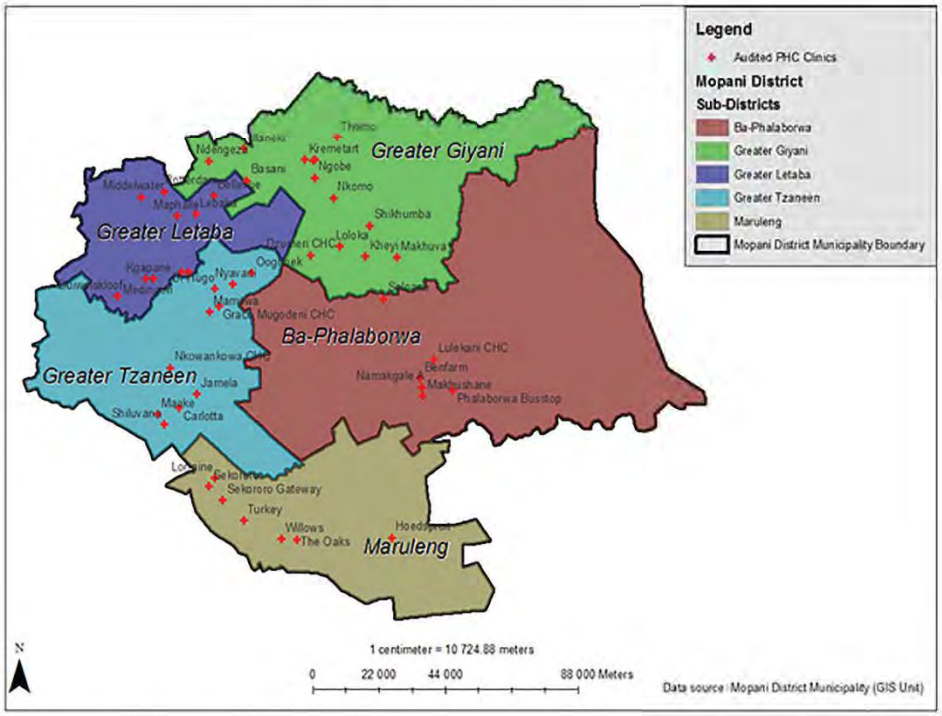

Fig 1. Geographic location and distribution of the audited primary healthcare clinics in the Mopani District, Limpopo province, South Africa. Image created by authors on ESRI's ArcGIS 10.8.2; no copyrighted material was used.

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because 81% of the population reside in rural areas, 14% in urban areas, and 5% on farms [23]. Most rural residents are poor and have no income because the local economy cannot provide remunerative jobs or self-employment opportunities [24]. As a result, most of the population in the study area relied on the public health system for health services.

Sampling strategy

We purposively sampled 47 out of 105 PHC clinics to participate in the study. This sampling technique involved selecting PHC clinics based on the size of the serviced population. PHC clinics with large (> 19 000), moderate (10 001–19 000) and small (3 000–10 000) populations were selected to ensure generalizability of the audit results.

Recruitment strategy

We contacted PHC clinic sub-district managers to ask for access to the PHC clinics and request participation of clinic staff. Upon approval from the PHC clinic sub-district managers, we sent a request to the operational managers to visit the clinics. The personnel involved in the SCM system, operational managers, professional nurses, and pharmacist assistants were asked to complete the audit tool.

Audit tool

The audit tool used (S1 Fig) in this study was developed based on the WHO guidelines for improving the quality of POC testing [25] and the Management Sciences for Health (MSH) diagnostic SCM guideline [26]. We focused solely on aspects related to SCM and used these documents to evaluate the challenges that resource-limited settings face in accessing appropriate, quality-assured, and adequate POC diagnostics, as well as to identify potential strategies for addressing these challenges. The audit tool included clinic characteristics such as: i) annual headcount, or number of patients who present to the PHC clinic regardless of the health service provided; and ii) the ideal clinic score, where an ideal clinic is defined as a clinic with good infrastructure, adequate staff, adequate medicine and supplies, good administrative processes, and sufficient adequate bulk supplies [27].

Data collection

We conducted an audit of the sampled PHC clinics from June to September 2022. The audit team consisted of the principal investigator (PI) and a research assistant. The audit questionnaire was administered by the PI after presenting a summary of the study and obtaining consent from participants. The audit was carried out at the PHC clinics where the participants worked. To ensure that the audit did not affect the daily operations and duties at the PHC clinic, we adhered to the scheduled appointments and time limits to complete the questionnaire. We followed the national COVID-19 regulations, guidelines, and protocols. We ensured that we had a COVID-19 researcher toolkit when interacting with the participants. This toolkit included own mask, masks for participants, thermometer, alcohol-based hand sanitizer, sanitizer for surfaces, a box to put all informed consent forms in, and paper-based questions, box of tissues, and a bag for disposal of used masks and tissues.

Scoring and rating guide

The audit tool had 42 questions categorized into 9 main sections, including selection, quantification, storage, procurement, quality assurance, distribution, re-distribution, inventory management, and human resource capacity. The response modalities of the questions were "yes",

"no" and "n/a". If "no" or "n/a" responses were selected, further explanation was probed for under the comment section to establish the barriers and enablers of SCM on accessibility of SARS-CoV-2 POC diagnostic services.

To evaluate how compliant PHC clinics were with SCM guidelines for SARS-CoV-2 POC diagnostic services, we summarized the audit scores. A point was allocated to each question when all the requirements were met. We summed all the rating scores for each component to obtain the percentage rating score per component (S1 Table). The overall percentage rating score was the sum of all the rating scores for each component. Compliance to SCM was interpreted as follows: rating scores between 90–100% indicated that the PHC clinic was compliant to SCM guidelines (satisfactory compliance), rating scores < 90% indicated non-compliance to SCM guidelines (unsatisfactory compliance).

Statistical methods

The data were captured in a Microsoft Excel spreadsheet, which was then cleaned, validated, and exported to Stata software version 17 for analysis. Frequencies, means, standard deviations, as well as 95% confidence intervals (CIs) for the audit scores were calculated. An analysis of variance test was conducted to test any differences between the compliance scores of the sub-districts followed by a Bonferroni post-hoc test to confirm where the differences occurred between the sub-districts. A further pairwise correlation analysis was done to establish any relationship between the overall SCM compliance score and the clinic characteristics. The results were statistically significant at $p \leq 0.05$. A qualitative thematic analysis of the nine components of the SCM system was conducted on R software.

Ethical considerations

Permission was obtained from Mopani District Directorate before conducting this study. Ethical approval of the main study was granted by the University of Pretoria, Faculty of Health Sciences, Research Ethics Committee (Reference No: 655/2021, Dated: November 24, 2021) and the Limpopo Department of Health Ethics Committee (Reference No: LP_2021-12-007, Dated: February 27, 2022). All study participants signed informed consent before participating in the study. Participant names were kept confidential. We de-identified the facilities to ensure that the compliance score could not be linked to a facility.

Results

Characteristics of the PHC clinics in Mopani

We audited 47 PHC clinics. Of these, 14 were in Greater Giyani, seven in Maruleng, six in Ba-Phalaborwa, 10 in Greater Letaba, and 10 in Greater Tzaneen. The total population of the audited PHC clinics ranged from 4,534 to 29,605. The clinic annual headcounts, the number of patients who present to the PHC clinic regardless of the health service provided, of the audited PHC clinics ranged from 13,431 to 78,036. The mean ideal clinic score was 71% (95% CI: 66.9%–75.1%). All the audited PHC clinics provided COVID-19 POC diagnostic services, specifically the Abbott Panbio™ COVID-19 Antigen rapid test. The audit tool was completed by 27 (57.45%) operational managers (OPMs), 19 (40.43%) professional nurses, and 1 (2.12%) pharmacist assistant. These professionals are part of the SCM of COVID-19 POC tests and they identified themselves as inventory controllers, procurement officers, and end-users. (Table 1).

Table 1. Characteristics of audited PHC clinics in the Mopani District, Limpopo Province, South Africa.

Name of Clinic	Total Population	Headcount	Ideal clinic score (%)	SARS-CoV-2 point-of-care testing	Occupation of assessor
Clinic 1	15538	38671	76	Yes	Professional nurse
Clinic 2	8431	22651	66	Yes	OPM*
Clinic 3	7052	19906	61	Yes	OPM*
Clinic 4	6731	18025	80	Yes	Professional nurse
Clinic 5	20914	52697	65	Yes	Professional nurse
Clinic 6	4534	13431	59	Yes	Professional nurse
Clinic 7	6045	17305	88	Yes	OPM*
Clinic 8	9467	27130	40	Yes	OPM*
Clinic 9	29326	78036	62	Yes	OPM*
Clinic 10	8513	22485	78	Yes	Professional nurse
Clinic 11	17116	53813	39	Yes	Professional nurse
Clinic 12	10218	28970	63	Yes	OPM*
Clinic 13	9103	25277	64	Yes	OPM*
Clinic 14	8528	21401	57	Yes	Professional nurse
Clinic 15	29605	56461	93	Yes	OPM*
Clinic 16	12274	23457	54	Yes	OPM*
Clinic 17	15193	29921	70	Yes	OPM*
Clinic 18	8514	17604	91	Yes	Professional nurse
Clinic 19	14655	31554	83	Yes	OPM*
Clinic 20	10947	22630	95	Yes	OPM*
Clinic 21	6591	19777	79	Yes	Professional nurse
Clinic 22	7784	20577	71	Yes	OPM*
Clinic 23	6317	24338	60	Yes	Professional nurse
Clinic 24	9201	21880	85	Yes	OPM*
Clinic 25	7629	20746	66	Yes	Pharmacist Assistant
Clinic 26	11377	37707	52	Yes	Professional nurse
Clinic 27	10274	32896	61	Yes	OPM*
Clinic 28	7145	18657	71	Yes	OPM*
Clinic 29	7208	19827	78	Yes	Professional nurse
Clinic 30	13722	32370	75	Yes	Professional nurse
Clinic 31	10970	25811	79	Yes	Professional nurse
Clinic 32	13102	31173	57	Yes	OPM*
Clinic 33	8638	17436	51	Yes	OPM*
Clinic 34	10955	27708	69	Yes	Professional nurse
Clinic 35	10013	24592	44	Yes	Professional nurse
Clinic 36	15862	36750	91	Yes	OPM*
Clinic 37	11241	27520	84	Yes	OPM*
Clinic 38	19398	34021	79	Yes	Professional nurse
Clinic 39	12993	27533	87	Yes	Professional nurse
Clinic 40	20400	42884	71	Yes	Professional nurse
Clinic 41	11167	22738	72	Yes	OPM*
Clinic 42	17615	42946	80	Yes	OPM*
Clinic 43	20076	45065	88	Yes	OPM*
Clinic 44	19226	41503	62	Yes	OPM*
Clinic 45	17688	41582	84	Yes	OPM*
Clinic 46	12419	27234	71	Yes	OPM*

(*Continued*)

Table 1. (Continued)

Name of Clinic	Total Population	Headcount	Ideal clinic score (%)	SARS-CoV-2 point-of-care testing	Occupation of assessor
Clinic 47	8598	17079	84	Yes	OPM*

*OPM = Operational Manager

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Overall audit scores for the audited PHC clinics in Mopani District

The audit results showed that the average SCM compliance score ranged between 60.5% and 89.2%. Based on our criteria, none of the clinics had satisfactory SCM compliance scores, with all PHC clinics scoring < 90%. The highest score of 89.2% was recorded for Clinics 9, 38, 40, 43, 44, and 47 (Fig 2).

Component scores per PHC clinic

The audit evaluated the nine components of the SCM system: selection, quantification, storage, procurement, quality assurance, distribution, redistribution, inventory management and human resource capacity. All the PHC clinics scored highest for procurement, redistribution, and quality assurance with mean rating scores of 100%, followed by storage (mean = 95.2%. 95% CI: 90.7–99.7), quantification (mean = 89.4%, 95% CI: 80.2–98.5), and selection (mean = 87.5%, 95% CI: 87.5%–87.5%). The lowest mean ratings were found for inventory management (mean = 53.2%, 95% CI: 47.9%–58.5%), distribution (mean = 48.6%, 95% CI: 44.6%–52.7%), and human resource capacity (mean = 50.6%, 95% CI: 43.3%–58.0%) (Fig 3).

Audit component scores per sub-district

We analyzed the SCM compliance scores per sub-district. Greater Tzaneen obtained the highest audit score (mean = 86.4%, 95% CI: 84.2%–88.6%). This was followed by Ba-Phalaborwa (mean = 82.1%, 95% CI: 80.5%–83.7%), Maruleng (mean = 80.9%, 95% CI: 77.6%–84.3%), and Greater Letaba (mean = 80.3%, 95% CI: 77.4%–83.3%). Greater Giyani had the lowest compliance score (mean = 75.5%, 95% CI: 70.6%–80.5%). Greater Giyani also had the highest variation in audit scores with an interquartile range (IQR) of 28.7%. Ba-Phalaborwa had the least varied audit scores with an IQR of 3.8% (Fig 4).

Post-hoc analysis of the SCM components per sub-district revealed that Greater Tzaneen and Greater Giyani differed significantly in terms of overall score ($p = 0.004$), quantification ($p = 0.026$), distribution ($p = 0.033$), and human resource management ($p = 0.0009$). Greater Giyani and Greater Letaba differed significantly in terms of quantification ($p = 0.026$). In terms of human resource capacity, significant differences were observed between Greater Tzaneen and Ba-Phalaborwa ($p = 0.046$), and Greater Tzaneen and Greater Letaba ($p = 0.005$). There were no significant differences observed for selection, storage, inventory management, procurement, re-distribution, and quality assurance between the sub-districts.

Barriers and enablers of the supply chain management audit components

We qualitatively described the barriers and enablers of each individual component below, while providing a summary of the SCM component scores in Fig 3.

Selection. The mean score for selection of POC tests was 87.5% (95% CI: 87.5%–87.5%). Selection comprised seven questions. All the PHC clinics noted that the staff was not actively involved in selecting POC tests. Participants reported that the POC diagnostic tests were sensitive with very few false negative and very few false positives. Participants reported that the

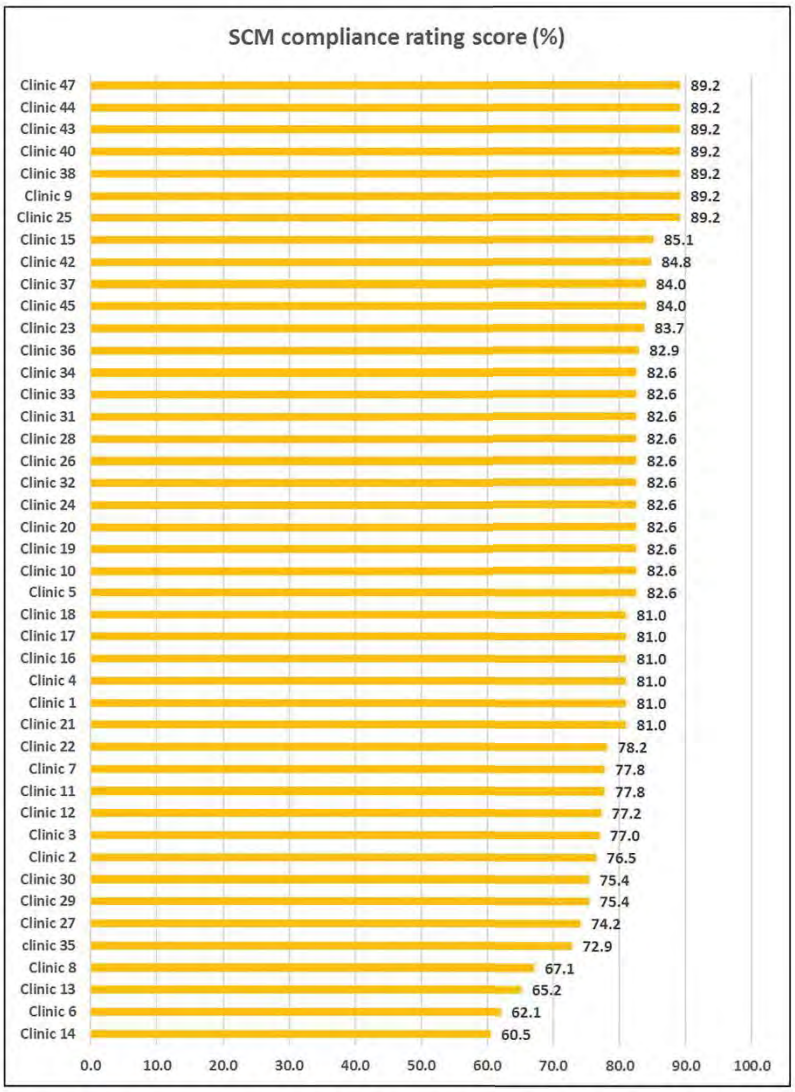

Fig 2. Supply chain management compliance rating of the audited PHC clinics, Mopani District, Limpopo Province, South Africa.

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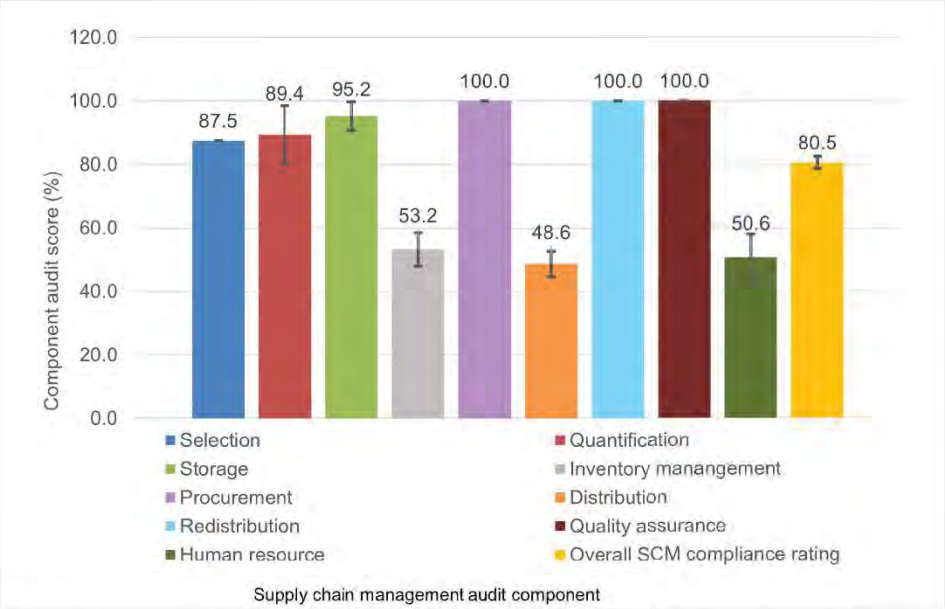

Fig 3. Average score per supply chain management component of the audited PHC clinics, Mopani District, Limpopo Province, South Africa.

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POC diagnostic tests were user friendly, simple to perform, required minimal training, enabled rapid testing at first visit, and were robust because they did not require refrigeration. Participants reported that there was no wastage of POC tests.

Quantification. The mean score for quantification of POC tests was 89.4% (95% CI: 80.2%–98.5%). PHC clinic operational managers are responsible for predicting the demand of POC tests based on seasonal variations (COVID-19 waves) to ensure that PHC clinics had enough POC tests. OPMs in 42 (89.4%) PHC clinics successfully predicted the demand for POC tests. The remaining five (10.6%) PHC clinics predicted the demand based on the number of people visiting the PHC clinic.

Storage. The mean score for storage of POC tests was 95.2% (95% CI: 90.7–99.7). Storage facilities were available in 45 (95.7%) PHC clinics. Thirty (66.6%) PHC clinics stored POC tests in the dispensary with other health commodities while 15 (33.3%) stored the POC tests in a separate room that had been converted into a storeroom. Two (4.3%) PHC clinics did not have dedicated storage facilities, but stored POC tests in testing rooms. Most of the PHC clinics (n = 43, 91.5%), had functional air conditioners and professional nurses monitored the temperature of the dispensary storeroom twice daily using a thermometer. Two PHC clinics (4.3%) had non-functional air conditioners and two (4.3%) PHC clinics had no air conditioners.

Inventory management. The compliance score for inventory management was 53.2% (95% CI: 47.9%–58.5%). OPMs and pharmacist assistants usually were responsible for inventory management, but occasionally this responsibility was delegated to professional nurses.

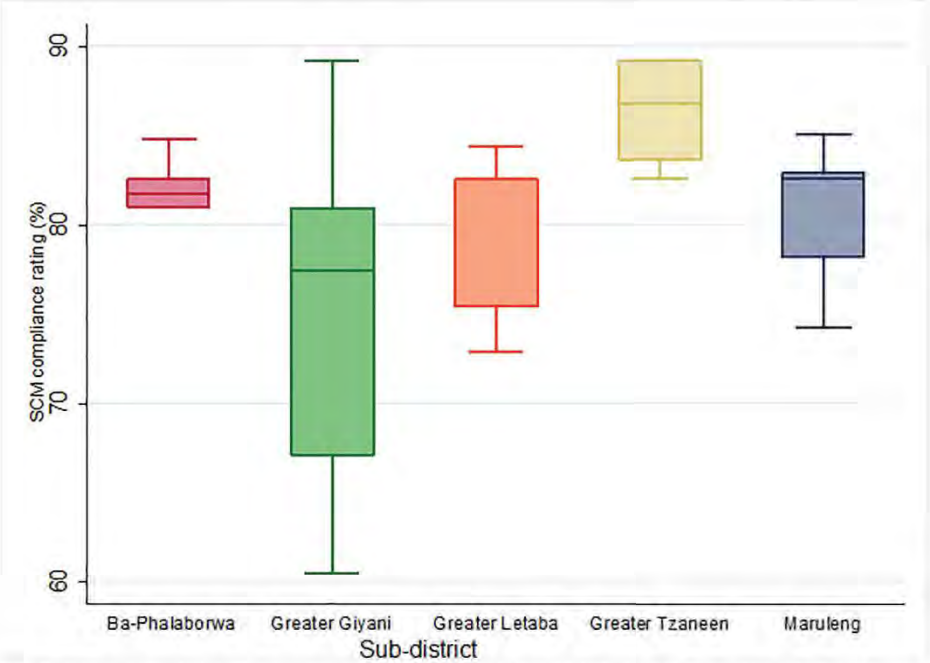

Fig 4. Variation in the supply chain management audit scores of the audited PHC clinics, in the five sub-districts of Mopani District, Limpopo Province, South Africa.

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Pharmacist assistants did not work on weekends, raising issues of inventory management in their absence. Most PHC clinics (97.9%) had personnel whose duties included managing COVID-19 POC diagnostic tests, while one clinic (2.1%) did not have any inventory management processes in place. An updated list of existing COVID-19 POC tests in the last three months was available in 87.2% of PHC clinics. Most PHC clinics (91.5%) did not have documents for recording the expiry dates of existing COVID-19 POC tests as all the tests were new.

All the PHC clinics used manual systems (stock/bin cards and inventory control forms/books) for inventory management. An updated inventory management list (tests available at the beginning of the week, number of both negative and positive tests conducted, and tests available at the end of the week), was sent to the sub-district managers weekly via WhatsApp by 44 (93.6%) PHC clinics. The sub-district managers then reported to the district office on a weekly basis. Three PHC clinics mentioned that they reported on the National Health Laboratory Service (NHLS) COVID Screening Application (CSA) portal.

Procurement. PHC clinics scored 100% for procurement. Requisitions were made from district hospitals and sub-district PHC offices, which were responsible for distributing POC tests. Thirty-four (72.3%) PHC clinics made requisitions based on demand, seven (14.9%) made weekly requisitions, and six (12.8%) made quarterly requisitions. In 32 (68.1%) PHC clinics requisitions were made when one box, containing 25 tests was remaining. In 15 (31.9%)

PHC clinics requisitions were made when 5–10 POC tests were remaining. Ba-Phalaborwa and Maruleng sub-districts reported that they had to submit proof that they had used previously supplied POC tests hence inventory management forms were available in these sub-districts. In all PHC clinics, the turnaround time ranged from daily to weekly. For example, Ba-Phalaborwa sub-district received stock daily because it had a delivery vehicle, a designated driver, and was close to the dispensing sub-district PHC clinic. PHC clinics in sub-districts which made requisitions from district hospitals received their stock on a weekly basis with the delivery of other health commodities. PHC clinics that had mobile clinics and local area drivers collected POC tests from district hospitals. When the requisition was urgent, PHC clinic OPMs would collect directly from district hospitals.

Distribution. Distribution had a SCM compliance score of 48.6% (95% CI: 44.6%–52.7%). District hospitals were responsible for distributing COVID-19 POC tests after receiving the requisitions made by the PHC clinics. All 47 PHC clinics reported that they always received stock after making a requisition. No stock outs were reported. Most PHC clinics, 43 (91.5%) reported that they check the delivery note that came with the supplies against the requisition made however there was no system in place to document the differences. Forty-six (97.9%) PHC clinics reported filing all delivery forms in a safe place. Only nine (19.1%) PHC clinics ensured that the driver or delivery person signed the delivery form and only 23 (48.9%) PHC clinics wrote down delivery information in a ledger book.

Redistribution. SCM compliance scores for redistribution were 100%. All 47 PHC clinics reported having procedures in place to redistribute COVID-19 POC tests to other facilities when the expiry date was close. All the sub-districts reported having WhatsApp groups for communicating between PHC clinics. Stock rotation between PHC clinics was done through WhatsApp or by completing a short-dated form to return the stock to a district hospital which then rotated the stock to PHC clinics in need. PHC clinics also reported using the first-in, first-out (FIFO) principle. This ensured that diagnostic tests did not expire before being used.

Quality assurance. The audit revealed that all PHC clinics had efficient quality assurance measures in place (100% SCM compliance score). All PHC clinics indicated that the person receiving the new batch of COVID-19 test kits verified that the box was properly sealed and that the individual test kits were also sealed upon delivery. All professional nurses also verified that the test kit was sealed before testing.

Human resource capacity. The average SCM compliance score for human resource capacity was 50.6% (95% CI: 43.3%–58.0%). As professional nurses were responsible for performing the tests at PHC clinics, training was essential. Provincial and district offices were responsible for training the professional nurses. When first introduced, 44 of the 47 PHC clinics (93.6%) reported that they received training on the POC diagnostic test. Two or three professional nurses per PHC clinic attended the training course, then trained the others at their PHC clinics. The training workshops were facilitated by the district office, either at the PHC clinics or at the district hospitals. Two PHC clinics reported that they received training from officials from Anova Health Institute. Three out of the 47 PHC clinics (6.4%) reported that they were not trained and that they trained themselves. They stated that the test was easy to perform and was similar to other POC tests used to test for diseases such as HIV and diabetes. All PHC clinics reported that training updates would be necessary if a new test were to be introduced, or if the current POC was modified. All the PHC clinics did not have standard operating procedures (SOPs) for performing the COVID-19 test, inventory management, and safe disposal of COVID-19 test kits but most participants reported that they followed COVID-19 test kit instructions. Nine of the 47 PHC clinics (19.1%) reported that they used SOPs for other diseases such as HIV and diabetes.

Relationship between PHC clinic characteristics and SCM compliance

Overall SCM compliance scores were significantly correlated with clinic headcount ($r = 0.38$ and $p = 0.008$ (Fig 5). The larger the headcount of the PHC clinic, the higher the SCM compliance score.

SCM compliance scores were also significantly correlated with the ideal clinic score ($r = 0.43$, $p = 0.003$) (Fig 6). A high ideal clinic score represents a PHC clinic with good infrastructure, adequate staff, adequate medicine and supplies, and good administrative processes. A high SCM compliance rating means that the SCM processes in place are satisfactory hence adequate accessibility to COVID-19 POC tests.

Discussion

This study determined to effect of SCM on accessibility of SARS-CoV-2 POC tests through an audit of 47 PHC clinics in Mopani District. The audit results revealed that none of the audited PHC clinics were compliant (score < 90%) with all the criteria stipulated by the audit tool, based on WHO and MSH guidelines. Clinics scored 100% for procurement, quality assurance, and redistribution, obtained moderate scores (87.5%—95.2%) for selection, quantification, and storage, but scored lowest on inventory management (53.2%), distribution (48.6%), and human resource capacity (50.6%). This study confirmed that access to POC diagnostic tests

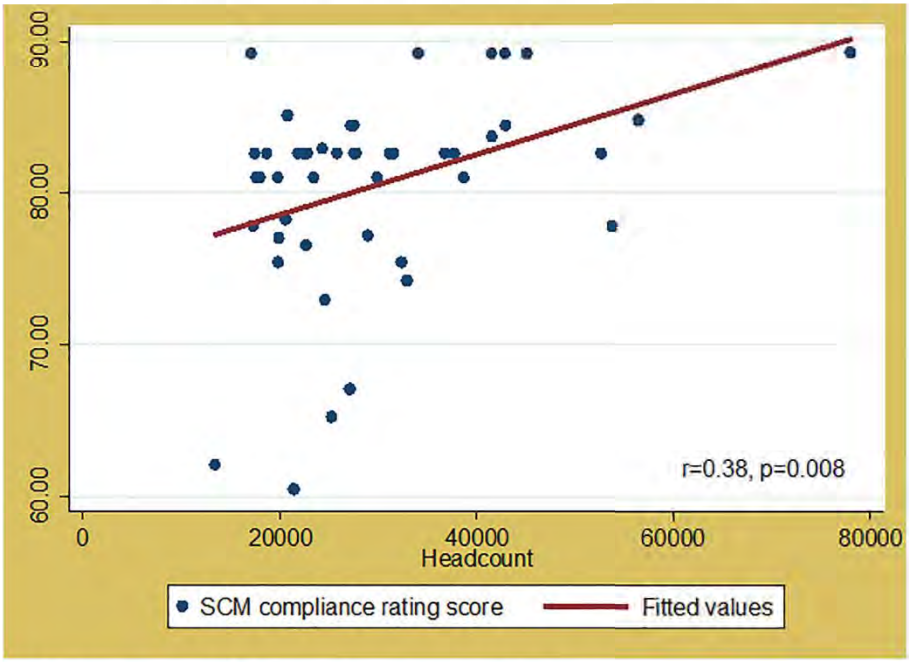

Fig 5. Correlation between supply chain management compliance score and clinic headcount of the audited PHC clinics in Mopani District, Limpopo Province, South Africa.

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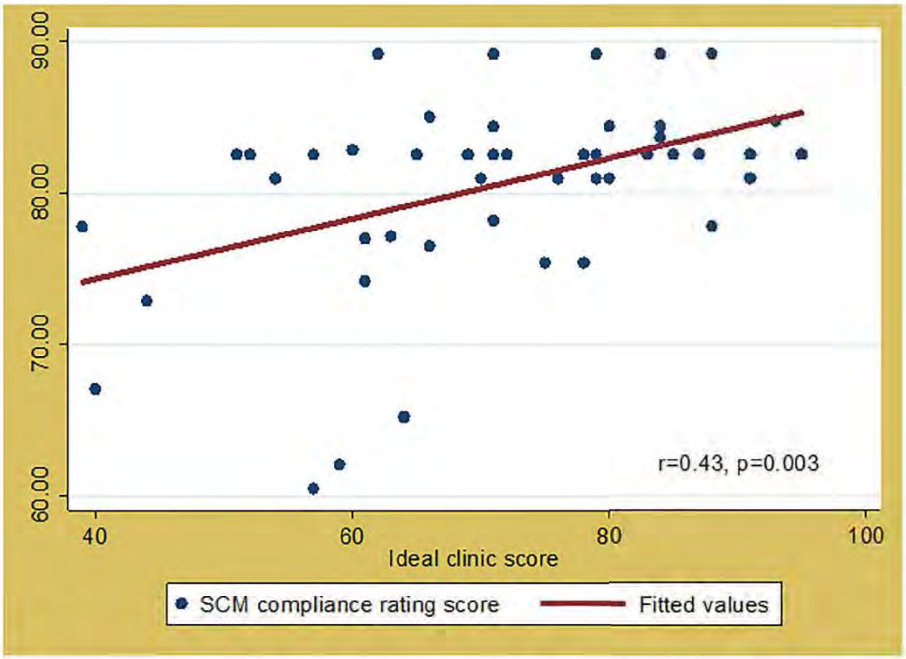

Fig 6. Correlation between supply chain management compliance score and ideal clinic score of the audited PHC clinics in Mopani District, Limpopo Province, South Africa.

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are impacted by SCM systems especially in resource-limited settings where the distribution of COVID-19 POC tests depends on the availability of POC tests at district hospitals and sub-district offices.

Inventory management, distribution and human resource capacity were found to be the greatest barriers of all the 9 SCM parameters within this study setting. Evidence from other LMICs show that inventory levels usually guide the quantity of stock procured [15, 28] and that adequate inventory levels are facilitated by clear communication between PHC facilities and the provincial or district offices that control the distribution of stock [10, 29, 30]. Currently, in Mopani District other health commodities are managed through the stock visibility system (SVS), a computerized inventory management platform. COVID-19 POC tests are not yet available on SVS hence the manual recording system used at the PHC clinics. Kihara and Ngugi [31] found that good inventory management systems using barcode labels and barcode scanners reduce human error by eliminating manual documentation.

The district hospitals relied on supplies from provincial and national levels. This created a ripple effect. If there is no flow in supply from the national or provincial level to the district hospitals, there will be no flow in supply to the PHC clinics therefore affecting access to POC diagnostic tests. The study found that within this setting, POC tests were usually distributed within 24 hours to a week depending on urgency and availability of delivery vehicles at the district hospitals. This finding agrees with findings by Kuupiel et. al. which revealed that, POC

diagnostics to PHC health facilities in Ghana depended on the availability of the tests at the national and regional medical stores as well as at the district health directorate stores [7].

In the Mopani district, SCM is negatively affected by human resources shortfalls. Nurses are key links in PHC clinic SCM as they are responsible for inventory management, quality assurance, redistribution and procurement. In Uganda, supply chain functions across all levels of care were negatively affected by inadequately skilled personnel, which resulted in staff taking on supply chain functions in addition to their key roles and responsibilities in health facilities, which contributed to poor performance in priority SCM areas [32]. This finding confirmed that adequately trained clinic staff are well empowered to fulfil essential supply chain functions and to make decisions that positively impact health supply availability and supply chain operations [33].

To the best of our knowledge, ours is the first study to evaluate SCM of SARS-CoV-2 POC diagnostic services in resource-limited settings. The 47 PHC clinics audited in this study can be used as a model for other similar resource-limited settings. A strength of our study is that it provides a sound methodology for evaluating SCM in resource limited settings. Limitations include that although the audit tool covered test performance, sensitivity, and specificity, we could only collect data on the perceived sensitivity and specificity of POC tests, without confirmatory laboratory test results. Another limitation was that this audit was only conducted in one district, which doesn't allow comparison with other areas.

Recommendations

Based on the findings of this study, we recommend the following:

- Adoption of efficient inventory management tools, especially software systems, linking national, provincial, district, and PHC facilities. Currently, inventory is tracked manually, which may result in inefficient logging of orders or deliveries, especially in understaffed environments.
- Implementation of a robust human resource management system by adopting a nurse-centric approach to improve SCM.
- Structured training course for POC SCM in resource-limited settings such as our study area to help improve compliance to standards. Additionally, we recommend regular workshops for PHC clinic staff to improve distribution of POC tests that are inadequately managed due to documentation challenges. SOPs for testing, inventory management, and safe disposal of test kits should be available to staff to prevent them from working blindly.
- Strengthening the supply chain and logistics at a national level to ensure that high quality POC test kits and consumables are available at all testing sites and that stock outs are minimized.
- A follow up study to evaluate SCM of SARS-CoV-2 POC tests at a provincial or national level in order to evaluate the selection and procurement process. This will provide an opportunity to evaluate the SCM at a higher level and establish the barriers and enablers of all 9 components of the SCM system in detail.

Conclusion

Our results revealed that the PHC clinics in the Mopani District, Limpopo, South Africa do not comply with international SCM guidelines. The audit results revealed deficiencies in inventory management, distribution, and human resource capacity. PHC clinics were

compliant in procurement, redistribution, and quality assurance. The audit also revealed variations in the SCM compliance scores between the sub-districts showing inconsistencies in the SCM processes currently in place. We highly recommend the adoption of centralized online inventory management tools and structured training for healthcare workers on SCM of POC diagnostics. SCM strategies for POC diagnostics need to be well planned to ensure accessibility of POC diagnostic services in rural resource-limited settings.

Supporting information

S1 Fig. Supply chain management audit tool.
(DOCX)

S1 Table. Characteristics of the 47 participating PHC clinics in Mopani District.
(DOCX)

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Chapter 6: Manuscript addressing Objective 4

Chapter 5 revealed areas of non-compliance with SCM guidelines, highlighting the need for improvement in SCM practices within Mopani District PHC clinics. To address objective 4, to collaborate with key stakeholders in the co-creation of a novel approach for improving SCM for SARS-CoV-2 POC diagnostic services in resource-limited settings, we conducted an NGT.

Chapter 6 presents the findings from this collaborative effort. This chapter is presented in a manuscript format in line with the target journal. The manuscript is currently undergoing peer-review with *BMC Health Services Research*. The title of the manuscript is *"Co-creation of a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in Mopani District, Limpopo Province: Nominal Group Technique."*

Article

Co-creation of a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in Mopani District, Limpopo Province: Nominal Group Technique

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Abstract

Background

The participation of various stakeholders, government institutions, and regulatory agencies is essential for effective Supply Chain Management (SCM) of point-of-care (POC) tests. The responsibility of administering and overseeing the procurement, quality assurance, storage, inventory management, distribution, and human resource capacity of POC tests falls on the national, provincial and local levels of government. The main objective of this study was to collaborate with key stakeholders in the co-creation of a novel approach for improving SCM for SARS-CoV-2 POC diagnostic services in resource-limited settings, using Mopani District in Limpopo province, South Africa, as a study setting.

Methods

We invited key stakeholders to participate in an online workshop. We conducted purposive sampling to include key stakeholders involved in SCM of COVID-19 diagnostic services. We employed the nominal group technique (NGT) method for data collection. The NGT workshop was conducted in two consecutive phases. Phase 1 focused on determining barriers faced in the supply chain of COVID-19 rapid tests and phase 2 was aimed at determining strategies to overcome the priority barriers identified in phase 1. The participants ranked the barriers and strategies from lowest to highest priority using a Likert scale of 1-5. The overall ranking score was calculated for each of the identified barriers and strategies.

Results

Eleven key stakeholders from national, provincial, and local levels of government, research entities, and non-governmental organizations participated in the study. The most significant barriers faced in the supply chain of COVID-19 rapid tests, as identified by participants, were availability of testing kits, unknown demand, information on SCM during a pandemic, methods of controlling stock, and procurement of stock. Key stakeholders suggested several strategies to address these barriers. The most effective strategy to improve the availability of COVID-19 rapid tests was monitoring of stock levels and optimization of the stock visibility system. Visibility of information and consistent update of data capturing systems

were identified as the most effective strategies to address the unknown demand and improve information on SCM during a pandemic. Capturing of data and digitization were identified as the most effective methods of controlling stock. To improve the procurement of stock, key stakeholders suggested implementing demand planning and standardized procurement processes at a national level.

Conclusion

Successful collaboration with key stakeholders in the co-creation of a novel approach to improve SCM for COVID-19 diagnostic services in resource-limited settings was enabled through the NGT. This study has the potential to support the provision of COVID-19 diagnostic services in resource-limited settings. To assess the feasibility of implementing this approach, a follow-up study is recommended.

1. Introduction

The healthcare sector's supply chain management (SCM) systems have been exposed to vulnerabilities due to the complex nature of the coronavirus disease 2019 (COVID-19), fluctuations in demand for certain commodities, and the fact that they deal with human lives (1). SCM involves regulating the flow of medical and essential goods and services from the manufacturer to the patient (1, 2). It is a complex and fragmented process, regardless of the outbreak's severity (3). The government had to take unprecedented measures to prevent or mitigate the risk caused by the COVID-19 outbreak, particularly in the supply and distribution of point-of-care (POC) tests essential for controlling and managing COVID-19 (1, 4, 5).

The participation of several stakeholders, including government institutions and regulatory agencies, is required in SCM for POC tests (6, 7). The government is responsible for administering SCM of POC tests to primary healthcare (PHC) clinics, including procurement, quality assurance, storage, distribution, and human resource capacity (8, 9). The provincial government, which receives funding from the national government, must follow a thorough procurement process to ensure value for money while not compromising on the quality of POC tests procured (10).

The SCM of COVID-19 rapid tests in Mopani District had two phases. The first phase was characterized by emergency procurement processes, a lack of standardization, and poor stock management (11, 12). The provincial office controlled SCM

processes and emergency procurement was necessary due to a lack of prior knowledge about the disease (13). Stock was donated by an international organization, and there was no consistency in stock management across the district. Stock was collected by Van Velden hospital, which became the distribution centre, and stock control was manual. Reporting was also poor in this phase, with only 57.6% of facilities reporting on the CSA reporting application (14). In the second phase, which began in 2021, the pharmaceutical depot took over SCM. However, due to poor stock management in phase 1, there was no historical data on consumption, making it difficult for the pharmaceutical depot to determine how much POC tests each facility should take (15). They adopted a push allocation model, which resulted in overstocking and an equal allocation to all PHC clinics, regardless of usage (16). District hospitals had different approaches to delivering stock to PHC clinics based on their resources. This unequal distribution deprived some PHC clinics that were using more stock.

The main objective of this study was to collaborate with key stakeholders in the co-creation of an acceptable SCM approach for improving SARS-CoV-2 POC diagnostic services in resource-limited settings, using Mopani District in Limpopo province, South Africa, as a study setting. It is anticipated that the results of this study will help provide a sustainable SCM approach for improving SARS-CoV-2 diagnostic services in resource-limited settings.

2. Methods

2.1. Study setting

Mopani District municipality, located in Limpopo province, South Africa, has a population of 1 202 916 and is made up of 16 urban areas and 354 villages (17). The district is divided into five sub districts or local municipalities, namely Greater Giyani, Ba-Phalaborwa, Greater Letaba, Greater Tzaneen, and Maruleng. Despite its size, the district faces several service delivery challenges and reports lower averages than the national averages in providing basic services (18).

2.2. Study Population

Key stakeholders involved in the SCM of SARS-CoV-2 point-of-care diagnostic services were recruited into the study. We defined key stakeholders as people who

have expert knowledge on SCM of POC diagnostic tests and have an interest in implementation of an efficient SCM process for POC diagnostic tests in Mopani District, Limpopo, South Africa. The key stakeholders are identified as: healthcare providers, government employees, non-governmental organisations, research entities and community leaders.

2.3. Study Design

This study was part of a multi-phase study aimed at developing a novel approach for improving SCM for SARS-CoV-2 point of care diagnostic services in resource-limited settings. Specifically, the study focused on the Mopani District Municipality in Limpopo province, South Africa. The protocol of the main study has been published elsewhere (19). The main study employed a mixed methods approach, which was conducted in four phases. The first phase involved conducting a scoping review to map evidence of SCM systems of POC diagnostic services in low- and middle-income countries, globally (20). In the second phase, a geospatial analysis was performed to investigate the spatial distribution of COVID-19 testing services in Mopani District Municipality, Limpopo, South Africa. In the third phase, an audit of POC diagnostic services was conducted, including its supply chain, to evaluate the effect of SCM on accessibility of SARS-CoV-2 POC diagnostic services and reveal SCM barriers and enablers of accessibility of SARS-CoV-2 POC diagnostic services. In this study, which constitutes phase four, a nominal group technique was used to collaborate with key stakeholders in co-creation of a novel approach for improving SCM systems for SARS-CoV-2 POC diagnostic services in the study setting.

2.4. Sampling

To obtain a representative sample of relevant key stakeholders from national, provincial, and local levels of government, research entities, and non-governmental organizations who assisted in developing a novel approach for improving SCM for SARS-CoV-2 POC diagnostic services, purposive sampling was used. One online nominal group discussion was conducted using the Zoom platform, with at least one participant from the identified key stakeholders to ensure representation.

2.5. Recruitment strategy

The identified participants were invited via email to participate in the stakeholder engagement. The invitation included a summary of the purpose of creating a

platform for key stakeholders to discuss innovative approaches to improving SCM of SARS-CoV-2 POC diagnostic services.

2.6. Data collection

To collect data on barriers and potential strategies for improving SCM for SARS-CoV-2 diagnostic services in Mopani District, a nominal group technique was used. This method involved collaboration between a small group of relevant stakeholders to reach a consensus on key issues. The online discussion was facilitated by the principal investigator (PI) and a research assistant. The nominal group technique was conducted in two consecutive phases.

In phase 1, participants were asked to share their knowledge on the barriers faced in the supply chain of COVID-19 rapid tests. After a break-away session for silent brainstorming, the group reconvened, and participants shared their ideas. The PI grouped the ideas into themes and created a Google form with the themes for participants to rank using a Likert scale of 1-5.

In phase 2, key stakeholders were asked to propose potential strategies to overcome the top 5 barriers identified in phase 1. After another break-away session for silent brainstorming, participants shared their proposed potential strategies. The PI grouped the strategies into themes on a Google form to enable participants to rank them using a Likert scale of 1-5.

2.7. Data management and analysis

To analyse the data collected from the nominal group technique, a mixed-methods approach was employed. The quantitative data collected in phases 1 and 2 were analysed using Stata statistical software. Participants ranked the ideas using a Likert scale of 1-5, and the priority scores were calculated by summing up the votes allocated to each idea. The highest priority scores indicated the most important barriers and effective strategies for improving SCM for SARS-CoV-2 POC diagnostic services. On the other hand, the qualitative data collected in phases 1 and 2 were analysed using NVivo software. The data were first grouped into common topics and issues, and the resulting themes were labelled to represent the themes that emerged. More qualitative data were collected from the participant's recorded presentations to elaborate further on the themes. This allowed for a more in-depth

understanding of the barriers and strategies identified in the nominal group discussion.

3. Results

3.1. Characteristics of participants

Eleven SCM key stakeholders aged 26–55 years, agreed to participate in our workshop. Of these, 10 (90.9%) were female. The majority 8 (72.7%) of the study participants were employed, two (18.2%) were post-doctoral research fellows and one (9.1%) was a full-time PhD candidate. The characteristics of the study participants and their roles in SCM are presented in Table 1.

Table 1: Characteristics of participants

Gender	Age (years)	Occupation	Role in SCM
Female	26-35	Pharmacist	Managing dispensing of COVID-19 rapid tests
Female	36-45	Program Lead	Supporting the acceleration of POC rapid testing
Male	46-55	Pharmaceutical depot manager	Overseeing the distribution of COVID-19 rapid tests to all districts in the province
Female	36-45	Pharmacist & Warehouse manager	Coordinating the receiving and distribution of COVID-19 rapid tests and maintain accurate inventory records
Female	36-45	Laboratory & Blood Service Deputy Director	Coordinating laboratory and blood services
Female	26-35	Medical Doctor & Research Clinician	End-user (COVID-19 testing) and generation of new knowledge by conducting clinical trials
Female	36-45	Post-doctoral research fellow	Conducting research of optimal implementation of POC diagnostics services

Female	26-35	Post-doctoral research fellow	Conducting research of optimal implementation of POC diagnostics services
Female	26-35	PhD candidate	Conducting research of optimal implementation of POC diagnostics services
Female	46-55	Professional Nurse & Mopani District Public Health	Coordinating disease control unit & facilitate distribution of COVID-19 rapid tests
Female	46-55	Professional Nurse	End-user (COVID-19 testing)

3.2. Stakeholders' perspective on the barriers faced in the supply chain of COVID-19 diagnostic services in Mopani District

The stakeholders identified 15 barriers encountered in the supply chain of COVID-19 rapid tests in Mopani District. Figure 1 displays the ranking results of the barriers, arranged in ascending order based on their priority scores. According to the voting results, the availability of testing kits was deemed the highest priority with a score of 46, followed by information on supply chain management during a pandemic (score of 45), unknown demand and procurement of stock (score of 44), methods of controlling stock (score of 42), time of delivery (score of 41), and the delivery approach of the healthcare facility (score of 40).

On the other hand, mobile data costs were ranked as the least severe barrier with a score of 29, followed by lack of capturing and reporting of results (score of 31), network and connectivity (score of 33), incorrect stock delivered (score of 34), cost of rapid tests (score of 35), educating users on how to use, interpret, and report results (score of 36), and identifying points of sourcing the rapid tests (score of 39).

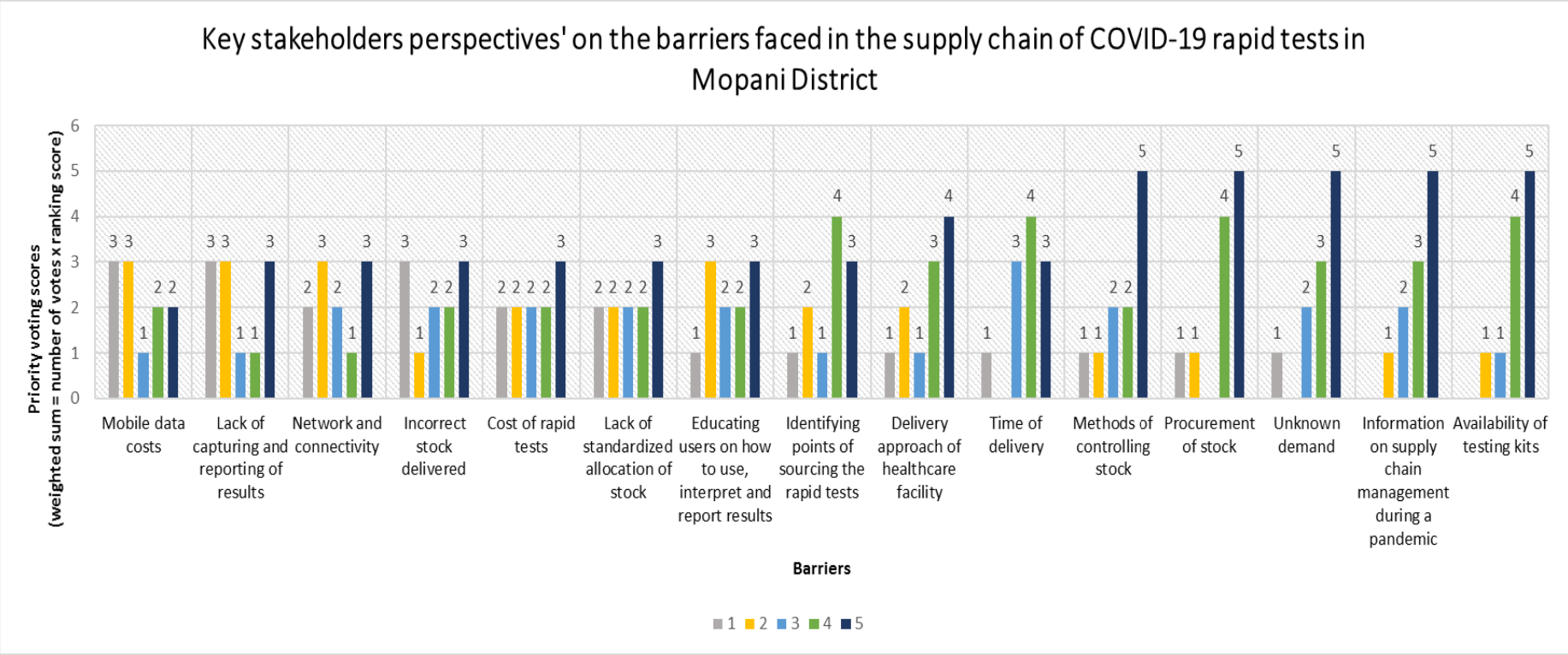

Figure 1: Key stakeholders' voting scores on the barriers faced in the supply chain of COVID-19 rapid tests in Mopani District

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3.3. Proposed potential strategies to overcome the barriers to SCM for COVID-19 rapid tests

Table 2 presents the 28 proposed potential strategies suggested by participants to overcome the five highly ranked barriers in the supply chain of COVID-19 rapid tests in Mopani District, which are availability of testing kits, information on SCM during a pandemic, unknown demand, procurement of stock, and methods of controlling stock. The participants ranked these strategies based on their effectiveness to overcome the identified barriers.

The key stakeholders ranked monitoring of stock levels (96.4%) and optimization of stock visibility systems (SVS) (98.2%) as the most effective strategy to improve the availability of COVID-19 rapid tests. To improve the unknown demand, visibility of information (90.9%) and consistent updating of data capturing systems (92.7%) were ranked as the most effective strategies. For improving information on SCM during a pandemic, putting policies in place at the national level (87.3%) and reporting on facilities that have received and consumed supplies (90.9%) were the most effective strategies. Capturing of data (90.9%) and digitization (90.9%) were ranked as the most effective methods of controlling stock. To improve the procurement of stock, participants suggested that demand planning should be in place (89.9%) and standardized procurement procedures (89.9%).

Table 2: Proposed strategies to overcome the top five barriers to SCM of COVID-19 rapid tests

Proposed strategies to improve the top 5 barriers to SCM of COVID-19 rapid tests	**Summing by votes 1 = less effective 5 = highly effective**					**Total number of voting scores (weighted sum = number of votes × ranking score)**
	1	2	3	4	5	**55**
Availability of testing kits						
● Policies to be put in place on a national level	1	2	2	1	5	40
● Buffer stock to be provided		1	5	2	3	40
● Understanding needs of community healthcare facilities	1		3	3	4	42
● Managing processes from procurement to end user			2	5	4	46
● **Monitoring of stock levels**				**2**	**9**	**53**
● **Optimization of stock visibility system (SVS)**				**1**	**10**	**54**
Unknown demand						

● Forecasting demand review to draw up historical data for demand planning			2	6	3	45
● Feedback from healthcare facilities			1	4	6	49
● **Visibility and information**			**1**	**3**	**7**	**50**
● **Consistent update of data capturing systems**				**4**	**7**	**51**
Information on SCM during a pandemic						
● National Treasury to provide instruction notes	1	1	3	3	3	39
● Strategies to be provided to communities at large from NDoH		1	2	6	2	41
● Standard guidelines to be provided	1		2	4	4	43
● **Policies to be put in place on a national level**		**1**	**2**		**8**	**48**
● **Reporting what facilities have received and consumed**			**1**	**3**	**7**	**50**
Methods of controlling stock						
● Apps should be free		1	1	2	7	48
● Educating users on using and interpreting data			2	3	6	48
● Availability of stock to be reported				6	5	49
● Weekly counts to check stock				6	5	49
● **Capturing data**			**1**	**3**	**7**	**50**

● **Digitization**			**1**	**3**	**7**	**50**
Procurement of stock						
● Provinces should have personalized procedures specific to each province	1		3	4	3	41
● Understand needs of community healthcare facilities		1	1	3	6	47
● Policies to be put in place on a national level		1		4	6	48
● What is to be procured must be clear			1	5	5	48
● **Demand planning to be in place**			**2**	**2**	**7**	**49**
● **Standardized procurement procedures**		**1**	**1**	**1**	**8**	**49**

3.4. Relationship between barriers and strategies

As SCM is a connected system where the success of the whole is reliant on the effective functioning of each part, we carefully considered the relationship between the highly ranked barriers and the proposed potential strategies by the stakeholders. Table 3 presents a table matching the SCM barriers with the proposed strategies, highlighting the three primary relationships that emerged: digitization, visibility of information, and procurement policies. Six out of the ten proposed strategies concentrate on the digitization of SCM systems, with a particular emphasis on optimizing the SVS. These strategies include monitoring of stock levels, consistent updates of data capturing systems, capturing of data, reporting what facilities have received and consumed, demand planning, and optimizing the SVS. The digitization of SCM systems will provide a platform for real-time data capturing, facilitating the monitoring of stock levels and implementation of demand planning based on available data. Meanwhile, two of the ten proposed strategies are linked to procurement policies, specifically putting policies in place at a national level and standardizing procurement processes.

Table 3: Matching the SCM barriers with the proposed strategies for improving SCM of COVID-19 rapid tests

Barriers	Proposed strategies	Relationship
Availability of testing kits	Monitoring of stock levels	Digitization
	Optimization of SVS	Digitization
Unknown demand	Visibility of information	Visibility of information
	Consistent update of data capturing systems	Digitization
Information on SCM during a pandemic	Policies to be put in place at national level	Procurement policies
	Reporting what facilities have received and consumed	Digitization
Methods of controlling stock	Capturing data	Digitization
	Digitization	Digitization

Procurement of stock	Demand planning to be put in place	Digitization
	Standardize procurement processes	Procurement policies

3.5. Comments from key stakeholders on the proposed potential strategies

All 11 key stakeholders were requested to comment and provide additional suggestions on the implementation of the proposed potential strategies for improving SCM of SARS-CoV-2 diagnostic services. We qualitatively described the comments and suggestions of the proposed strategy below.

3.5.1. Digitization

The key stakeholders suggested various strategies linked to digitization as some of the ways to improve the SCM of COVID-19 rapid tests:

"Currently, Stock Visibility System is the only means of monitoring stock that is available in our country. We need to get the rapid test to be part of the Stock Visibility System listed items so that at a click of a button, all stakeholders will know the number of tests the facility received, the number of tests the facility used and the number of tests they have at hand"

"The government must integrate SVS with other systems like electronic health records to provide a more holistic view of inventory levels and the patient needs"

"Real-time data can be analysed remotely which is good for the control of infectious diseases like COVID-19 where human contact must be limited. It is also beneficial for establishing trends and forecasting future demand"

"Digitization comes with network and mobile data issues therefore, the government must invest in the development of apps that do not need data to work, for example similar systems to bank apps"

"The data capturing function should be allocated to data capturers in order to ease the burden on clinical personnel who have to do the testing and also report. These data capturers must be registered and trained to capture results on SVS. This is a

good way to close the unemployment gap by roping in unemployed pharmacist assistants, people with inventory management skills"

"The National Department of health must create guidelines and manuals on inventory management and distribute them to all the relevant parties as a method to standardise data capturing across the healthcare facilities"

"To ensure that SVS is meeting its objectives it would be good for the National Department of Health to monitor and evaluate the system regularly to help in identifying areas for improvement and ensuring that the system is being used to its full capacity.

3.5.2. Visibility of information

The key stakeholders suggested that visibility of information could be one of the strategies to improve the unknown demand caused by COVID-19:

"Addressing pandemics such as COVID-19 requires a collaborative response and information sharing of data, research findings and approaches that can be implemented among the relevant stakeholders, for example National Department of Health, researchers, healthcare providers & policy-makers"

"Information needs to be disseminated timeously by the National Department of Health on various platforms, which includes our televisions and social media platforms. This information must be in different languages for the communities to understand. If information is readily available, it will reduce the spread of fake news in our communities"

"COVID-19 information must be visible. If you go into any health care facility now, there are no pamphlets or posters on COVID-19. Even during the pandemic, there were no posters available at our taxi ranks on where people can go and test"

"Improve internal communication of stakeholders by meeting regularly where all stakeholders are kept well-versed and trained on the importance of their outputs"

3.5.3. Procurement policies

The key stakeholders suggested putting policies at a national level and standardising procurement process as some of the strategies to improve procurement of COVID-19 rapid tests:

“When there is a pandemic, the national government has to lead in terms of building and guiding by providing standard guidelines and policies relating to SCM during a pandemic. The provinces can then build from what the national government have started”

“The National Treasury should disseminate circulars and instruction notes to relevant stakeholders for transparency that outline the procurement processes that we need to follow and what we need to procure”

“The National Treasury could have implemented strict procurement guidelines and processes to prevent corruption, such as the open tender system instead of using the emergency procurement system where there is no accountability”

“Contracts must be awarded to qualifying and reputable suppliers and this information must be available to the public for transparency of the tender processes”

“We can use independent auditors to conduct regular audits on the procurement processes in the department and those who don’t comply must be taken to task”

4. Discussion

Through collaboration with key stakeholders, this study identified the most critical barriers in the supply chain of COVID-19 rapid tests and proposed priority areas for improving supply chain management (SCM) of COVID-19 diagnostic services through co-creation of a novel approach. The study ranked availability of testing kits, unknown demand, information on SCM during a pandemic, methods for controlling stock, and procurement, as the most significant barriers in the supply chain of COVID-19 rapid tests. The key stakeholders recommended focusing on digitization (monitoring stock levels, optimising SVS, updating data capturing systems, reporting on facilities' consumption, capturing data, and demand planning), visibility of information, and procurement policies (implementing national policies and standardizing procurement processes) in co-creating a novel approach for improving SCM of COVID-19 diagnostic services.

The literature supports the findings of this study on the importance of digitization for improving SCM processes. Specifically, research has shown that transitioning from a traditional paper-based system to a digital supply chain can increase the efficiency and transparency of supply chain processes through integration and

interconnectedness (21, 22, 23, 24). As emerging technologies such as Radio Frequency Identification (RFID), Big Data, cloud computing, Internet of Things (IoT), Unmanned Aerial Vehicle (UAV), and Artificial Intelligence (AI) become more prevalent, organizations are able to create self-optimizing and integrated supply chain systems that respond proactively to market changes (25, 26). With the shift towards online and real-time processes, physical warehouses are being replaced by data centres, and physical boxes are being replaced by bits and bandwidth (25). Given these trends, it is becoming increasingly clear that digitalization is critical for organizations looking to improve their supply chain management.

In this study, it was discovered that digitization among the national, provincial and local levels of government is still in its early stages. The South African National Department of Health (NDoH) is implementing a web-based application called the stock visibility system (SVS) at PHC level, which replaces paper-based tools. The SVS captures real-time data, acts as an early warning system, and alerts supply chain stakeholders of PHC clinics with low stock levels, which can cause supply interruptions (21, 27). In addition, the SVS detects PHCs with high stock levels to redistribute POC tests and prevent overstocking (27). However, COVID-19-related commodities are not yet included in the SVS, which means digital inventory management for COVID-19 commodities could not be implemented. A similar study conducted in a South African setting found that the SVS improved access to medicine by improving stock management in healthcare facilities (28). In line with our finding that data capturing workload should be assigned to data capturers and pharmacist assistants, the study also identified a few challenges with the introduction of the SVS, such as increased workload for staff who need to capture data weekly and insufficient training on SVS (28).

In addition to optimizing the SVS, it is essential to have efficient and effective procurement policies in place to ensure an effective response to the pandemic. These policies play a crucial role in the availability and distribution of essential medical supplies, equipment, and services required to manage the health and economic consequences of the pandemic (29, 30). The standardization of SCM processes has been shown to provide consistency and uniformity in the SCM processes, leading to increased transparency, accountability, and quality of products and services (31, 32, 33). It also reduces costs and minimizes waste, while

improving communication and coordination between different actors in the supply chain (34, 35).

Collaboration between different sectors, including government, healthcare systems, scientific communities, businesses, and civil society, has become crucial during the COVID-19 pandemic, particularly in terms of promoting public health and preventing the spread of the virus through the visibility of information about COVID-19. Accurate and accessible information is essential to help individuals and communities understand the risks associated with the virus, take necessary precautions, and make informed decisions (36). It is also critical in combating misinformation and rumours about the virus, which can create panic and confusion among people. Misinformation can cause people to ignore public health guidelines, leading to an increase in infections and fatalities (37, 38, 39, 40). Therefore, the visibility of information from trusted sources is crucial in providing accurate information and preventing the spread of misinformation (41).

To ensure healthy lives and promote well-being for all, a key component of SDG 3, it is necessary to strengthen health systems and improve access to health services in response to the ongoing COVID-19 pandemic. This study stands out as the first to collaborate with key stakeholders in co-creating a novel approach for improving the SCM of COVID-19 rapid tests in resource-limited settings. The study exhibits several strengths, including the use of the nominal group technique (NGT), an innovative research method that ensured methodological rigor and facilitated collaboration with a wide range of key stakeholders to co-create a novel approach to improving SCM for COVID-19 diagnostic services. The use of a virtual platform was also advantageous, as it enabled the gathering of key stakeholders from different sub-districts while limiting the need for travel, which could have disrupted daily operations. However, the use of a virtual platform also had limitations, as participants experienced network issues from time to time due to load shedding. Additionally, the NGT generated many ideas, reflecting the multi-faceted nature of SCM, which made it challenging to cover all the barriers and strategies identified.

Recommendations

Based on the findings from the study, the following priority areas should be the focus of the recommended novel approach for improving SCM for SARS-CoV-2 diagnostic services:

- Enhancing the collaboration among key stakeholders; the government, non-governmental organisations, private sector suppliers, and research entities. Such collaborations will allow sharing of information and resources, research findings, best practices and improve distribution networks.
- Strengthening transparency and accountability across all levels of the supply chain through publicizing all procurement contracts and making them easily accessible to the public, ensuring that pricing is fair and transparent, and that suppliers are held accountable for meeting their commitments.
- Standardization of data capturing systems by South African NDoH across all healthcare facilities to ensure consistent and accurate data entry. This will help to ensure that the data collected is reliable and can be used for informed decision-making.
- Integrating the stock visibility system with other systems such as electronic health records, to enable a more comprehensive view of inventory levels and patient needs. This will allow healthcare providers to make more informed decisions about inventory management and patient care.
- Improve data analytics by adopting advanced data analytics tools such as machine learning and artificial intelligence. This will help to identify patterns and trends in inventory levels and demand, which can be used to optimize inventory management and improve supply chain efficiency.
- Continuous training of staff on how to use the stock visibility system effectively. This will help to ensure that the data collected is accurate and up-to-date, and that staff can use the system to make informed decisions about inventory management.
- Monitor and evaluate the SVS regularly to ensure that it is meeting its objectives. This will help to identify areas for improvement and ensure that the system is being used effectively.

5. Conclusion

This study highlights the significant barriers in the supply chain of COVID-19 rapid tests and proposes a novel approach to improving the SCM of COVID-19 diagnostic services. The study emphasizes that digitization, visibility of information, and procurement policies are crucial for improving SCM of COVID-19 diagnostic services. Although the South African National Department of Health is implementing the stock visibility system, COVID-19-related commodities are not yet included in the system. The study recommends optimizing the SVS, implementing national policies, and standardizing procurement processes to improve the availability and distribution of COVID-19 rapid tests. However, for this novel approach to be fully functional, it requires collaboration among different sectors, including government, healthcare systems, scientific communities, non-governmental organizations, and civil society. A follow-up study is recommended to assess the feasibility of implementing this approach.

Declarations

Ethics approval and consent to participate: The NGT was performed in accordance with the Declaration of Helsinki. Data collection commenced after obtaining full ethical clearance from the University of Pretoria Faculty of Health Research Ethics Committee (Reference No: 655/2021, Dated: 24 November 2021) and the Limpopo Department of Health ethics committee (Reference No: LP_2021-12-007, Dated: 27 February 2022). All study participants signed informed consent before participating in the study.

Consent for publication: Not applicable

Availability of data and materials: The raw data analysed in this study is available upon reasonable written request submitted to the corresponding author.

Competing interests: The authors declare that they have no competing interests.

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Abbreviations

SARS-CoV-2	Severe acute respiratory syndrome coronavirus type 2

COVID-19	Coronavirus 19
POC	Point-of-care
SCM	Supply chain management
SVS	Stock visibility system
NDoH	National department of health
PI	Principal Investigator
NGT	Nominal group technique
PHC	Primary Healthcare

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Chapter 7: Synthesis of findings

1. Introduction

This chapter provides a summary and discussion of the findings obtained through various activities conducted as part of this thesis. It also presents methodological strengths and limitations of the entire thesis, followed by the conclusions drawn from the study and recommendations to guide policy, practice, and future research endeavours.

2. Background

The WHO recognizes the importance of robust SCM in ensuring access to essential healthcare resources, including diagnostics, during public health emergencies like the COVID-19 pandemic (51). Similar to other countries, South Africa has been confronted with the complexities of procuring, distributing, and ensuring the availability of supplies and equipment for POC testing (52). Ensuring the availability and accessibility of POC testing supplies is a critical concern in South Africa. The country faces several challenges in its supply chain, including delays in procurement, inefficiencies in distribution, stockouts, and inadequate forecasting and inventory management (52, 53, 54). These challenges disrupt the smooth flow of POC testing resources, leading to gaps in testing capacity and potentially compromising the overall effectiveness of COVID-19 response efforts (5, 55). Consequently, this study aimed to develop a novel approach to enhance SCM for SARS-CoV-2 POC diagnostic services in a setting with limited resources.

3. Summary of key findings

This thesis has successfully informed development of a novel approach to improve SCM for SARS-CoV-2 POC diagnostic services. This was achieved through a mixed methods study that identified various challenges associated with SCM for SARS-CoV-2 in a setting with limited resources. Table 1 summarizes the main findings of the study. The scoping review revealed a lack of research on SCM of POC diagnostic services in resource-limited settings. The included studies highlighted two main themes: the improved accessibility and availability of POC diagnostic services and the reasons for stockouts of diagnostic tests. POC tests have enhanced access to same-day screening and treatment, leading to better health outcomes. However, stockouts were attributed to procurement, inventory management, storage,

distribution, and quality assurance issues. Challenges included inadequate procurement processes, poor inventory management, improper storage conditions, distribution delays, and limited quality assurance. Addressing these challenges through effective SCM practices is essential for ensuring uninterrupted supply and enhancing the accessibility and availability of POC diagnostic services in resource-limited settings.

In this study, a GIS-based accessibility analysis was conducted to examine the spatial distribution of COVID-19 diagnostic services in Mopani District with a population of 1,202,916. The district had 105 PHC clinics and seven district hospitals, serving an average of approximately 11,456 people per clinic. The analysis revealed that PHC clinics were generally well distributed throughout the district, but some disparities existed. The majority of the population (78.5%) lived within a 5 km radius of a PHC clinic, and 68.4% of the clinics were located within a 30 km radius of a district hospital. Ba-Phalaborwa and Maruleng sub-districts demonstrated good access to healthcare services, while Greater Giyani had the lowest percentage of the population living within 5 km of a clinic. To ensure equitable access, the study recommended strengthening areas with limited COVID-19 diagnostic services by exploring new approaches and innovations in testing. This will help reach a larger population and effectively control the spread of COVID-19.

Once we had determined the accessibility of COVID-19 diagnostic services, our next step was to evaluate the SCM for SARS-CoV-2 POC diagnostic services in Mopani District. Audits were conducted on PHC clinics to evaluate SCM compliance and identify factors affecting accessibility. The findings revealed that the audited clinics had suboptimal adherence to international SCM guidelines, with varied compliance scores across different components and sub-districts. Barriers and enablers were identified for each SCM component, and areas needing improvement included inventory management, distribution, and human resource capacity. Recommendations include adopting efficient inventory management tools, implementing a robust human resource management system, providing training courses for POC SCM, strengthening the national supply chain and logistics, and conducting follow-up studies to evaluate SCM at higher levels.

To improve SCM for SARS-CoV-2 POC diagnostic services, a collaborative effort with key stakeholders was undertaken. The study identified barriers and strategies, resulting in three primary themes: digitalization, visibility of information, and procurement policies. Strategies focused on digitizing systems, improving stock visibility, and standardizing procurement processes. Stakeholder feedback emphasized integrating systems, collaborative information sharing, and implementing national guidelines. The findings underscore the significance of digitalization, information visibility, and procurement policies in overcoming barriers. Priority areas for the recommended approach include collaboration among stakeholders, transparency and accountability, standardization of data capturing systems, integration of stock visibility with other systems, improved data analytics, continuous staff training, and regular monitoring and evaluation. Implementing these recommendations can enhance the supply chain, ensuring availability of testing kits and improved inventory management for better diagnostic services.

Table 1: Summary of key findings of this study

Journal article title	Objective	Approach	Key findings	Recommendations
1. A Scoping Review of Supply Chain Management Systems for Point of Care Diagnostic Services: Optimising COVID-19 Testing Capacity in Resource-Limited Settings	To map global evidence on SCM systems for POC diagnostic services, specifically focusing on optimizing COVID-19 diagnostic services in resource-limited settings.	A scoping review guided by the Arksey and O'Malley framework, 2005 (56), and further enhanced by Levac et al. (2010) (57)	Two main themes emerged: **1. Accessibility and availability of POC diagnostic services** ● Improved accessibility and availability ● Enabled same-day screening and treatment, leading to improved health outcomes ● Decentralization increased detection, patient management, and prompt treatment initiation **2. Reasons for stock outs of POC diagnostic tests** ● Procurement ● inventory management ● storage ● distribution ● quality assurance	● Further research to investigate the COVID-19 SCM of POC diagnostic services ● Explore SCM systems utilised in high-income countries with the aim of adopting sustainable solutions for LMICs ● Conduct primary studies investigating the barriers and enablers of SCM systems in resource-limited settings to provide sustainable solutions to SCM challenges.

2. Spatial distribution of COVID-19 diagnostic services in Mopani District, Limpopo province, South Africa	To investigate the spatial distribution of COVID-19 testing services in Mopani District	GIS accessibility analysis to establish the travel distances from i) places of residence to the nearest PHC clinics and ii) PHC clinics to the nearest district hospital	● Total population of 1,202,916 ● 105 PHC clinics ● 7 district hospitals ● Each clinic served approximately 11,456 people. ● PHC clinics were generally well distributed throughout the district but exhibited some disparities ● Majority of the population (78.5%) lived within a 5 km radius of a PHC clinic ● Among the 105 PHC clinics, 72 (68.4%) were located within a 30 km radius of a district hospital.	● Focus on strengthening areas with limited COVID-19 diagnostic services by exploring new and innovative approaches to testing that can reach a larger population and effectively control the spread of COVID-19.
3. Evaluating supply chain management of SARS-CoV-2 point-of-care (POC) diagnostic services in primary healthcare clinics in	To evaluate the SCM for SARS-CoV-2 POC diagnostic services in resource-limited settings to	An audit of the 9 aspects of SCM in the PHC clinics	● PHC clinics in the Mopani District, Limpopo, South Africa do not comply with international SCM guidelines. ● The audit results revealed deficiencies in: ✓ Inventory management	● Adopt efficient inventory management tools, such as software systems, to connect national, provincial, district, and PHC facilities ● Implement a strong human resource management system

Mopani District, Limpopo Province, South Africa	determine the effect of SCM on accessibility to SARS-CoV-2 POC tests and to identify barriers and enablers of accessibility to SARS-CoV-2 diagnostic services in Mopani District, Limpopo Province, South Africa.		✓ Distribution ✓ Human resource capacity ● PHC clinics were compliant in: ✓ Procurement ✓ Redistribution ✓ Quality assurance ● The audit also revealed variations in the SCM compliance scores between the sub-districts showing inconsistencies in the SCM processes currently in place.	with a focus on nurses to enhance SCM practices ● Provide structured training courses and regular workshops, accompanied by standard operating procedures ● Strengthen the national-level supply chain and logistics to ensure availability of high-quality test kits and minimize stock outs
4. Co-creation of a novel approach for improving supply chain management for SARS-CoV-2 point of care	To collaborate with key stakeholders in co-creation of a novel approach for improving	An online workshop with key stakeholders to identify barriers faced in the	**Significant barriers:** ● Availability of testing kits ● Unknown demand ● Information on SCM during a pandemic ● Methods of controlling stock	● Foster collaboration among key stakeholders to share information, resources, and best practices ● Promote transparency and accountability by publicizing

diagnostic services in Mopani District, Limpopo Province: Nominal Group Technique	SCM for SARS-CoV-2 POC diagnostic services.	SCM of COVID-19 rapid tests and come up with ways to overcome the identified barriers.	● Procurement of stock. **Proposed strategies:** ● Monitoring of stock levels ● Optimization of the stock visibility system ● Visibility of information ● Consistent update of data capturing systems ● Capturing of data ● Digitization ● Implementing demand planning ● Standardized procurement processes at a national level **3 main themes:** ● Digitization ● Visibility of information ● Procurement policies	procurement contracts, ensuring fair pricing, and holding suppliers accountable ● Standardize data capturing systems across healthcare facilities ● Integrate stock visibility systems (SVS) with other healthcare systems for a comprehensive view of inventory and patient needs ● Employ advanced data analytics tools to optimize inventory management and improve supply chain efficiency ● Continuous training of staff on system usage and regular monitoring and evaluation of the SVS

4. Discussion

Improving SCM for SARS-CoV-2 diagnostic services in South Africa is crucial for better healthcare access and ensuring a consistent supply of diagnostic tests. The thesis successfully developed a novel approach to enhance SCM for SARS-CoV-2 POC diagnostic services. This was achieved through a thorough mixed methods study that explored the challenges related to SCM for SARS-CoV-2 in a resource-limited setting.

The scoping review provided a comprehensive understanding of the SCM of POC diagnostic services. The review demonstrated the positive impact of POC diagnostic services in improving accessibility and availability, particularly in resource-limited settings (58, 59, 60, 61, 62, 63). Additionally, a GIS-based travel-distance analysis was conducted to assess the accessibility of POC diagnostic services. The findings indicated that 78.5% of the population had good accessibility to SARS-CoV-2 diagnostic services, although there were variations among sub-districts. Specifically, Greater Giyani exhibited poor accessibility (40.0%) compared to the other sub-districts. Identifying areas with limited accessibility is essential for analysing gaps in healthcare services, which in turn facilitates healthcare planning and resource allocation (64, 65, 66, 67).

The scoping review further emphasized that POC testing was a suitable alternative for controlling infectious diseases like COVID-19 in settings with limited access to laboratory diagnostic services. However, the review also identified several challenges reported in the literature, including procurement, inventory management, storage, distribution, and quality assurance. Addressing these challenges was identified as crucial for ensuring a continuous supply of POC tests and enhancing the effectiveness of SCM (16, 68, 69, 70, 71, 72, 73, 74). The audit findings aligned with the findings of the scoping review. The audit specifically focused on evaluating the nine parameters of SCM, namely selection, quantification, storage, procurement, quality assurance, distribution, redistribution, inventory management, and human resource capacity. The results revealed that, overall, the PHC clinics did not adhere to international SCM guidelines. Among the nine evaluated SCM parameters, only procurement, redistribution, and quality assurance were found to be satisfactory and did not require improvement. However, it is important to note that all parameters are

crucial for ensuring the optimal functioning of SCM systems and equitable access to SARS-CoV-2 POC diagnostics in resource-limited settings.

Based on this backdrop, the study engaged in another research endeavour to collaborate with key stakeholders in order to identify the barriers in SCM and propose strategies for improving these barriers within the study setting. In the subsequent paragraphs, each of the nine SCM parameters will be discussed individually, highlighting the findings and offering possible recommendations for enhancing SCM based on the insights gained from the GIS-based accessibility analysis, audit, and NGT conducted.

- **Selection**

The audit results indicate that the healthcare professionals were not actively involved in the selection of POC tests. The key stakeholders who participated in the NGT highlighted that the responsibility for selecting POC tests lies with the National Department of Health, who engage in collaborative decision-making with relevant stakeholders including healthcare professionals, researchers, and regulatory bodies such as the South African Health Products Regulatory Authority (SAHPRA). It is crucial for the National Department of Health to ensure that POC tests undergo examination by SAHPRA to guarantee compliance with essential safety, quality, and efficacy standards (35, 36).

To ensure the effectiveness of the novel approach, it is recommended to adopt a continuous review and update strategy. This involves regularly assessing and refining the selection process to incorporate emerging technologies, scientific advancements, and evolving healthcare needs. It is important to foster a culture of continuous improvement by monitoring the performance of selected POC tests and actively seeking feedback from healthcare professionals and end-users.

- **Quantification**

At the PHC clinic level, operational managers have the responsibility of predicting the demand for POC tests based on seasonal variations, such as COVID-19 waves, to ensure an adequate supply. These managers successfully forecast the demand by considering COVID-19 waves and the number of visitors to the clinics. On the provincial level, the pharmaceutical depot is responsible for quantifying POC tests

based on COVID-19 waves. However, the lack of an electronic system that detects stock levels makes it challenging to accurately forecast future needs.

For the success of the novel approach, several recommendations are proposed. First, it is suggested to develop forecasting models that consider historical data, seasonal variations, COVID-19 wave patterns, and other relevant factors. These models should be continuously refined and updated based on feedback and improved data collection methods to enhance the accuracy of predicting future demand. Second, providing training to operational managers at PHC clinics and staff at the provincial pharmaceutical depot in effective quantification methods, data analysis techniques, and the use of electronic stock management systems is crucial. Strengthening their skills and knowledge will contribute to better accuracy in demand prediction. Lastly, conducting regular reviews and evaluations of the quantification process, seeking feedback from stakeholders, and incorporating lessons learned into future strategies will further improve the quantification of POC tests. By implementing these measures, it will be possible to anticipate demand more effectively and ensure an adequate supply of POC tests at PHC clinics.

- **Storage**

The temperature in Mopani District can reach a high of 42°C therefore maintaining appropriate storage conditions for COVID-19 POC tests is crucial to ensure reliable results and prevent damage (75, 76). Storage facilities were present in all audited PHC clinics, and regular temperature monitoring was conducted. The majority of the facilities reported having a functional air conditioner in their storage areas. However, it is worth noting that some facilities had non-functional air conditioners, which raises concerns about the reliability of the test results. Exposure to high temperatures can potentially damage the COVID-19 rapid tests. To enhance storage, measures such as temperature monitoring, adequate facilities, dedicated storerooms, education and awareness, regular inspections, and contingency plans are recommended. By implementing these measures, the tests can be stored within the recommended temperature range, minimize fluctuations, raise staff awareness, comply with storage requirements, and prepare for unforeseen situations. This improves the accuracy of test results and reduces the risk of false negatives or damage from exposure to warm temperatures.

- **Procurement**

Based on the audit and NGT results, there was a discrepancy in the evaluation of procurement. While the audit indicated satisfaction, the key stakeholders who participated in the NGT identified areas requiring improvement. This disparity can be attributed to the audit's focus on PHC clinics requisitioning from district hospitals or distribution centres based on demand, while the NGT examined higher-level procurement led by the provincial government following the National Department of Health's guidance. It is important to note that the national and provincial governments hold greater procurement powers, and deviations at these levels can impact the availability of POC tests at lower government levels. The key stakeholders who participated in the NGT revealed the absence of procurement policies or standardized procedures from the National Department of Health due to emergency procurement practices that were implemented.

To ensure the success of the novel approach, it is crucial to develop supportive policies and regulatory frameworks. Clear guidelines should be established for procurement processes, quality assurance standards, data privacy, and technology adoption. Encouraging compliance through incentives and implementing accountability measures can promote responsible SCM practices. The National Drug Policy in South Africa already aims to enhance medical supply procurement through measures like strengthening the public sector coordinating body, conducting national-level price negotiations, standardizing tendering, and monitoring supplier performance (40, 41, 42). The policy emphasizes the use of standardized procurement systems, participation in national tenders, preference for national manufacturers, while considering international options for cost-effectiveness (43, 44). Transparency, accountability, fair pricing, and supplier responsibility are highlighted.

To enhance the system further, the government should focus on monitoring and enforcement, providing capacity building and training, strengthening supplier evaluation and performance monitoring, publicizing procurement contracts and opportunities, embracing technology, and regularly reviewing and updating the guidelines. Implementing these measures will promote transparency, fairness, and accountability, ultimately benefiting the country's economic growth and the well-being of its citizens.

- **Quality assurance**

Both the audit and NGT results confirmed that effective quality assurance measures were in place at all PHC clinics, district hospitals, and the pharmaceutical depot. These measures included verifying the proper sealing of the box and individual test kits upon delivery, as well as professional nurses confirming the seal before conducting tests. At the national level, SAHPRA was identified as responsible for overseeing all quality assurance checks.

To further enhance quality assurance in the SCM of COVID-19 test kits, it is crucial to focus on the following strategies. Firstly, comprehensive training programs should be conducted for all staff involved in receiving and administering the test kits, emphasizing the importance of quality assurance measures. This training should increase awareness about proper verification procedures for sealed boxes and individual test kits upon delivery, with particular attention given to training professional nurses on verifying the seal before conducting tests. Secondly, standardized protocols and guidelines should be developed to ensure consistency in quality assurance checks across all levels, including PHC clinics, district hospitals, and the pharmaceutical depot. These protocols should clearly outline the steps to be followed during the verification process, emphasizing the significance of sealed boxes and individual test kit seals. Lastly, regular audits should be conducted to assess the effectiveness of quality assurance measures at each facility. These audits should involve checking compliance with verification protocols, reviewing documentation, and addressing any identified gaps or issues. By implementing these recommendations, the quality assurance of COVID-19 test kits can be further strengthened, ensuring the reliability and integrity of the testing process throughout the healthcare system.

- **Distribution**

The GIS-based accessibility analysis showed that the majority (68.6%) of PHC clinics are located within a reasonable travel distance of 30km from district hospitals, which serve as distribution centres. However, the key stakeholders who participated in the NGT revealed that the delivery of POC tests lacked standardization when the COVID-19 pandemic began. Initially, a push allocation model was adopted, where the provincial pharmaceutical depot directly delivered POC tests to district hospitals

without considering the specific needs and headcount of each PHC clinic. This approach resulted in overstocking and an equal allocation of tests to all clinics, regardless of their usage. Moreover, district hospitals used different methods to distribute stock, leading to unequal distribution and depriving some clinics of enough supplies. In response, the pharmaceutical depot shifted to a demand-based allocation model, which considered the headcount and usage of each clinic. The audit results demonstrated the positive impact of this approach, with all 47 audited PHC clinics consistently receiving stock after making requisitions. The turnaround time for stock delivery varied from daily to weekly, depending on factors such as proximity and available resources.

To implement a novel distribution approach, the government should optimize delivery routes, particularly for PHC clinics located more than 30km from a district hospital. Establishing regular delivery schedules will ensure timely and consistent stock replenishment. Collaboration with local area drivers or the utilization of mobile clinics can help facilitate the distribution process and minimize delays. Improving communication and coordination between district hospitals, PHC clinics, and the provincial pharmaceutical depot is crucial. Clear channels for requisitioning should be established, and PHC clinics should receive timely updates on stock availability and delivery schedules. Strengthening coordination mechanisms will enable prompt handling of urgent requisitions. Resource disparities among district hospitals should be assessed, and additional resources should be allocated to those with limited capabilities for stock distribution. Providing support such as delivery vehicles and designated drivers to PHC clinics far from district hospitals will enable more frequent stock deliveries and reduce turnaround times. Continuous monitoring and evaluation of the distribution process are essential to identify and address any bottlenecks or inefficiencies. Regular reviews and refinements of the distribution approach based on feedback and lessons learned should be conducted. Engaging PHC clinic operational managers and staff to gather insights on their specific needs and challenges related to stock distribution is important. Their feedback should be incorporated into improvement initiatives, ensuring their perspectives are considered in decision-making processes.

- **Redistribution**

The audit findings revealed that all 47 PHC clinics have established protocols to redistribute COVID-19 POC tests prior to their expiration. Communication among the clinics is facilitated through WhatsApp groups, while stock rotation is managed either through WhatsApp or by completing short-dated forms. The clinics diligently adhere to the first-in, first-out (FIFO) principle to prevent the tests from expiring unused. In order to further enhance the redistribution process, it is crucial to strengthen communication channels, standardize stock rotation procedures, underscore the importance of effective stock management principles, implement robust monitoring mechanisms, foster collaboration between clinics, and provide adequate support and resources. The redistribution of POC tests can be further improved by utilizing the SVS to identify PHC clinics with excessive stock levels. This valuable information can then be utilized to redistribute the tests to other facilities that are facing shortages. This approach helps optimize stock levels, ensuring that no facility is overstocked while simultaneously addressing the needs of those with insufficient supplies.

- **Inventory management**

Based on the findings from the audit and NGT, it was determined that inventory management was conducted manually. However, the Stock Visibility System (SVS) is currently being utilized to track inventory for other medicines. The SVS operates by capturing real-time data, serving as an early warning system, and notifying supply chain stakeholders about PHC clinics with low stock levels, which can lead to supply disruptions. Additionally, the SVS identifies PHCs with excessive stock levels, allowing for the redistribution of POC tests to prevent overstocking. Nevertheless, the SVS does not include COVID-19-related commodities, impeding the implementation of digital inventory management for these items.

To enhance inventory management, a novel approach can be taken. The initial step is to expand the SVS to incorporate COVID-19 commodities. This integration will enable digital inventory management, providing real-time data and enhancing visibility of stock levels. It will also serve as an early warning system for supply chain stakeholders, enabling proactive measures to address low stock levels promptly. Moreover, it is crucial to continuously review and improve the inventory management

system, considering feedback from supply chain stakeholders, embracing emerging technologies, and incorporating best practices. This will ensure that the system remains effective and adaptable to future needs and changes in the healthcare landscape.

- **Human resource capacity**

The audit findings revealed that professional nurses were responsible for both POC testing and inventory management at the PHC clinics. However, the nurses had never received training on inventory management. Interestingly, clinics that had a pharmacist assistant performed significantly better in inventory management compared to those relying on untrained healthcare personnel. As a result, the audit recommended the implementation of a robust human resource management system that adopts a nurse-centric approach to improve SCM.

The key stakeholders who participated in the NGT emphasized the importance of continuous training for staff on effectively using the SVS. This training would ensure accurate and up-to-date data collection and enable staff to make informed decisions regarding inventory management. The key stakeholders also proposed assigning the data capturing function to trained data capturers, relieving clinical personnel of this task. Unemployed pharmacist assistants with inventory management skills could be considered for these roles, helping to address unemployment while enhancing SCM efficiency.

The novel approach should prioritize investment in education and training programs for healthcare workers involved in SCM. These programs should focus on SCM principles, inventory management, data analysis, quality assurance, and technology utilization. (77, 78). By enhancing the competencies of personnel, informed decision-making, best practices, and an efficient supply chain can be achieved. (79). Capacity building and training enable individuals to adapt to changes in the healthcare landscape, keeping them updated on emerging technologies and regulations. (80, 81). Well-trained SCM personnel contribute to efficiency, cost-effectiveness, optimized inventory, reduced wastage, and streamlined procurement and distribution processes. These efforts result in timely availability of diagnostic tests, cost reduction, and maximized resource utilization.

By considering these factors and implementing a comprehensive and tailored novel approach, South Africa can improve SCM for POC diagnostic services. Such improvements can lead to enhanced healthcare accessibility, reduced stockouts, improved inventory management, and ultimately better health outcomes for the population.

5. Strengths of the study

The thesis focused on a resource-limited, predominantly rural setting with limited access to tertiary healthcare facilities and laboratory infrastructure. This allowed for a realistic understanding of the challenges faced in managing healthcare services and diagnostics in similar regions. The research provided insights and solutions applicable to other resource-limited areas with similar constraints. Additionally, this thesis focused on a region impacted by the COVID-19 pandemic with most of the population relying on the public healthcare services, It also provided an opportunity to develop targeted interventions to address the unique needs and challenges of resource-limited, predominantly rural and high disease-burden settings.

The thesis employed a mixed method approach, combining qualitative and quantitative data, to gain a thorough understanding of the research topic. A scoping review was conducted as the initial step, allowing the researchers to map existing evidence and identify research gaps to inform the thesis objectives. The review employed a transparent and reproducible method to identify, analyse, and appraise articles, incorporating various study designs (56). The strength of the scoping review lies in its comprehensive literature search across relevant electronic databases, encompassing articles from inception to the present and without language restrictions (82). To ensure inclusiveness, the review utilized a wide range of keywords and Medical Subject Heading (MeSH) terms.

The GIS-based travel-distance analysis provided spatial accuracy by accurately mapping and measuring travel distances using geographic data layers, aiding in understanding healthcare facility proximity and accessibility (83). This method provided an opportunity to optimize resource allocation by identifying underserved areas and adjusting services accordingly, minimizing travel burdens for patients. During emergencies such as COVID-19, this method supports evidence-based

decision-making by identifying the closest healthcare facilities for prompt response and efficient allocation of resources.

The use of an audit tool in a cross-sectional mixed methods study allowed for a comprehensive assessment of the phenomenon under study, capturing multiple dimensions. By integrating quantitative and qualitative methods, the study was able to explore the interplay between variables, identify patterns, and gain a deeper understanding of the underlying mechanisms or processes involved (84, 85). For quantitative data analysis, Stata statistical software was utilized, while Nvivo was employed for qualitative data analysis.

The NGT ensured a collaboration with relevant key stakeholders in the co-creation of a novel approach for improving SCM for POC diagnostic services. This technique allowed generation of ideas by engaging experts in the field (86). It also promoted equal participation and structured decision-making among the key stakeholders. Overall, these approaches contributed to the study's scientific rigor and provided valuable insights into the research topic.

The study leveraged the timely dissemination of results by submitting the manuscripts to peer-reviewed open access journals, ensuring the timely publication of results for each study objective. Additionally, the manuscripts submitted for peer-review were also published as pre-prints. Publishing in open science journals offers advantages such as increased visibility and reach, fostering collaborations and citations (87). It also promotes transparency and reproducibility by providing unrestricted access to methods, data, and findings (88). A policy brief generated following synthesis of the thesis results, will be published to ensure appropriate dissemination of thesis findings to policy makers and implementers of POC diagnostics. Additionally, we intend to disseminate findings to clinics and stakeholders through research meetings and posters after degree confirmation.

In recognition of the importance of stakeholder engagement in community-based studies such as this, we engaged stakeholders throughout the thesis lifecycle. This was done to ensure relevance, building trust, enhancing data quality, facilitating participant recruitment and retention, promoting community ownership, and upholds ethical considerations as well as improve uptake of the thesis results into policy and practice (89).

6. Limitations of the study

While our study contributed valuable insights and proposed a novel approach to improving SCM for SARS-CoV-2 diagnostic services, it is important to acknowledge certain methodological limitations. The study conducted in Mopani District, as a prototype for a resource-limited setting, limits the generalizability of the results to similar resource-limited settings. It is important to note that resource-limited settings vary in terms of their levels, some being extremely remote and primitive, inaccessible by car. Conducting the study in a single resource-limited setting poses a limitation in terms of generalizability due to the unique characteristics and contextual factors specific to that setting (90). Local infrastructure, population demographics, available resources, and specific challenges and opportunities influence the findings. Therefore, caution should be exercised when extrapolating the results to broader populations or different resource-limited settings without considering these contextual variations. To enhance generalizability, future studies should include multiple resource-limited settings to capture a wider range of perspectives and contextual factors. In addition, the choice of Mopani district was purposive, rather than a random selection, and therefore this limits the generalizability of findings to the whole country.

The fact that the study was conducted during the pandemic, with usual processes set aside due to the unprecedented service demand, can limit the generalizability of the results. The unique circumstances of the pandemic, such as increased healthcare demand and resource constraints, may not be representative of typical healthcare settings. Therefore, the findings might not be directly applicable to non-pandemic situations. The high demand for COVID-19 diagnostic services during the pandemic might have influenced the availability, accessibility, and efficiency of testing facilities. This could have implications for the study's findings, as the service demand during the pandemic may not reflect the situation during non-pandemic periods. Future research should consider SCM in the context of other POC diagnostic tests for a broader scope when generalizing the results. Different diagnostic tests may have varying logistical and supply chain requirements, making the findings specific to the context of COVID-19 testing.

Despite efforts to conduct a comprehensive scoping review, there is a possibility that some relevant published and grey literature may have been missed, given the

continuously evolving research landscape surrounding COVID-19. Additionally, no primary studies assessing the SCM of COVID-19 POC diagnostic services were identified in the review, highlighting a gap in the existing literature.

Geospatial analysis relies on secondary data, which introduces concerns regarding data quality. Secondary data, collected by other researchers or organizations for their own purposes, may vary in terms of quality and accuracy. This variation can lead to errors, inconsistencies, or missing information within the dataset, ultimately impacting the reliability of the findings (91, 92). The lack of fixed residential addresses in rural communities necessitated the use of catchment areas and PHC clinics as proxies for linking residential areas to the nearest district hospital. This approach may not fully capture the precise accessibility of healthcare services for individuals. Furthermore, the analysis focused solely on travel distance as a measure of accessibility, thus overlooking other important factors such as cost, quality, and socio-cultural barriers that can impact healthcare access and utilization. Another limitation of the study is the assumption that patients would always choose the nearest healthcare facility, while in reality, patients in South Africa have the freedom to select their healthcare providers. Additionally, rural areas often have well-connected roads and public transportation, enabling patients to access healthcare facilities near their workplace or along transportation routes. These factors were not considered in the analysis, potentially limiting the accuracy of accessibility assessments.

In the audit, while the tool covered aspects such as test performance and sensitivity, the data collected were based on perceived sensitivity and specificity of POC tests rather than confirmed laboratory test results. This introduces a degree of uncertainty in the findings. Moreover, the audit was conducted in only one district, which limits the ability to compare findings with other areas and may not fully represent the broader context.

The utilization of a virtual platform for data collection has demonstrated its viability as an alternative method (93). However, it is important to acknowledge that technical challenges have been reported as one of the limitations associated with this approach. In the context of the NGT, the use of a virtual platform presented certain constraints. Participants experienced network issues resulting from electricity load

shedding, which caused potential disruptions and communication difficulties. Furthermore, the NGT generated a wide array of ideas, reflecting the intricate nature of SCM. Consequently, it became challenging to address all the identified barriers and strategies comprehensively within the given scope.

7. Conclusion

In conclusion, this study focused on contributing evidence towards the development of a novel approach to improve SCM for SARS-CoV-2 POC diagnostic services in resource-limited settings, specifically focusing on the Mopani District Municipality in Limpopo Province, South Africa. The thesis undertook a comprehensive analysis of SCM systems, including selection, quantification, procurement, inventory management, storage, distribution, redistribution, quality assurance and human resource capacity. This thesis identified the following areas of severe non-compliance: procurement, inventory management, storage, distribution & human resource capacity. The findings guided the development of an intersectoral evidence-informed framework for optimizing POC diagnostics SCM for resource-limited settings with similar characteristics to Mopani District Municipality in Limpopo Province, South Africa. Key stakeholder involvement is recommended in assessing the feasibility of implementing the proposed intersectoral evidence-informed framework.

8. Recommendations

8.1. Recommendations for practice

Insights are derived from the comprehensive scoping review, analysis of geographic accessibility of SARS CoV-2 POC diagnostics using GIS, findings obtained from the audit and the NGT workshop with key stakeholders have informed the proposed framework for improving SCM for POC diagnostics in resource-limited settings (Figure 2). This framework provides recommendations for implementers and policy makers for POC diagnostics services in settings that are similar to Mopani District, Limpopo Province, South Africa. The proposed framework encompasses intersectoral evidence-informed approaches. The framework sheds light on areas of non-compliance, suggesting solutions, and identifying the sectors accountable for implementing these solutions.

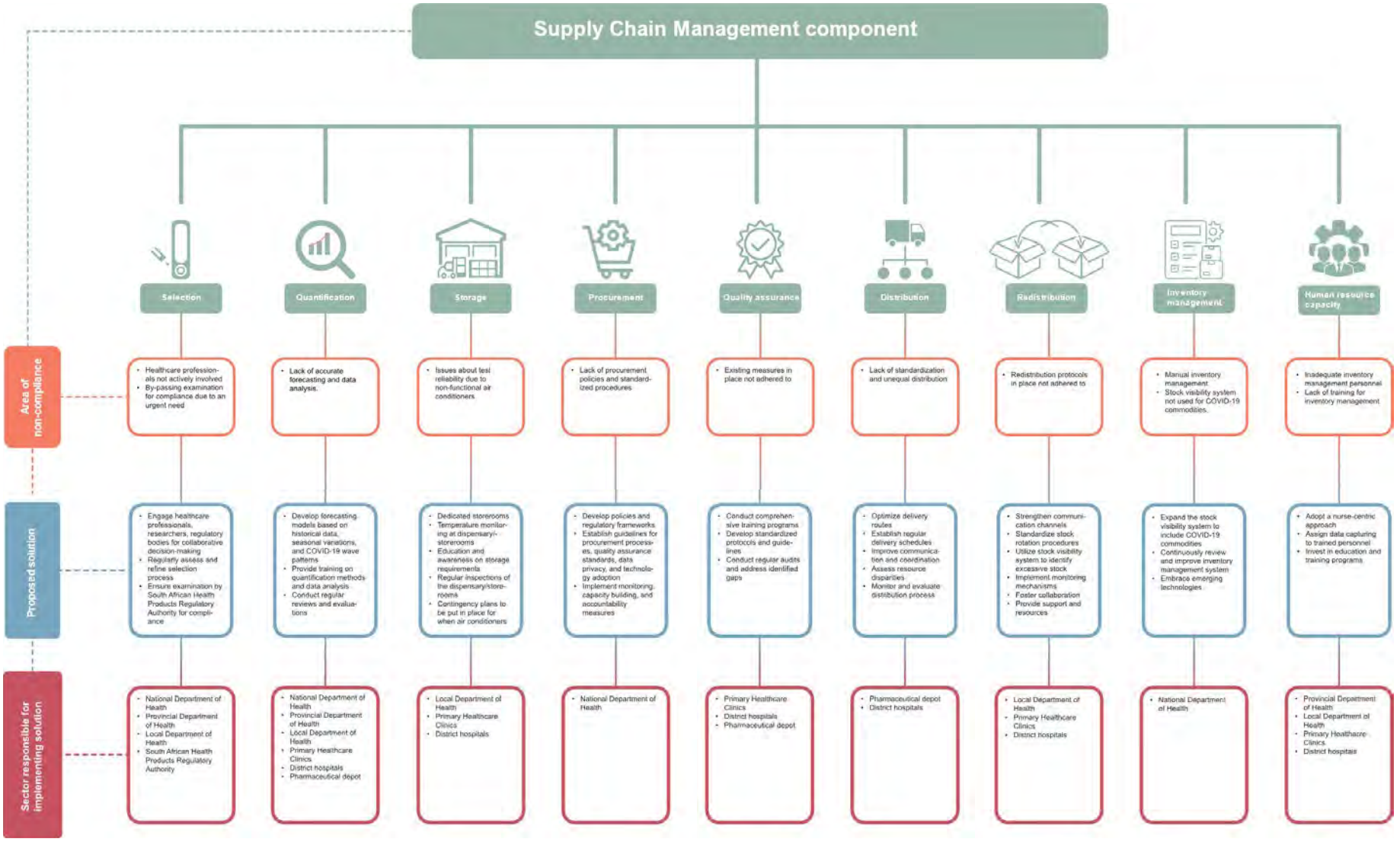

Figure 2: Intersectoral point-of-Care diagnostics supply chain management framework for resource-limited settings

8.2. Recommendations for future research

- Although our study findings will make a substantial contribution to the existing body of evidence on SCM of COVID-19 diagnostic services in resource-limited settings, there is still a gap in the available evidence on the most acceptable approach for improving SCM for COVID-19 POC diagnostic services. This highlights the need for further research in this area.
- Given the limited scope of our research, which focused on a specific district, it is recommended to conduct further studies that target the provincial and national levels of government. This broader research approach will provide a more comprehensive understanding of SCM practices and challenges in different contexts.
- We recommend conducting a study to assess the feasibility of implementing the intersectoral evidence-informed framework for improvement of SCM for POC diagnostics in resource-limited settings. The study will assess the impact of the framework, identify areas for improvement, and adapt strategies accordingly. It is important to implement performance indicators, conduct periodic audits, and gather feedback from stakeholders to obtain valuable insights and facilitate iterative enhancements to the SCM system.

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Appendices

- **Appendix A: University of Pretoria Ethics Approval**

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IORG #: IORG0001762 OMB No. 0990-0279 Approved for use through February 28, 2022 and Expires: 03/04/2023.

Faculty of Health Sciences **Research Ethics Committee**

24 November 2021

Approval Certificate
New Application

Dear Miss K Maluleke

Ethics Reference No.: 655/2021
Title: Developing a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in resource-limited settings: A case study of Mopani District Municipality in Limpopo province, South Africa

The **New Application** as supported by documents received between 2021-11-02 and 2021-11-24 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2021-11-24 as resolved by its quorate meeting.

Please note the following about your ethics approval:
- Ethics Approval is valid for 1 year and needs to be renewed annually by 2022-11-24.
- Please remember to use your protocol number (655/2021) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

On behalf of the FHS REC, Dr R Sommers
MBChB, MMed (Int), MPharmMed, PhD
Deputy Chairperson *of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

Research Ethics Committee
Room 4-60, Level 4, Tswelopele Building
University of Pretoria, Private Bag x323
Gezina 0031, South Africa
Tel +27 (0)12 356 3084
Email: deepeka.behari@up.ac.za
www.up.ac.za

Fakulteit Gesondheidswetenskappe
Lefapha la Disaense tša Maphelo

- **Appendix B: University of Pretoria Ethics**

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 18 March 2022 and Expires 18 March 2027.
- IORG #: IORG0001762 OMB No. 0990-0278 Approved for use through August 31, 2023.

Faculty of Health Sciences **Research Ethics Committee**

13 October 2022

Approval Certificate
Annual Renewal

Dear Miss K Maluleke,

Ethics Reference No.: 655/2021 – Line 2
Title: Developing a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in resource-limited settings: A case study of Mopani District Municipality in Limpopo province, South Africa

The **Annual Renewal** as supported by documents received between 2022-09-26 and 2022-10-12 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2022-10-12 as resolved by its quorate meeting.

Please note the following about your ethics approval:
- Renewal of ethics approval is valid for 1 year, subsequent annual renewal will become due on 2023-10-13.
- Please remember to use your protocol number (655/2021) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

On behalf of the FHS REC, Dr R Sommers
MBChB, MMed (Int), MPharmMed, PhD
Deputy Chairperson *of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

Research Ethics Committee
Room 4-60, Level 4, Tswelopele Building
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Fakulteit Gesondheidswetenskappe
Lefapha la Disaense tša Maphelo

- **Appendix C: Limpopo Department of Health Ethics Approval**

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

Department of Health

Ref : LP_2021-12-007
Enquires : Ms PF Mahlokwane
Tel : 015-293 6028
Email : Phoebe.Mahlokwane@dhsd.limpopo.gov.za

Kuhlula Maluleke

PERMISSION TO CONDUCT RESEARCH IN DEPARTMENTAL FACILITIES

Your Study Topic as indicated below;

Developing a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in resource- limited settings, Mopani District Municipality in Limpopo province, South Africa.

1. Permission to conduct research study as per your research proposal is hereby Granted.
2. Kindly note the following:
    a. Present this letter of permission to the institution supervisor/s a week before the study is conducted.
    b. In the course of your study, there should be no action that disrupts the routine services, or incur any cost on the Department.
    c. After completion of study, it is mandatory that the findings should be submitted to the Department to serve as a resource.
    d. The researcher should be prepared to assist in the interpretation and implementation of the study recommendation where possible.
    e. The approval is only valid for a 1-year period.
    f. If the proposal has been amended, a new approval should be sought from the Department of Health
    g. Kindly note that, the Department can withdraw the approval at any time.

    Your cooperation will be highly appreciated

pp **Head of Department** **Date** 27/02/2022

Private Bag X9302 Polokwane
Fidel Castro Ruz House, 18 College Street. Polokwane 0700. Tel: 015 293 6000/12. Fax: 015 293 6211.
Website: http/www.limpopo.gov.za

- **Appendix D: Mopani District Approval Letter**

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH
MOPANI DISTRICT

Ref No: S4/2/2
Enquiries: S Chuma
Tel Direct: 015 811 6633
Email: Shadrack.Chuma@dhsd.limpopo.gov.za

To: **Ms. Maluleke Kuhlula**
165 Krematart
Giyani
0826

PERMISSION TO CONDUCT RESEARCH IN THE DEPARTMENTAL HEALTH FACILITIES OF MOPANI DISTRICT: YOURSELF

1. Your letter dated the 7 March 2022 has reference.
2. This serves to inform you that permission is granted to your request to conduct research within Mopani District.
3. Your research is on "**Developing a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in resource-limited settings, Mopani District in Limpopo province, South Africa**".
4. Note that this permission is valid for 1 year as per the approval from the provincial office.
5. You will be required to furnish the Manager of Information Management Section with this letter for the purposes of access and assistance.
6. You are further expected to abide by all prescripts governing public service during the course of your research.
7. Thanking you.

S. h—a
.....
pp **DIRECTOR: CORPORATE SERVICES**

2022/03/09
.....
DATE

- **Appendix E: informed consent forms**

INFORMED CONSENT (AUDIT)

Student name: Kuhlula Maluleke Student no: 15266304

School of Health Systems and Public Health, Faculty of Health Sciences, University of Pretoria, South Africa.

Mobile: +2782xxxxxxx

Email: u15266304@up.ac.za

You are being invited to consider participating in a study titled: Developing a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in resource-limited settings. One of the objectives of the study is to evaluate the effect of SCM on accessibility of SARS-CoV-2 POC diagnostic services and to reveal SCM barriers and enablers of accessibility of SARS-CoV-2 point of care diagnostic services. The study will utilise an audit tool with set questions to collect data. In order to reveal the barriers to accessibility of SARS-CoV-2 point of care diagnostic services, we will probe further through an individual interview to all non-complaint sections. The duration of your participation if you choose to enrol and remain in the study is expected to be about 40 minutes.

There are no risks associated with participation in this study.

The participants will have an opportunity to reflect on, share and make recommendations on how SCM of SARS-CoV-2 POC diagnostic services may be improved.

This study has been ethically reviewed and approved by the University of Pretoria Research Ethics Committee (approval number 655/2021). and the Limpopo Department of Health Research Ethics Committee (approval number LP-2021-12-007)

Your participation in this research is voluntary. You have the right to withdraw your participation at any point. The information we will collect from you will be kept confidential. We will identify you by a number and not by your name. Your name will not appear when we disseminate the results.

In the event of any problems or concerns/questions you may contact the researcher at the above contact details or the University of Pretoria Research Ethics Committee, contact details as follows:

University of Pretoria Research Ethics Committee

Tswelopele Building, Level 4, Rooms 4-59 and 4-60

Dr Savage Road, Gezina, Pretoria

Tel: +2712 356 3084 or +2712 356 3085

Email: fhsethics@up.ac.za

CONSENT

I

…….

have been informed about the study entitled “Developing a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in resource-limited settings.” by Kuhlula Maluleke or research assistant (Name)

……

I understand the purpose and procedures of the study.

I have been given an opportunity to ask questions about the study and have had answers to my satisfaction.

I declare that my participation in this study is entirely voluntary and that I may withdraw at any time.

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher on mobile number +2782xxxxxx or e-mail: u15266304@up.ac.za

Name of Participant: _____

Signature: _____ Date _____

Name of Witness: _____

Signature: _____ Date _____

Name of person obtaining consent: _____

Signature: _____ Date: _____

INFORMED CONSENT (NOMINAL GROUP TECHNIQUE)

Student name: Kuhlula Maluleke Student no: 15266304

School of Health Systems and Public Health, Faculty of Health Sciences, University of Pretoria, South Africa.

Mobile: +2782xxxxxxx

Email: u15266304@up.ac.za

You are being invited to consider participating in a study titled: Developing a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in resource-limited settings. One of the objectives of the study is to collaborate with key stakeholders in co-creation of a novel approach for improving supply chain management for point of care diagnostic services in resource-limited settings. The participants will be expected to participate in a workshop where they will be expected to share their SCM experiences with the aim of developing a novel approach to improve supply chain management for point of care diagnostic services. The duration of your participation if you choose to enrol and remain in the study is expected to be about 3 hours.

Below is an outline of what to expect from the workshop:

Time	Activities	Method
09:00-10:00	1. Introductions by the participants 2. Purpose of the workshop by PI 3. PI poses the main question 4. Silent brainstorming by each participant 5. Note down relevant ideas	The discussion will start with brief introductions by the participants on how they are involved in the SCM of SARS-CoV-2 POC diagnostic services. The PI will give a background of the workshop and share the program of the day. A question will be posed to initiate the discussion. There will be a break-away session where each participant will be given 10-15minutes for silent brainstorming

		and to write down all the ideas that come to mind. Discussions will not be allowed at this stage however participants will be able to seek clarity from the facilitators.
11:00-12:00	1. Group reconvenes 2. Discuss and note down emerging themes 3. Remove duplicate themes	The group will reconvene, and the participants will be given an opportunity to present the main themes. As the participants are presenting, the facilitators will write down the emerging themes on a chart sheet. Further explanations will be probed from the participants as they are presenting. After the discussion, the facilitators will group similar themes and duplicate themes will be removed. The results of the discussion will be presented by the facilitators to the group as priority areas to be ranked during the next phase.
12:00-13:00	1. Ranking of ideas individually 2. Collate and analyse results	This phase involves ranking of ideas, assigning a value to an idea according to its priority. A Google form will be used. The top five priority themes will be ranked using a Likert scale of 1-5, with 1 representing a very low priority and 5 representing the highest priority. The participants will complete the Google form independently. The

		results will be collated and analysed by the facilitators.

There are no risks associated with participation in this study.

The participants will have an opportunity to reflect on, share and make recommendations on how SCM of SARS-CoV-2 POC diagnostic services may be improved.

This study has been ethically reviewed and approved by the University of Pretoria Research Ethics Committee (approval number 655/2021). and the Limpopo Department of Health Research Ethics Committee (approval number LP-2021-12-007)

Your participation in this research is voluntary. You have the right to withdraw your participation at any point. The information we will collect from you will be kept confidential. We will identify you by a number and not by your name. Your name will not appear when we disseminate the results.

In the event of any problems or concerns/questions you may contact the researcher at the above contact details or the University of Pretoria Research Ethics Committee, contact details as follows:

University of Pretoria Research Ethics Committee

Tswelopele Building, Level 4, Rooms 4-59 and 4-60

Dr Savage Road, Gezina, Pretoria

Tel: +2712 356 3084 or +2712 356 3085

Email: fhsethics@up.ac.za

CONSENT

I

……

have been informed about the study entitled “Developing a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in resource-limited settings.” by Kuhlula Maluleke or research assistant (Name)

……

I understand the purpose and procedures of the study.

I have been given an opportunity to ask questions about the study and have had answers to my satisfaction.

I declare that my participation in this study is entirely voluntary and that I may withdraw at any time.

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher on mobile number +2782xxxxxxx or e-mail: u15266304@up.ac.za

Name of Participant: _____

Signature: _____ Date _____

Name of Witness: _____

Signature: _____ Date _____

Name of person obtaining consent: _____

Signature: _____ Date: _____

Appendix F: Proof of submissions to journals for publication

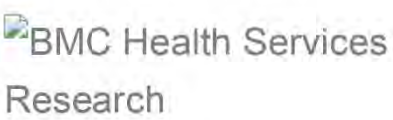
BMJ Public Health

Spatial distribution of COVID-19 diagnostic services in Mopani District, Limpopo province, South Africa

Journal:	*BMJ Public Health*
Manuscript ID	bmjph-2023-000234
Article Type:	Original research
Date Submitted by the Author:	23-May-2023
Complete List of Authors:	Maluleke, Kuhlula; University of Pretoria Faculty of Health Sciences, Department of Public Health Medicine Musekiwa, Alfred; Faculty of Health Sciences University of Pretoria Private Bag, Faculty of Health Sciences Mckelly, David; CSIR, Inclusive Smart Settlements and Regions (ISSR) Central Baloyi, Ethel; Ekurhuleni Metropolitan Municipality, Legislature Mashamba-Thompson, Tivani; University of Pretoria, Faculty of Health Sciences
Keywords:	COVID-19, Public Health, Community Health

This is a new page that we are continually improving. We would love to hear your feedback and suggestions.

BMC Health Services Research



My account

Co-creation of a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in Mopani District, Limpopo Province: Nominal Group Technique

Current status

Your submission has passed the technical checks and is now in peer review

We will now find the most suitable editor to manage the next steps of your submission. If your submission is successful, they will invite reviewers to peer review your work. This process can take a few weeks.

We will email u15266304@tuks.co.za if there are any revisions you need to make.

Progress so far

Progress so far

1. Submission received - complete
2. Initial technical check - complete
3. Peer review - in progress

Your submission

Your submission

Title

Co-creation of a novel approach for improving supply chain management for SARS-CoV-2 point of care diagnostic services in Mopani District, Limpopo Province: Nominal Group Technique

Type

Research

Journal

BMC Health Services Research

Submission ID

8e4530e6-690a-41c1-a2c0-21aba2531c07

Submission history

1. **Peer review**

Submission status	Date
Submission under peer review	17 May 2023

2. **Technical check**

Submission status	Date
Submission passed technical check	17 May 2023
Amendment received	17 May 2023
Amendment received	15 May 2023
Submission is under technical check	15 May 2023

3. **Submission received**

Submission status	Date
Submission received	15 May 2023

Need help?

If you have any questions about this submission, you can email the Editorial Office.

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