

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

Kuhlula Maluleke (✉ u15266304@tuks.co.za)

University of Pretoria School of Health Systems and Public Health <https://orcid.org/0000-0003-0002-4697>

Thobeka Dlangalala

University of Pretoria School of Health Systems and Public Health

Alfred Musekiwa

University of Pretoria School of Health Systems and Public Health

Kabelo Kgarosi

University of Pretoria Department of Library Services: University of Pretoria

Sphamandla Nkambule

University of KwaZulu-Natal School of Nursing and Public Health

Tivani Mashamba-Thompson

University of Pretoria School of Health Systems and Public Health

Protocol

Keywords: Scoping Review Protocol, chain management systems, diagnostics services, COVID-19, testing capacity, Rapid and specific diagnostic tests

Posted Date: June 9th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-591015/v1>

License:  This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Version of Record: A version of this preprint was published at Diagnostics on December 8th, 2021. See the published version at <https://doi.org/10.3390/diagnostics11122299>.

Abstract

Background

Rapid and specific diagnostic tests are essential for severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) testing to allow prompt isolation and early treatment initiation if necessary. Currently, reverse transcription polymerase chain reaction (RT-PCR) tests are the gold standard for SARS-CoV-2 testing but are difficult to implement in resource-limited settings with poor access to laboratory infrastructure. Point of care (POC) testing may be more feasible in resource-limited settings because POC testing is cost-effective, easy to perform, results are rapid, and they can be performed at all levels of healthcare by health professionals with minimal training. To ensure equitable access, it is important that SARS-CoV-2 testing is optimised through well-established supply chain management (SCM). Here we outline a protocol for a scoping review aimed at mapping literature on SCM for POC testing in resource limited settings to guide both future research and the implementation of SARS-CoV-2 POC diagnostics.

Methodology

This scoping review will be guided by an adapted version of the Arksey and O'Malley methodological framework. We will search the Medline Ovid, Medline EBSCO, Scopus, PubMed, PsychInfo, Web of Science and EBSCOHost databases. We will search gray literature in the form of dissertations/theses, conference proceedings, websites of international organisations such as the World Health Organisation and government reports. We will include articles reporting evidence published since inception. Language restrictions will not be applied. We will use a search summary table to test the effectiveness of the search strategy. Two reviewers will screen eligible studies using a tool developed for this scoping review. The quality of the included studies will be appraised using the mixed method appraisal tool (MMAT) version 2018.

Discussion

The proposed scoping review will gather relevant studies on SCM systems for POC diagnostics services globally. We anticipate that this review's findings will guide future research on SCM systems for POC diagnostics services in resource-limited settings. The results will be published in a scientific journal, presented at relevant conferences and form part of workshops with key stakeholders involved in SCM systems for POC diagnostics services.

Background

The World Health Organisation (WHO) recommends using reverse transcription polymerase chain reaction (RT-PCR) tests for detecting severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) as a gold standard for diagnosing coronavirus 19 (COVID-19) (1–3). RT-PCR requires sophisticated laboratory equipment, often lacking in resource-limited settings, hindering fast and accurate detection of SARS-CoV-2 (4). Additionally, RT-PCR is time-consuming and getting results may take a number of days

(5). In resource-limited settings this has resulted in a large backlog when testing patient samples suspected of SARS-CoV-2 (4).

In resource-limited settings, alternative diagnostic methods such as point of care (POC) testing may ease the burden on healthcare facilities and laboratory services (1, 2). POC testing refers to diagnostic testing that uses innovative medical technologies that enable near patient disease diagnosis to inform clinical decisions (6). POC tests are cheap, easy to perform and can be deployed both at the site of triage and outside health care facilities to guide disease management (1, 6). POC tests deliver prompt results, therefore, they are of utmost importance in containing highly infectious diseases such as SARS-CoV-2 (6). The WHO recommended scaling up testing programmes for SARS-CoV-2 by testing all suspected cases (7). This recommendation was prompted by a resurgence of COVID-19 and the continuum of limited testing capacity in settings that have poor access to laboratory infrastructure (8).

For the efficient control and management of COVID-19, POC tests are required on a large scale (9). Globally, POC tests are being rapidly developed for SARS-CoV-2 (10). To ensure 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 (11, 12). Optimal SCM of SARS-CoV-2 POC tests will ensure that health care professionals have the available resources to perform tests for patients (6). An ineffective SCM may limit the availability and accessibility of POC tests and negatively impact health outcomes (12, 13). Evidence on supply chain systems for POC diagnostics is not clear. This scoping review protocol outlines the methods that will be used to map evidence of SCM systems of POC diagnostic services globally. We anticipate that the results of the planned scoping review will guide future research on SCM for SARS-CoV-2 POC testing and guide implementation of SARS-CoV-2 POC diagnostics in resource-limited settings. In this study, we define resource-limited settings as settings with poor access to laboratory infrastructure.

Methodology

This study is part of a multi-phase PhD study investigating supply chain management of SARS-CoV-2 POC diagnostic services. To map evidence on SCM systems for POC diagnostics services, we will conduct a scoping review. The review will be guided by the methodological framework proposed by Arksey and O'Malley (14) and further advanced by Levac et al. (15). According to this framework the review will be conducted in 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 proposed a sixth stage comprising optional consultation with key stakeholders to provide insights beyond those found in literature. This scoping review will not include consultation with stakeholders.

Identification of the research question

The research question is: What is the evidence on 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

Framework for determining the eligibility of the research question

Population	Point of Care (POC) diagnostics services Diagnostics services that use innovative medical technologies that enable near patient disease diagnosis (6).
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 (11, 12).
Context	Globally

Identification of relevant studies

We will identify relevant studies by conducting a comprehensive and reproducible search of all literature published in the following electronic databases: Medline Ovid, Medline Elton B. Stephens Company (EBSCO), Scopus, PubMed, PsycInfo, Web of Science and EBSCOHost. We will also search gray literature including dissertations/theses, conference proceedings, websites of international organisations such as WHO and government reports. We will identify additional relevant studies by manually searching all references cited in the included studies to identify studies that have not been indexed by the electronic databases. Language restrictions will not be applied to minimise the risk of excluding relevant articles.

The comprehensive search strategy will be co-developed 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 will be 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". Keywords may be refined to suit each database. Each search will be documented in detail showing the keywords/MeSH terms, date of search, electronic database and number of retrieved studies. We piloted the search strategy on one of the electronic databases and the results of the search are tabulated in table 2.

Table 2

Results of pilot search in PubMed

Date of search	Electronic Database	Keywords/MeSH terms	Number of retrieved studies
18/05/2021	PubMed	((("supply chain management") AND ("point of care testing"))) OR ("point of care diagnosis") OR ("point of care diagnostics services")	2 711

We will optimise our search strategy by adopting the search summary table (SST) outlined by Bethel et al (16) as a guide (Table 3). The SST will be used to improve and report on the effectiveness of the search strategy to ensure the retrieval of high-quality, relevant and scientifically sound articles. The search strategy will continuously be improved. An update search (re-run) is essential because SARS-CoV-2 is a novel virus and new research is published frequently.

Table 3: Search summary table reporting the effectiveness of the search strategy

Project Title: A Scoping Review Protocol for point of care diagnostic services supply chain management systems: Optimising COVID-19 testing capacity in resource-limited settings
 Contributor Author:
 Document Title: Search Summary Table (SST)

Project - The effectiveness of a search strategy - Protocol Stage																
Included references	Format	Database searches (date run, date re-run)										Supplementary searches				
		d/b 1	d/b 2	d/b 3	d/b 4	d/b 5	d/b 6	d/b 7	d/b 8	d/b 9	d/b 10	fcs	bcs	hs	wss	org
Included ref 1																
Included ref 2																
Included ref 3																
Included ref 4																
Included ref 5																
Included ref 6																
Included ref 7																
Included ref 8																
Included ref 9																
No. included refs		0	0	0	0	0	0	0	0	0	0					
No. unique refs																
Total no. refs downloaded																
No. refs screened																
No. included refs																
No. unique refs																
Yield																
No. refs screened																
Sensitivity		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#VALUE!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!					
Precision		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!					
No. database searches carried out =																
Sum of yields =																
No. refs screened at Ti&Ab =																
No. refs screened at FT =																
No. of included refs from searching =																
Total no. of included refs =																

<p>Codes</p> <p>x = found from the search</p> <p>y = in database; found when search strategy re-run</p> <p>n = not in the database</p> <p>z = in the database; not found using the search strategy</p> <p>(red) = databases where searches re-run</p>	<p>Format codes</p> <p>jnl = journal article</p> <p>ths = PhD thesis</p>	<p>Other codes</p> <p>NNR = number needed to read. 1/overall precision</p> <p>NNR FT = number needed to read at FT to find one included reference</p> <p>NNS = number needed to screen to find one reference to include for FT screening</p> <p>FT = full text</p>	<p>Supplementary search codes</p> <p>fcs = forwards citation search</p> <p>bcs = backwards citation search</p> <p>hs = hand search</p> <p>wss = web site search</p> <p>org = from contacting organisation</p>
--	---	---	--

Selection of eligible studies

Relevant studies will be selected using the following criteria:

Inclusion 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 published since inception

Exclusion criteria

Articles will be excluded from the scoping review if they have the following characteristics:

- Articles that lack evidence on SCM systems for all POC diagnostics services
- Articles reporting SCM systems of laboratory based POC diagnosis
- Articles that do not report primary outcomes

All eligible studies will be exported to an Endnote 20 library and duplicates will be removed. The articles will be screened in two stages, namely abstract and full article screening. The PI will screen titles and abstracts in parallel with the co-reviewer. After screening titles and abstracts, the reviewers will discuss any discrepancies in selected articles until a consensus is reached. Two independent reviewers will then screen the full texts of articles selected during the first stage. A third screener will resolve any discrepancies in selected articles after full text screening. Both abstract and full article screening will be guided by the above inclusion/exclusion criteria.

The level of agreement between screeners' results after screening abstracts and full articles will be determined by calculating Cohen's kappa statistic. The kappa statistic will be 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. The process of study selection will be reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping review (PRISMA-ScR) flow chart as depicted in figure 1, and will be updated once the review process is completed (15).

Charting the data

We developed a data charting form to capture information from each relevant study as outlined in table 3. Two independent reviewers will pilot the data charting form before commencing with the scoping review. The data charting form will be modified based on the reviewers' feedback and it will constantly be updated throughout the duration of the scoping review.

Table 3

Data charting form

Author & year of publication
Publication journal
Title of study
Aim of study
Study population
Study setting
Sample size
Study design
Type of point-of-care test investigated
Main findings
Other significant findings

Collating, summarizing and reporting the results

We will summarise the relevant literature in a narrative report. We will extract data from all included studies and map evidence on SCM systems of POC diagnostics services, summarise existing research findings and reveal gaps in the existing literature. The results will be described in the form of a table and graphs. We will include a map showing the countries where the studies were conducted. A thematic summary will describe how the findings from the included studies relate to the research question.

Quality appraisal

We will use the mixed method appraisal tool (MMAT) version 2018 to evaluate the quality of the included studies (17). Two independent reviewers will carry out the quality appraisal process. The following percentage scores will be used to grade the quality of evidence: i) $\leq 50\%$ will represent low quality evidence ii) 51-75% will represent average quality evidence iii) 76-100% will represent high quality evidence. This quality appraisal method will enable us to appraise a variety of study methods, i.e. qualitative, quantitative or mixed methods studies (17).

Ethical considerations

This scoping review involves synthesis of current evidence therefore ethical approval is not required.

Discussion

To control the spread of SARS-CoV-2, governing bodies across the globe enforced travel restrictions to limit the movement of people (18). Policymakers have been working around the clock to ensure that supplies of essential medical equipment remain uninterrupted (18). To optimise the supply of essential medical equipment, efficient SCM operations are needed to ensure accessibility and availability of POC tests, especially since the WHO has encouraged all countries to scale up SARS-CoV-2 testing services. To ensure that all countries have enough supplies of SARS-CoV-2 POC tests, the WHO established the COVID-19 supply chain system (CSCS) that provides essential SARS-CoV-2 supplies to all countries (19). The CSCS coordinates multiple-channel procurement and distribution through the identification of demand, demand aggregation, forecasting, certification, market scanning, sourcing, allocation and delivery of essential supplies to where they are needed most at national and subnational level (19).

Managing SARS-CoV-2 requires accurate laboratory diagnosis and POC testing can supplement laboratory testing to boost testing capacity in resource-limited settings with poor laboratory infrastructure. In this scoping review, we will exclude all articles reporting SCM systems of laboratory diagnosis and focus solely on POC testing to provide a clear overview of the available research evidence. We will also exclude articles that do not report SCM systems of POC diagnostic services as this will not address the research question.

The proposed scoping review will collate global evidence on SCM systems of POC diagnostics services published since inception. We anticipate that the scoping review will provide a comprehensive insight on the evidence of SCM systems of POC diagnostics services globally and reveal research gaps. Our review will also guide implementation of SARS-CoV-2 POC diagnostics in resource-limited settings. The results will be published in a scientific journal, presented at relevant conferences and form part of workshops with key stakeholders involved in SCM systems for POC diagnostics services.

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

Declarations

Availability of data and materials

All data generated or analysed during this study will be included in the scoping review article.

Acknowledgements

The authors would like to extend their appreciation to Ninety-One SA (Pty) Ltd for paying tuition fees and providing a stipend for the PI, Dr. Cheryl Tosh for editing and the University of Pretoria Faculty of Health Sciences Library Services for their assistance with optimising the search strategy.

Funding

Not applicable

Contributions

KM conceptualised and wrote the draft protocol under the supervision of TMT. SM contributed to the development of the methodology. KB optimised the search strategy. KM prepared the draft manuscript, TMT, AM and TD critically reviewed it. All the authors contributed to the reviewed draft version of the manuscript and approved the final version.

Ethics declarations

Ethics approval and consent to participate

Ethics approval is not applicable for this scoping review protocol.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

References

1. Ricco M, Ferraro P, Gualerzi G, Ranzieri S, Henry BM, Said YB, et al. Point-of-Care Diagnostic Tests for Detecting SARS-CoV-2 Antibodies: A Systematic Review and Meta-Analysis of Real-World Data. *J Clin Med.* 2020;9(5).
2. Peeling RW, Mabey D. Point-of-care tests for diagnosing infections in the developing world. *Clin Microbiol Infect.* 2010;16(8):1062-9.

3. Tahamtan A, Ardebili A. Real-time RT-PCR in COVID-19 detection: issues affecting the results. *Expert Rev Mol Diagn.* 2020;20(5):453-4.
4. Arumugam A, Faron ML, Yu P, Markham C, Wu M, Wong S. A Rapid SARS-CoV-2 RT-PCR Assay for Low Resource Settings. *Diagnostics (Basel).* 2020;10(10).
5. Cheng MP, Papenburg J, Desjardins M, Kanjilal S, Quach C, Libman M, et al. Diagnostic Testing for Severe Acute Respiratory Syndrome-Related Coronavirus 2: A Narrative Review. *Ann Intern Med.* 2020;172(11):726-34.
6. Kuupiel D, Bawontuo V, Mashamba-Thompson TP. Improving the Accessibility and Efficiency of Point-of-Care Diagnostics Services in Low- and Middle-Income Countries: Lean and Agile Supply Chain Management. *Diagnostics (Basel).* 2017;7(4).
7. Diseases NfC. The use of antigen testing for diagnosis of SARS-CoV-2 in South Africa South Africa NICD; 2020 [
8. Lone SA, Ahmad A. COVID-19 pandemic - an African perspective. *Emerg Microbes Infect.* 2020;9(1):1300-8.
9. Peeling RW, Wedderburn CJ, Garcia PJ, Boeras D, Fongwen N, Nkengasong J, et al. Serology testing in the COVID-19 pandemic response. *The Lancet Infectious Diseases.* 2020;20(9):e245-e9.
10. Ravi N, Cortade DL, Ng E, Wang SX. Diagnostics for SARS-CoV-2 detection: A comprehensive review of the FDA-EUA COVID-19 testing landscape. *Biosens Bioelectron.* 2020;165:112454.
11. Pinna R, Carrus PP, Marras F. Emerging Trends in Healthcare Supply Chain Management – An Italian Experience. *Applications of Contemporary Management Approaches in Supply Chains*2015.
12. Francis JR. COVID-19: Implications for Supply Chain Management. *Front Health Serv Manage.* 2020;37(1):33-8.
13. Kuupiel D, Bawontuo V, Drain PK, Gwala N, Mashamba-Thompson TP. Supply chain management and accessibility to point-of-care testing in resource-limited settings: a systematic scoping review. *BMC Health Serv Res.* 2019;19(1):519.
14. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *International Journal of Social Research Methodology.* 2005;8(1):19-32.
15. McGowan J, Straus S, Moher D, Langlois EV, O'Brien KK, Horsley T, et al. Reporting scoping reviews-PRISMA ScR extension. *J Clin Epidemiol.* 2020;123:177-9.
16. Bethel AC, Rogers M, Abbott R. Use of a search summary table to improve systematic review search methods, results, and efficiency. *J Med Libr Assoc.* 2021;109(1):97-106.
17. Hong QN, Fàbregues S, Bartlett G, Boardman F, Cargo M, Dagenais P, et al. The Mixed Methods Appraisal Tool (MMAT) version 2018 for information professionals and researchers. *Education for Information.* 2018;34(4):285-91.
18. Illahi U, Mir MS. Maintaining efficient logistics and supply chain management operations during and after coronavirus (COVID-19) pandemic: learning from the past experiences. *Environ Dev Sustain.* 2021:1-22.

Figures

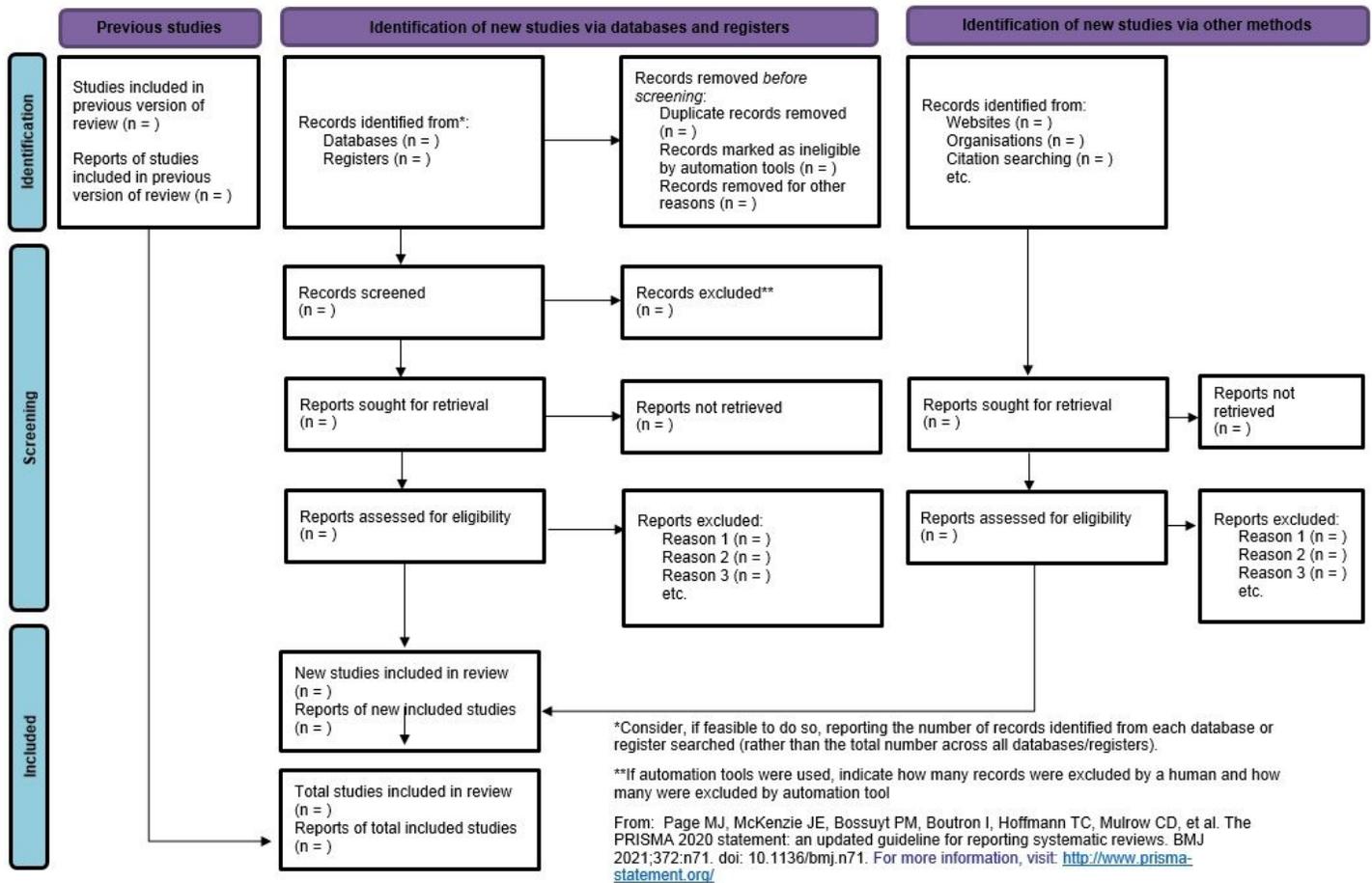


Figure 1

(PRISMA-ScR) flow chart

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [PRISMAPchecklistKuhlulaMaluleke.docx](#)