Protocol for Exploring Effective Clinical Governance Strategies in South Africa's Eastern Cape and Mpumalanga Provinces

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Study Protocol

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Abstract

Background: Hospitals are an integral part of the national health system. They provide a hub for health services that cannot be provided in the primary care setting, provide facilities for advanced investigation, diagnosis, and treatment, and constitute the platform for training and development of health professionals. However, when inspections were done at public sector facilities in preparation for the implementation of the NHI, the lowest average performance score was in leadership and corporate governance. This study aims to assess the effectiveness of clinical governance interventions in selected public hospitals in South Africa's Eastern Cape and Mpumalanga provinces.

Methods: This will be a cluster randomised study where there will be two intervention sites (a tertiary hospital and a regional hospital) and control sites (non-intervention central and regional hospitals). The intervention will comprise a focused implementation of clinical governance protocols (through training and coaching of hospital management and frontline health workers). There will be a pre-intervention baseline assessment; an assessment immediately at the end of the 12 months long intervention and an assessment at 36 months post-intervention. This builds on existing policy initiatives, quality improvement initiatives and tools. Information will be sourced through six sub-studies – three qualitative and three quantitative. Ethical clearance with reference number**: 040/21** has been granted by the Research Ethics Committee of the Faculty of Health Sciences at Walter Sisulu University. Approvals to access the research sites with refence numbers: **EC_202106_019** and **MP_202106_009** have been granted by the Eastern Cape and Mpumalanga Provincial Health Research Committees respectively.

Discussion: There is a need for a deeper understanding of how tertiary and regional hospitals operate, how these hospitals ensure provision of safe high-quality patient-centred clinical care and factors enabling them or hindering them from achieving higher performance. In addition, it is necessary to explore if the performance of the hospitals improves where there is a focused implementation of clinical governance protocols.

Background

South Africa's two-tier health system continues to face a quadruple burden of diseases, namely communicable diseases (HIV/AIDS epidemic and TB); non-communicable diseases; high maternal and child mortality; and high levels of violence and injuries (1,2). The current system is characterised by a chronically under-resourced public health sector, which serves more than 80% of the population and a highly resourced private health sector serving less than 20% of the population (3). The quadruple burden of diseases and chronic underfunding of the public health system impact negatively on access to quality hospital care, funding of hospital services, and general hospital performance (1,2). The launch of the White Paper on the National Health Insurance suggests major transformation of the health system to improve equity of access to quality health services (1).

A hospital is an important component of the health system, which accounts for a significant proportion of national health budgets (4–6). It is increasingly accepted that hospitals are a significant link in a complex continuum of care in which patients move between levels and types of care (7). They are central to building and maintaining healthy populations around the world. They often serve as the first point of access for acute care, offer access to specialist treatment, and influence standards for national health systems at large (8). Hospital policies determine access to specialist services and have a major impact on how healthcare is delivered in the national health system. A hospital should also be considered within the wider hospital network, within a country's health system, and within the broader socio-economic and political environment (4–6). The clinical teams who work in hospitals account for a significant contribution to clinical and professional leadership within any national health system (9). In addition, technological

advancements, pharmaceutical developments, research, and evidence-based healthcare demonstrate that hospital services make a significant contribution to population health (10). Improving the performance of hospital clinical staff and the hospital as an organisation is therefore critical in light of the role played by hospitals within the health system (11).

Of note, South African hospitals continue to show historical patterns in ownership and/or operation, funding, and distribution (11). For instance, public hospitals, especially central or quaternary, tertiary, and regional hospitals are largely concentrated in urban areas, and rural populations continue to depend on smaller district hospitals for hospital services (3). This is the major contributor to inequitable distribution of available hospital services, medical specialists, and district hospital beds (12). The inadvertent result of this is the persistent concentration of health professionals in urban areas and in upper levels of the health system, and chronic understaffing of rural hospitals (3). This has meant that the rural provinces such as the Eastern Cape, North West, Mpumalanga, Limpopo and Northern Cape have underdeveloped hospital services, fewer health professionals and beds for the populations they serve, inadequate access to quality specialist hospital services and generally poor health outcomes (7). The underdevelopment of hospital services and chronic shortage of health professionals inevitably affects development of hospital support services in management, operations, administration, and clinical support (13). In addition, the poor quality of hospital services, leadership and management inevitably contributes to the underdevelopment of primary care services (13). The audit of health facilities conducted by the South African National Department of Health in 2011 (14) confirmed some of these findings in the public health sector. This audit demonstrated underperformance in key areas of clinical care delivery, namely; health technology (54%), pharmacy (48%), blood services (34%), laboratory (30%) and clinical management (46%). A study of clinical governance implementation in four district hospitals of the Eastern Cape, reported similar underperformance in clinical areas (15).

Public hospitals operate in an ever-changing complex environment. They implement their programmes within a difficult fiscal and policy framework. These hospitals must contend with the political context, resource allocation and priority setting by various provincial authorities (16). This has consequently affected planning, financing and development of hospital services, governance and management of hospitals, and allocation of hospital budgets (3). The fiscal federalism model where each of the nine (9) provincial health departments exercise their authority to manage their respective hospital service platforms has contributed to a lack of uniformity in hospital service delivery, hospital administration and quality of hospital care (17,18). According to the South African National Planning Commission, in spite of the delivery of health services and care of patients taking place at hospitals, hospital managers continue to lack the power to make decisions and manage effectively (14). In addition, health managers continue to demonstrate a lack of confidence in their competencies (14). There is a high need for further training and development in financial and human resource management, health-specific skills (e.g., clinical governance) and soft skills such as leading teams and change management (3).

South Africa is in the process of implementing the national health insurance (NHI) system, which seeks to provide universal high-quality healthcare for all South Africans regardless of their ability to pay (19). The NHI aims to ensure the right to health for all, entrench equity, fairness and social solidarity in our health system and improve efficiency and effectiveness of the health system to realise universal health coverage (UHC) (20). The phased implementation of the NHI is intended to ensure integrated health financing mechanisms that pool resources of the public and private health sectors under one national fund that will purchase quality health services for the benefit of all South Africans (1,20). In order to achieve UHC, there is a need to reform the health system to develop a robust healthcare provider network and address the persistent challenges in the health sector, including poor management, system inefficiency, poor quality, lack of accountability, and lapses in patient safety (1,20). Strengthening the effectiveness

of the health system provides the foundation upon which interventions to improve and sustain health outcomes can be built. The foundation of such a system includes a well-coordinated integrated primary care base, competent district hospitals, good access to first-line general specialist services (regional hospitals) and good access to first-level tertiary and central hospital services (21). These need to be further supported by functional preventative, promotion, rehabilitative, and palliative community-based health services (21,22). As part of the initial NHI preparatory work to improve health systems performance, interventions to improve service delivery and provision are being implemented at all levels of the health system (21). The focus areas of these interventions include improving the management of health facilities, strengthening infrastructure programme and procurement of equipment, health information systems and technology, the implementation of and compliance with national quality standards for health, and re-engineering of Primary Health Care.

The capacity to analyse, manage, and deliver quality hospital services is essential for the hospitals to be prepared to play a pivotal role in the NHI implementation (19). Hospitals meeting the defined standards will thus be classified as being ideal hospitals (23). Central to this is the capacity of hospitals to develop systems that support primary care including having efficient referral pathways, up-to-date clinical guidelines and standard operating procedures, outreach and support programmes, health promotion and rehabilitation programmes, development of hospital services in response to population needs, bringing needed specialist clinical services closer to where patients live, strengthen clinical leadership and management, and ensure hospital reform initiatives that improve equity, quality, efficiency and patient safety. As a result, the Health Systems Enablement and Innovation Unit in South Africa proposes an intervention whose primary purpose is to generate knowledge and build capacity in public hospitals, clinical management systems, hospital services and governance in health as the country prepares itself for the national health insurance. There is a need for a deeper understanding of how tertiary and regional hospitals operate, how these hospitals ensure provision of safe high-quality patient-centred clinical care and factors enabling them or hindering them from achieving higher performance. In addition, it is necessary to explore if the performance of the hospitals improves where there is a focused implementation of clinical governance protocols.

This study aims to determine the effectiveness of selected clinical governance interventions in four public hospitals in South Africa's Eastern Cape and Mpumalanga provinces. Specifically, this study seeks to answer the following research questions:

- What are the key clinical governance areas and factors that should be considered when strengthening the hospital's capacity to perform?
- What is the baseline clinical governance performance in selected regional, central, and tertiary public hospitals in South Africa's Eastern Cape and Mpumalanga provinces?
- Do clinical governance interventions change the performance of the selected intervention hospitals on selected clinical governance indicators?
- How have hospitals adapted their clinical governance protocols during the covid-19 pandemic?

Methods

Aim

The aim is to determine the effectiveness of selected clinical governance interventions in four public hospitals in South Africa's Eastern Cape and Mpumalanga provinces.

Study design

This will be an applied multi-methods cluster randomised study characterised by co-design of the intervention with the participants. The design allows for the study to be kept iterative thereby allowing for modifications to be made throughout the study to incorporate new insights. Pre-intervention baseline assessment of clinical governance performance, documents review, interview of key informants and focus groups will produce findings that will form the fundamental pillars of the intervention, which will be co-designed with the involvement of hospital management, clinicians, frontline health workers, hospital boards and organised labour. This design process will draw from hospital experience, experience of the researcher and performance on a set of clinical governance indicators, guidance from the World Health Organization (WHO) and international literature.

Information will be sourced through a multi-method approach of six sub-studies comprising of three phases: a baseline, 12-months long intervention with an assessment at the end, and assessment at 36 months. The six sub-studies will be three quantitative studies and three qualitative studies. The quantitative studies will be conducted at baseline, 12- months, and 36-months, while the qualitative studies will only be conducted at baseline and 36 months.

The intervention entails the co-design of 8 carefully selected clinical governance protocols with two of the four hospitals for participants partaking in sub-studies 2 to 4. These protocols include complaints management protocol; patient safety incidents management protocol; infection prevention and control protocol; clinical auditing protocol; clinical guidelines protocol; clinical education and training protocol; and hospital governance protocol.

The research methods are summarised in Table1.

Study setting

The study is located in two rural provinces with a high degree of under-development and marginalisation, namely Eastern Cape and Mpumalanga provinces. A significant proportion of the population in these provinces live in rural areas (24). Most of the people rely on public health facilities for healthcare. Both provincial departments of health consist of a network of hospitals ranging from district hospitals to tertiary hospitals in Mpumalanga and up to a central hospital in the Eastern Cape province. Regional hospitals in these provinces are not developed enough to provide first-line general medical specialist services and do not have adequate capacity to provide reasonable access to specialist hospital care and thus do not protect tertiary and central hospitals from unnecessary referrals (25). Strong district hospitals and regional hospitals provide an important foundation for a sustainable referral network. Both provinces have developing tertiary hospital services, which provide tertiary care for a majority of the population in the public sector.

However, these hospitals have not yet reached their full potential. Based on anecdotal evidence, the Eastern Cape Province consistently demonstrates poor health outcomes despite significant interventions, strategies and investments made to strengthen the capacity of the health system to deliver quality health services. On the other hand, Mpumalanga Province demonstrates gradual improvement in health outcomes. In addition, an assessment of performance indicators amongst various district hospitals in the Eastern Cape and Mpumalanga provinces revealed differences in performance indicators between district hospitals of the provinces and within district hospitals of the same district. For example, in the OR Tambo Health District, performance assessments ranged from 4 to 11 days for average length of stay, 51 to 99 percent for bed utilisation rate, caesarean section rate ranging from 0.1 – 10 percent, a facility crude death rate ranging from 3-19 percent, a perinatal mortality rate ranging from 15-75 per 1000 live births, stillbirth rate ranging from 14-39 percent and costs per patient day equivalent ranging from a high of R3

398 to a low of R900 (26). The study setting is four hospitals: two in the Eastern Cape Province (a central and a regional hospital), and two in Mpumalanga Province (a tertiary and a regional hospital).

Population and Sampling

The purposive sampling technique was used to select the study hospitals. The hospitals were selected based on their levels of care, gazetted specialist package of care and concerns about hospital performance. The four hospitals have also been prioritised by respective provincial health management for improved service package, improved patient experience, reduction of user complaints and improved health outcomes. The central and tertiary hospitals will be placed in a separate pot from the two regional hospitals. One hospital will be drawn from each of the two pots to select the intervention hospitals. The hospitals that will remain undrawn from the pots will be non-intervention (control) sites.

A triangulation of approaches will be used to select study participants from the four hospitals.

Sub-study 1: Qualitative in-depth interviews (corporate management)

All hospital board chairpersons, CEOs, corporate services managers, and provincial representatives who oversee clinical governance activities will be recruited into the study to participate in individual semi-structured in-depth interviews. Sixteen individuals are therefore expected to participate in this part of the study.

Sub-study 2: Qualitative in-depth interviews using a Delphi technique (clinical management)

All clinical managers, quality assurance managers and nursing services managers will be recruited to participate as experts in this aspect of the study from each of the four hospitals. The number of participants will depend on the number of staff in each hospital as some hospitals have one and others three clinical managers and nursing managers.

Sub-study 3: Qualitative Focus Group Discussions (division heads)

All Heads of clinical Department (HODs), Operational Managers (OM) and Clinical Support and Allied health managers will be recruited to participate in focus group discussions. Identified participants will be randomly assigned to a focus group based on a plan to have a maximum of 5 focus groups per hospital. Each focus group will initially be assigned 4 participants and increased by one participant until saturation.

Sub-study 4: Quantitative cohort study (clinical staff)

Stratified random sampling of clinical staff will be undertaken to recruit medical doctors, nursing staff, dentists, pharmacists, and allied health professionals through a three-stage process.

First: a total combined sample size for all four hospitals will be calculated using the equation, $n = \frac{p(100-p)z^2}{d^2}$ for a one-sided 95% confidence interval and a 5% significance level (z=1.96). Because the proportion (p) of clinical governance information available is not known, this (p) will be set at 50% and the desired precision (d) will be set at 4%. This thus yields a total minimum sample size of 600. To factor for data entry errors and loss-to-follow-up a further 20% (120) will be added to yield a desired sample size of 720 participants for all four sites.

Second: the clinical staff from the four hospitals as of 25 March 2021 were added together to provide the total population size (N = 2492), wherein hospital 1 = h1 (712); hospital 2 = h2 (480); hospital 3 = h3 (900); and hospital 4

= h4 (400). The weighted hospital sample size was calculated based on the equation, $sample_{hy} = \frac{hy}{N}\ x\ 720$ where y is the value 1 to 4 depending on the hospital being calculated.

Third: clinical staff will be allocated into strata based on their profession. This will thus allow for a calculation of the strata specific sample per hospital. The calculation will be similar to that of calculating the hospital specific sample as above. Table 2 summarises the required samples for each of the hospitals.

Sub-study 5: Quantitative cross-sectional study (end- users)

Systematic random sampling of patients attending the outpatient's department will be conducted by approaching every 5th patient in the queue until the sampling size has been reached. A total combined sample size for all four hospitals will be calculated using the equation, $n = \frac{p(100-p)z^2}{d^2}$ for a one-sided 95% confidence interval and a 5% significance level (z=1.96). Because the proportion (p) of patients who are either satisfied or not satisfied with the quality of care received is not known, this (p) will be set at 50% and the desired precision (d) will be set at 4%. This thus yields a total minimum sample size of 600. To factor for data entry errors a further 10% (60) will be added to yield a desired sample size of 660 participants for all four sites. Participants will then be recruited proportionally to yield a sample size of 165 end-user participants per site.

Sub-study 6: Quantitative cross-sectional study (document review)

Information will be extracted from all documents with hospital plans, protocols, reports, and meeting minutes related to clinical governance for the most recent 12-month period. Five clinical records will be randomly sampled for each clinical department. Out of these clinical records, five will be randomly sampled to respond to the questions on the extraction tool. For discipline specific questions, the five clinical records from that clinical department will be used.

Measurements

Description of measurements

A multi-method approach to data collection will be adopted to get a comprehensive picture of the study before and after the intervention, to also compensate for the potential limitations of a single data collection method and to triangulate the data as a means of checking the consistency of the study findings.

Sub-study 1: Qualitative in-depth interviews (corporate management)

An in-depth interview guide (Appendix A) will be used for collecting data from the corporate management of the hospitals. The in-depth interviews will be conducted to solicit important perceptual information from the participants in their own words. The aim of the key informant interview is to probe understanding and beliefs about the intervention through the eyes of the hospital management and provide in-depth descriptive information to enhance our understanding of the ways in which respondents construct their understanding of the intervention. The use of an interview guide will allow for probing of topics that can be difficult to engage adequately in a structured questionnaire. This instrument asks questions on: Hospital challenges; Understanding of hospital performance; Indicators of hospital performance; Understanding of clinical governance; Presence of clinical quality improvement or Clinical governance plan; Implementation of the clinical quality improvement or Clinical governance plan; Systems for implementing key clinical governance activities/clinical quality improvement activities in the hospital; Existing structures for enforcing the implementation of clinical governance activities/clinical quality improvement

activities; Barriers and facilitators to implementation of clinical governance/clinical quality improvement activities. With permission from the participant, an audio recorder will be used to capture the interview. In addition to the audio recorder, a notebook will be used to capture the discussions. In-depth interviews will only be conducted at baseline and at 36 months.

Sub-study 2: Qualitative in-depth interviews (clinical management)

A Delphi technique will be used for collecting data from the clinical management of the hospitals. The Delphi technique has an inherent ability of being a forecasting process framework. In this instance, the researchers are interested in establishing clinical management views on how they foresee clinical governance in future. The Delphi technique will be employed to solicit expert opinion about key areas and factors to be considered to strengthen hospital's capacity to perform. Additionally, this approach will allow for probing understanding and beliefs about the intervention through the eyes of the hospital management and provide in-depth descriptive information to enhance our understanding of the ways in which respondents construct their understanding of the intervention. The in-depth interview guide (Appendix B) questions will be used for this process. The use of an interview guide will allow for probing of topics that can be difficult to engage adequately in a structured questionnaire. This instrument asks questions on: Hospital challenges; Understanding of hospital performance; Indicators of hospital performance; Understanding of clinical governance; Presence of clinical quality improvement or clinical governance plan; Implementation of the clinical quality improvement or clinical governance plan; Systems for implementing key clinical governance activities/clinical quality improvement activities in the hospital; Existing structures for enforcing the implementation of clinical governance activities/clinical quality improvement activities; Barriers and facilitators to implementation of clinical governance/clinical quality improvement activities; and adaptation of clinical governance protocols during the covid-19 pandemic. With permission from the participant, an audio recorder will be used to capture the interview. In addition to the audio recorder, a notebook will be used to capture the discussions. The Delphi technique collection will only be conducted at baseline and at 36 months.

Sub-study 3: Qualitative Focus Group Discussions (division heads)

The main aim for conducting focus group discussions is to provide for group interactions that will reveal common experiences amongst clinical staff and frontline health workers about the intervention. This will help us get a perspective of what is happening on the ground as against what is ought to happen. A focus group interview guide (Appendix C) will be used to guide focus group discussions so that topics that can be difficult to engage adequately in a structured questionnaire can be probed. This instrument asks questions on: Hospital challenges; Understanding of hospital performance; Indicators of hospital performance; Understanding of clinical governance; Presence of clinical quality improvement or clinical governance plan; Implementation of the clinical quality improvement or clinical governance plan; Systems for implementing key clinical governance activities/clinical quality improvement activities in the hospital; Existing structures for enforcing the implementation of clinical governance activities/clinical quality improvement activities; Barriers and facilitators to implementation of clinical governance/clinical quality improvement activities. The clinical governance management team will comprise of head of departments/divisions/units. An audio recorder will be used to capture the interview if permission has been granted by the participant. In addition to the audio recorder, a notebook will be used to capture the discussions. Focus groups will only be conducted at baseline and at 36 months.

Sub-study 4: Quantitative cohort study (clinical staff)

The main aim for conducting this survey is to quantify the views of general clinical and support staff in relation to the implementation of clinical governance in their respective hospitals. A validated structured questionnaire (Appendix D) consisting of questions on demographic data; governance and management; patient safety and leadership; clinical effectiveness; adverse events management; organisational culture; complaints management; clinical information monitoring; infection prevention and control; and performance management systems adopted from a study on assessment of clinical governance implementation study (15)will be used. Data will be solicited from ward-based clinical staff including pharmacy, dental and allied health professionals. This survey will be conducted at baseline, at 12 months, and at 36 months.

Sub-study 5: Quantitative cross-sectional study (end-users)

The aim of this survey is to get the user perspective. The general patient experience survey (Appendix E) used by the South African department of health will be adopted and used for collecting data. This instrument asks questions on biographical data; access to care; availability and use of medicines; patient safety; cleanliness; values and attitudes; waiting times and clinical audits. This questionnaire will be translated into local languages such as isiXhosa, siSwati, and isiZulu to accommodate participants who might not be comfortable with English. This survey will be conducted at baseline, at 12 months, and at 36 months.

Sub-study 6: Quantitative cross-sectional study (document review)

Document review (Appendix F) will be conducted in addition to the key informant interviews and focus group discussions. The main aim of the document review is to provide access to hospital documents with historic information which pre-dates the study and provide important context about official statements, policies, priorities, and strategies that can be compared to what is observed through primary data collection. During the review, the focus will be on official policy documents, strategic plans, annual operational plans, hospital reports and recent reviews of the performance of the hospitals to add weight and granularity to other sources of data. Relevant information will be extracted to give insight to research objectives. In addition, information from clinical records will be used to validate responses given during the interview of clinical staff. The review will be conducted at baseline, at 12 months, and at 36 months.

Biases, validity, and reliability

Potential biases include power imbalances between researcher and patient, where a patient's voice may be suppressed, interviewer bias, selection bias and measurement bias. All those who will be involved in the collection of data will undergo similar training to ensure standardisation. All data collection instruments will be standardised and validated to ensure reliability. Tools will be piloted in one regional hospital each in Eastern Cape and Mpumalanga provinces, thereafter all necessary adjustments to the tools will be made.

Data analysis

Qualitative data (key informant interviews and focus group discussions) will be analysed looking for the meaningful and symbolic content of data collected using NVIVO version 12. This will be achieved through a process of inductive analysis of qualitative data to allow research findings to emerge from the dominant themes derived from the raw data (27). Emerging findings will be summarised in descriptive words, phrases, themes, or patterns to assist in the understanding and interpretation of emerging themes. Analysed data will be interpreted in the context of existing literature to show how it corroborates existing knowledge or bring new insights to the existing body of knowledge.

Post-hoc analysis will be undertaken for information arising out of the document reviews using prevailing themes. Quantitative data analysis will include capturing survey data into the Redcap software and exporting the data into STATA version 17 (STATA Corp, College Station, Texas, USA) for analysis. Some descriptive and categorical data will be compared using frequencies, percentages, and graphs. Numerical data will be explored for normality using the Shapiro-Wilk test. If normally distributed the mean, range and standard deviation will be used. If not normally distributed, then the median, and interquartile range (IQR) will be used. The Chi-squared or Fisher's exact tests will be used depending on the value of the expected frequencies. The level of statistical significance will be set at p-value $\leq$0.05. The 95% confidence interval will be used for the precision of estimates. The survey database will be used to perform descriptive analysis and examination of data for reliability and validity. The survey will be administered, in part, to triangulate and confirm the in-depth information gleaned from the interviews, document reviews and focus groups. The emerging findings from the qualitative data (key informant interviews and focus groups) and the quantitative findings from the survey data will be integrated to gain insight and deeper understanding of hospital performance and the intervention.

Ethical considerations and Dissemination

Ethical clearance with reference number**: 040/21** has been granted by the Research Ethics Committee of the Faculty of Health Sciences at Walter Sisulu University. The study has also received approval to access the research sites from the Eastern Cape and Mpumalanga Provincial Health Research Committees with refence number: **EC_202106_019** and **MP_202106_009** respectively. Entry to the study sites will be further negotiated with the hospital CEOs before data collection. The study will abide by the four ethical principles of autonomy, beneficence, non-maleficence, and justice.

Before commencement of all data collection, participants will be asked to sign an informed consent form including consent for the qualitative study interviews to be recorded. The consent forms will be explained in detail, including the purpose of the study, the objectives of the study, what is expected of a research participant and any risks and benefits that accrue from participating in the study. A provision will be made in the event that a study participant does not wish to be recorded, wherein a second researcher will always be at hand to take notes by hand. Participants will be informed that their participation in this study is voluntary and that their confidentiality will be maintained throughout the study. All research staff will always sign a confidentiality agreement, agreeing to maintain and protect participant confidentiality. Research staff taking the informed consent will provide study participants with all the necessary information they require to make an informed decision to participate and will allow time for any questions to be addressed prior to signing the consent. Participants will also be assured that they are free to withdraw at any stage of the study and could opt out of questions that they are not comfortable with without any adverse consequences. Furthermore, participants will also be assured that there is no risk posed by their participation in the study. Even though findings from this study will benefit the broader public through improvement in quality of healthcare, there won't be individual benefits or incentives for participating in this study. All identifying information will be removed including data on audiotape collected during one-on-one interviews/focus groups. Furthermore, audiotapes will be downloaded to a computer that will be locked with a password, after which the recorded information will be deleted from the tape recorder. Once the audiotape has been transcribed, the audio recording will be destroyed to ensure confidentiality. All electronic records will be accessed through a password encrypted database that only the principal investigator has access to.

There is a potential burden on clinical staff for taking time out from patient care to participate in a focus group discussion. Benefits include the interactions between the research team, hospital management, clinical staff, and

patients, who will provide the opportunity for introspection, reflection on own practice, and space to reflect on their roles as individual health professionals and as members of a healthcare team.

Finally, research findings will be communicated through several dissemination mechanisms including workshops or seminars to engage with the stakeholders, policy briefs, technical reports, and publication in peer-reviewed journals.

Discussion

To reiterate, in phase 2, this study will implement an intervention package of clinical governance protocols over a 12-month period. The intervention is summarised in Table 3.

Timeline of the project:

This research will be conducted over a period of 36 months in three phases: (1) Baseline assessment; (2) Intervention and (3) Sustainability monitoring and this is summarised in Figure 1.

Abbreviations

CEO- Chief Executive Officer

DOH- Department of Health

EC- Eastern Cape province

ECDOH- Eastern Cape Department of Health

MP- Mpumalanga province

NDOH- National Department of Health

NHI- National Health Insurance

UHC- Universal Health Coverage

WHO- World Health Organisation

HOD- Head of Department

OM- Operations Manager

IQR- Interquartile Range

Declarations

Ethics approval and consent to participate

Ethical clearance (**Ref: 040/21**) was sought from the Research Ethics Committee of the Faculty of Health Sciences at Walter Sisulu University. The study has also received approval to access the research sites from the Eastern Cape and Mpumalanga Provincial Health Research Committees with refence number: **EC_202106_019** and **MP_202106_009** respectively.

Consent for publication

Not applicable

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

Competing interests

The authors declare that they have no competing interests.

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Author contributions

WWC conceived the research, sourced funding, engaged stakeholders, completed the first draft of the manuscript, and jointly approved final draft. ORM edited and commented on versions of the manuscript and incorporated and addressed feedback from the co-authors, facilitated ethics and research access approvals. SAM and VE, joint senior authors, edited versions of the manuscript, provided methodological strategy, and jointly approved. DJH, LG, BS, NW, AMM, JSN, SP, KM, TM, MM, KM, PMPB, and GM edited versions of the manuscript.

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Authors' information

Authors are based in the following institutions: Health Systems Enablement and Innovation unit, University of the Witwatersrand, South Africa; Department of Public Health, Walter Sisulu University, South Africa; The George Institute for Global Health, University of New South Wales, Australia.

Footnotes

None

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Tables

Table1: Research methods summary (under study design sub-section)

Sub-study	Study design	Objectives	Analysis
1	Qualitative, individual in-depth interviews with corporate management	To assess their understanding of clinical governance and to understand about the systems in place to monitor implementation of good and up-to-date clinical governance practices.	Inductive analysis approach to interpret emerging themes.
2	Qualitative, individual in-depth interviews with clinical management using a Delphi technique	To assess the lived experiences of implementing clinical governance protocols, their utilities, monitoring and evaluation strategies, gaps and factors that need to be improved	Inductive analysis approach to interpret emerging themes.
3	Qualitative, focus group interviews	To provide for group interactions that will reveal common experiences amongst clinical staff	Inductive analysis approach to interpret emerging themes
4	Quantitative survey for general staff	To determine clinical governance practices implemented in the hospitals at baseline, 12 months, and 36 months.	• Frequency tables, percentages, and graphs to summarise categorical variables. • Mean, standard deviation and range to summarise normally distributed numerical variables. • Median and interquartile range to summarise skewed numerical variables. • Chi-squared statistics or Fisher's exact test to compare categorical variables between groups. • Parametric and/or non-parametric tests to compare numerical variables between groups.
5	Patient Experience of Care Survey	To determine end-user experiences on the quality of healthcare received, a patient care experience survey will be undertaken using a quantitative cross-sectional study.	
6	Baseline, 12-month, and 36 months document review	To compare information found in records with information reported by clinical staff on clinical governance practices in their respective hospitals.	

Table 2: Strata specific samples for study sites

Staff category	Rob Ferreira	Themba	NMAH	St Elizabeth
Nursing staff:				
Professional Nurse	77	52	97	43
Enrolled nurse	16	11	20	9
Enrolled Nursing assistant	46	31	58	26
Medical:				
Medical officers and Registrars	51	34	65	28
Dentists	2	1	2	1
Pharmacists	4	3	5	2
Allied health professionals	10	7	13	6
Total	206	139	260	115

Table 3: Summary of clinical governance intervention (under Discussion section)

Figures

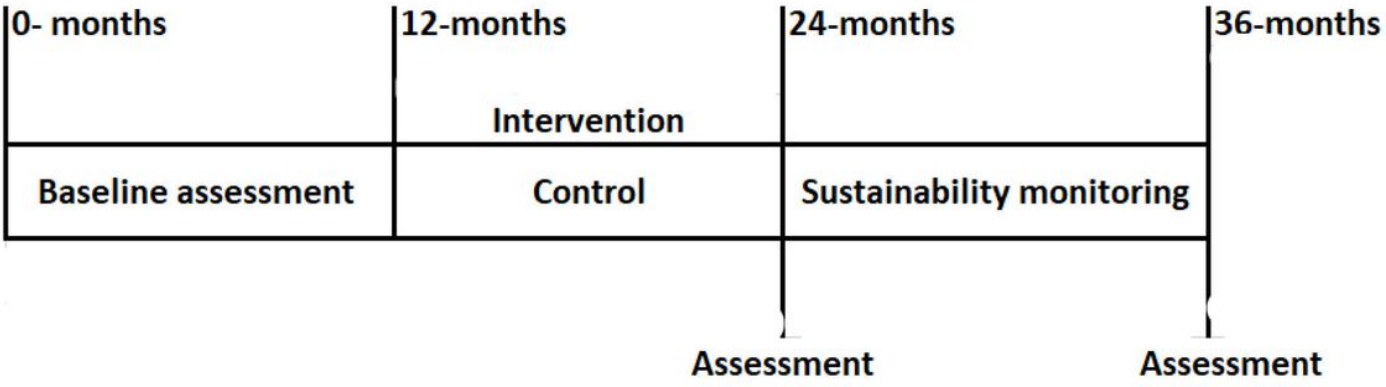

Figure 1

Project Timeline

Supplementary Files

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

- AppendixA.pdf
- AppendixBInterviewguide.pdf

Level	Protocols	Tools	Indicators of clinical governance performance (output indicators; outcome indicators)
Team	Introduce: • Ward rounds • Complaints management • Adverse events management • Folder/record reviews • In-service training • Infection prevention • Control and management • Policies and procedures	Introduce a clinical governance portfolio which will comprise of: • Team members • Maintenance record • Clinical governance programme for the year • Evidence-based practice • Projects and activities • User and carer projects • Compliments, complaints, and incidents • Education & Training • Away days and • Clinical governance information, policies, guidelines.	• Improved culture of accountability among health professionals • Percentage increase in training and development • Improved understanding of clinical governance among clinical staff
Department level	Use of clinical guidelines; Clinical Protocol discussions; Mortality & Morbidity Reviews; Clinical Training	Capacitate the clinical governance team/ committee through workshops and encourage in-service training Co-design context specific clinical governance SOPs/ protocols.	• Increased reporting of adverse events or • Percentage reduction in serious clinical events • Percentage reduction in complaints • Change in key hospital indicators.
Institutional/ organisational level	Clinical operations & care coordination (business status report); Clinical staff performance management system; Clinical governance committee/ Quality Improvement Plan Committee	• Design programmes to ensure accountability and monitor adherence • Provide adequate resources at all levels • All committees to meet at least twice in a quarter • Introduce hospital performance-based feedback sessions on key clinical governance indicators at least once in six months.	• Positive patient experience; • Positive staff experience; • Reduced harm/patient safety; • Improved clinical outcomes.

- AppendixCInterviewguide.pdf
- AppendixDquestionnaire.pdf
- AppendixEquestionnaire.pdf

- AppendixFquestionnaire.pdf