Communication and Collaboration

An exploration of Clinical Governance Interventions in the Western Cape Department of Health over the past Twenty Years

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Abstract

The tension between the increasing cost of healthcare provision and the need to provide a quality level of care to a rising number of people is a global phenomenon. A focus on one over the other could result in a rise in adverse patient outcomes, or a health system too costly to be sustainable. Clinical governance is an approach policymakers can use to walk the middle line of creating a healthcare service that meets quality of care standards in a cost-effective manner, as has been done in Australia, Burundi, Egypt, Spain, UK and Yemen (Goyet et al, 2019; Abd El Fatah et al, 2019, Mannion et al, 2015; Aguilar Martin et al, 2019).

This study examines the practice of clinical governance in one LMIC setting that has been able to successfully do this balancing walk for 20 years. Understanding how this was done in the Western Cape province of South Africa helps inform how clinical governance can be used to continue adding value as the health system moves towards universal healthcare.

A mixed methods qualitative design was used for data collection and involved three phases: (1) a document review of all policies in the province to identify clinical governance structures; (2) observation of these structures in action, comparing lived to written experience of clinical governance; and (3) interviews with key

stakeholders in the province to get their perspectives on past, present and future forms of clinical governance. The Donabedian model was used to frame analysis into three dimensions of care, viz. structure, process and outcome.

Beyond a comprehensive policy framework, collaborative structures and consultative leadership styles facilitated strengthened clinical governance. For example, clinical audits and M&E events become punitive and corrosive without communication and supportive relationships between colleagues. Family physicians have become the champions of clinical governance in a decentralized health system and when supported in this by policy and management, the quality of care in health systems thrive.

Clinical governance is an effective strategy or tool LMICs can use to ensure quality of care is maintained or improved upon, even in resource-challenged settings. But while some structures, processes and outcomes may be borrowed from other LMIC or HIC settings, these need to be contextualized to local conditions. Appropriate clinical governance champions need to be identified and given the appropriate mandate. Human relationships are key to the successful implementation of interventions of this nature and space needs to be created in policy for this to be cultivated.

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Abbreviations

AIDS - Autoimmune Deficiency Virus

C^2AIR^2 - Caring, Competence, Accountability, Innovation, Responsiveness & Respect

CEO - Chief Executive Officer

CG - Clinical Governance

CHC - Community Health Center

CNP - Clinical Nurse Practitioner

DMC - District Management Committee

FP - Family Physician

FPF - Family Physician Forum

HIC - High Income Country

HIV - Human Immunodeficiency Virus

HS - Health System

HSS - Health System Strengthening

GSA - Geographic Service Area

IT - Information Technology

KPI - Key Performance Indicator

LMICs - Low- and Middle-Income Countries

M&E - Monitoring and Evaluation

M&M - Morbidity and Mortality

MO - Medical Officer

NCS - National Core Standards

NDoH - National Department of Health

NHI - National Health Insurance

NHLS - National Health Laboratory Service

NHS - National Health Service

NQHS - National Quality Standards for Health

OHSC - Office of Health Standards Compliance

PC - Primary Care

PCGC - Provincial Clinical Governance Committee

PHC - Primary Health Care

PHCIS - Primary Health Care Information System

SA - South Africa

SCWG - Service Co-ordinating Working Group

TB - Tuberculosis

UH - Universal Healthcare

UHC - Universal Health Coverage

UNDP - United Nations Development Programme

UK - United Kingdom

WC - Western Cape

WholeSystSA - Whole System Change South Africa

WCDoH - Western Cape Department of Health

Contents

Part A: Dissertation Protocol

1. Introduction

South Africa has undergone a significant change process since achieving democracy in 1994 and continues to do so as evidenced by the recent activity in the political, economic and social spheres. This has been a deliberate process in the case of the public health system, where the design and engineering of the system has had to evolve to meet the growing expectations of a newly-enfranchised population.

While the vision of the future of the public health system is largely a unified one at national level, the way in which this is realised differs from province to province. It is up to the provincial Departments of Health to design, implement and evaluate how exactly change will occur on the ground to achieve this national vision. Looking at the differences in health outcomes between provinces twenty years later, it is apparent that not all provinces fared equally in improving the health status of their beneficiaries (Coovadia et al, 2009). The Western Cape stands out as one of the provinces that has been able to create sustainable and effective change. What makes the change process in this province different from what occurred elsewhere?

2. Background

Health systems are today recognized to be influential determinants of health (WholeSystSA, 2016). The ways in which they are designed, operated and financed can potentially create positive value for users, in the form of better health outcomes, enhanced system responsiveness, greater protection from social and financial risk for citizens and improved efficiency during service provision, as described in the WHO Health System Framework (WHO, 2007).

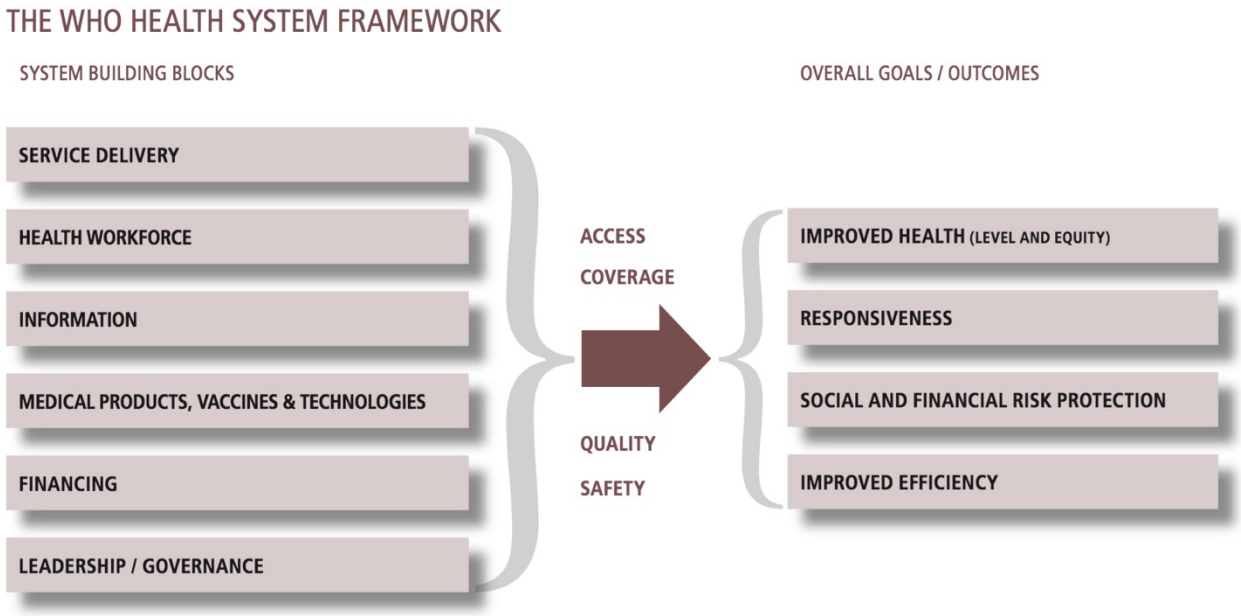


Diagram 1: WHO Health System Framework

"Leadership and governance" is a key building block in this framework, where the term is used to refer to the need for strategic goals, policies and plans that are sensitive to the needs of citizens; provide effective oversight, regulation and

accountability; and improve organisational capacity through the building of supportive coalitions and partnerships.

Bevir (2013), defines governance as "all processes of governing, whether undertaken by a government, market or network, whether over a family, tribe, formal or informal organisation or territory and whether through laws, norms, power or language." The focus is on **social practices and activities** that create value for stakeholders and how these are regulated, sustained and held accountable.

In the context of the health system, clinical governance is differentiated from corporate governance, where the former refers only to those aspects that affect the delivery of care to patients and the latter to other operational activities.

Clinical governance is a process first described in the United Kingdom (UK) in the late 1990's, as a form of quality assurance, developed in response to inadequacies identified in the scope and quality of service provision in the UK National Health Service (NHS) at the time. The pressure to contain costs through clinical budgeting, resource management and medical auditing activities grew and the application of quasi-market competition ideologies to the health sector eventually led to breaches in the ability of the health system to provide quality care to all citizens (Flynn, 2002).

A need was identified to establish and maintain the standard of care provided, while at the same time managing the costs thereof. Clinical governance soon became viewed as a tool that could be used to support the safe improvement of cost efficiency within the health system without disrupting the provision of care (Buetow and Roland, 1999; Ferguson and Lim, 2001).

But in a broader sense, clinical governance speaks to accountability for the quality and safety of healthcare. A 2013 review by Brennan and Flynn describes how its definition has evolved to now include:

1. **Processes** to continuously monitor and improve the quality of care
2. The creation of an **organisational culture** that supports safe, high-quality, patient-centered service provision
3. Broader **stakeholder involvement** in leadership and management processes
4. Increased **accountability** and responsibility for monitoring and oversight of clinical activities by stakeholders

Stakeholders may include politicians, regulators (e.g. governments and professional bodies), governors (e.g. boards of directors), internal and external auditors, managers, clinicians, academics, patients and members of the public.

Organisational culture in this study refers to "the way things are done around here" as a result of shared elements such as languages, ideologies, beliefs, values and rituals (Davies et al, 2007; Deal & Kennedy, 1982; Pettigrew, 1979; Prenestini et al, 2015). This bears a resemblance to Bevir's definition of governance in that it speaks to the intangible elements that make up the social practices within an organisation. Theories on how organisational culture is created and sustained differ between contexts and the purpose of the organisation or program, but most contain some form of top-down and/or bottom-up diffusion of the elements listed above.

In the case of organisational culture in the context of change management, the *upper echelons theory* proposes that the characteristics of top management strongly influence the attitudes and behaviors of personnel and the perspective of the organisation to strategic change. A health organisation, such as a private hospital group or a public health system, that undertakes to implement clinical governance practices as part of its program to maintain quality of care, commits to a change in the practice and scope of business which will impact on all strata of the organisation. Managing change in any organisation should be an active process if the desired outcomes are to be achieved with a degree of certainty. (Chaganti & Sambharya, 1987; Cameron, 1985; Gerowitz et al, 1996; Prenestini et al, 2015).

Gauld (2014) elaborates further on how a health system needs to adapt to changes brought on by clinical governance initiatives and the outcomes that can be achieved thereby. He found that systems that place clinical governance and leadership at the center of health policy observed significant improvements in performance across a range of cost and quality measures. In his opinion **health professionals** have the responsibility of both providing care and improving the system within which care is delivered, while **governing boards and managers** of health care organisations have the responsibility of ensuring both the quality of clinical service delivered and the financial sustainability of the facility or system. Key to the success of clinical governance initiatives is the migration of health professionals from clinical management to organisational management roles.

As clinicians step into the organisational world, this potentially creates tension between seemingly inconsolable cultures, leadership styles and priorities, with the medical world leaning towards autonomy in decision-making and prioritizing patient care and the organisational world towards some form of collaborative or removed decision-making and prioritizing organisational efficiency. Denis & Ross Baker (2015), describe these competing logics as a dichotomy that must be traversed if health systems are to remain effective and sustainable.

Flynn states in his paper Clinical Governance and Governmentality, 2002, that while the degree of self-determination, self-surveillance and self-management required by clinicians to regulate clinical practice may be an essential aspect of the management of health risks, this style of leadership and governance conflicts with conventional organisational governance practices. In the latter, decentralized responsibility and centralized, and often hierarchical, control over strategy, resources and priority-setting are the norm and this fails to create a culture that welcomes and supports the integration of clinicians into leadership and governance roles.

Conventional styles of governance, which may include quality assessment activities such as staff appraisals, quality audits and performance indicators, only serve to further extend formal centralized control and erode professional autonomy, while appearing to delegate and incorporate those charged with service delivery.

He believes that a governance system based on the principles of "soft bureaucracy" is more accommodating of the unique characteristics of clinician leaders and "achieves legitimacy among professionals in an entrepreneurial and decentralized organisation" while still functioning with the more rigid forms of externalized legitimacy required by a centralized corporate, political or health system.

"Soft bureaucracy" is a term used by Courpasson in 2000, to describe "managerial strategies which are oriented towards the construction of political centralization, where processes of flexibility and decentralization co-exist with more rigid constraints and structures of domination." He based this analysis on empirical studies into French political and business organisational structures.

His subsequent analysis of clinician-led organisations that had successfully transitioned through the policy change process found that systems of self-governance had evolved that contained characteristics drawing from both hard and soft organisational strategies, including:

1. Clear assignation of responsibility, especially in cases of failure
2. Orientation of behaviour by professionals to maintain their reputations
3. Adoption of standardised criteria for performance by professionals while initiating and influencing their definition to preserve a grey area around the definition of success or failure
4. The practice of some form of flexible cooperation, where control over autonomy is exchanged for recognition of expert effectiveness.

This last point in particular is contrasted by Courpasson against what he terms "hard bureaucracy" strategies, borrowed by managers from the corporate world, that try

to exercise control by instrumentalising success and failure (e.g. performance appraisal tools) and objectifying responsibility, removing room for human error in ways very similar to the conventional practices described by Flynn above.

"Soft bureaucracy" strategies build and sustain collaboration and partnerships between clinical and non-clinical stakeholders who share a common vision of improved health system performance. A shared vision in turn contributes towards the creation of a cohesive organisational culture that is more adaptable to policy change. The WHO, in its 2006 publication on quality of care, states that it is the connections and relationships between policy makers, health-service providers and communities and service users that facilitate clear definitions of roles and responsibilities and subsequently efficient implementation of clinical governance initiatives.

Prenestini et al. (2015), found that, in the context of the Italian health system, clinical governance was shaped by the rapport that exists between (clinical and non-clinical) members of the management team. In teams with a more cohesive rapport, a more positive outlook was observed towards clinical governance and the changes initiated in its pursuit, both within the team and in the organization at large.

They found that the creation of a supportive organisational culture that nurtures a shared perspective towards clinical governance among managers is an active process and calls for a series of active policy and management actions. The existing dominant culture needs to be identified, evaluated in terms of its ability to support new clinical governance policies and initiatives, and a change process initiated if it is found to be lacking. The future selection of top managers should also consider their leadership style and aptitude to grow and develop the appropriate culture. Existing managers and clinicians may require training to reinforce practices that are consistent with the desired organisational culture.

Viitanen et al. (2015), during their examination of hospital management teams in Norway, found that in teams composed of individuals with divergent cultural backgrounds, communication and the free flow of information were stressed as critically enabling factors towards the creation of a unified and effective organisational rapport or team culture. And importantly, definitions of information included both content relevant to the operations of individual teams within the organisation as well as content that helped create a big picture overview of the organisations goals and directives. This helped individual managers and teams locate themselves and their teams within the larger health organisation.

Lairumbi et al. (2012), in their review of clinical governance initiatives in high income settings, identified five additional factors that contribute to the success of clinical governance initiatives:

1. The perception of complexity of clinical governance initiatives and its indicators among stakeholders
2. The complexity of the system within which clinical governance is introduced, particularly in coordinating the differences in interests, power and influence of different stakeholders
3. The level of engagement among stakeholders and whether this encourages convergent or divergent organisational cultures
4. The level of engagement on the part of leadership to build connections between different stakeholders and create enthusiasm for, commitment to and engagement with clinical governance initiatives
5. Whether organisations include the establishment of trust - "to do the right thing" - as a core tenet of clinical governance policies instead of relying only on measurement.

While communication is not mentioned explicitly by Lairumbi at al. (2012) as a key factor, it is evident, as in Viitanen et al. (2015), that only with healthy and clear pathways of communication and collaboration between stakeholders will the

defined clinical governance initiatives be successful. Lazarus and France (2014) go further to position communication as a key enabler of all of the building blocks of the health system and not only leadership and governance, as demonstrated in their proposed adaptation of the WHO framework from diagram 2.

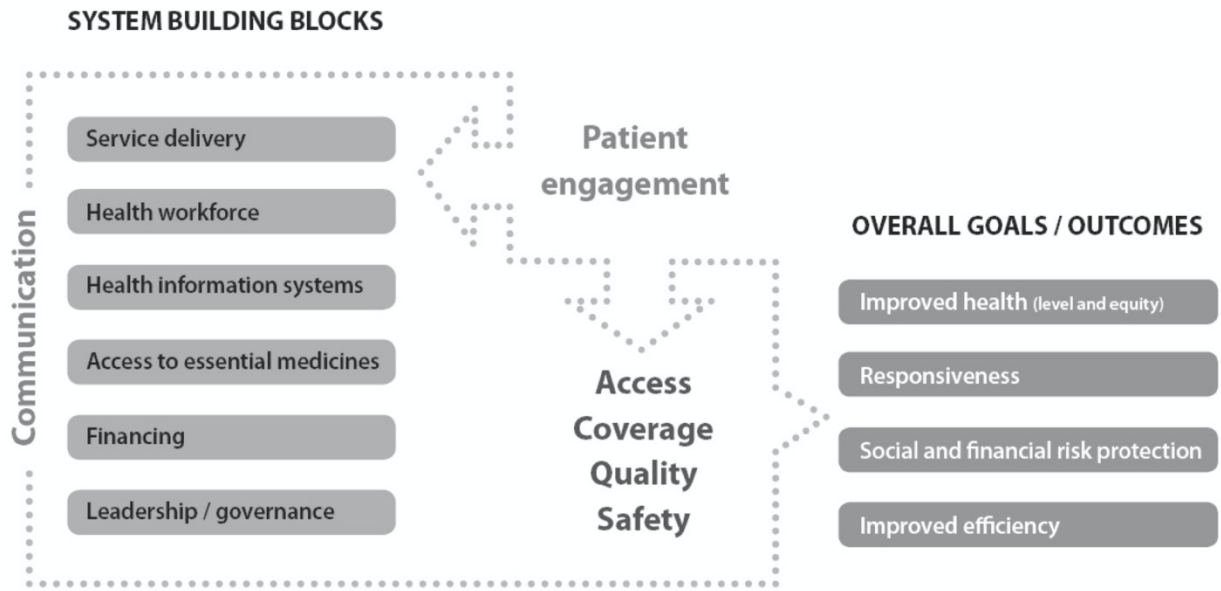


Diagram 2: WHO Health System Framework, adapted by Lazarus and French (2014)

Their definition of communication is broad, extending from the interpersonal to the digital, but the consensus is that this dimension is too influential not to be considered independently during any health system policy design or implementation process. (Lazarus & French, 2014). These are, after all, social practices in a health system setting, as described by Bevir (2013) above.

In the planning or evaluating clinical governance initiatives, public and private organisations around the world tend to rely on a handful of models to structure these processes, borrowing from broader governance literature (Siddiqi et al., 2008). These include the WHO's domains of stewardship, the Pan American Health Organisation's (PAHO) essential public health functions, the World Bank's six basic aspects of governance and the United Nations Development Programme (UNDP) principles of good governance. The last is used by the Western Cape Department of Health (WCDoH) to frame its clinical governance initiatives and includes the principles in table 1 (as described in Graham et al., 2003) and diagram 3.

Participatory	All men and women should have a voice in decision-making, either directly or through legitimate intermediate institutions that represent their intention. Such broad participation is built on freedom of association and speech, as well as capacities to participate constructively.
Consensus Oriented	Good governance mediates differing interests to reach a broad consensus on what is in the best interest of the group and, where possible, on policies and procedures.
Strategic Vision	Leaders and the public have a broad and long-term perspective on good governance and human development, along with a sense of what is needed for

	such development. There is also an understanding of the historical, cultural and social complexities in which that perspective is grounded.
Responsive	Institutions and processes try to serve all stakeholders.
Effective and Efficient	Processes and institutions produce results that meet needs while making the best use of resources.
Accountable	Decision-makers in government, the private sector and civil society organizations are accountable to the public, as well as to institutional stakeholders. This accountability differs depending on the organizations and whether the decision is internal or external.
Transparent	Transparency is built on the free flow of information. Processes, institutions and information are directly accessible to those concerned with them, and enough information is provided to understand and monitor them.
Equitable and Inclusive	All men and women have opportunities to improve or maintain their well- being.
Follows the Rule of Law	Legal frameworks should be fair and enforced impartially, particularly the laws on human rights.

Table 1: UNDP Principles of Good Governance (Graham et al, 2003)

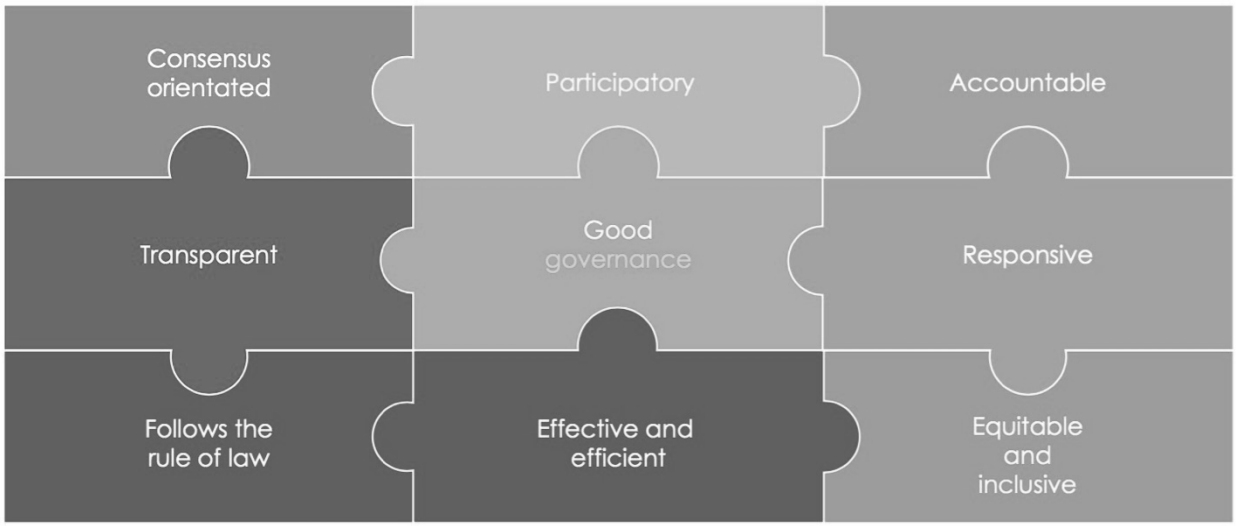


Diagram 3: UNDP Principles of Good Governance (WCDoH, 2014)

Health systems across the world, from national health systems in Ireland, New Zealand and Thailand, to privatized health systems such as the Kaiser Permanente or the Geisinger Health organisations in the USA (Denis & Forest, 2012), have adopted clinical governance policies as a means to circumscribe the potential risk to the quality and scope of patient care associated with efforts to improve the cost-effectiveness of service delivery and to ultimately strengthen the health system.

The systematic application of clinical governance initiatives has proven to strengthen the health system as a whole and not just impact on the elements of governance, quality and improved health (as laid out in the WHO model). In the UK, for example, the establishment of the National Service Framework and the NICE guidelines created a common set of standards all actors in the health system are

required to adhere and aspire to (Lairumbi et al., 2012). By clearly articulating policy and institutional arrangements, individual actors were more aware of how the desired changes impacted on their individual roles and responsibilities. This in turn had an impact on other building blocks and outcomes of health system strengthening activities, including levels of responsiveness, efficiency, service delivery and on the level of communication and cooperation within the health workforce in general.

Lairumbi et al., 2012, in their review of existing clinical governance initiatives in HICs, also found that successful clinical governance initiatives required active assessment and management of the power relations between various clinical and non-clinical actors, strengthened leadership to facilitate implementation and an awareness of the complexity of the health system in order to anticipate possible problems and promote more stakeholder engagement. These all rely on a healthy level of communication and similarly speak to broader strengthening of the health system.

While both high-income countries (HIC) and low- and middle-income countries (LMIC) run the gauntlet between providing quality service provision and maintaining cost-effectiveness, very little literature is published on how health systems in LMICs do so. This researcher found a 2015 primary survey of the Iranian

health system (Sadeghifar et al.) and a review of 16 case studies from LMIC settings on the role of governance in health workforce policy implementation (Dieleman et al.). The latter concluded that governance, while evident in its influence on health system change, was not explicit enough in policy and calls for more research "to better understand how governance influences…policy development and implementation." The former found that most policy documents made mention of clinical governance initiatives but that it was mostly formulaic and that there was a lack of appropriate mechanisms to monitor, evaluate and reflect on past experience.

This research will itself be located within a larger project, entitled WholeSystSA, which was a research project conducted by health systems researchers at the WCDoH, the University of Cape Town and the University of the Western Cape between 2015-2016. They sought to "understand the experience of health system transformation in the Western Cape" (WC) (*CHESAI* 2020). This project was inspired by the passing of twenty-two years since the end of apartheid and the question of how much had changed (in the context of the health system), especially for the most vulnerable and previously disadvantaged since the onset of democracy. (*UK Research and Innovation*, 2019)

Using a series of interviews, workshops and document review, WholeSystSA looked to identify enabling and constraining factors, including context, policies, processes and actors, within the WC health system that helped shape health system transformation in the province. This was done in order to better understand how past efforts gave rise to current achievements and how these may be used to inform future efforts to improve health care, the health system and the health of communities in both the Western Cape and broader South Africa. (Gilson et al, 2017)

The WC health system was chosen as the case province because of its reputation for having relatively effectively transitioned from serving the needs of the privileged during apartheid to serving the needs of the many in democratic South Africa. (*UK Research and Innovation*, 2019) Contrasting this against the national context provided new insights into HSS activities and support for future policy and management decision-making.

3. Research Focus

3.1. Research Problem

As health systems expand to meet the growing needs of a growing population, often without a comparable increase in budget, the tension between cost-effective service delivery and the quality of service delivery becomes more apparent and poses a clear risk to the beneficiaries of the system. Clinical governance initiatives have been described in the literature as one means by which this risk can be reduced. But how are these initiatives are designed in low- and middle-income countries (LMIC) for sustainability and efficacy is not adequately described in the literature.

Clinical governance has formed part of health system strengthening over the past 20 years in South Africa and particularly in the province of the Western Cape, a consequence of initiatives with explicit clinical governance goals or a result of the pursuit of other system strengthening goals. How these outcomes were achieved, sustained and integrated into the wider change process remains to be described.

3.2. Research Questions

1. How did clinical governance structures evolve within the Western Cape province over the past 20 years?

2. How are these clinical governance structures operationalized and governed?

3. What are the outcomes of clinical governance structures and what is their impact?

3.3. Research Aim

The WholeSystSA exploration of the activities of the WCDoH to strengthen its health system provide a valuable opportunity to observe clinical governance initiatives at play in-situ. It also provides an opportunity to observe them in a LMIC setting where health systems are particularly stressed by cost-cutting initiatives. The systemic challenges faced in the Western Cape are shared by other provinces within South Africa and other LMICs but the improvement in health indicators and service delivery differs to some degree.

This study makes use of the Donabedian model to frame the study on a macro level. This is a conceptual model that was first described by Avedis Donabedian, a physician and health services researcher from the USA, in 1966 and has since become the dominant paradigm used to examine governance and the practice of policy making in relation to health services and quality of care (Donabedian, 1988; McQuestion, 2006; McDonald et al, 2007). In the model, three *dimensions of care* are described, viz. structure, process and outcome, where:

1. Structure describes the organizational structure and legal/policy frameworks in place to facilitate an intervention.
2. Process denotes the relationships and flow of information between the structures, higher-level policy makers and lower-level managers, as well as between different stakeholders present within the structure itself.
3. Outcomes refer to the intended impact of the structure or intervention on key measures of performance (who defines these KPIs?).

This model is flexible enough to apply to the study of both the quality of healthcare within a single facility or a larger health system, as well as the underlying structure and process that lies upstream of service provision.

4. Research Methodology

4.1. Approach

Using the above framework, this study proposes to:

1. Describe the structure of clinical governance in the Western Cape, in terms of history and evolution.
2. Understand the process of how these structures are operationalized and governed
3. Assess and evaluate the outcomes of clinical governance initiatives.

By studying the clinical governance activities in this province as a case study, this research will add to the understanding of how clinical governance activities need to be adapted to the unique environment of the developing world, ultimately contributing towards strengthening the health systems in these provinces and countries and improving the health of its beneficiaries.

4.2. Data Collection

This study employs a flexible design and iterative and concomitant cycles of data collection and analysis allow subsequent phases of the study to be informed by earlier phases. Four phases of data collection are planned:

4.2.1. Phase 1 - Scoping Review

To begin with, a scoping review of publicly available provincial policy documents such as Healthcare 2030, annual performance plans, annual District Health Barometers and published literature will be conducted to establish the range of clinical governance initiatives that have been planned and/or actioned within the province. The minutes of already identified clinical governance initiatives, e.g. GSAs, will also be sought out and added to the data set. Analysis will follow thematic guidelines using terms including "clinical governance", "governance", "quality", "accountability", "communication" and "collaboration".

The WholeSystSA project has already conducted a comprehensive review of policy and planning documents, evaluation reports and research reports on the WC health system. This study will crosscheck its data set against the WholeSystSA review and

borrow from and build on that foundation with a specific focus on clinical governance.

There is a risk that the literature will not accurately describe or differentiate between contemporary and historical, theoretical and actual clinical governance initiatives. Should this scenario arise, the researcher may elect to begin with select key informant interviews, as described in Phase 3, during Phase 1 in order to improve his understanding of the policy and implementation environment. This will be conducted concomitantly to Phase 2 and continue into Phase 3.

4.2.2. Phase 2 - Group Observation

Once active clinical governance initiatives have been identified through the Phase 1 review, the researcher will seek to directly observe the activities of a sample of these initiatives, e.g. observing a GSA meeting, in-situ. The intention is to gather data through both observer note-taking, reflexivity journals and the use of video/audio transcripts to understand further the structure, process and outcomes of functioning clinical governance initiatives and to compare these with the plans for such activities laid out in the policies reviewed in Phase 1. The researcher acknowledges that legal and administrative guidelines may preclude the use recording devices and will be guided by WCDoH precedent.

While the activities selected to be observed will be limited by time and resources, the intention is to observe at least one initiative in the Cape Town Metro district and one outside this district, each at least on one occasion. Other less formal meetings will also be included to further understand the broader cultural perspective towards clinical governance, e.g. a regular meeting of specialist anaesthetists identified through personal networking. The researcher plans to triangulate these against the findings of the Phase 1 review to assess for differences based on location and positioning (local, district, provincial) within the health system.

Participant observation is a form of direct observation data collection whereby the researcher gathers data about the culture and behaviour of groups or individuals through passive, non-intervening, naturalistic observation (Zechmeister et al, 2009) but the researcher will eschew non-participatory in favor of passive participation because of the nature of the group structures – meetings take place in small office boardrooms where the researchers presence will be obvious and engagement to some degree with those being observed inevitable.

Passive participation calls for the researcher to play a bystander role as opposed to non-participation that calls for no contact with the population or field of study. Limitations may include difficulty establishing rapport or adequate immersion in the field (Spradley, 1980). The aim is to systematically record the behaviour and

activities of participants during clinical governance activities such as a GSA meeting to better understand the structure, process and outcomes of these activities as well as to understand the behaviour of individuals towards these activities.

Observer note taking and post-observation reflective journaling, along with potential transcripts of audio/video recordings, will be coded using a schedule created during the Phase 1 review and the results analyzed using a thematic approach. The findings of the transcripts will be triangulated with the reflective journal and observation notes as well as the findings of the Phase 1 review.

4.2.3. Phase 3 - Key Informant Interviews

The third level of exploration is a series of semi-structured interviews with key senior managers in the WCDoH, who will be initially purposively selected from those who participate in the clinical governance activities under observation in Phase 2 and stratified by position (provincial vs. district level, primary vs. tertiary care), work experience, background (administrative and clinical) and the type of clinical governance activity participated in (GSA vs. some other form of activity). Further interviewees will be recruited through a snowballing process. The target number of interviews is 20, more if time and resources allow, less if saturation is reached earlier.

The findings of the preceding two phases will be used to generate and frame an interview guide from whence the interview will set out, with the aim being to garner further insight into the structure, process and outcomes of clinical governance initiatives at play.

The interviews will take place in the offices of participants to facilitate ease of access and audio/video recordings will be made to aid with transcription, carried out by the researcher. Coding and analysis will also make use of analyses of previous phases of this study as well as the Donabedian model and the Competing Values. Participants will be offered the option to have their participation in this study anonymized during the consent process preceding the interview.

4.3. Data Analysis

Post-field work data analysis will be continuous and iterative, using the Donabedian framework described above to guide the process of data analysis after each phase of investigation. The findings of preceding phases will contribute to the methodology of subsequent phases, as described above.

Data will be coded using a code book developed during Phase 1 and added to during subsequent phases. Thematic analysis will be used to identify common

themes around clinical governance, organisational culture, quality control, accountability, communication and collaboration. The findings from the policy documents, which lay out what the WCDoH intends to do, will be compared to the findings of the observation and interview phases, which is what has actually manifested, and the difference between the two will be assessed in terms of how it has influenced the levels of quality and cost-efficiency within the WCDoH. Has the policy-implementation gap helped or hindered these outcomes? What are the important elements to hold on to from policy? What can be surrendered? What elements have not been described in the policy but has been essential to the realisation of the outcomes measured?

The data collection-analysis-data collection cycle will continue until information saturation has occurred and a greater understanding is gained about how clinical governance is planned into policy, how these activities are actioned, what organisational cultural norms surrounds these initiatives and the impact of these initiatives on quality control and broader organisational culture. Primarily, this research seeks to understand the role of implemented clinical governance initiatives in the WCDoH on levels of quality of care in the province but will also seek to identify potential linkages between these initiatives and cost-efficiency measures.

4.4. Data Management

The results of the Phase 1 survey, notes and transcripts from the Phase 2 observations, transcripts from the Phase 3 interviews and responses from the Phase 4 questionnaires will be in English and will collectively be accessible only to the researcher and senior WholeSystSA team members. The researcher will also act as data manager. This data set will be kept in safe storage by the researcher and backups will be made and stored in a second location. Original recordings/questionnaires will be destroyed once the study is complete to protect confidentiality, with only anonymous forms of the data set remaining for future analysis should the participant have elected to have his/her data anonymised during the consent process.

4.5. Reflexivity and Ethics

The researcher is a qualified medical doctor with 10 years of experience in the public and private health sectors of South Africa and the UK. This affords him the ability to identify with the needs and challenges faced by clinicians as they transition from the clinical to the administration spheres. He holds an MBA from the University of Cape Town where his focus was on leadership and governance. His knowledge of and experience in using qualitative research methodology to explore the

software issues of communication, relationships and change management in leadership structures in the health system will be useful in understanding the layers of interconnectivity and overlap inherent in the study of clinical governance initiatives in the WCDoH.

Informed consent for phases 2 and 3 will be sought from both the WCDoH and all individual participants at the beginning of each phase. Participation will be entirely voluntary. Participants will be given the opportunity to withdraw or have their contribution to the study transcripts removed at any stage of the study. No remuneration will be paid. Once provincial ethics approval has been granted there may be some degree of coercion present in getting employees of the WCDoH to participate because of employment contracts. This will be mitigated to some degree during the informed consent process.

At the beginning of each in-depth semi-structured interview a discussion will be held on the conditions for confidentiality and trust, and what would necessitate a breach of that confidentiality. The reasoning for recording the interviews need to be explained and criteria for when it would be possible to switch the equipment off will be shared at the onset of each interview. The data management protocol will be shared with participants. A similar process will be followed for observation of

clinical governance activities like the GSA meeting but will be guided by WCDoH protocol for researcher interaction with departmental procedures.

The intentions of the study will be expressed clearly and simply, in the language of choice, at each interaction with the study sample. The name and contact details of the researcher will be provided to the participants. Participants will be given the opportunity to withdraw at any stage of the study and will have access to avenues of discussion to address any problems or complaints they noted during their interaction with the study.

Feedback for each phase will be provided in the form of summated findings to participants of that phase in electronic format and if time and opportunity allows, these findings will be presented to the clinical governance groups/meetings the study has observed during Phase 2.

Ethical approval will be sought for this study through the ethics approval board of UCT as well as from the ethics structure of the WCDoH. Consideration has been given to the benefits and harms of the following identified affected parties:

1. Participants:

If adherence to the guidelines described in the Healthcare 2030 forms part of a manager's job description, admitting to deviations from them may lead to disciplinary repercussions, which may prejudice some participants against engaging with the research at all or being open about their or others' experiences. This will be mitigated by the ability to anonymize information gathered and will be offered to all participants.

There are no direct benefits to the participants. Indirect benefits include accruing insight into individual belief systems and obstacles to their relationship with clinical governance as well as the health system in general. This will ultimately lead to an improvement in organizational culture, and employee trust in the health system.

2. Researchers:

Benefits include successful completion of the study and helpful insights gained into clinical governance, policy implementation, and the role of communication and collaboration in health system strengthening. This may lead to further research or to policy. Insights garnered may also contribute to greater self-understanding in the

researchers leading to improved levels of interpersonal communication and collaboration. Other benefits may include career and academic opportunities.

4.6. Rigor

The principles of rigor will be applied as follows:

1. Purposive sampling is employed during all four phases of data collection.
2. The researcher undertakes to assess for and minimise observer bias through validating his findings from the phase 2 observation and data analysis processes with his research supervisor and the interviewees in phase 3.
3. During phase 3, interviews will be conducted in English as managers are required to have a working knowledge of the language to perform their duties. Should the researcher find that the interview findings are being compromised by the choice to conduct them in English, the interviewees will be offered the opportunity to respond in a language of their choice and the transcripts will be anonymised and translated before analysis.
4. Data sets are triangulated in terms of both data sources and data analysis. Findings from the qualitative review will frame and inform the subsequent qualitative group observations and interview processes. Findings from the document review framed and informed the subsequent qualitative

observation and interview processes. The findings of the qualitative interview phase were used to interpret and add context to the results of the document review and observation phases. Theoretical triangulation is also employed during analysis to support rigor and credibility.

5. Limitations of Study Methodology

The researchers clinical background may bias him as he seeks to understand the nature of the relationship between clinicians and administrators in clinical governance activities. This may also influence the willingness of clinician or non-clinician participants to share information. This will need to be considered during analysis.

His positivist education may bias his analysis of the data and the subsequent application of the use of theory in creating understanding from it. This will be mitigated to some degree by his more relativist personal philosophy.

The study is largely reliant on theory developed in HIC and largely takes place in urban environments. The implementation of clinical governance policies is contextual and the influence of LMIC and non-urban settings on outcomes will need to be considered during analysis. The attempt to include at least one clinical

governance activity from outside the Cape Metro district, should time allow, attempts to mitigate this to some degree.

6. Dissemination

A summary of the findings of this study will be electronically shared with all participants of this study. Feedback will also be provided in the form of a presentation to the clinical governance groups, forums and meetings identified and observed during Phase 2 as well as to managers and policy makers to facilitate ease of understanding. This will be done by reporting the findings of the thematic analysis as well as a detailed audit trail to ensure reliable and verifiable reporting. The aim of this form of dissemination will be to inform future policy design around clinical governance and organisational culture and to inform managerial decisions in practice. The study design and results will also be documented in a series of journal-ready articles for submission to a range of local and international peer-reviewed journals, including Health Policy and Planning, Journal of Public Health Policy, BMJ Quality and Safety, Journal of Health Economics, the International Journal for Quality in Health Care and Health Policy.

7. Timeline

Stage	Month					
	1	2	3	4	5	6
Phase 1 *Review*						
Phase 2 *Observe*						
Phase 3 *Interview*						
Phase 4 *Analyse*						

Part B: Literature Review

Topic: Clinical Governance as a tool for Health System Strengthening in LMICs

1. Introduction and Objectives

The objective of this literature review is to explore the definition and meaning assigned to the terms "Clinical Governance" (CG) and "Heath System Strengthening" (HSS) in contemporary literature and to examine the intersection of the two, particularly in low- and middle-income countries (LMICs). The researcher is looking to understand the value CG can add to HSS activities, especially in primary care (PC) settings.

This review is intended to inform primary research conducted by the researcher, evaluating 22 years (1994 - 2016) of CG policy and action in the Western Cape Provincial Department of Health (WCDoH) in South Africa. This research is itself located within a larger project, entitled WholeSystSA, which sought to "understand the experience of health system transformation in the Western Cape" (WC) (*CHESAI* 2020).

This researcher seeks to understand the role CG played in this transformation process and how it can be used to further support HSS activities in the future. He interviewed key actors in the WCDoH on the topic of CG policy and implementation, observed CG in action and reviewed past WCDoH policies. The results of his empirical research follow in Part C of this dissertation.

Understanding CG as a tool in HSS in LMICs is particularly important now as the South African health system navigates the process of implementing Universal Health Coverage (UHC) and the adoption of a unified National Health Insurance (NHI) financing model - a significant change from the two-tiered public- and private-model currently at play (*Health Policy Project*, 2016). In the published NHI White Paper, the South African government places CG at the core of both (1) improving and maintaining the quality of care to citizens, (2) the selection of service providers and (3) the bouquet of services covered (The Republic of South Africa, 2017).

Regarding the selection of service providers, the NHI White Paper specifically states that individual health care service providers will be assessed against indicators of clinical governance, in place of perceived quality of service assessments, to determine their eligibility for accreditation by the NHI Fund and thus participate in the health care provision marketplace.

Health care facilities will also have to meet a set of quality improvement initiatives in order to retain the ability to provide services to patients. These are documented in the National Quality Standards for Health (NQHS) (*PHISA*, 2019), where "Patient Safety, Clinical Governance and Care" is described as one of seven core domains, with "Patient Rights," "Clinical Support Services," "Public Health," "Leadership and Corporate Governance," "Operational Management" and "Facilities and Infrastructure" being the other six. The NHI White Paper calls for the Office of Health Standards Compliance (OHSC) to continue its role of health facility accreditation and monitoring but using this new tool to assess facilities against.

The bouquet of services offered will also have to adapt to the merger of public and private sectors, with further focus on building a stronger primary health care (PHC) service that covers all citizens. In the current private sector, patients are routinely over-serviced, e.g. c-section rates of 68% in the private sector compared to 18% in the public sector. The NHI White Paper speaks to using CG protocols and population data to help determine the bouquet of services matched to the needs of the community being served.

CG is set to become a key element of the envisaged integrated health system and a determinant of its success. The better policy makers, clinicians and administrators within the health system understand what CG means and how to utilize it, the better

prepared they will be to ensure a stronger, more accountable and more responsive health system is realized.

2. Literature Search Strategy

This review takes the form of a rapid scoping review, which shares components with a systematic review but is simplified to allow the review to be conducted in a timely manner. (Tricco et al, 2017). It is a form of knowledge synthesis that can be used to examine a broad range of literature and identify gaps and opportunities for further research (Arksey and O'Malley, 2005).

The review began with a search of Google Scholar, EbscoHost and PubMed as the three primary electronic platforms for gathering published literature. Both empirical research, reviews and commentaries were included.

Limitations included articles published in English only and between 2010 and 2019, unless particularly relevant literature fell outside of this search period. This time period was initially selected to allow for the most recent arguments presented in published literature to be identified and considered. But this was not fixed, particularly where an area needed further investigation and this was only supported

through engaging with literature/documents published before 2010. Policy documents from the WCDoH from pre-2010 were included in this research.

Articles were screened by title and abstract during initial selection and assessment for selection bias was conducted by the researcher at this stage. Full-text screening was conducted at a second occasion before inclusion in the cohort for this review. A limitation is the absence of a second researcher to review the selected articles independently for bias.

Key inclusion terms used included the following:

- Clinical Governance
- Health System*
- LMIC*

* signifies that in addition to the search including references to "health system" and "LMIC", it also included permutations beginning with the term in inverted commas and ending with an additional word or phrase. For example, this search included "health system strengthening", "health system research" and "health system policy and research."

This review serves to inform research being conducted in South Africa - a LMIC with a unique set of characteristics not shared by non-LMIC countries. Much of the work on CG comes out of the UK and USA. Therefore LMIC* was a term used to refine the search for articles most appropriate to this review. However, this is still a comparatively under-researched area and articles from outside the LMIC setting were also considered when necessary to add depth to the understanding of the role of CG in HSS.

CG and HSS are also two fields of research with growing bodies of work but it is the intersection between these two that is of interest in this review and this results in a further limitation to the number of documents available to the researcher.

A secondary selection process involved the "backward" and "forward" approach recommended by Wester & Watson, 2002, where the citations of the articles selected above were also evaluated for pertinent articles to include in this review.

Finally, a broader Google search was conducted to identify grey literature, including the WCDoH website for policy documents, annual reviews and other published material. The search for additional literature was stopped once the researcher had exhausted the databases for publications.

3. Summary and Interpretation of the Literature

3.1. What is Clinical Governance?

Scally and Donaldson, in the context of the United Kingdom (UK) National Health Service (NHS), describe CG as "*a framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish*." (*Healthcare Improvement Scotland*, 2018; Macfarlane, 2019; Halligan & Donaldson, 2001)

CG is differentiated from corporate governance, where the former refers to those aspects that affect the delivery and quality of care to patients and the latter to other operational activities that make the practitioner-patient interface possible.

The history of CG begins in the late 1980's, after a series of highly-publicised breaches in patient safety, most notably the Bristol Inquiry into children's heart surgery between 1984-1995 (*UK Department of Health*, 2001), which were put down to interplay between increases in patient numbers and their healthcare needs, increasing patient willingness and ability to communicate what they required from the health system, increasing healthcare costs and increasing medicolegal litigation

(Braithwaite & Travaglia, 2008). Reforms were required and CG and the idea of involving clinicians in quality reforms and clinical governance took root.

This began in the form of a non-legislated "medical audit" activity, self-administered by doctors working in the NHS, assessing the quality of their daily clinical practice (Background and overview of Clinical Governance, 2002). In 1993, "medical audits" were turned into "clinical audits" when it was realized that other practitioners besides doctors were involved in delivering clinical services, *e.g*. nurses.

While "clinical audit" activities were well funded and regularly undertaken in departments and facilities across the NHS, they remained non-legislated and there was no statutory obligation on practitioners or the facilities in which they worked to do anything to improve the quality of clinical care provided to patients. Problems were identified but little or no resources were allocated to correcting them.

This was largely due, at the time, to the competitive, free-market healthcare system at play, which in turn put the pressure on decision makers and clinicians to contain costs through clinical budgeting, clinically insensitive resource management and non-binding clinical auditing activities. This system was not driven by the desire to improve the quality of care and service to patients (Flynn, 2002).

But this changed in the late 1990's. Scally and Donaldson published their paper on CG in 1998, introducing the concepts of accountability and continuity to quality improvement activities. And in 1999, the new UK Labor government introduced the new Health Act, making quality of care a statutory responsibility of the management teams of facilities through their CEO, equal in importance to financial profitability, and using CG as the framework through which quality of care can be improved and maintained (Background and overview of Clinical Governance, 2002).

A 2013 review of CG literature by Brennan and Flynn expands on the original 1998 definition of CG, describing how it has evolved to now include:

1. **Processes** to continuously monitor and improve the quality of care,
2. The creation of an **organisational culture** that supports safe, high-quality, patient-centered service provision,
3. Broader **stakeholder involvement** in leadership and management processes,
4. Increased **accountability** and responsibility for monitoring and oversight of clinical activities by stakeholders.

Processes begin with the routine gathering of data through monitoring activities that are used to feed clinical indicator models tailored to the nature of the health system being observed - indicators used in the UK health system differ from those

used in more developing countries like Iran and South Africa (Azami-Aghdash et al, 2015). Trends in these indicators are then used to improve or maintain quality of care. However, processes extend beyond monitoring and evaluation of clinical "service provision" activities.

They include (1) creating and sharing job descriptions and responsibilities relating to CG activities with staff across the organisation, (2) managing CG-related knowledge and sharing information through open disclosure, (3) promoting evidence-based practice and continuous education, (4) managing practitioner experiences - risk exposure, note taking/reporting, performance reviews and adverse incidents, (5) managing patients experiences - informed consent, focus on patient safety, encouraging participation in the decision-making process and effective complaint management, and (6) ongoing accreditation of practitioners, facilities, clinical guidelines, technologies and operational processes that impact on clinical service delivery (Braithwaite & Travaglia, 2008).

Vanu Som, 2004, expands on the above by stating that all levels of a healthcare organisation need to be included in CG processes if improved healthcare service delivery is to be achieved. This ranges from front-of-house staff (e.g. receptionists and data capturers) to back-end staff (e.g. cleaning staff and catering staff), clinical service providers (nurses, doctors, etc.) to management (ward- and organisation-

tier management). Modern healthcare organisations are very complex and the greater the complexity, the greater the need for a coordinated, multi-disciplinary approach to improving the delivery of care.

This also speaks to the second and third points of Brennan and Flynn's definition, relating to *organisational culture* and *stakeholder involvement*. While Brennan and Flynn included the above-mentioned stakeholders from inside an organisation or healthcare facility in their definition of stakeholders, they extend their definition to include stakeholders from outside the organisation or facility. This may include politicians, regulators (e.g. governments and professional bodies), governors (e.g. boards of directors), internal and external auditors, academics, patients and members of the public - anyone impacted by, and/or with influence over, the way in which care is provided and the quality thereof.

With this many stakeholders involved, it is imperative that a unified approach to CG is shared, even if the specific responsibilities assigned to individual stakeholders differs in scope, practice and accountability. This is facilitated by a shared definition or understanding of CG and a shared organisational culture that fosters the common goal of safe, high-quality, patient-centered service provision.

Organisational culture in this study refers to "the way things are done around here" as a result of shared elements such as languages, ideologies, beliefs, values and rituals (Davies et al, 2007; Deal & Kennedy, 19823; Prenestini et al, 2015). This bears a resemblance to Bevir's (2013) broader definition of governance, which describes it as "all processes of governing, whether undertaken by a government, market or network, whether over a family, tribe, formal or informal organisation or territory and whether through laws, norms, power or language." The various stakeholder tiers in the Brennan and Flynn's definition mirror Bevir's list of spheres of influence in his governance model.

Bevir also speaks to the intangible elements that make up the social practices within an organisation, how these create value for stakeholders and how these are regulated, sustained and held accountable.

Theories on how organisational culture is created and sustained differ between contexts and the purpose of the organisation or program, but most contain some form of top-down and/or bottom-up diffusion of the shared elements described above. One such theory is the *upper echelons theory*, which proposes that the characteristics of top management strongly influence the attitudes and behaviors of personnel and the perspective of the organisation to strategic change. A health organisation, such as a private hospital group or a public health system, that

undertakes to implement clinical governance practices, as part of its program to improve and maintain quality of care, commits to a change in the practice and scope of business which will impact on all strata of the organisation. Managing change in any organisation should be an active process if the desired outcomes are to be achieved with a degree of certainty. (Chaganti & Sambharya, 1987; Cameron, 1985; Gerowitz et al, 1996; Prenestini et al, 2015).

Witter et al, 2019, through their review of HSS publications, show how engaging with stakeholders not traditionally included in a decision-making forum, e.g. civil participation, potentially has a positive impact on improvements in quality of care. The culture of an organisation or health facility extends beyond the employees within the organisation and the involvement of communities affected by changes in quality levels in creating a culture supportive of improved CG practices increases accountability within the organisation and helps improve patient expectations and satisfaction levels (West, 2001).

But how to move from the theoretical to the practical? How do organisations go about implementing CG policies? Vanu Som (2004) expands on this by applying a modified version of the Donabedian model to expand CG policy into the three dimensions of the model, *viz*. (1) Structure, (2) Process and (3) Outcome plus an additional dimension of (4) Input. The Donabedian model was first described in

1966 by Avedis Donabedian, a physician and health services researcher from the USA and has since become the pre-eminent model used to examine governance and the practice of policy making in relation to health service delivery and managing quality of care. (Donabedian, 1988; McQuestion, 2006; McDonald et al, 2007).

In the model, three *dimensions of care* are described, viz. structure, process and outcome, where:

1. Structure describes the organizational structure and legal/policy frameworks in place to facilitate an intervention.
2. Process denotes the relationships and flow of information between the different levels of management within an organisation, as well as between intra- and extra-organisation stakeholders.
3. Outcomes refer to the intended impact of the CG interventions on key measures of performance, as defined by the stakeholders involved.

This model is flexible enough to apply to the study of both the quality of healthcare within a single facility or a larger health system, as well as the underlying structure and process that lies upstream of service provision.

Table 1, below, displays the inputs, structures, processes and outcomes as described in the CG review by Vanu Som (2004) which serve as a starting point for stakeholders to consider when crafting CG policy and implementation strategies for their own organisations.

ORGANISATIONAL DIMENSION	**ELEMENTS**
INPUT	Financial resources (additional commitments, new investments)
	Infrastructure (new buildings, equipment, etc.)
	Human resources (creation of new posts: CG leads, new recruitment to fill vacancies)
	Policy (recognition of quality as statutory duty of the organisation)
	Latest information on evidence-based medicine
STRUCTURE	Clinical Governance Committee
	Performance management for total quality of care
	Protocols and guidelines for clinical care
	Education, training and Continuous Professional Development (CPD) strategies for staff
	Clinical audit
	System to integrate all quality activities
	CEO made accountable for quality in healthcare
	Clinical risk management strategies
	Reporting system for errors and adverse incidents
	System to receive patients' feedback
	Promoting evidence-based medicine
	Leadership development programme
PROCESS	Implementation, monitoring and evaluation of risk management
	Job descriptions to include quality as an individual responsibility

	IT training and access for use of latest electronic information
	Multi-disciplinary management of clinical care
	Recognition of human resource for quality improvement
	Regular multi-disciplinary clinical audit
	Sharing information, communication and co-ordination
	Systematic clinical supervision to deal with under performance
	Training to help health staff cope with their changing role in the organisation
	Promoting increased co-ordination among different professional groups
	Training to share information with patients, obtain patients' consent and understand the willingness of patients to participate in treatment
	Management of patients' information and safeguarding its confidentiality
	Systematic evaluation of clinical errors and adverse incidents
	Regular collection of data on clinical care
	Take prompt action on patients' feedback and complaints
OUTCOME	Continuous quality improvement
	Reduced waiting lists
	Patient satisfaction
	Reduced number of adverse incidents
	Better patient-clinician relationship
	Improved co-ordination between professionals and managers
	Increased treatment based on evidence-based medicine

Table 1: Inputs, structures, processes and outcomes associated with clinical governance policy implementation

3.2. Clinical Governance in LMIC settings

The differences in clinical indicators measured in high-income countries (HICs) compared to LMICs has been briefly described above (Azami-Aghdash et al, 2015). LMIC healthcare facilities do not have access to the same medical technology, information systems and staffing levels as better-resourced HIC facilities and will therefore collect and interpret data differently. For example, monitoring septic tanks in Iranian hospitals, as a KPI of environmental risk management, will not be mirrored in most urban German or Australian hospitals. Social and cultural differences, as well as differences in the administration and management systems, also influence the selection of indicators.

Similarly, the experience of creating and implementing CG policy will differ between the HICs and LMICs. Stakeholders in both settings face similar challenges of providing high-quality yet cost-effective health care to an ever-increasing population using ever-advancing health technology. But the political, social and economic circumstances within which this challenge is faced differ between HICs and LMICs.

The majority of published peer-reviewed literature on CG implementation is located in HIC settings. For example, the results of the Google Scholar search for

publications, from 2014 to 2019, describing CG policy and implementation set in LMICs produced one national- or HS-level publication, in Lebanon and Jordan (El-Jardali and Fadlallah, 2017). The remaining publications focused on programme-specific CG policies and interventions, e.g. HIV, maternal and child health, and mental health, and were set in various locations, including Kenya (1), Pakistan (1), Malawi (2), Brazil (2), Ghana (2), Uganda (2), Malaysia (2), Iran (3) and South Africa (6). These studies certainly add to the understanding of the practice of CG in LMICs, e.g. Bardfield et al, 2015, looking at capacity building in HIV programmes in Namibia, as a means to both improve quality and increase resilience in the human resource section of that organisation. But the scope for reproducibility and inference outside of the programme focus is understandably limited. By comparison, in the period 2014 to 2019, over 2000 studies describing CG activities in HIC settings are listed on Google Scholar.

Prior to 2014, CG is insinuated in the literature under broader HSS and quality improvement activities. Ciccone et al, 2014, and Peters et al, 2009, are two examples of reviews conducted on LMIC-located literature looking at broader HSS activities and including quality of care or quality improvement as an area of interest. Ciccone et al found only 28 appropriate studies, of which only 9 studies show a direct link between governance and a positive health outcome and 4 an indirect

link. Of these, only 1 (set in Brazil) used "quality of care" as a construct, without the use of the term CG but implying a similar meaning.

Peters et al found 98 studies which mentioned quality improvement as a desired outcome of more general HSS activities but yet again, no reference to CG specifically as a means to action quality improvement. Another example, the 2015 book edited by Herdt and Olivier de Sardan, contains studies on governance and HS strengthening policy and action in Sub-Saharan Africa but CG is presented more as a secondary benefit of broader HS, governance or quality improvement measures rather than a primary change strategy leading to HSS, stronger governance and improved quality.

The book edited by Braithwaite et al, 2015, entitled Healthcare Reform, Quality and Safety: Perspectives, Participants, Partnerships and Prospects, provides the most concentrated collection of articles specifically on quality of care practices in LMIC settings this researcher found. Representatives 30 LMICs from across the world were invited to present at the 2013 International Society for Quality in Health Care (ISQuA) annual meeting in Scotland. Provided with a template by the editors, these researchers created presentations on reforms in their local contexts that fostered improvements in quality of care practices. Some key findings include:

a. The influence of per capita income on quality policy implementation - when countries are still creating core service capacity, due to increase disease burden or limited financing, quality reforms fall by the wayside.
b. Improving access to equitable services that are culturally and lingually sensitive are important in countries with multiple cultures and ethnicities. These serve to enhance the patient experience even if infrastructure and other CG indicators are slower to improve.
c. The management of health IT and the sharing of patient data determines how efficiently and quickly the HS can upgrade and grow.
d. Mandated hygiene behaviour among clinical staff and continuous training thereon are examples of how effective top-down policy implementation and the resultant evolution of organisational culture can have a real impact on patient outcomes.
e. Training on leadership and evidence-based clinical guidelines across all staffing tiers helps unify approaches to adverse event reduction.

3.3. Clinical Governance in South Africa

In South Africa, access to health care is enshrined in the constitution. But this does not translate into equal and equitable access to health care for all. Gilson and McIntyre in a 2007 study showed how despite the presence of policy to the contrary, many South Africans did not enjoy health care access, leading to an unequal distribution of health services. This can also be called the *inverse care law*, where those with the greatest need are afforded the least access. Challenges to equitable service provision in the South African context include a history of inequitable resource allocation and unequal health system development, a quadruple burden of disease, a chronic shortage of qualified staff, a lack of adequate skills development, infrastructure gaps and financing challenges (Chopra et al., 2009; Mayosi et al., 2012.)

The South African government recognized these shortcomings and acknowledged the role that health system strengthening activities could play in enabling the National Department of Health (NDoH) to successfully fulfill its mandate of providing all citizens with equitable access to quality health care. It has subsequently positioned "an accessible, caring and high-quality health system" at the core of its strategy to improving patient care, staff satisfaction, the efficiency and

effectiveness of service provision and ultimately trust in the public health system (NDoH, 2010, Whittaker et al, 1998).

It established the Office of Health Standards Compliance (OHSC) within the NDoH, through the National Health Act (2013). This body is tasked with advising the Minister of Health on the norms and standards the NDoH should aspire to and abide by, and to ensure compliance with these standards through the licensing, accreditation and certification of healthcare establishments, as well as ongoing monitoring and evaluation activities (Whittaker et al, 2011). It acts as an ombudsman for public complaints relating to the health system and is also responsible for developing and operationalizing quality assessments and management systems.

One such system is the National Core Standards (NCS) framework, developed with the following purpose:

1. Develop a common definition of quality of health care to guide the public, managers and staff
2. Establish a benchmark against which the process of service delivery and the structure of public health facilities can be assessed
3. Provide a framework for the assessment and certification of public health establishments

This framework is intended to promote clinical governance activities and asks managers to assess service delivery in seven domains, which are areas identified as potential risks to quality and safety, described by Connell (2014) to include seven domains as listed in table 2 below. Clinical Governance and Leadership and Corporate Governance is listed as Domains 2 and 5 respectively, with Quality Management and Communication included as sub-domains in the latter.

This can be a rather complex and time-consuming framework to work through for a facility manager, so as a form of assistance, the OHSC prioritized problem areas it identified during the licensing, accreditation and certification process of health facilities and these were subsequently published as the "Fast Track to Quality" plan in 2011, borrowing data gathered from the Constitution of SA, the Patient's Rights Charter and the NCS (NDoH, 2011; Whittaker et al, 2011).

Domain	Sub-domain
Domain 1: Patient Rights The domain of Patient Rights sets out what a hospital or clinic must do to make sure that patients are respected and their rights upheld, including getting access to needed care and to respectful, informed and dignified attention in an acceptable and hygienic environment, seen from the point of view of the patient, in accordance with Batho Pele principles and the Patient Rights Charter.	Respect and dignity Information to patients Physical access Continuity of care Reducing delays in care Emergency care Access to package of services Complaints management
Domain 2: Patient Safety, Clinical Governance and Care The Patient Safety, Clinical Governance and Clinical Care domain covers how to ensure quality nursing and clinical care and ethical practice; reduce unintended harm to healthcare users or patients in identified cases of greater clinical risk; prevent or manage problems or adverse events, including health care-associated infections; and support any affected patients or staff.	Patient care Clinical management for improved health outcomes Clinical leadership Clinical risk Adverse events Infection prevention and control
Domain 3: Clinical Support Services The Clinical Support Services domain covers specific services essential in the provision of clinical care and includes the timely availability of medicines and efficient provision of diagnostic, therapeutic and other clinical support services and necessary medical technology, as well as systems to monitor the efficiency of the care provided to patients.	Pharmaceutical services Diagnostic services Therapeutic and support services Health technology services Sterilisation services Mortuary services Efficiency management
Domain 4: Public Health The Public Health domain covers how health facilities should work with NGOs and other healthcare providers along with local communities and relevant sectors, to promote health, prevent illness and reduce further complications; and ensure that integrated and quality care is provided for their whole community, including during disasters.	Population-based service planning and delivery Health promotion and disease prevention Disaster preparedness Environment control
Domain 5: Leadership and Corporate Governance The Leadership and Corporate Governance domain covers the strategic direction provided by senior management, through proactive leadership, planning and risk management, supported by the hospital board, clinic committee as well the relevant supervisory support structures and includes the strategic functions of communication and quality improvement.	Oversight and accountabiity Strategic management Risk management Quality managment Effective leadership Communications and public relations
Domain 6: Operational Management The Operational Management domain covers the day-to-day responsibilities involved in supporting and ensuring delivery of safe and effective patient care, including management of human resources, finances, assets and consumables, and of information and records.	Human resource management and development Employee wellness Financial resource management Supply chain management Transport and fleet management Information management Medical records
Domain 7: Facilities and Infrastructure The Facilities and Infrastructure domain covers the requirements for clean, safe and secure physical infrastructure (buildings, plant and machinery, equipment) and functional, well managed hotel services; and effective waste disposal.	Buildings and grounds Machinery and utilities Safety and security Hygiene and cleanliness Linen and laundry Food services

Table 2: NCS Domains and Sub-Domains (NDoH, 2011)

This plan contains six priority areas, based on the first three domains of the NCS, one of which is “keepings patients safe and providing reliable care by reducing adverse events resulting from care given, including operations and failures of the system and its workers through ignorance, inadequate inputs, systems failure or

negligence" (Whittaker et al, 2011). This calls for a change in the organizational culture around clinical governance, making it a priority area.

While the policies in place nationally may be relevant and necessary, implementation is not uniform across the nine provinces as provincial departments of health retain a significant degree of autonomy in determining how to integrate national directives into existing provincial, district and local environments.

The WCDoH, for example, has undertaken a series of health system reforms to improve service delivery to citizens since 1994, published in a series of periodic strategic policy documents, the latest of which is the *Healthcare 2030* document. These policy documents describe how the WCDoH plans to localize national health directives while addressing local priorities at the same time, given the resources available to it. For example, in the case of leadership and governance, the WCDoH committed in *Healthcare 2030* to creating enabling conditions that allow for good governance to manifest, including the necessary policy development (e.g. District Health Council Act and Health Facility Boards Act), institutional arrangements, authority- and decision-making arrangements (WCDoH, 2014).

For this section on leadership and governance, it has borrowed from two frameworks to frame its perspective on governance, *viz*. the UNDP Principles of

Good Governance framework, discussed above, and the Competing Values framework. It uses the former to frame the discussion on the role of leadership and governance in improving the quality of care and the latter to speak to the changes required in organisational culture to enable these initiatives.

The Competing Values Framework, visualized in diagram 1 below, contains four contrasting domains of organizational effectiveness, where the inherent value of people within an organization is contrasted against their value based on the results they achieve, and the ability of an organization to adapt to change and innovate new processes contrasts with the need for stability and continuity through the use of rules and guidelines (WCDoH, 2014). It is assumed that prevalent organisational culture is a result of a mix of competing values from each cultural type but that one of these types dominates each team/unit/organisation (Prenestini et al., 2015).

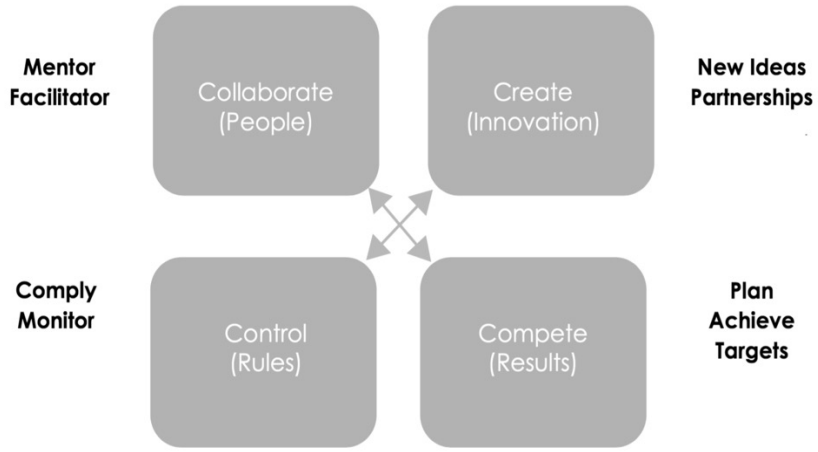


Diagram 1: Competing Values Framework (WCDoH, 2014)

It has been used extensively to study the intersection of organisational culture and clinical governance, especially the relationships between actors and the impact of culture on a variety of organisational issues including human resource management and change management. (Goodman et al, 2001; Prenestini et al, 2015; Viitanen et al, 2015).

Ultimately, the WCDoH used the Competing Values framework to create its own clinical governance framework where clinical governance is defined as "a framework through which organizations are accountable for continuously improving the quality of their services and safeguarding high standards, through creating an environment in which excellence in clinical care can flourish" (WCDoH, 2014).

The components of this framework include:

(i) Clinical accountability with clear clinical and professional standards against which performance of health workers is measured

(ii) Effective teamwork with interdisciplinary co-operation

(iii) Well-defined, comprehensive service packages for various levels of care

(iv) The use of evidenced-based clinical interventions to achieve clinical effectiveness

(v) Continuous monitoring and evaluation of individual health outcomes, adverse incidents and adherence to clinical standards and guidelines so as to effectively manage risk

(vi) Continuous professional development

This framework places the responsibility on both clinical and organisational leadership and management and emphasizes the role management culture has on this process.

However, the process of translating policies and frameworks into practice involves more than writing policies and frameworks and sending them down the bureaucratic pipeline. It is influenced by the actors involved, the content of the policy, the context within which the policy is being introduced (incl. situational, structural, cultural and international) and the process used to both develop, implement and evaluate the policy (Buse et al, 2012). And it requires monitoring and evaluation to assess if the service experienced by consumers is the same as the service described by policy makers. While one can evaluate the more tangible outcomes of policies, such as those directed at clinical governance initiatives, by assessing for concrete changes in the level or quality of service delivery, it is equally

valuable to evaluate how implementation took place to observe for factors that facilitate or hinder policy implementation both in general and with regards to specific policies.

This will be invaluable as the NDoH gears up to implement NHI. In the new bill, published in July 2019, it builds on existing CG-related structures like the OHSC by (1) introducing the Benefits Advisory Committee (BAC), a wide-reaching committee that will be responsible for determining the mix of facilities, providers and services in different communities using health and demographic data, and (2) further decentralizing of the health system, taking decision-making and cost centers down to district level, coordinated centrally by the District Health Management Office which will be located in Pretoria. A concern is that the NHI Fund puts itself forward, in conjunction with the District Health Management Office, as the guardian and evaluator of clinical governance nationally and that it will use this information to determine how service providers will be remunerated for services rendered.

4. Conclusion

Clinical governance offers stakeholders invested in creating a more equitable HS for all a tested and practical means to achieve their goal. It crosses discipline and political lines and unites stakeholders under the goal of doing better by patients. It

is this multidisciplinary and multifaceted approach that allows it to adapt to a variety of circumstances and environmental factors yet have implementation strategies remain focused on improving the user experience of the health system. Gray, 2005, defined it as a comprehensive means to effectively manage resource use, the patient experience, clinical effectiveness, risk and strategic growth while encourage ongoing engagement with the above among stakeholders. It is truly a versatile tool when wielded skillfully.

This skill is one that borrows from knowledge and experience in both academic and field-based settings and allows the dissemination of knowledge and tools between HICs and LMICs. While each has its own set of unique demands and risks, there is opportunity for collaboration and mutual learning across the development divide. In order for practitioners, policy makers, administrators and other interested stakeholders to hone their CG skill set, more needs to be done to increase awareness of the practical application of CG models and theory and to share this case history between geographical and economic divides. As countries across the world grapple with the cost-vs-quality challenge, CG will prove invaluable in guiding the back to the path of creating a more patient-centered health system.

Part C: Journal-Ready Article

Journal targeted: BMC Health Services Research

Title of the article: An Exploration of Clinical Governance Policy and Practice in an LMIC setting

Author: Dr Yesheen Singh

1. Abstract

1.1. Background

The tension between the increasing cost of healthcare provision and the need to provide a quality level of care to a rising number of people is a global phenomenon. A focus on one over the other could result in a rise in adverse patient outcomes, or a health system too costly to be sustainable. Clinical governance is an approach policymakers can use to walk the middle line of creating a healthcare service that meets quality of care standards in a cost-effective manner, as has been done in Australia, Burundi, Egypt, Spain, UK and Yemen (Goyet et al, 2019; Abd El Fatah et al, 2019, Mannion et al, 2015; Aguilar Martin et al, 2019).

This study examines the practice of clinical governance in one LMIC setting that has been able to successfully do this balancing walk for 20 years. Understanding how this was done in the Western Cape province of South Africa helps inform how clinical governance can be used to continue adding value as the national health system moves towards universal healthcare. In addition, this South African experience adds to the still small pool of relevant experience from low- and middle-income countries reported in the international literature.

1.2. Methods

A mixed methods qualitative design was used for data collection and involved three phases: (1) a document review of all policies in the province to identify clinical governance structures; (2) observation of these structures in action, comparing lived to written experience of clinical governance; and (3) interviews with key stakeholders in the province to get their perspectives on past, present and future forms of clinical governance. The Donabedian model was used to frame analysis into three dimensions of care, viz. structure, process and outcome.

1.3. Results

Beyond a comprehensive policy framework, collaborative structures and consultative leadership styles facilitated strengthened clinical governance in the Western Cape. For example, although corporate-governance-inspired structures, such as clinical audits and M&E events, may become punitive and corrosive, the potential negative impact on clinical governance outcomes and organisational culture was tempered by healthy communication and supportive relationships between colleagues. Family physicians have become the champions of clinical governance in a decentralized health system and when supported in this by policy and management, the quality of care in health systems thrive.

1.4. Conclusions

Clinical governance is an effective strategy or tool LMICs can use to ensure quality of care is maintained or improved upon, even in resource-challenged settings. But while some structures, processes and outcomes may be borrowed from other LMIC or HIC settings, these need to be contextualized to local conditions. Appropriate clinical governance champions need to be identified and given the appropriate mandate. Human relationships are key to the successful implementation of

interventions of this nature and space needs to be created in policy for this to be cultivated.

2. Keywords

Clinical governance, Quality of care, Low- and middle-income setting, Family physician

3. Background

This study began as part of a larger research project called WholeSystSA, a broad study to evaluate 20 years of health system transformation in the Western Cape province of South Africa, from democracy (1994) until 2016, when WholeSystSA began. WholeSystSA was conducted by a team from the University of Cape Town, the University of the Western Cape and the Western Cape Department of Health, who used interviews, workshops and document reviews to understand what factors enabled the heath system in this province to fare better than other provinces. Examples of these successes include a higher "TB-cure rate (new smear-positive)" of 80% compared to a national average of 74% (Gilson et al, 2017) and an "Antenatal 1st visit before 20 weeks rate" of 67.7% compared to a national average of 61.2% in 2015/2016 (Nsibande & Ngandu, 2017).

During the WholeSystSA study, clinical governance was brought up on multiple occasions as an influential factor to the success of the Western Cape health system. Subsequently, this researcher was tasked with exploring the history of clinical governance in the province.

By exploring past and present clinical governance initiatives, the hope is that the use of this tool for future health system strengthening and quality improvement will become easier and more accessible.

Clinical governance has a become a globally recognized strategy, involving peer-review, to achieve improved quality of care (Campbell et al, 2001). It is also a central tenet in the South African discourse around universal healthcare and has a central role in current proposals for National Health Insurance (NDoH, 2019). The proposals suggest that in future providers will be contracted to the NHI fund only if they are certified as of adequate quality. However, there is widespread public concern, be it warranted or not, that the quality of public service is sub-optimal and could compromise their health outcomes.

The term clinical governance was first coined in the late 1980s in the UK to describe a solution to quality issues being faced by the UK health system at the time. An early definition, is that by Scally and Donaldson, 1998, who describe it as "*a framework*

through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish."

Activities included under the term include (1) **Processes** that monitor, improve where quality is found lacking and hold accountable stakeholders responsible for the above, (2) the creation of an **organisational culture** that supports safe, high-quality, patient-centred service provision, (3) broad **stakeholder engagement**, such a politicians, regulators, managers, patients and the broader public, in creating positive change in the health status of a community, and (4) increased **accountability** and responsibility for monitoring and oversight of clinical activities by all stakeholders, particularly management (Brennan and Flyn, 2013; Gunst et al, 2016).

This aim of this study is threefold:

1. To describe the structure of clinical governance in the Western Cape, in terms of history and evolution,
2. To understand the process of how these structures are operationalized and governed,
3. To assess and evaluate the outcomes of clinical governance initiatives.

4. Methods

4.1. Study Design

The design employs a mixed methods qualitative approach, structured into three iterative and concomitant phases, continuing in cycle until information saturation occurred or time ran out. In each phase a different set of data were collected.

Phase 1 - Scoping Review

A scoping review was conducted using publicly available policy documents and published literature. The purpose was to identify clinical governance structures mandated by or defined in the policy and to understand the role these played in clinical governance in the province. These included Western Cape Department of Health (WCDoH) 10-year strategy plans, the provincial annual performance plans and National Department of Health policy documents.

Phase 2 - Direct Observation

Direct observation of accessible clinical governance structures currently in use. Three GSA committee meetings were attended in November 2016, in the Cape Metro, Eden and Winelands districts, and one Family Physician Forum was

attended. The aim was to observe clinical governance in action and compare this to what is described in policy documentation.

Phase 3 - Semi-Structured Interviews

Eleven semi-structured interviews were conducted with senior clinicians and/or managers in the Western Cape Department of Health between September and December 2016, who were, at the time, engaged with clinical governance initiatives in the public sector. Although it had been intended to conduct 20 interviews, several were unable to create space in their schedules and some did not respond to the invitation. Participants were recruited either by word of mouth or through the Phase 2 observations.

4.2. Study Setting

The study was set in the public health system of the Western Cape province of South Africa. This province was chosen because despite sharing similar financial constraints and national policy directives with other provinces in the country, its health system has a reputation of performing more strongly than other provinces, as considered further in then larger study to which this CG work was linked (Gilson et al, 2016).

4.3. Data Collection and Analysis Methods

Phase 1 required the researcher to do a substantial review of all policy documents published by the Western Cape Department of Health between 1994 and 2016, that could potentially contain reference to clinical governance (or quality improvement) activities or structures. A search through each policy was initially made using key words/phrases including "clinical governance" and "quality control" but this proved inaccurate as several clinical governance structures were described without the use of these key phrases. Thereafter all policies were reviewed in full and analyzed using the Donabedian model.

WholeSystSA also conducted a policy review and this researcher looked to their study for broader policy guides and contextualizing factors.

The observations of Phase 2 were not allowed to be recorded due to the sensitive nature of some of the topics of discussion. Therefore, observer notes and reflexivity journal entries served as a data source. These were analyzed using the Donabedian model and compared to the findings of Phase 1.

The interviews of Phase 3 were first transcribed and then thematically analyzed using the Donabedian model and compared to the findings of Phases 1 and 2.

This study uses the Donabedian model as a framework through which to analyse its findings. Three *dimensions of care* are described, viz.:

1. Structure - describing the organisational structure and legal and policy frameworks that facilitate an intervention
2. Process - describes the way in which an intervention is conducted, the relationships and flow of information between levels within an organisation and between organisations and stakeholders.
3. Outcomes - describes the impact of an intervention and the indicators used to monitor and evaluate it.

4.4. Ethics and Rigor

Ethics approval for this study was obtained from the Ethics Committee at the University of Cape Town in September 2016, reference number 630/2016. Written informed consent was obtained from each interviewee and each participant of any meeting or forum observed during the course of this study.

The principles of rigor applied in the study were:

1. Minimising observer bias through validating findings from the phase 2 observation and data analysis processes with the interviewees in phase 3.
2. During phase 3, interviews were primarily conducted in English as managers are required to have a working knowledge of the language to perform their duties. Although the interviewees were offered the opportunity to respond in a language of their choice, all were comfortable speaking English.
3. Data sets were triangulated in terms of both data source and data analysis. Findings from the document review framed and informed the subsequent qualitative observation and interview processes. The findings of the qualitative interview phase were used to interpret and add context to the results of the document review and observation phases. Theoretical triangulation was also employed during analysis to support rigor and credibility.

5. Findings

5.1. The Structure of Clinical Governance

The first objective, of three, of this study is to define the structure of clinical governance in the Western Cape and how it has changed since 1994, the onset of democracy in South Africa. From the Donabedian model, this describes the organisational structure and legal and policy frameworks introduced that relate to clinical governance within the Western Cape province.

1990 - 1994: Pre-Democracy

To give context to the findings of this study, the researcher began by exploring health system interventions pre-1994 but *en route* to the new political dispensation. Pre-democratic SA was a fragmented society in many ways. With respect to the health system, health departments existed for each of the four government-defined racial groups (black, mixed race, Indian and white), distributed semi-nationally (some groups were not allowed in some provinces) in the country, and for each of the 10 Bantustans (ethnic homelands), created to locate communities of black people outside the borders of SA, removed from their economic and political agency. Financing of these 14 departments of health was neither equal nor

equitable, with everything from regulatory bodies to staffing levels, access to drugs and technology to standards of care, differed between them all (Baker, 2010; Maphumulo & Bhengu, 2019).

The task to desegregate the disparate health systems into one syncretic HS began in 1990, soon after President FW de Klerk took office, and fell to the first female cabinet minister in SA history, Dr Rina Venter, a PhD social worker, in her position as Minister of National Health and Population Density. The HS was a hospital-centric one and the 240 hospitals in existence at that point were opened to all races with Dr Venter announcing that service delivery would be based on the principles of equality and accessibility (Allen, 1991; Los Angeles Times, 1990).

While no policies or publications from peri-democratic SA (1990-1994) could be sourced that spoke to the form clinical governance or quality improvement initiatives took during her time in office, there was some indication that Dr Venter favored a multidisciplinary comprehensive approach when reading commentaries on the HIV/AIDS plan devised by her department (Meyer, 2004).

When the political borders went down, population movement across the country saw three key system-shaping developments occur, that also shaped the health system South Africa currently operates with:

1. Rapid urbanization - people followed the money and moved from low-resource settings in the previous Bantustans to higher-resourced settings in urban centers around Cape Town, Johannesburg-Pretoria, Durban and other larger cities. The health systems in these cities were not built to manage the influx of people and quickly became overwhelmed. Health funding and resources did (could) not move to match population movement fast or adequately enough.
2. Increasing privatization - people from previously or more-privileged population groups, fearful of not being able to access quality healthcare on demand, sought an alternative to the public health system that previously was able to meet their needs (Young, 2016). This allowed private healthcare funders and providers to mushroom. With bigger pools of money to spend, the private sector attracted more specialists, health technology and healthcare infrastructure for the population served compared to public sector and has resulted in disparate per capita healthcare spends - $150 per capita in the public sector and $1,500 in the private sector (Benatar, 2013).
3. The dawn of the quadruple burden of disease - (i) HIV/AIDS and TB; (ii) Maternal, Newborn and Child Health; (iii) Non-Communicable Diseases; and (iv) Violence and Injury. In addition to facing the challenge of creating a new health system with equitable distribution of human resources, infrastructure, technology, etc. across a larger population group, the new National

Department of Health (NDoH) would have to grapple with the unique challenges associated with each of the above-mentioned disease burdens.

1994 - 2002: Provincial Health Plan 1995

Post-democracy, Dr Venter was succeeded by Dr Nkosazana Dlamini-Zuma (1994-1999), a medical doctor-political activist, who steered the new National Department of Health through further desegregation and reconfiguration into one functional health system. This transition period was guided by a series of documents that influenced and guided subsequent policy and system engineering, including the *National Health Plan for South Africa* (1994), the Western Cape *Provincial Health Plan* (1995), the *Constitution of the Republic of South Africa* (1996), and the *White Paper for the transformation of the Health System in South Africa* (1997).

During this period, the focus of health system development shifted to the development of a decentralized, primary healthcare-focused HS that was organized into national-, provincial-, local- and district-level structures (NDoH, 1994). In the Western Cape, this was exemplified by hospital beds being closed in some areas while Community Health Centers (CHCs) were extended or upgraded in others. Budgetary constraints reduced the number of doctors, nurses and pharmacists in the health system and clinical nurse practitioner, community health worker and

pharmacy assistant roles were created to more appropriately fill in the needs of a decentralized health system. And to further the decentralization objective, comprehensive service provision as close to where the patient lives was encouraged, while ensuring integration into broader district, regional, provincial and national structures.

The term *clinical governance* had not yet been coined but some reference to what would come to be included under the umbrella of clinical governance does get inferred in the policies listed above.

The Western Cape's **Provincial Health Plan, 1995**, was quite focused on laying out the *who*, *what* and *where* of the new provincial health system and did not speak explicitly to the *how* beyond points on coordinated service provision, community participation in decision-making processes and ongoing education, training and evaluation of personnel in response to future needs analyses.

The **National Health Plan for South Africa, 1994**, mentions "…maintenance of good quality of care," as a responsibility for the new health authority at a level decentralized to the lowest level possible within the local-district-provincial-national structure. Licensing was to be explored as a mechanism to encourage high quality of care and facilities would be supported to improve and strengthen their ability to

deliver quality health care to citizens. No mention is made on how these measures would be carried out, who would be responsible and the origin of funding.

Overall, the policies of this period are focused on setting up the nuts and bolts physical infrastructure of an equitable heath system, filling these with appropriately trained and skilled staff, technology and drugs, and financing all these activities. How these parts work together and with what level of efficiency comes later.

No interviewees could recollect further CG-specific structures or activities from this period, with one saying it was assumedly the way things were done: *"…provide the best quality of service you could, given the circumstances you were surrounded by at that time.*" (i5)

2003 - 2013: HealthCare 2010 and the Comprehensive Service Plan

HealthCare 2010 and the Comprehensive Service Plan (CSP) were the successors to the 1995 Provincial Health Plan as the guiding policy documents for broader health system design and engineering in the Western Cape. Desegregation and, to some degree, reconstruction of an integrated service, accessible to all citizens of the province, had taken place.

The gaps in service delivery and the infrastructure network had become apparent once the dust had settled and a new plan of action was needed to guide the HS towards ensuring equal access to quality health care for all citizens. HealthCare 2010 listed two challenges it intended to meet: (1) improve the quality of service delivery and (2) reduce the expenditure to within budget. To do so it put forward a series of far reaching plans, including:

1. Service delivery plan - defining and quantifying the services rendered, based on community needs analysis, and in a decentralized and integrated way.
2. Infrastructure Plan - increase the value of existing assets and provide for new assets (assets being buildings, equipment and maintenance thereof) along the needs identified in the Service Delivery Plan.
3. Human resource plan - appropriate staffing allocated to appropriate facilities to meet the requirements of Service Delivery Plan. This required a revision of existing staff establishments, which until then had simply taken the form of amalgamating staff from previous pre-apartheid structures into one new structure without a needs analysis being done. The challenge to recruit, train or retrain and retain clinical staff, particularly in the rural and underserved areas, was a significant and growing one as many qualified and experienced staff left for more lucrative local and international markets.

4. Financial implementation plan - budgets linked to measurable and time bound objectives to make service delivery affordable and sustainable.

According to one interviewee, HealthCare 2010 "*enabled the founding of clinical governance in the province. It was a road map…got people to do think and do difficult things…be accountable for resources they were responsible for.*" (i2)

For the majority of interviewees, this is when they recall clinical governance and a specific focus on quality improvement, entering the policy and implementation discourse in the province. One described "*consultants being flown in from the UK in the early 2000s to host workshops*" on this "strange, new topic" where hundreds of clinicians and service providers were introduced to the concept of clinical governance. (i1)

At a systems level, quality of care or clinical governance was spoken to in the provincial Annual Report (on financial statements, performance indicators and departmental activities) and the provincial Annual Performance Plans. For example, the **Annual Performance Plan 2005/2006** discusses the establishment of a Quality Assurance Unit to "*monitor quality of care via monitoring complaints and compliments, morbidity and mortality meetings, client satisfaction surveys and evaluation of safety and security risks to patients and staff.*" This time period is

marked by “brain drain” - the movement of quality health care professionals out of the public sector. Reports and Performance Plans for several years report this as a major factor impeding quality of care improvement strategies.

There is also mention of a NDoH 5-year priority plan, one being to “continue towards human dignity by improving quality of care.” The plan recommends (1) strengthening community participation at all levels, (2) improving clinical management of care at all levels of the health care delivery system and (3) strengthening the hospital accreditation system in line with national norms and standards. The province responded with a number of initiatives, including developing a provincial policy on Quality Assurance - which one interviewee pointed out was, in his opinion, directed more to managing the patient experience via complaint management and patient surveys than improving clinical governance.

The main practitioner-directed intervention was the introduction of clinical Monitoring and Evaluation (M&E) meetings, also known as Morbidity and Mortality (M&M) meetings, at district level with a designated official responsible for coordinating quality management in that facility or district. One interviewee spoke of M&E meetings as being either useful or quite damaging to clinician moral, mental health and ultimately retention, depending on whether the M&E meetings were conducted as spaces errors were highlighted punitively or as opportunities to

contextualize the incident, self-reflect and learn. Her example was of a doctor having seen 50-60 patients on a particular workday, going on call that evening already fatigued and making an error that caused harm to a patient. They were either only judged on the error or supported to learn from and improve on the experience. (i4)

This interviewee further reported that chairs of M&E meetings aren't routinely trained on how to turn these meetings from demoralizing "blame games" to reflection and learning opportunities, and that it only her experience as a family physician and further training on clinical coaching from the University of Stellenbosch Department of Family Medicine and the Royal College of GPs that gave her this skill set. (i4)

Annual Performance Plan 2006/2007 is the first mention of a new strategy to introduce family medicine as a speciality in CHCs to "provide clinical governance to PHC particularly for chronic disease Management (sic)." The relationship between family medicine practitioners or family physicians (FPs) and clinical governance (CG) in the public sector will continue to grow, as discussed below.

Annual Performance Plan 2006/2007 is also the first to mention the appointment of clinical co-ordinators, one for each major discipline, such as paediatrics or

anaesthetics, whose spend 50% of their time in this coordinating role. This includes working on (1) quality and safety of care, (2) uniform clinical guidelines, (3) seamless patient care management, and (4) ensuring the right patient gets managed at the right level and with the right skills and at the right costs. These were specialists from tertiary level who moved through the various levels of the HS and across the whole province.

One interviewee viewed being appointed as a "co-ordinating clinician" as his first step into the CG arena. There was no written CG mandate, but it was understood to be part of his role. But he also described the role as "having no teeth" - "you were on the ground, with eyes and ears throughout the province, and short reporting lines to top management, but without any real power to do something about problems you saw" (i1). Co-ordinating clinicians were dissolved 2-2.5 years later because if this inability to effect change.

This plan also describes the need to (1) develop evidence-based treatment protocols that are accepted by all stakeholders, (2) have clinician-developed management tools to monitor quality of care and (3) create a multidisciplinary quality assurance team. These fit neatly into the elements of the Structure dimension of the Donabedian model as described by Vanu Som, 2004, and described above.

Annual Performance Plan 2008/2009 reiterates the role of FPs responsible for CG at district level and tasks them with instituting annual clinical audits at every facility, implementing a PHC information system (PHCIS) to gather data to support said audits, and to improve quality of care in the chronic disease, HIV/AIDS and other disease management systems. It lists as key performance indicators (KPIs) the number of FP registrars employed in the district health system and the number of district hospitals with FPs, indicating a desire to ensure a steady growth in the number of trainee and qualified and experienced FPs available to the HS.

Annual Performance Plan 2009/2010 introduced a new organisational structure to the HS in terms of clinical service delivery - PHC, followed by Level 1, 2 and 3 - each with a different level of clinical services. From an infrastructure perspective, PHC would be a clinic in a local community, staffed mostly by clinical nurse practitioners (CNPs) and occasionally a medical officer (MO) or specialist FP. Level 1 would be district level facility, with a mix of CNPs, MOs and specialist FPs and able to offer a more comprehensive set of services.

Level 2 and 3 would be central and tertiary/training hospitals, would see increasingly complex clinical cases and had a mix of MOs, registrars and specialists organized into three clusters: Cluster 1 (emergency medicine, internal medicine,

psychiatry), Cluster 2 (surgery, orthopaedics and anaesthetics) and Cluster 3 (obstetrics and gynaecology, paediatrics and neonatology).

As one moves up from PHC to Level 3, the number of patients and facilities decrease but the cost as well as the complexity of care provided increase. The goal is to service patient needs at lower levels as much as possible and mirrors the goal of HealthCare2010 to decentralize service provision.

At PHC and Level 1, FPs continue to lead CG initiatives. But in 2 and level 3 facilities don't have FPs. The Annual Performance Plan 2009/2010 speaks of the appointment of level 2 clinical heads for each speciality who will share the CG strengthening role with FPs in their respective facilities and districts/areas. Co-ordinating clinicians were described as functioning across all levels of care and playing a unifying role between FP and Level 2 head.

Annual Performance Plan 2010/2011 builds on the previous by requiring junior doctors to also receive training and support to improve quality of care and makes this the responsibility of FPs and Family Medicine registrars.

Annual Performance Plan 2011/2012 introduces provincial co-ordinating structures in each discipline, dedicated to "*developing uniform clinical guidelines, system*

strengthening strategies and skills development at less specialised levels of care." These are also known as the Provincial Clinical Governance Committees (PCGCs) and are comprised of all the specialists in a particular field from throughout the province, along with some representation from WCDoH management and a family physician, whose task it was to communicate the findings from the PCGCs to Level 1 and PHC staff, via other FPs in the province, and through them to the rest of the healthcare team. Specialists would disseminate findings to their respective Level 2 and 3 departments (i4, I5, I6, i9).

They meet every three months and are an opportunity for colleagues in a field to share experiences, foster a common perspective on challenges and share problem-solving solutions. Despite the wording of the policy paper, very little clinical guideline development took place, with the norm being more the localization of guidelines sent down from national level. This was mentioned by several interviewees as a disappointing shortcoming of the PCGCs - "all talk, no teeth" as one interviewee put it (i1).

Another shortcoming mentioned during interviews was that unless the participating physicians chose to, non-physician service providers were not included in discussions or had outcomes shared with them. For example, in the anaesthetic PCGC discussing theatre protocols, theatre nurses and theatre management were

not involved and as such no decisions or implementation strategies could actually be settled on. This lack of a multidisciplinary approach goes against a key CG approach to ensure all members involved in a particular service share the same degree of training, awareness and attention to detail that creates good quality of care.

Family physicians and family medicine registrars are once again described as key CG champions and CG policy in the province is aligned with national directives on quality assurance coming from the Office of Standards Compliance and the National Core Standards, discussed below.

This plan also describes a new organisational structure in the province, Geographical Service Areas (GSAs), initiated in 2010 and still active at the time of this research in 2016. These were functional committees that did not impinge on other statutory or administrative/managerial structures. They were multi-disciplinary in nature and demarcated along district/geographic lines:

1. Two urban GSAs in the Cape Metro District:
    a. <u>Metro West</u>
        i. Facility: New Somerset Hospital
        ii. Area: Central and Southern Cape Town

b. Metro East

i. Facility: Tygerberg Level 2 Hospital

ii. Area: Northern and Eastern Cape Town

2. Three rural GSAs from the remaining five districts of the Western Cape:

a. Worcester

i. Facility: Worcester Provincial Hospital

ii. Districts: Cape Winelands and Overberg - combined for operational and logistics reasons.

b. Paarl

i. Facility: Paarl Provincial Hospital

ii. District: West Coast - Paarl/Drakenstein falls geographically into the Cape Winelands district and therefor the Worcester GSA but the West Coast refers patient to Paarl Hospital and therefore their GSA was located there.

c. George

i. Facility: George Provincial Hospital

ii. Districts: Central Karoo and Eden - geographically large but sparsely populated.

The intention was "*to strengthen service coordination and communication between institutions and across levels of care*" within a GSA region. Representatives from all

facilities and all disciplines present within a GSA region were included. They were subdivided into working groups called Service Co-ordinating Working Groups (SCWGs), based on 6 domains - (1) women's health, (2) child health, (3) chronic disease, (4) mental health, (5) emergency services and (6) surgery, orthopaedics and anaesthetics. Each SCWG would discuss challenges faced in their region and domain, workshop solutions and implement changes pertinent to them as all the required decision makers (clinicians, policy makers, managers) were present.

The GSA would meet monthly at the Level 2 facility, each month chaired by a different SCWG who would present their recent challenges, solutions and insights to the broader GSA. While a paediatric nurse may not necessarily be interested in the same issues as an orthopaedic surgeon, this shared forum served to keep everyone in the HS informed of challenges and changes in the whole HS and allowed the process of collaboration, problem solving, innovation and M&E to be shared between more- and less-adept SCWGs.

GSAs were the main forum listed by interviewees for cross-disciplinary engagement on key CG-related topics and had the most positive feedback in terms of efficacy in improving CG and quality of care in the province.

From interviewee feedback and observing both urban and rural GSA meetings, this researcher concluded that this was true in the rural GSAs, which continued unchanged in structure and process today as when first begun in 2010. But the urban GSA had changed significantly from the 2010 beginning.

The two urban GSAs were combined into one Metro GSA in 2014 and according to one interviewee, this resulted in too many people with too diverse a set of conditions in which to work (i7). This respondent further stated that the disease burdens, sociopolitical and cultural norms, and infrastructure challenges in Metro East and West are too diverse for colleagues from both sides of the Metro district to share similar solutions to common problems. Beyond acting as a networking opportunity, this had led to decreased enthusiasm for GSA participation and lower expectations for real action-driven problem solving. No reasons for why Metro East and Metro West were combined could be elicited from the policy documents or from the interviews. However, some old SCWG formations had continued to function without amalgamating West and East, e.g. the Surgery- Anaesthetic SCWG of Metro West, who continue to function according to original efficiencies. (i1)

Annual Performance Plan 2012/2013 sees the debut of National Health Insurance (NHI) and Universal Healthcare (UH) into the policy space at provincial level. The plan lists, (1) Increasing the family physician head count in the district health system

and, (2) strengthening the collaboration between family physicians and specialists in the GSA structure through the appointment of Heads of General Specialist Services to each GSA, as two key CG-supporting improvements taking place during this period. In addition to supporting CG initiatives, these new Heads will also be responsible for skills development and monitoring referral pathways - similar to the task set of the Co-ordinating Physicians of the early 2000s. The GSAs had also become a key vehicle through which CG strengthening and clinical leadership development activities organized by provincial management are to take place.

2013 - 2016: HealthCare 2030

HealthCare 2030 is the successor to HealthCare 2010 as the overarching strategic plan for the province and sees a refinement of the decentralized, people-centered service delivery focus of the previous policy. However, the focus now moves from a curative paradigm to a preventative one, where positive health and wellness levels in communities are actively nurtured. It is more value-driven with values incl. caring, competence, accountability, innovation, responsiveness and respect (C^2AIR^2) being positioned as equally important as historic KPIs (Gilson et al, 2017).

Quality of care is a central tenet, following in the footsteps of the NDoH. It invokes the frameworks and mechanisms of the National Health Act, the National Core

Standards and the Office of Health Standards Compliance to support this positioning of quality of care. A policy framework for CG was developed "*through which organizations are accountable for continuously improving the quality of their services and safeguarding high standards, through creating an environment in which excellence in clinical care can flourish*" leaning on the definition of CG put forward by Scally and Donaldson, 1998.

The **Policy Framework for Clinical Governance, 2011** positioned patient satisfaction as a result of the technical quality of the interaction between the client and provider, and that this technical quality is improved upon or influenced by clinical governance (Western Cape Department of Health, 2011). The expectations and perceptions of the client of their entire experience of engagement with the HS, extending beyond the clinical consultation, are also included as influential factors. As are factors leading to low provider performance, e.g. burn-out, depression, etc. "Caring for the carers" becomes as important as caring for the patients.

Part of the dissemination process of the framework included various workshops, where cross-discipline coordination of care and communication were described as important to the success of CG implementation. GSAs and PCGCs were described as structures that could serve this purpose, thus their continued presence in successive performance plans and HS strategic documents.

FPs were also seen as holding the primary responsibility for developing a site-specific strategy and implementation plan for CG at district level (Connell, 2014). They were given the lead of guiding the district multidisciplinary clinical team in engaging with CG but not being seen themselves as the sole executor of CG. To support and develop the FP's CG-function, Family Physician Forums (FPF) were identified as platforms for sharing best practices and peer learning while remaining accountable to management. (Gunst, 2016). These forums had been in place prior to the launch of policy framework and were an informal means for FPs to connect and share. After being formalized through this framework implementation process, they created a "terms of reference" for meetings and reporting line to the District Management Committee (DMC).

One interviewee described this formalization process as positive: "*felt like we've got more of a voice now as we're expected to feedback to the DMC, and they consult us on policies and strategies that affect how we work.*" (i5) This interviewee goes on to elaborate by saying that the link between FPF and DMC allowed urban FPs access to management structures and an opportunity to create change, while rural FPFs didn't enjoy a similar relationship because the DMC structure did not exist in the same way there.

A rural FP interviewee responded by clarifying that their FPF enjoyed simpler and easier access to management because there were fewer management structures in the rural setting. One director, 5 deputy directors (finance, HR, pharmacy, professional support systems {aka hospitals} and comprehensive care {primary care and programmes}) and 1 FP make up the District Management Team where decisions are made. (i4, i6)

The **National Core Standards, 2011,** referred to above are a national policy that describe seven domains that provide the minimum legislated standards the HS must meet in order to deliver quality health services that achieve the desired health outcomes. These include (1) Patient rights, (2) Patient Safety, Clinical Governance and Care, (3) Clinical Support Services, (4) Public Health, (5) Leadership and Corporate Governance, (6) Operational Management, and (7) Facilities and Infrastructure. How these standards are converted into policy and implemented is left to the provincial health authorities, *e.g*. HealthCare 2030 for the WCDoH. (National Department of Health, 2011).

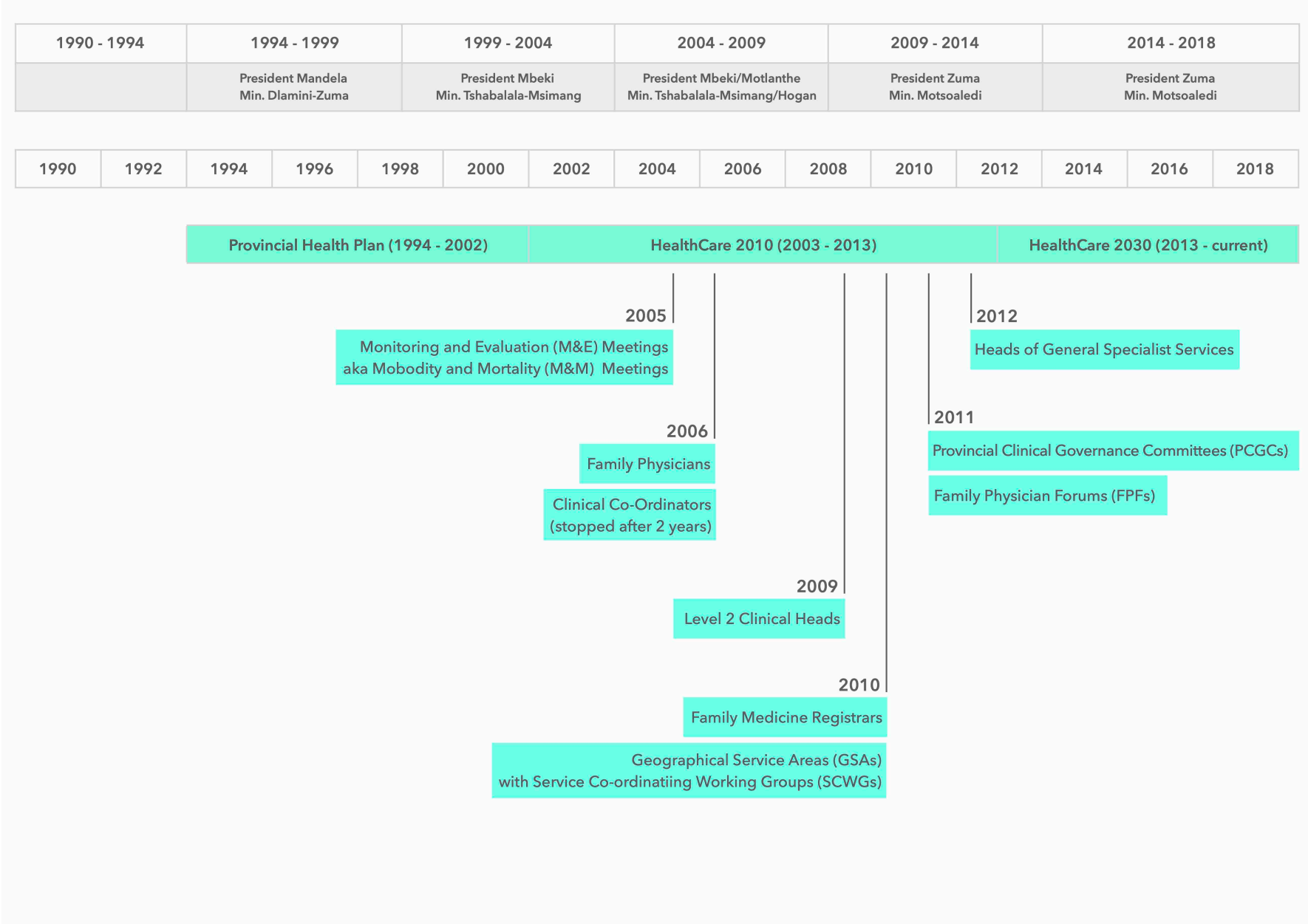
Annual Performance Plan 2012/2013, Annual Performance Plan 2014/2015 and **Annual Performance Plan 2015/2016** build on the previous performance plans, reinforcing the importance of CG to HSS and the role of the GSA and PCGC in implementing CG in the province.

Annual Performance Plan 2013/2014 references national NHI policy and from a more aligned perspective. A key component of the NHI system is a stronger district health model but how that would take form was uncertain at that stage. Ten pilot sites were set up nationally to explore innovations and experiences and one, in the Eden district of the Western Cape, was on the list. While no mention is made of CG-specific policies trialed during this pilot, the role of the FP, as lead on CG in the district health system is highlighted, with support from specialists at regional hospitals, GSAs and PCGCs.

In addition to the above policy-mandated structures, many interviewees reported hosting or participating in additional regular meetings between colleagues in the same discipline, of similar or varying seniority, and between colleagues of varying disciplines who work in the same environment, where problem cases are discussed, positive and negative experiences shared, policies and protocols debated, etc. These serve to both improve clinical governance directly, as providers more regularly are presented with input on the subject, and indirectly, through the strengthening of the relationships between colleagues and the creation of a shared operational culture.

Figure 1 that follows visually summarises the key clinical governance structures discussed above.

Figure 1: Key Clinical Governance Structures



5.2. The Process of Clinical Governance

The second objective of this study is to examine the process of clinical governance in the Western Cape - what are the relationships and pathways of information flow between levels and structures of the health system?

By working through the process of each of the key structures identified in the previous discussion we begin to understand how CG takes place.

5.2.1. M&M or M&E Meetings

These are monthly, quarterly meetings held at facility or district level, where noteworthy cases are selected and presented to the meeting. Attendees usually comprise health care providers, managers and other invested parties and the intention is to understand why errors or successes (less often) occur, what system factors underlie these and discuss if and how these can be changed.

This is an opportunity for collaborative problem-solving and shared learning and when conducted in a non-punitive way, are very effective at building confidence and moral. But as discussed above, this requires a skill set, clinical coaching, that not many practitioners have.

Relationships between colleagues within a facility or district are developed and information flows directly from clinical staff involved with a case to other clinical and non-clinical staff.

5.2.2. Family Physicians and Family Medicine Registrars

Family Physicians have become central to the process of clinical governance in the provincial district health system. They operate in multiple levels of the health system, moving information, knowledge and insight up and down, e.g. from clinic to Family Physician Forum to PCGC or management committee or vice versa, as well as across the health system, e.g. regional or provincial Family Physician Forums.

They are mandated to develop and implement clinical governance in their region or district and do so by gathering health data and conducting clinical audits (against clinical guidelines), supporting caregivers and dealing with patient complaints, conducting ward rounds and/or folder reviews, supervise and train clinical and non-clinical staff on evidence-based protocols, all while seeing patients at the same time. All of the family physicians interviewed reported enjoying the wide scope of their jobs but felt overwhelmed by the volume of work expected from them.

Some enjoyed their clinical role more, others the clinical governance and leadership role. One noted that it would be beneficial to the health system to allow those with an affinity for the latter to reduce their clinical scope and spend more time and resources creating a more robust quality improvement and clinical governance system.

Outside of their clinical role, they are deeply involved in relationship building and information transfer, particularly the distribution of evidence-based guidelines and research findings.

Family Medicine Registrars serve a similar role to Family Physicians, understandable given they are essentially Family Physicians in training. They also bring an additional academic aspect, as most are still tied into networks at the training institutions they are registered with. This allows the exchange of new ideas and information, and new ways of doing clinical practice and clinical governance, between academia and the "real world" and renders both stronger and more resilient.

They receive training during their four-year registrar training that increases their competencies in key areas in addition to the clinical one. These include (1) developing their own leadership style, (2) facilitating a quality improvement cycle, (3) leading meetings looking at risk, *e.g.* M&E meetings, (3) teaching and training,

(4) familiarizing themselves with the process of clinical guideline implementation, (5) developing communication skills and (6) expanding on their ability to take routine information, *e.g*. the appropriate use of pharmaceuticals, and reflect upon this with their multidisciplinary teams, with the goal of improving the knowledge base of their teams and, thereby, clinical outcomes (i3).

Family Physicians are also mandated to train and provide oversight to junior medical staff in their facility or district. One interviewee reported how fortnightly "sharing sessions" with junior doctors in the district had helped reduce mental health problems and improve moral, leading to improved clinical outcomes and staff retention.

5.2.3. Co-Ordinating Clinicians, Level 2 Clinical Heads and Heads of General Specialist Services

Similar to the role Family Physicians play in the district and regional levels (PHC and Level 1) of the health system, Co-ordinating Clinicians, Level 2 Heads and Heads of General Specialist Services (acting in Level 3) act as "system navigators" in higher levels (Level 2 and 3) of the health system. They are clinical specialists who understand the clinical, political and bureaucratic environments within which they operate, who the key stakeholders are and what evidence-based best practice is.

They serve to enable staff within their facilities to implement clinical governance and quality control strategies and to act as clinical governance advisors to colleagues in their own discipline across the province.

They are effective because of the relationships they have throughout the health system, from executive management to facility managers, and they are also responsible for information transfer between structures and facilities through their participation in the structures of clinical governance described here, e.g. GSA or PCGC structures.

5.2.4. Geographical Service Areas

GSAs, and the Service Co-ordinating Working Groups (SCWGs) contained within them, were one of the few mandated forums for cross-disciplinary information sharing and engagement on the topic of clinical governance. They fostered relationship building by allowing participants to network between disciplines, facilities, structures and levels of the health system and similarly encourage the flow of information.

For example, a discussion between an anesthetist and a theatre nurse on cost-effective hand hygiene practices in a surgery-anaesthesia SCWG, when presented

to the broader GSA, allowed the outpatient Clinical Nurse Practitioner from gynaecology to learn a skill or process that improved quality of care of her and her team. The Level 2 Head or representative of the executive management structure passed this learning on to policy makers and this potentially become part of future policy on hand hygiene best practice.

5.2.5. Provincial Clinical Governance Committees

These provincial-level committees comprised of specialists, management structures related to that speciality and a family physician representative. There was one for every major speciality or discipline and they served to pull clinicians together from throughout the province to develop a common perspective on clinical governance matters related to their speciality. These could range from localizing national clinical protocols to discussing quality assessment audit outcomes. Generally, they met every three months, with some PCGCs functioning better than others. They viewed themselves more as advisors to policy makers than as policy makers themselves - even though they did have representation of management on the committee, it had no mandate to do anything more than advise.

PCGCs served to build relationships and share information between colleagues of the level of the same speciality but part of their challenge lay in the fact that specialists are not decision-makers at the facilities they operate in. Today, a collaborative management approach is prevalent and an anesthetist, for example, cannot comment on or commit to a course of action that will impact his or her theatre operations without the input of the theatre nurses and theatre management. PCGC's were not mandated to share their discussions with non-speciality colleagues like GSAs are, and relied on the personal decision of individual participants on whether and how much information to share.

But it appeared that the Family Physicians present on PCGCs had stepped into that role to some degree. One interviewee said they routinely fed back on the outcomes of their PCGC to their local clinician team and the Family Physician forum, who in turn disseminated important information further. For example, new asthma referral protocols from the NDoH were localized to the Western Cape by the pulmonary PCGC and this information was shared by the Family Physician to the facilities and practitioners who were going to be seeking referral to the specialists in the PCGC.

5.2.6. Family Physician Forums

Similar to PCGCs in that these forums are comprised on a single specialty - Family Physicians - but different in that they existed before they were put into the policy. They were created with the purpose of developing bonds between Family Physicians from across the region or province and sharing information and experiences to foster improved levels of care. They are self-driven, had access to power (through FPs who sat on PCGCs or engaged with management in other formal or informal channels) and worked so well that the policy makers incorporated them into the policy mix and gave them a direct reporting line to the executive managerial team. They both localize district and PHC-level policies and protocols passed down from national and provincial levels, as well as pass feedback and requests for new policy interventions upstream.

Relationships between Family Physicians across a region or across the province are strengthened, creating networks for collaboration and innovation, and information Family Physician representatives on PCGCs, GSAs, academic institutions and other organisational structures is shared across the forum. This, in turn, is disseminated to healthcare teams in the facilities or districts where Family Physicians are based.

5.3. The Outcomes

The third and final objective of this study was to examine the impact of clinical governance initiatives on the quality of care and any KPIs associated with this. The KPIs associated with clinical governance and described in the Annual Performance Plans studied include:

1. Mortality and Morbidity rates
    a. Per District, Regional and Central Hospital clusters
    b. Per individual hospital
2. The number of customer survey questionnaires
    a. With positive feedback
    b. With low scores
3. Complaints
    a. Received
    b. Resolved
    c. Resolved within 25 working days
4. Number of Family Physicians and Family Medicine Registrars employed

However, data was not accessible to the researcher to allow for assessment of whether positive or negative change was observed in these KPIs over time and if so, what were the mitigating circumstances - policy change, sociopolitical change, etc.

6. Discussion

In the initial years after the end of apartheid the focus of policy makers was on desegregating the health system and creating one system that served all citizens equitably. With resources concentrated in urban centers, it would take time to create a network of care that covered the entire country and the quality of that care was secondary. As one interviewee put it: "*In the 90s, one top manager said 'I haven't got time for this family medicine touchy-feely nonsense. I need people who can cut.'*" (i3). But management beliefs change, as personified in HealthCare 2030, where patient- and/or person-centeredness take center-stage as quality of care becomes a central focus.

Another interviewee said that, given the contemporary literature on the value of CG structures on cost-reduction and quality improvement, "*there is no need for policy makers to wait to add clinical governance into the system engineering mix. New health systems should be designed with them in place from the beginning... they are worth the resource spend*" (i3). This is particularly important as South Africa embraces UHC and welcomes all the change that will accompany it.

The health system envisioned in the NHI Bill, 2019, places a decentralized, district level, community-based organisational structure at the center of service provision,

coordinated centrally in Pretoria. The role of the current provincial departments of health and their existing district-level structures appears unclear from this document. The bill is very much focused on infrastructure changes and operational structure and gives little space to how the new health system will function once it is set up, not discussing topics like communication channels and clinical governance - in contrast to the comment by the interviewee described above.

And while the bill lists the District Health Management Office as the administrative lead of clinical governance in the country, it says little about how clinical governance will look in practice or who will be responsible for it within the district teams being invested in. The NHI White Paper, 2017, places family physicians in this role and it waits to be seen if this will be carried over to the implementation of the NHI Bill.

South African literature on family physicians in the public sector (Mash et al, 2016) and the field work for this study show how family physicians had successfully taken up the mantle of clinical governance leadership in the district health service. But consistent feedback from interviewees was that without a dedicated mandate, their time, resources and attention continued to be stretched between clinical and governance worlds, leading to less-than-ideal outcomes for both individual and intervention. It must be remembered that FPs were primarily clinicians who were trained in clinical governance. They were employed as clinicians in the HS and this

occupied the main portion of their time and attention. At the same time, none of the other participants in the multi-disciplinary district health team, incl. nurses, administrators, pharmacists, physios, etc., were equally trained in clinical governance. This created further tension for the FP because, as one interviewee put it: "*family physicians may be leaders of clinical governance on the team, but they are not responsible for doing clinical governance.*" FPs instead had the responsibility of guiding and upskilling teammates to action clinical governance in appropriate ways. This added teaching and ongoing CG coaching/training to their CG-related tasks within their facilities and/or sub-/districts.

This did not cover the responsibility of coordinating CG within a district, region or province. At the time, some rural districts in the Western Cape had a coordinating FP who sat above facility level and coordinated across facilities and sub-districts. Others had Level 2 Heads and Heads of General Specialist Services who filled this "system navigator" role. All interviewees reported on the value of this role, over and above that of the meetings, forums and committees available to them, for keeping CG programmes integrated, coordinated and in action. This included the role of caring for the carers. As one interviewee put it: "*if you want people to treat patients as people, they need to feel like they are also being seen as a person and not just a cog in the wheel*" (i8). But there is no such role described in neither the NHI White paper nor NHI Bill. Instead, it speaks of practitioner accreditation by the OHSC and

penalties in terms of a change in accreditation status if quality audits didn't meet expected standards. This, in turn, would prevent practitioners from consulting with patients and invoicing for services rendered.

Another reason why more direction is needed from the NDoH in this regard is the current governance environment at facility or district level. Both national and provincial policies espouse a collaborative approach to leadership and governance and FPs are trained to emulate this during their 4-year registrarship. But they enter facilities or districts with operational managers who, for the most part, continue to run a "*legacy-based, command-and-conquer leadership style*" (i3).

The relationship between clinical and corporate governance structures is fundamental to the successful implementation of CG policies. One interviewee stated that "*it's difficult for clinical governance to be done without support services working, like supply chain, HR, infrastructure, information systems...*" (i4). More guidance is needed on how the two should relate to one another and where ownership and responsibility lies. Equally important, and in alignment with global CG literature, the responsibility for clinical governance should be included in the job descriptions for all top- and middle-level managers in the HS so that while they may not have the full skillset to create and implement programmes, they are obliged to support those who do.

Corporate managers have access to short courses on new leadership styles, but these serve mostly to highlight the need for change. "*Ongoing in-service training or mentorship* (following on from short courses) *needs to support this new awareness in order for leadership styles to sustainably change*" (i4). This should be built into the system operational manual. Family medicine researchers from the University of Stellenbosch one such trial in a district-level facility in Cape Town and saw "*great enthusiasm for change but as soon as we stopped visiting them regularly, managers reverted to non-collaborative ways when under pressure*" (i3).

How clinical governance looks in practice also needs to evolve to reflect a contemporary people-centered and participative approach. Currently, the influence of the British analytical approach to clinical governance is evident, from how it was introduced to the province ("*consultants flown in from London for massive workshops on a topic we didn't know much about,*" (i4)) and the frameworks drawn on to frame clinical governance policy in the province, which rely on the actions of clinical guideline adherence, M&E meetings and clinical audits. New approaches can and do incorporate some form of practice-level, peer-to-peer support structure (Campbell et al, 2008; Phillips et al, 2010). These structures are responsible for building leadership capacity at PHC level and "*creating opportunities for reflection on one's own professional practice and rendering clinical governance interventions locally relevant*" (i8).

These structures are most often clinician-led but engage with other members of the local, multidisciplinary health intervention team as well as with regional and national networks, to encourage stronger teams, more adaptive needs-driven health policy, efficient funding spend, integrated information systems and sustainable improvement in the quality of health care delivered (Phillips et al, 2010).

An example from this study was the management of CG in one local Western Cape district. Here, a FP was located within the office of the district manager, coordinating CG activities of FPs based at facilities and sub-district structures in their district. They engaged across all disciplinary divides and administration levels in a participative manner and also sat on provincial-level structures e.g. a PCGC. They had this to say of their experience of implanting CG with their team in a people-centered participative way: "*It's time to stop focusing just on continuous improvement and safeguarding high standards through continuous audits and M&E. It's time to focus on creating an environment clinical governance can flourish, where people feel safe and open enough to engage with it constructively and, if not, to ask why.*" (i4).

Another stated that "*good clinical governance depends on the strength of relationships between management and clinicians. If clinicians feel like they have a voice, they feel more empowered and more open to self-reflection and constructive criticism.*" (i5). Interviewee i6 said she was "*concerned by the current movement*

apart between management and clinicians. Many in management began as clinicians and assume they still have that experience to help them understand our world. But the clinical environment is changing so fast, you need to remain present in the clinical world in order to understand its opportunities and challenges."

Interviewee i2 said he "*felt so connected to HealthCare 2010 because we were consulted, and our feedback was heard. With HealthCare 2030 we were not. This leaves the department weaker and more vulnerable.*"

These comments describe a shift taking place, at the time, among some clinical governance practitioners in the province - a move from just focusing on the hard deliverables of clinical governance policy to including the softer interrelating aspects like communication and values, that facilitate the harder bits like clinical audits, M&E meetings and improved quality of care. An interesting question to explore in a future study is whether this shift is shared by FPs or clinical governance leads in other provinces and in other countries. Governance is a social practice that relies on relationships to create value for stakeholders (Bevir, 2013) - "*you don't need to know everything, you just need to know everyone on the team*" (i4).

7. Limitations

Time restrictions limited the number of GSAs observed to 3 and the number of visits per GSA to 1. Observations over a series of meetings would have assisted in understanding the process of information flow and relationship building better. Most understandings of GSA functionality come from the in-depth interviews.

Only 10 in-depth key informant interviews were conducted due to limitations of time. An executive managerial perspective would have been interesting to add into the mix of mostly clinicians.

Without access to KPI data this study was unable to adequately answer the third question posed - how efficacy and functionality differ between the various interventions described in the literature and discussed during the interviews.

This study was conducted in the Western Cape province only. This may influence the transferability of findings to other provinces and it is advised that the study be extended to other provinces before its conclusions are transferred to non-Western Cape settings.

This study focuses largely on describing the structure of CG in the WCDoH over the 20-year time period and provides a brief overview on the outcomes achieved through the implementation of these structures, viz. the differences in select health KPIs between the Western Cape and broader South Africa. However, it was not able to explore exhaustively the process of CG implementation due to restrictions on time and resources. This would be a valuable area for additional work following this paper as the author believes that it is in understanding the operationalization of policy and strategy in successful HSS case studies that important learnings may be gathered on how systems with similar challenges and pressures can be strengthened and made more resilient.

8. Conclusions

Clinical governance has grown to become key to both quality improvement measures and health system strengthening activities in the Western Cape. Designing a system around the provision of quality care places the patients' needs centrally, as evidenced by the HealthCare 2030 policy.

While the implementation of quality improvement or clinical governance policy requires a multidisciplinary approach, a lead is still required to ensure movement and momentum. Family physicians are the ideal candidate to champion clinical governance into the next iteration of the health system. In a study by Von Pressentin et al, 2018, the impact of family physicians in a variety of roles - care provider, consultant, trainer, leader, capacity builder - was highlighted as creating more value than other medical officers in similar district-based settings. This is interesting given that the new NHI Bill, 2019, places greater emphasis on a strong district health system.

However, asking a family physician to continue to wear both clinician and clinical governance hats, and expecting greater output on both areas without adequate support from line managers and the multi-disciplinary team responsible for both clinical and governance outcomes, will only result in less than desired results. Their

role as clinical governance lead, and the value of a robust clinical governance programme, should be valued enough to make FPs spending more of their time in the clinical governance environment mandatory.

In the new health system as envisaged by the NHI Bill, room should be made to continue with multidisciplinary clinical governance teams at facility/sub-district level and multi-disciplinary GSA meetings at district level. This will allow the dissemination of CG-related information throughout the HS and encourage a shared organisational culture towards clinical governance.

Two additional factors that positively influence the outcomes of clinical governance initiatives and should be included in future policy include (1) the presence of a coordinating FP or clinician who moves information and knowledge between levels and structures of the HS and (2) the freedom for the process of clinical governance to evolve beyond the models defined in rigid high-level policies - when given the space for the process to be tailored to the stakeholders and conditions of a local environment, engagement with and outcomes of CG policies improve.

These South African experiences contribute to the small pool of relevant experience from low- and middle-income countries reported in the international literature. Researchers in Egypt found that implementing CG through a multidisciplinary team

and developing stronger relationships between the executive and the clinical teams led to better quality outcomes (Abd El Fatah et al, 2019). Researchers in Burundi, Tajikistan and Yemen found that a multi-level approach provided improved CG outcomes in these countries (Goyet et al, 2019). And researchers in Iran found that both appropriate infrastructure and incorporation of stakeholder views and support, particularly family physicians, into CG policy implementation, led to better CG outcomes. These all support the overarching findings of this study that investing in building open and resilient communication channels across and through a health system and strengthening the relationships between all stakeholders in clinical governance policy pays dividends.

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Appendices

Appendix A: Consent Form

Consent Form

Research Title: Communication and collaboration, an exploration of clinical governance interventions in the Western Cape Department of Health over the past twenty years.

Participant Declaration:

I (name) _____ declare that I have read and understood the Information Leaflet about the Clinical Governance in the Western Cape Department of Health Research Project. By signing this consent form, I am agreeing to take part in the research project.

I understand that I can withdraw from the research process at any time if I feel that I can no longer continue, without any penalties.

Signature: _____

Date: _____

Investigator Declaration:

I (name) _____ declare that I have explained the process of my research project to (Participants Name) _____. I am convinced that s/he has understood everything satisfactorily, and has thus made an informed decision to take part in the study. S/He has the right to withdraw from the study at any time without being forced or coerced into continuing against her/his will.

Signature: _____

Date: _____

Appendix B: Information Leaflet

Information Leaflet

Research Title: Communication and collaboration, an exploration of clinical governance interventions in the Western Cape Department of Health over the past twenty years.

Investigator: Professor Lucy Gilson, Head of Division: Health Policy and Systems, UCT

Dr Yesheen Singh, email: yesheen@gmail.com

You are kindly invited to participate in this research project. Please take some time to read the information below. It is important that you are completely satisfied and that you understand what the research is about and how you may be involved.

What is this research study all about?

In this study we would like to explore how clinical governance is written into policy, actioned in the real world and whether the difference between these two helps or hinders the efforts of the Department of Health to improve the quality of health care it seeks to provide to patients. Part of this project will be to explore the organisational culture of the WCDoH and its sub-units and how this influences clinical governance initiatives.

Study Process:

This study may involve you in two ways:

1. We intend to observe existing governance meetings, forums, groups. This is purely to understand how these structures are set up, how they function and what they aim to do. This is in no way a personal evaluation exercise.

2. We intend to select a sample of managers and policy makers to interview one-on-one, to gain further insight on the structure, process and outcomes of clinical governance activities. You may be invited to be interviewed and participation is absolutely voluntary.

How will you benefit?

You will receive feedback in the form of a synopsis of the completed research that will assist you in gaining insight into what clinical governance is, why it is an important part of strengthening the health system in general and why it is an essential aspect of improving the quality of care provided. This information is helpful for both policy makers, managers and other stakeholders in the health system as we are all invested in creating a health system that is able to provide quality comprehensive, appropriate care to all citizens while maintaining cost-effectiveness and efficient resource allocation.

You will also contribute towards a deeper understanding of what makes the health system in the Western Cape different, and in some areas better, than health systems in other provinces. This is invaluable information which will help to hopefully strengthen the health system and improve the quality of care provided to all South Africans.

Appendix C: Ethics Approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

15 September 2016

HREC REF: 630/2016

Prof L Gilson
Health Policy and Systems
Public Health & Family Medicine
Room 1.39, Falmouth Building

Dear Prof Gilson

PROJECT TITLE: COMMUNICATION AND COLLABORATION: AN EXPLORATION OF CLINICAL GOVERNANCE INTERVENTIONS IN THE WESTERN CAPE DEPARTMENT OF HEALTH OVER THE PAST TWENTY YEARS (Masters candidate- Dr Y Singh) Sub-study linked 071/2016

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study subject to the following:

- Please add the HREC contact details to the Informed Consent form.
- The researcher should be aware that the Healthcare 2030 document is merely a strategic vision for the department and not an official policy document. It is hoped that future policy documents may emanate from the 2030 guiding document. Additionally, Clinical Governance up to now has been very ad hoc and there is no central process for the management of clinical governance in this province. The study will possibly show this, but it needs to rather be stated upfront in the protocol.

Approval is granted for one year until the 30th September 2017.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

The HREC acknowledge that the student, Dr Yesheen Singh will also be involved in this study.

Yours sincerely

signature removed to avoid signature online

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI),and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC 630/2016

Appendix D: Article Submission Guidelines

Journal Selected: *BMC Health Services Research*

Criteria

Research articles should report on original primary research, but may report on systematic reviews of published research provided they adhere to the appropriate reporting guidelines which are detailed in our editorial policies. Please note that non-commissioned pooled analyses of selected published research will not be considered. Studies reporting descriptive results from a single institution will only be considered if analogous data have not been previously published in a peer reviewed journal and the conclusions provide distinct insights that are of relevance to a regional or international audience.

BMC Health Services Research strongly encourages that all datasets on which the conclusions of the paper rely should be available to readers. We encourage authors to ensure that their datasets are either deposited in publicly available repositories (where available and appropriate) or presented in the main manuscript or additional supporting files whenever possible. Please see Springer Nature's information on recommended repositories. Where a widely established research community expectation for data archiving in public repositories exists,

submission to a community-endorsed, public repository is mandatory. A list of data where deposition is required, with the appropriate repositories, can be found on the Editorial Policies Page.

Preparing your manuscript

The information below details the section headings that you should include in your manuscript and what information should be within each section.

Please note that your manuscript must include a 'Declarations' section including all of the subheadings (please see below for more information).

Title page

The title page should:

- present a title that includes, if appropriate, the study design e.g.:
    - "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review"
    - or for non-clinical or non-research studies a description of what the article reports
- list the full names and institutional addresses for all authors
    - if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual

members of the Group to be searchable through their individual PubMed records, please include this information in the "Acknowledgements" section in accordance with the instructions below

- indicate the corresponding author

Abstract

The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. Reports of randomized controlled trials should follow the CONSORT extension for abstracts. The abstract must include the following separate sections:

- **Background:** the context and purpose of the study
- **Methods:** how the study was performed and statistical tests used
- **Results:** the main findings
- **Conclusions:** brief summary and potential implications
- **Trial registration:** If your article reports the results of a health care intervention on human participants, it must be registered in an appropriate registry and the registration number and date of registration should be in stated in this section. If it was not registered prospectively (before enrolment of the first participant), you should include the words 'retrospectively

registered'. See our editorial policies for more information on trial registration

Keywords

Three to ten keywords representing the main content of the article.

Background

The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study was necessary or its contribution to the field.

Methods

The methods section should include:

- the aim, design and setting of the study
- the characteristics of participants or description of materials
- a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses
- the type of statistical analysis used, including a power calculation if appropriate

Results

This should include the findings of the study including, if appropriate, results of statistical analysis which must be included either in the text or as tables and figures.

Discussion

This section should discuss the implications of the findings in context of existing research and highlight limitations of the study.

Conclusions

This should state clearly the main conclusions and provide an explanation of the importance and relevance of the study reported.

List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided.

Declarations

All manuscripts must contain the following sections under the heading 'Declarations':

- Ethics approval and consent to participate
- Consent for publication

- Availability of data and materials
- Competing interests
- Funding
- Authors' contributions
- Acknowledgements
- Authors' information (optional)

Please see below for details on the information to be included in these sections.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

Ethics approval and consent to participate

Manuscripts reporting studies involving human participants, human data or human tissue must:

- include a statement on ethics approval and consent (even where the need for approval was waived)
- include the name of the ethics committee that approved the study and the committee's reference number if appropriate

Studies involving animals must include a statement on ethics approval and for experimental studies involving client-owned animals, authors must also include a statement on informed consent from the client or owner.

See our editorial policies for more information.

If your manuscript does not report on or involve the use of any animal or human data or tissue, please state "Not applicable" in this section.

Consent for publication

If your manuscript contains any individual person's data in any form (including any individual details, images or videos), consent for publication must be obtained from that person, or in the case of children, their parent or legal guardian. All presentations of case reports must have consent for publication.

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